Increasing the supply of donor organs within the European Union

Volume II: Evidence
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Minutes of Evidence

TAKEN BEFORE THE EUROPEAN UNION COMMITTEE (SUB-COMMITTEE G)

THURSDAY 22 NOVEMBER 2007

Present
Gale, B
Howarth of Breckland, B (Chairman)
Kirkwood of Kirkhope, L
Lea of Crondall, L
Neuberger, B
Trefgarne, L
Wade of Chorlton, L
Young of Hornsey, B

Examination of Witness

Witness: Dr Eduardo Fernandez-Zincke, Medical Officer, European Commission, examined.

Q1 Chairman: Welcome. We are really grateful to you for taking the time to come and see us. This is an extraordinarily important inquiry that we have undertaken. We have had a lot of interest in the inquiry, from all sorts of groups, and we are hoping that the report that we make when we have heard the evidence will be of some value in the wider debate going on across the EU. Any help you can give us in starting us on this direction, as you are at the beginning of our inquiry, would be useful. Our specialist advisor, Professor Bobbie Farsides, is with us. She has been extremely helpful at the beginning in helping the Committee to understand what the issues are in relation to European donations. We have an hour for the session, which is open to the public. A transcript will be taken, a copy of which you will receive in a few days. Would you advise us, please, if there are any corrections to that transcript. Could you begin by stating for the record your name and your official title. You are then welcome to make a statement or to go straight into the questions. Perhaps you would tell us how you want to begin.

Dr Fernandez-Zincke: My name is Eduardo Fernandez-Zincke. I am a medical doctor. I work as a medical officer in the Directorate of Public Health and Risk Assessment, the Directorate-General of Public Health and Consumer Protection of the European Commission. My Lord Chairman, I would like to thank this group and this Committee for giving the opportunity to the European Commission to be here, to explain to you the future proposals on the area of organ donation and transplantation that we are working on. I would prefer to go straight to questions, to try to make it as interactive as possible.

Q2 Chairman: Thank you very much indeed. You have had some advance notice of where we are, but could you begin by explaining the steps you propose to take in establishing a European Union level role in the field of organ donation and transplantation, including which future documents would be likely to be published and whether proposals for a new Directive or regulation are planned. Could you set out the likely timetable for this, so that, if you like, we have some legal and structural picture in order to begin inquiring.

Dr Fernandez-Zincke: Thank you, my Lord Chairman. I would like to start, if I may, with a short briefing of why the European Union is working in this area and what is the background of this communications that the Commission has adopted in May this year. I have to say that there are some milestones in the work of the policy on organ donation and transplantation of the European Union and I would like to go through these milestones as I think that could be useful to understand why we published this communication in May. The first milestone was the conference of Porto held in 2000 by the Portuguese Presidency which established the basis of the Community line, let us say, on organ donation and transplantation. At the very same, it was incorporated in the Treaty of the European Union, what is now known as Article 152, which gives competence to the Union on establishing the highest standards of quality and safety for human organs, blood and blood components, and substances of human origin. The second milestone, which was linked with the conclusions of the Porto conference, was a second conference organised by the Spanish Presidency in Malaga in 2001, which established the basis of the Community line, let us say, on organ donation and transplantation. At the very same, it was incorporated in the Treaty of the European Union, what is now known as Article 152, which gives competence to the Union on establishing the highest standards of quality and safety for human organs, blood and blood components, and substances of human origin. The second milestone, which was linked with the conclusions of the Porto conference, was a second conference organised by the Spanish Presidency in Malaga in 2001, which established the basis of the Community line, let us say, on organ donation and transplantation. At the very same, it was incorporated in the Treaty of the European Union, what is now known as Article 152, which gives competence to the Union on establishing the highest standards of quality and safety for human organs, blood and blood components, and substances of human origin.
conclusions, the main key elements in the area of organ donation and transplantation. With these conclusions, the Commission published a statement, together with the Tissues and Cells Directive, saying that organs are different from tissues and cells or blood, we have to consider that they are lifesaving treatments in most of the cases, we have to consider that there are enormous organ shortages in all European Member States and the quality and safety principles which are basic and which are important should always take into account this context in the area of organ transplantation. So that is why, in this statement, the Commission also committed to present an evaluation of the situation and a number of possible actions to carry out in the area of organ donation and transplantation, and the communication that we have adopted in May is the result of this evaluation that the Commission has carried out during these years and it is proposing a number of possible actions to be taken at Community level. I will now make a very brief statement of the content of the communication, in order that you have a complete context, and then I will go into the future steps, if that is correct for you. In the communication we identify three main challenges or three main areas where we have to work at Community level. The first one is to ensure quality and safety rules and on the other side to respect and not to undermine donation rates in Europe.

Chairman: That is extremely helpful and clear, sorting out the issues and the timetable. Lady Neuberger, would you like to move on from that.

Q3 Baroness Neuberger: I think you have answered quite a lot of my second question in what you have already said. The bit of the question that, in a sense, you have not dealt with, is that there are members of the medical profession—and as a doctor yourself you will be only too well aware of this—who are worried that the EU package, when it emerges, may well over-bureaucratise what is already happening and not allow individual doctors or, indeed, transplantation programmes—to declare an interest, my brother-in-law is involved in one of those—to use their clinical expertise and judgment. You have said that you are bringing in the experts. To what extent can you give us reassurance that the experts feel thoroughly consulted and, indeed, are really contributing?

Dr Fernandez-Zincke: Thank you, Lady Neuberger. I think that is also our concern.

Q4 Baroness Neuberger: I should think so.

Dr Fernandez-Zincke: If you read the impact assessment which is attached to the communication, it is very clear that we are working in this line. In fact the approach that we are presenting to national
Lord Trefgarne: The Commission has the opportunity to do so. We want to give our input into the content of the document. If the Commission does regarding these kind of documents, we will anyway proceed in the normal action plan and the legal framework. After all these consultations, we will anyway proceed in the normal way that the Commission does regarding these kind of documents, and an open consultation on our web page will be launched in order that everyone who wants to give their input into the content of the documents has the opportunity to do so.

Q5 Lord Trefgarne: I am very concerned to be assured, as I think Lady Neuberger is, that the Commission are not going to involve themselves in what are clinical matters. They are not going to be interfering in the clinical judgment of the consultant or for that matter in the various professional organisations within the Member States which, in many cases, are so distinguished. Can you give me that assurance?

Dr Fernandez-Zincke: I can give the assurance that is the intention of the Commission. The intention of the Commission is not to interfere in the clinical decision. It is not to interfere in the healthcare system of Member States. That is why we are proposing a combination of two mechanisms. Even in the action plan there will be a number of measures intended to ensure quality and safety but we want to analyse which of the mechanisms of quality and safety should be in the legal mechanism and which should be in a national plan on a more voluntary basis. We believe there are some initiatives that should remain in a legal mechanism, because they should be established in all transplant systems, because no transplant system could work without these guarantees, but also we think that some measures intending to improve the quality of transplant should go into the other mechanism, which should be created on a more voluntary basis and taking into account the participation of the professionals.

Q6 Lord Trefgarne: There is likely to be a Directive resulting from all of this.

Dr Fernandez-Zincke: I think that the intention of the Commission is to have a Directive for one side plus an action plan on the other side. Of course you have to establish an impact assessment and try to analyse the different impacts.

Q7 Lord Trefgarne: Which article of the Treaty will that Directive come under?

Dr Fernandez-Zincke: 152.

Chairman: This leads in very well to Lord Wade's questions, I think.

Q8 Lord Wade of Chorlton: Thank you. I have a couple of questions that cover the current position and then some on what the longer-term objectives are. How would you characterise the present quantity and quality of organ donation and transplantation services across the EU? What do you see are the realistic aims for the short- and longer-term future in improving the quantity and quality of organ donation and transplantation services across the EU? In other words, how do you see they are now and how do you think they will improve as a result of these Directives?

Dr Fernandez-Zincke: I will start probably with the quantity and then we can go to the quality. I have to say that we have in mind two mechanisms, not only a Directive but also an action plan in order to strengthen cooperation between Member States. I have to say that, in general, organ shortage is a problem that is facing all Member States, so it is a common problem in Europe and in the world. The average donation rate of the European Union is 18.8 per million of population. If you compare this average with, for example, the average of the US, the US have achieved an average donation rate of 25.5 per million of population, so we are below. But what is more important, I think, is that the situation at the European level is not homogeneous. There is a wide variability of organ donation rates between Member States, which runs from 35.1 per million of population in some Member States to less than one per million of population in other Member States.

Q9 Lord Kirkwood of Kirkhope: To less than one?

Dr Fernandez-Zincke: Yes, it is 0.8 in some Member States, so practically non-existent. That is also transferred to a wide variability on transplantation activities. It is not only the donation part but also the transplantation activities, which rise from 1.6 to 57.6 per million population, depending on the Member State, in the case of kidney transplantation, or from 0.8 to 24 per million population in the case of liver transplantation. So, again, there is a wide variability between Member States. In Europe there were approximately 58,000 persons on the waiting list in
2006. I have mentioned some figures now regarding deceased donations and transplantation from deceased donors, but, if we look to living donations, the activity of living donations also varies completely in different Member States. In some Member States, 100% of the activity of kidney transplantations is coming from living donors; in other Member States, no living donation programmes are open. So, again, there are different experiences and different situations that vary widely. This situation of not being homogeneous also applies if you see the situation of waiting lists: how waiting lists are managed in different Member States; the sizes of waiting lists in different Member States; the conditions to include patients in the waiting lists in different Member States. That is also interesting: if you look to public awareness and if you look to the willingness to donate in the different Member States, that also varies widely from one to the other, and if you look to some indications like family refusals, the refusal of a family at the moment of the donation, that varies from 15–20% in some Member States to more than 40% in some Member States. If you combine these two indicators and you analyse for one side the willingness to donate of the population and the actual donation rates, you can see that these two figures are not always correlated. That means that in some Member States they have not enough success in transferring the willingness to donate into actual donation rates or, saying this in another way, some Member States have more success than others in doing so.

Q10 Chairman: We are almost halfway through our time and we have a long way to go. Your answers are superb and we are certainly going to want to have everything you have to give us, but I want to give some other members of the Committee the opportunity.

Dr Fernandez-Zincke: Thank you, my Lord Chairman. May I just mention one feature on quality and safety because there was a second part to your question. I think we have made a survey in 2003 on the situation of quality and safety systems in Europe and I also want to add that, again, there is a wide variability. There are some Member States who have all the systems in place and there are some Member States who do not have.

Q11 Lord Wade of Chorlton: To sum that up, you are saying that one of the objectives and one of the things we ought to see happen is much more equalisation of these services throughout Europe. The main method has to be in the areas that are weak rather than the areas that are strong.

Dr Fernandez-Zincke: I think that you have expressed it very well. I think we have to use the best practice and the experience of some Member States in trying to help other national systems in increasing their level of performance.

Q12 Lord Wade of Chorlton: The other question is what views do you have on the need for the EU to coordinate the policies relating to organ donation and transplantation with the health policies designed to reduce the prevalence of lifestyle-related diseases?

Dr Fernandez-Zincke: Absolutely, I think, this is a key question. Health prevention and health promotion policies have always been in the core, let us say, of the objectives of the European Union and, also, in the core of the public health problem of the European Commission. I think the Commission has adopted recently what is called the Health Strategy, a strategy that tries to be a comprehensive framework that brings together many new policies to work towards health goals, and I think that both the prevention and the promotion policies and the transplantation policies are included in the Health Strategy. I do not think we have to see this as a kind of competition between them but as a kind of complementary approach to a number of diseases.

Lord Wade of Chorlton: Thank you very much.

Chairman: Can we move on to Lady Young.

Q13 Baroness Young of Hornsey: My question concerns ways for improving the supply of organs for transplantation. Particularly with regard to the much higher organ donation rate in Spain, than is in the UK, what do you think is the relative importance for improving the supply of organs for transplantation, between, let us say, improving organ donation and transplantation services and, on the other hand, switching possibly from a system of opting in, which is what we do here to identify potential donors, to a system of opting out or this idea of presumed consent?

Dr Fernandez-Zincke: Thank you, Lady Young for your question. I can try to answer from my personal experience and my opinion. I think the key elements of the success of Spain in having the highest donation rate in the world is mainly because of the organisational system and the model of organisation that they do have. I think the Spanish model could be summarised in six elements: (i) a transplant coordinating network with a key person in all the hospitals who is in charge of the donation in that hospital and who belongs to the staff of this hospital; (ii) quality programmes which are evaluating continuously the performance of donations in the different hospitals; (iii) a competent authority of central office which is supporting all the system; (iv) a great effort in training professionals how to detect a donor, how to talk with the family, how to maintain the donor and how to follow up all those procedures; (v) hospital reimbursement. It is very important for the Spanish model to incentivise the hospital of
Donation: if a hospital sees that donation is a burden more than an incentive, then the donation rates will probably vary a lot. I think we have to incentivise hospitals to, let us say, promote organ donation; and (vi) a close attention to the media. I think that during these two decades the system in Spain has constructed a very important trust in the population. It has been built by establishing permanent contact with the media and by improving the media skills of professionals, mainly health professionals, who are part of the system. There is an important debate—and it is not only in the UK—about presumed consent and informed consent. I have to say, after reading a number of papers, that there is not a conclusive result of this, mainly because many of the presumed consent systems, like the Spanish system, do not apply the presumed consent law in a very restrictive way. In Spain, all families are asked before performing the donation. It is a presumed consent law which is applied in practice giving a lot of importance to the opinion of the next of kin.

Q14 Baroness Young of Hornsey: Are you saying that, because of the systems you have evolved in Spain, there is much more confidence in the system and that is the important factor rather than this strict adherence to a notion of presumed consent?

Dr Fernandez-Zincke: I think that the presumed consent law Spain gives, in a way, a guarantee to the professionals, but I think that the main element of the success of Spain is the organisational model.

Q15 Chairman: It is more structural than cultural, if you like.

Dr Fernandez-Zincke: Yes. Absolutely.

Chairman: That is an interesting point.

Q16 Lord Trefgarne: Are you Spanish?

Dr Fernandez-Zincke: Yes, I have to say that I am Spanish.

Chairman: This structural/cultural issue will come into Lord Kirkwood’s point too, which is about cross-border donations.

Q17 Lord Kirkwood of Kirkhope: Thank you. Good morning. I have a very simple and apparently naïve question to ask: what would be the principal two or three benefits to widening the number of nations that are involved in a scheme within Europe? At the moment there are six or seven, they are functioning well, and you have given us some interesting statistics, but what would be the two or three key things that would be different if we made this Europe-wide?

Dr Fernandez-Zincke: Thank you for your question, Lord Kirkwood. I think you are mentioning the example of Eurotransplant as a kind of regional structure of cooperation. I think the example of Eurotransplant shows that, once a common organisation and common rules are in place, the number of organs has since increased and contributes to maximise the opportunity for patients to obtain the best possible organs.

Q18 Lord Kirkwood of Kirkhope: Have you done any risk analysis of that. You are asserting that, and I guess it is true, it would seem to be logical, but have you done any modelling, any analysis or assessment?

Dr Fernandez-Zincke: I have to say that I personally have not done any risk analysis on this and it probably should be done. I think the Eurotransplant area has some studies on showing these results.

Q19 Lord Kirkwood of Kirkhope: If they exist, could we have access to them?

Dr Fernandez-Zincke: I will try my best.

Q20 Lord Kirkwood of Kirkhope: That is very kind. Thank you.

Dr Fernandez-Zincke: What I wanted to say is that regional cooperations have importance in a number of issues; for example, if you are in a very small Member State, with a very small donor pool, and you have a potential donor but you do not have a recipient on the waiting list, this donor will never be used. The second thing is that if you have an urgent patient—in many cases you have a hepatitis fulminating that requires a liver in three days—obtaining this organ on time could happen in Spain, it could happen in France, it could happen in Eurotransplant but it will be very difficult in Malta or in Cyprus or the other smaller Member States. For those cases it would be advantageous to organise a more extensive donor pool. Other examples could be, for example, a paediatric patient who requires a specific type of organs or those patients who are known as hypersensitised patients, patients who need organs that really match completely, again, extending the donor pool in this situation could help, let us say, the performance of the system. It does not mean that it has to be a European system. That is not the intention of the Commission. The idea is that probably regional cooperations will be really a very good idea in order to increase the performance of the transplantation system and efficiency.

Lord Kirkwood of Kirkhope: So it is a bigger pool. Thank you very much.

Q21 Chairman: You have said quite a lot on quality and safety already. Is there anything else you would like to add that has not been already said on quality and safety? Because you said a lot in your introduction. It is clearly a key area, is it not?

Dr Fernandez-Zincke: I think it is a key area. I think that probably you could find in the communication the key principles that we would like to introduce and
include into the legal framework. I probably can underline again that there are elements of quality and safety that probably will go into the action plan but not into the legal framework. That is the idea behind the Commission, after consulting some experts. For example, one element that we are not considering to introduce into the legal framework but on which we are trying to build a consensus between Member States, is the evaluation of post-transplant results, that is a measure of the quality of the transplantation. That never will or should go, in our opinion, into a legal, binding requirement but will be a collaborative action between Member States.

**Chairman:** That is clearly an area we need to look at. Could we move on to Lady Gale, who is going to deal with another area.

**Q22 Baroness Gale:** My question is on organ trafficking. Do you perceive there is a problem of organ trafficking across the EU? To what extent do you think there is a potential for this to become an even greater problem in the future? What role could there be at an EU level to monitor and combat any growth in the problem of organ trafficking?

**Dr Fernandez-Zincke:** Thank you, Lady Gale, for your question. I think the problem of organ trafficking in the European Union is not a major problem. I think it is very scarce, the cases that have been denounced of organ trafficking happening in the European Union Member States. The first role of the Commission probably in this area is always to have investigated and contacted with competent authorities in the Member States, in case of any suspicion of possible organ trafficking in the EU. Also, we have extended the mandate of Europol in order to be combating the existence of these kinds of cases, but, as I said, I do not think this is a major problem in the European Union. I think the type of organ trafficking that is a problem and which is happening—we have data—is when citizens, also European citizens, are going abroad to third countries to have an organ from the local populations in these countries. The Commission is working together with the World Health Organisation and with the Council of Europe in order to monitor also this situation in third countries. As far as our competence makes us competent to do something, we will try to avoid the situation, as has been mentioned also in the communication, but I think that, in this case, mainly it remains the competence of Member States. Probably where we can play a role is to try to agree with Member States common national positions regarding this problem.

**Q23 Lord Lea of Crondall:** Could I ask where organ trafficking becomes legal trafficking? I am very sorry, I have come in halfway through the discussion but presumably there is some subconscious worry that my organ might go somewhere I did not want it to go. Have you come across such a concept? Do you think people perhaps do not realise that they can get a better match if they go to a wider area? Presumably people do pay money, do they, in the official arena?

**Dr Fernandez-Zincke:** Thank you for your question. There is not any Member State in the European Union which allows the paying for human organs. This is obviously a debate that is probably happening in other parts of the world, mainly, probably, in the US, but even in the US this is not allowed. I think that basic ethical principles which are enforced in all Member States prohibits the payment for human organs for transplantation.

**Chairman:** Thank you very much indeed. That is extremely helpful. It would be helpful for the Committee if we could move on, out of order, to Lord Trefgarne, who is going to ask about the ethical issues, because he has to leave very promptly. With the Committee’s indulgence perhaps it would be possible for us to move on to the ethical issues next.

**Q24 Lord Trefgarne:** Thank you very much, my Lord Chairman. What have your investigations revealed as to the ethical concerns which presumably arise between different Member States in relation to this matter? How do you think these issues can be handled most sensitively to ensure that they do not interrupt the orderly flow of donation services while at the same time having regard to the sensitivities? The related issue is whether you are going to have to define more carefully the so-called point after death at which organs may be taken from donors. Is this when breathing ceases or when the heartbeat ceases or when brain-stem death is assumed to have occurred?

**Dr Fernandez-Zincke:** Thank you for your question. I would like to start stating that it is not the intention of the European Commission to harmonise ethical issues. I think we have a wide variability of social talk around religious values in Europe which does not make it possible, and it is not within our competence, to harmonise, let us say, the ethical issues. Saying that, I think I have elaborated a list of the main ethical issues linked with organ transplantation because this is a field which has a number of elements which are very important on ethical grounds. The first one is the need for consent. This is something that has to be very clearly stated in all Member States. It is not the intention of the Commission to say how consent should be organised the different Member States but, as we have done with the Tissue and Cells Directive, it is important to stress the need of consent, however the Member States organise this consent.
Q25 Lord Trefgarne: It is not going to be assumed consent.
Dr Fernandez-Zincke: No.

Q26 Lord Trefgarne: It will be positive consent.
Dr Fernandez-Zincke: It will be a need for consent and then I think Member States should choose the preferable options that they consider are more appropriate for their own societies, let us say. It is not something that will be coming from the European Union. The second element is the question of commercialisation of human organs. It is the question of ensuring voluntary and unpaid donations for organs, which I think is kept in the chapter from the fundamental rights of the European Union which says that there should not be financial gain from the parts of the human body, as such. I think that is, again, something that is already endorsed or promoted in the Blood Directive and in the Tissue and Cells Directive and I think it is something that is a basic principle where we are working on it. The third element is probably data protection and confidentiality of the organ donors. I think that is a principle that has been already announced before in the previous pieces of work. The other aspect that is important in the organ field is of course the allocation criteria of organs.

Q27 Lord Trefgarne: Before you move away from the area, have you take into account the various religious concerns? We have been seeking guidance from various people and we have not had very much. Have you had any representations of that kind? Have you taken them into account?
Dr Fernandez-Zincke: I think that taking into account the religious groups is very important in trying to make a policy on organ transplantation. In fact, last week, I was in a meeting at the Vatican and we had a discussion on organ donation and transplantation. We have asked, also Member States’ national experts what are their experiences regarding different ethnic and religious groups for organ donation and transplantation. But, again these are questions that—and I want to insist on this—are the subject of subsidiarity. It is something on which we could cooperate and put on the table.

Q28 Lord Trefgarne: What did they tell you in the Vatican?
Dr Fernandez-Zincke: I think the Catholic Church is one of the churches which is more active in the area of organ donation and transplantation and they are considering—and take this as non-official information—to organise some initiatives next year on organ donation and transplantation, which I think could be a very good idea.

Q29 Chairman: What about the Muslim states? Are there more problems and less donation in Eastern Europe because of some of the issues around cultural and religious beliefs?
Dr Fernandez-Zincke: We have tried to record some experiences of some Member States regarding Muslim populations. For example, I think in Spain and also in the Netherlands they have some experiences on how to promote donations in these populations. As far as I know, there is nothing in Islam against organ donation.

Q30 Chairman: It is knowledge.
Dr Fernandez-Zincke: In most of the practice I think there is not any official statement of the church, let us say, promoting this situation, as it is in the Catholic Church. I think that this kind of campaign or initiative focused on these ethnic groups or on these religious groups should be promoted. It is one of the ideas that we are thinking to incorporate in this action plan, trying to find best practice in different Member States and previous experience, and trying to share it then with other Member States.

Q31 Lord Lea of Crondall: Have you ever heard it advanced within any faith group that there may be some preference for stipulating that an organ can only go to somebody else in the faith group?
Dr Fernandez-Zincke: I have to say that this has not only happened on the specific ethnic group. Some persons come to the transplantation services saying, “Okay, I want my organ for this specific population, this specific country” et cetera. What it is important in the allocation rules in Member States is that you are not able to select to whom you are going to donate your organs because it is a gift, and it is a gift given to society. This element of equity should be maintained.

Q32 Lord Lea of Crondall: Other religious groups, as far as you know, go along with that.
Dr Fernandez-Zincke: I would not be able to give you this information.

Q33 Baroness Neuberger: When you said it is a question of education and particularly encouragement in particular groups, the issue that worries certainly relatively orthodox Muslims and Jews and which I think has been an issue for some Catholics as well is the definition of death. It is brain-stem death versus the cessation of breathing, and the definition of death being when somebody has stopped breathing for eight minutes which is often too late for taking some of the organs. I think there is a real issue and I wondered how much the EU is really taking that on and looking at the question about how you encourage ethnic groups and
relating to organ transplantation are a very cost-effective treatment. If you compare a kidney transplant, for example, with dialysis, dialysis costs six times more than a kidney transplant, so all the studies show that investment in organ procurement, in increasing organ donation rates, is, at the end of the day, a saving for the health system. Knowing that we have very good treatment and knowing that in terms of public health it is a very cost-effective treatment, I think that it is another reason to try to promote this type of medical treatment.

Q36 Lord Wade of Chorlton: Thank you. What is your view of the problems posed by the European Working Time Directive for medical practitioners who need to work sufficient continuous hours in order to see through, from the beginning to the end, an episode of organ transplantation?

Dr Fernandez-Zincke: I can probably only give a partial answer to this question because it is not my direct competence. It is my colleagues in DG-Employment who are dealing actually with the Working Time Directive. I can say that the Commission has already incorporated a number of measures to this Directive in order to make more flexible this Directive in the field of health. Discussions are currently taking place in the Council and we will have a solution by December this year. So far, that is all I can say.

Chairman: You may be interested to know that this Committee produced a report on the Working Time Directive which would be very supportive of making it more sensible. Our country has tried to press that, along with, I know, a number of other Member States. It is an important issue.

Lord Lea of Crondall: Could I add a supplementary and declare an interest. I had something to do with the creation of the Working Time Directive years ago and the junior hospital doctors in this country had to fight for years to get some prejudices within the profession addressed. They had to work ridiculously long hours and the idea—and I am putting it to you to comment on that—that there are no downsides to doctors working until they are exhausted and almost fainting on the job is ridiculous. We have to see some balance in this and I am sure that that is in your mind. Would you like to comment on the problems of balance within Working Time and genuine worries?

Chairman: Lord Lea, I think this witness just said this is not his area of expertise and we may have an opportunity to ask someone else. The question is that these procedures do take this length of time, and, in order to get these operations seen through, that is what we are looking for in the balance. I think that is the point you were making, was it?

Lord Lea of Crondall: But does it have to be the same person hands-on all the time? That is a non sequitur, I would have thought.

Chairman: Sometimes cases have to be seen through.
Baroness Neuberger: One person has to be in charge.

Chairman: That is the evidence that has been given.

Lord Wade of Chorlton: I do not know the answer, not being a medical person, but how long might one of these operations take? How long does it take to do a heart transplant?

Chairman: Our specialist adviser informs me that it varies. Especially with a non heart-beating donor, from the identification of the donor, from the withdrawal of the treatment to the donor dying, it can go over days.

Baroness Neuberger: The view would be, from most of the doctors I know in this country who are involved with it, that they may not have to be there absolutely all the time but they need to be on call all the time because there is a time when you have to get up and do it. That is the problem.

Q37 Chairman: That is the problem about Directive, about the continuation. That is what we looked at when we did the inquiry. I have one last question about research and information, which I am sure you think is an absolutely crucial area. We are interested in knowing what proposals the Commission have for promoting and funding new research and improvements of information, in order to provide a sounder basis for organ donation and transplantation activities.

Dr Fernandez-Zincke: Thank you, my Lord Chairman. The European Union is already supporting collaborative research in a number of areas. I have a list of areas that very kindly our colleagues of the EU research have provided to me: immune tolerance to avoid/reduce the need for immune suppressive drugs; regenerative medicine approach, notably cell transplantation to regenerate diseased or injured organs; artificial organs; xenotransplantation; and identification of best practice, organisation of services, et cetera, at the level of the Health Service system. I also want to mention that the Research Directorate-General, in the sixth framework programme, has financed a project called ALLIANCE-O. ALLIANCE-O is a project that was looking into different research programmes on transplantation in the different Member States, for example, UK transplant was present in partnership, and trying to, let us say, approximate and coordinate these transplant programmes. The project has issued a number of conclusions that I can provide to you if that could be of any use.

Q38 Chairman: Also, what might be useful is where you think the gaps might be, where we need more information and research.

Dr Fernandez-Zincke: One of the gaps of transplantation research at Community level is that it is very fragmented. There are different research groups working in different Member States and there is not always effective coordination. One of the conclusions of this project shows that it is very important to try to have coordination of the research programmes at a national level. At the moment, few Member States have this kind of organism doing this job, to organise and coordinate the different efforts of different transplant groups. From the Community perspective, we have already funded a number of important projects in the last years. I want to mention the project of DOPKI, which is looking into methodologies to increase organ donation and mainly to see how the level of risk in the use of what we call “expanded donors” or donors who are not, in principle, ideal candidates. Also, the project RISET is a project that consists of researching into reprogramming the immune system in order to avoid as far as possible the rejection of the organ. The DG Information Society has also funded a project on Eurodonor and EUROCET, which is a platform in order to inform the public about issues relating to organ transplantation and also trying to make a register of activities of organ transplantation and tissues and cells transplantation at the European level. Just to finalise: our Public Health Directorate is funding two other projects. The first one is on the training of professionals and the training of donor coordinators, and the second one is on living donation, trying to see what the different practices of living donations are around the European Union in order to try to establish guidelines for living donation programmes.

Q39 Lord Lea of Crondall: Chairman, I would like to add something to what was said earlier, a bit of supplementary information. It was news to me, but I think the speaker said that Spain was a net importer of organs, that Spain had more organs coming into Spain than went out. Did you say that?

Dr Fernandez-Zincke: No, no.

Q40 Lord Lea of Crondall: I am sorry.

Dr Fernandez-Zincke: On the contrary, there is a few exchange of organs from Spain and other third countries. I said that, from all the donors that are, let us say, in the hospitals in Spain, 9% of these donors are coming from other Member States or from other countries. It is not the organ which goes to Spain, it is the donor who is living in Spain or who is resident in Spain and who decides to be a donor in Spain. My point is that more and more in our populations we will have a higher percentage of foreign population living with us, and this population will increasingly be more important for the donor programme.

Q41 Chairman: The important message I took from that is that the structure of the way you do it is more important than all the other issues: if you get the
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Dr Eduardo Fernandez-Zincke

structure right in terms of the way you manage organ donation, you will get more people coming forward. That is something we need to take on pretty strongly in terms of our inquiry. It is 11 o’clock. We are extraordinarily grateful to you. I know the Committee have found that very informative and I have found it absolutely fascinating. We are sorry we have to rush through at such a pace but that is the way these committees do work. I think we have an extraordinary amount of information from you. If there is anything you think we have not heard that we should have heard, please do let us know. If there is any other question we want to ask you, I am sure you would be only too delighted to correspond with us if that was needed. Thank you very much indeed. Dr Fernandez-Zincke: Thank you very much, on behalf of the Commission, for giving us the opportunity to be here today.
Chairman: Welcome. We are very grateful that you have taken the time to come and answer questions this morning. We see this as an extraordinarily important. We hope to see the minister responsible towards the end of the inquiry but it is because your 2006 Annual Report *Organ Transplants: The Waiting Game* was published and of interest that we wanted to have your views early in this inquiry. It is going to attract a lot of public interest. We really want to try to get as close to an evidential base of thinking through it as we can but we know there are a lot of feelings and emotional responses in relation to this topic. We are assisted by our Specialist Adviser Professor Bobby Farsides who is with us today. We have scheduled this session until 11 o’clock this morning, and it is open to the public and recorded for possible broadcasting or webcasting. A transcript will be taken and put on the parliamentary website and your official record in printed form and on the webcasting. A transcript will be taken and put on the record and then you may wish to make an opening statement or move straight into questions.

Sir Liam Donaldson: Thank you. I am Liam Donaldson. I am the Chief Medical Officer for England and the UK Government Chief Medical Adviser.

Ms Norman: I am Triona Norman. I am the Department of Health Policy Leader on Transplantation.

Chairman: Would you like to make an introductory statement?

Sir Liam Donaldson: I am not intending to make an introductory statement because I think the questions you have suggested cover the ground very well. I am not an expert on European legislation and so I may be drawing on Triona Norman’s expertise a little bit in that area in answer to some of the questions.

Chairman: We have all had an opportunity to look at your documents. We were interested, particularly, in the gap between those people who say they will be donors and actual donations, and also to read that 148 heart transplants and nearly 2,000 kidney transplants were carried out. We would like you to describe, if you would, the overall assessment of the present and potential future significance of organ transplantation as medical therapy. How would you characterise the relative importance of organ transplantation in relation to other NHS priorities?

Sir Liam Donaldson: My view would be that it is an important area of healthcare and medical practice and likely to become increasingly important as the population ages and develops more chronic diseases which precipitate the failure of organs. An obvious example would be the increase in the incidence of diabetes, which is a relatively common cause of kidney failure. Many patients with kidney failure have the choice of going on dialysis, which is inconvenient, unpleasant and often leads to poor quality of life, versus transplantation, which removes many of those difficulties, so it is an important area of medicine. The disappointment is that it has not been able to fulfil its full potential because of the shortage of donors, and 1,000 people a year, at least, are dying for lack of a transplant. That figure represents only those we know have been put on the waiting list and do not make it through to transplant before they die; there are others, I am sure, who are not put on transplant waiting lists because doctors know there is no hope of them getting treatment, and they are dying silently, as it were. Transplantation involves the straight taking of an organ from one person and putting it into another. To look at the scope for alternatives, over the years there has been research into other ways of creating transplant tissue or organs. The idea of using animal organs, modified genetically or otherwise, is one alternative. Also, in some fields of transplantation the idea of using mechanical organs has been researched and is still being researched, particularly a mechanical heart. Then, thirdly, there is the prospect of stem cells being produced in the future which, in the first instance,
could yield tissue for transplantation and then the challenges of turning that tissue into the architecture of an organ would be a scale even above that. There are other fields of research of relevance. Although in the early days of transplantation stopping the organ from being rejected by the immune system was a big problem, things have improved there, with the benefit of new immune suppression drugs, but still there is a risk of rejection and there is also a greater incidence of cancer because a person’s immune system is suppressed and the immune system does not remove cancer cells as easily as in somebody with a fully competent immune system. Then there are other more diagnostic areas. For example, more sophisticated scanning techniques are being researched which will allow doctors to assess whether the early stages of rejection are starting. At the moment that is a rather crude science but, with sophisticated scanning and marking of tissues, it is possible that early warning could be given to that. In the mainstream transplantation field, the key issue is just the straight shortage of organs. There are some other fields of research to provide alternatives to the straight replacement of organs which offer some promise but none that offers the opportunity to replace the conventional form of transplantation and then there are other fields of research which are targeted mainly at reducing the risks of rejection and being more selective about the suppression of the immune system that does not bring other side effects.

Q45 Chairman: In answering that question I think you have given us the answer to some of the trends too. Perhaps I could pursue a little bit the issue about the relationship with other NHS priorities. We heard in previous evidence that contrary to what one might anecdotally believe, because these sound expensive operations, they in fact save money in the long run because people get better and are not living on drugs or dialysis or whatever for the long term. Could you comment on that economic?  
Sir Liam Donaldson: Certainly in the case of kidney transplants—which are the commonest form of transplant, as you know—there is a straightforward economic comparison, because the costs of dialysis can be easily quantified and they are more expensive than a transplant because they are ongoing. In the other fields, it really depends on how long people survive if they are not going to get a transplant and they are in need of one, and their costs are variable according to the organ that is diseased. Most of them will be on drugs of one sort or another, many will require periods of hospital admission whenever they become acutely ill. For the people who do have transplants, we need to set against the cost of the transplant the costs of immune suppression drugs—which people do need for life really—and any complications they develop from their immune system being suppressed. It is possible to do a full cost-benefit analysis of the options and I am sure that if you want further information on that we can send it.

Q46 Chairman: I want to move on but we are really interested in where it fits in the priorities, if you like, in the NHS.  
Sir Liam Donaldson: The subject of priorities in the NHS is a difficult one because the NHS, by its nature, has to run with multiple priorities. If you asked me for a rank order of priorities I could give you one but it would be drawn from just one perspective. For example, in the annual NHS priority document certain targets are picked out, but that does not mean that the rest of the service is ignored or the needs of patients are ignored. It really is a highly subjective opinion when you ask me: Where does this stand in the pecking order? I would say it has a relatively high priority because people’s lives can be saved and you would not willingly deny them treatment if that treatment was available.

Q47 Lord Lea of Crondall: I am new to this and I was astonished, as is brought out in your document The Waiting Game—and I do not know about a game but it looks like a dance of death to me—that there is an astonishing gap between supply and demand. In connection with the reasoning which laid the formulation of the conclusions, do you happen to know whether the gaps are as big in other countries? What do you think about any European role? Some people might think that anything to do with Europe is bureaucracy gone mad but would you comment on that in relation to your own document The Waiting Game?  
Sir Liam Donaldson: Looking at the statistics of organ transplantation across Europe, in general countries which have an opt-out system of consent have higher rates of donation of organs. Some argue that that is not solely due to the fact that the consent approach differs. They say that in those countries, for example, Spain—which has done very, very well in recent years in increasing its organ donor rate and did introduce an opt-out consent mechanism—it is not purely due to that; it is due to the infrastructure of services for retrieving and coordinating the availability of organs. I suppose at the simplest level, without getting into any question of European Directives or European legislation, there is a theme of sharing good practice and learning from the countries which do it differently from us. Going to the other end of the spectrum—would there be any scope for a European Directive which prescribed that all countries should work in exactly the same way?—I probably am not the best person to judge that because some measures are popular and easily accepted by countries and others are not and I do not know where different
European Member States would stand on that one. But there is a clear area where Europe already does have legislation in similar fields and that is the field of safety and protecting people. There are European Directives and rules in relation to blood and tissue safety. There are risks associated with not taking the necessary medical precautions in the transplant of organs which put people at risk of catching diseases like HIV and hepatitis and so on. There is another area, which is to do with the trafficking in organs, particularly the purchasing of organs from people in developing countries and then making them available to people in developed countries, and then there is a so-called transplant tourism strand. In the areas of safety and trafficking and exploitation, I think the European Commission would have an important role. In relation to facilitating Member States getting together and sharing good practice I think it would have an important role. I am probably not the best judge in knowing whether any standardised form of procedure would be acceptable or desirable.

**Q48 Lord Wade of Chorlton:** I would like to explore with you the legal implications of introducing presumed consent in the UK. What amendments to the Human Tissue Act 2004 do you envisage would be needed to introduce a system of presumed consent for organ donation in the UK? What rights, if any, do you think such amended legislation should give to a qualifying relative to refuse consent for the removal of an organ from a deceased person who had not opted out of the system?

**Sir Liam Donaldson:** Let me start with a general philosophy of the legislation and then I might ask my colleague to chip in on some of the detail. I had a big part in the action that led to the current legislation because I reviewed the situation following the so-called scandal in Alder Hey and Bristol, where, after children had died, usually following heart operations, their organs were retained without the consent or even the knowledge of the family. I spent a lot of time with the families from Liverpool and Bristol and I made recommendations about amendments to the law which basically involved much more explicit consent. That was somewhat controversial because the research and scientific community felt that we were going too far overboard in taking account of the views of relatives and thus restricting good scientific research, sensible scientific research, from going forward. It was quite a controversial set of proposals but, given some of the abuses that took place, I felt it was necessary. At that time, because we were amending the more than 30-year old Human Tissue Act, the opportunity was taken also to look at the transplant area. There were some changes made there but they did not go so far as introducing presumed consent—although I understand that was debated at the time in both Houses. Since my Annual Report was published, I have had some letters from parents in Alder Hey and Bristol saying that they are very disappointed in this proposal because they see it as backsliding on the measures that we put in to get explicit consent on the donation of organs and tissues after post-mortem examination, but I do think there is a clear distinction between that field of donation and the transplant field. There will always be controversy about a proposal to introduce opt-out, but if it were introduced it would mean a change to primary legislation. Perhaps I could ask Triona Norman to say what that change would be.

**Ms Norman:** The Human Tissue Act 2004, as you probably know, is the relevant legislation and it would be necessary to change part 1 of that Act. At the moment consent is required. If the deceased has made his or her wishes known, that consent in law is the consent that is followed. If he or she has not made that consent known, then obviously they turn to the relatives, and there is a hierarchy of whom they approach first to seek consent. In practice we obviously need the support of the relatives because we have to take a social and medical history before donation would go ahead, but, in law, as I understand the advice we have had from our lawyers, if we wanted to move to a system of presumed consent we would have to amend that part of the legislation.

**Q49 Lord Wade of Chorlton:** Clearly you have had a lot of experience discussing with the public the issue of consent and presumed consent.

**Sir Liam Donaldson:** Yes.

**Q50 Lord Wade of Chorlton:** From that experience you have had with them—and I come from near Merseyside, so I am aware of the enormous emotional tension caused by the Alder Hey issue—what do you think would be the likely response of the public if we were to suggest presumed consent of organ donation should be accepted?

**Sir Liam Donaldson:** There have not been any scientifically conducted surveys of public opinion. All we have to rely on are the sorts of surveys which the media carry out and the hits on websites and that sort of thing. However, after I made the recommendation in the Annual Report those sorts of surveys did show a majority of people in favour. Indeed, in so far as it is relevant, the BBC Radio 4 Today programme has an annual poll for listeners to say what they think, and the second most popular request for legislation was this. It could be that these were just supporters of the idea phoning in but I think it is fair to say that there was a considerable public sympathy. I think the objections of the parents from Liverpool and Bristol are based on a misunderstanding and I think some will be reassured.
Lord Trefgarne: Q51 objection, then I do not think you could go ahead.

involved. If somebody registered a really strong unacceptable. I think there would need to be an at the end, even with an opt-out, would be

But I think cutting the relatives out of it completely they are alive to make their intentions well known.

people to have a discussion with their families while they have an opt-out clause, they still go to the relatives and rely very heavily on what the relatives want and if the relatives show any objection then they would not take the organ. The distinction between that and what we have at the moment is quite difficult to draw and it really, I suppose, depends on the nature of that discussion with the relatives and how much time you put into saying, “Well, in the area of the country you lived there was a lot of information. He surely would have taken the opportunity to opt out had he wanted it.” I think the modern approach to doing this is to try, as far as possible if you did go for opt-out, to publicise it very well and encourage people to have a discussion with their families while they are alive to make their intentions well known. But I think cutting the relatives out of it completely at the end, even with an opt-out, would be unacceptable. I think there would need to be an engagement with the relatives so that they were involved. If somebody registered a really strong objection, then I do not think you could go ahead.

Q51 Lord Trefgarne: Sir Liam, is there not a difference or should there not be a difference between consent given for organs to be taken for research and consent given for organs to be taken for transplant? Most of us have no problem with allowing the organs of ourselves or maybe even our child to save the life of somebody else but to be used for research is different. If one recalls the Alder Hey case, where thousands of organs had annually been taken, they were not used for anything.

Sir Liam Donaldson: It is a good point. The new Human Tissue Act has made the recurrence of such a situation in the future very, very unlikely and I do not think anyone would suggest taking away the forms of consent which are now required for post-mortem tissue in order to be taken. I absolutely agree with you that the situation in Alder Hey was deplorable and the organs were not used, but, on the other hand, the majority of parents I spoke to from Liverpool who were involved said that they would have been very willing to allow their child’s organs or tissues to be used for research “had they been asked”—and that was the key thing. It is probably fair to argue, as well, that good research on post-mortem tissue could indeed save lives—perhaps not in the immediate sense of the transplant but over time. The adding to medical knowledge, the discovery of the cause of diseases like breast cancer and so on, could lead to the saving of lives if it is properly conducted and regulated.

Chairman: Lady Gale, you are going to pursue this issue about consent.

Q52 Baroness Gale: Yes. I have three questions and they are all related to presumed consent. What do you see as the key issues that the Organ Donation Taskforce study of presumed consent should address? To what extent would you see it as sensible for the Government to move ahead to implement the findings of the Taskforce first report which related to the organisation of organ donation and transplantation services in the UK within the present legal framework—in advance of the findings of a second report relating to the issue of presumed consent?

Sir Liam Donaldson: Let me deal with the second two questions first. We have only relatively recently received the report of the Taskforce and ministers are still considering it, so I cannot go into the detail of it. It may be that when you interview Elisabeth Buggins she will give you more information on that. The report does not deal with presumed consent, as you are well aware; it deals with other action that can be taken to strengthen the opportunities to increase the organ donation rate, including looking at methods of containing organs, co-ordination of services across the country and so on. On the specifics, I cannot say we would address every recommendation yet, but, in general terms, I think those changes would be necessary anyway because the experience of other European countries that have opt-out is that you do need to give attention to the infrastructure and the co-ordination and the organisation of proper service as well as the method of consent. Coming to what we would like them to look at, I think we would like them to do an analysis of the success and the reasons for the success and any drawbacks of the use of opt-out in other European countries or other countries in the world. We would like them to try to draw an assessment of the relative benefits of the pure change to the consent versus the other factors to which I have referred, and then I think we would like them to do some analysis of some of the underlying ethical points and, where possible, draw attention to public opinion and public attitudes.

Q53 Baroness Gale: Do you think there is some sort of consensus on which is the best way forward? Presumed consent or, as you say, the idea of the improvement of organ donation and transplantation services? Would that increase the supply better than just saying, “We’ll have presumed consent”?
Sir Liam Donaldson: There is not a firm evidence base to give you an exact assessment of the relative contributions of each because the research has not been done, and, indeed, it would be difficult to do. As far as a consensus is concerned, I do not think there is yet an overall consensus. Certainly I am in favour of it, as I made clear in my report. I think quite a lot of people in the transplant field—although not all—are in favour. I think the majority of public opinion—but not the wholesale majority of public opinion—is in favour.

Q54 Baroness Gale: For young children who die it would be the parents’ consent which would be needed, would it not? You would not presume consent the consent of a child, would you?
Sir Liam Donaldson: No. A personal view would be that children initially should be excluded from this. I think there are too many difficulties and too much baggage with the Alder Hey and Bristol cases. Although some of the other European countries do include children in their presumed consent, my own personal view would be that that would be too difficult for the public to accept.

Baroness Gale: I would agree with that.

Q55 Chairman: What is the alternative there? Parental consent?
Sir Liam Donaldson: Yes, it would be as it is at the moment, which is parental consent. Once children reach a certain age, then their opinion is taken into account and in some cases they are regarded as autonomous.

Q56 Lord Trefgarne: What age is that?
Sir Liam Donaldson: I think it is around 12.
Ms Norman: I think it would also depend on the child to a certain extent.

Q57 Chairman: Age and understanding.
Sir Liam Donaldson: Yes.

Q58 Baroness Gale: What is your view of the degree of acceptability that a system of presumed consent would find across the medical profession? To what extent do you think that the opposition which might exist could lead to difficulties in implementing such a system?
Sir Liam Donaldson: As far as professional opinion is concerned, the British Medical Association have come out some time ago in favour of it. Many people in the transplant speciality of medicine are in favour of it, but not all. As far as the acceptability of it is concerned, I think there are things that could be done to increase the acceptability. That would largely be about educating and informing the public and making absolutely sure that every opportunity was taken to make people aware of their right to opt out.

The opt-out rates vary between European countries. For example, in Belgium it is only 2% who opt out and in other countries it is slightly higher. I am not aware, from my limited contacts with other European countries, that there have been major problems of errors where there have been serious complaints.

Q59 Chairman: Could I clarify one point before we move on: are you saying that you really need the structural changes in which you can then place presumed consent? Are you saying that those two things need to be together in order to achieve what you are looking for?
Sir Liam Donaldson: Let us imagine you introduce presumed consent and did very little to change the organisation of services, then, at the very least—and it would be a serious problem—you would suddenly have a flow of additional organs. If the services were not equipped to receive them and deal with them and allocate them to patients, there would be a serious problem. You are more or less bound to look seriously at the way services are organised and coordinated and the infrastructure—whether there are enough staff and transplant surgeons and so on—before you implement presumed consent.

Chairman: Yes, that is an important point for us to hold on to.

Q60 Lord Lea of Crondall: If a law came in, would that totally close the gap between supply and demand? On the face of it, there are thousands extra. Is there something erroneous in that?
Sir Liam Donaldson: It would make a big difference. We do not know really, I suppose, how many people are below the surface who are just not being put forward at all for transplants. The demand is suppressed by the fact that there are not the opportunities for operations. For example, we do not know whether there are elderly people who could benefit from an improved quality of life from transplant who are not even being referred for surgery because the referring doctors know there is no chance of them being treated.

Q61 Lord Lea of Crondall: This is what I am getting at. There is a presumed gap.
Sir Liam Donaldson: Yes.

Q62 Lord Lea of Crondall: There is a statistical straightforward gap.
Sir Liam Donaldson: Yes.

Q63 Lord Lea of Crondall: It is in one of your documents that there are 1,000 kidneys, or whatever it is.
Chairman: That is an important issue. It goes back to this priorities issue too, does it not? Our priorities are set in relation to expectations.

Baroness Young of Hornsey: Good morning. You have already said something about the difficulties in trying to gauge public opinion regarding presumed consent, so I will not go over that again, but can you say something about your assessment of general knowledge in relation to organ transplantation and donation issues amongst the general public? Also, to what extent do you feel the raising of public awareness about those issues could be made much more effective? I am thinking particularly amongst black and minority ethnic populations, where the discrepancy between the number of people who need transplants and those who are willing to give consent to it seems to be much bigger than it is amongst the general population. I wonder if you could say something about some of those issues, please.

Sir Liam Donaldson: I think a big factor is that the media are not particularly interested. If you look at other areas of health where people are dying for want of treatment, the media make a lot of comment on it and criticism. There is virtually nothing. When my report was published there was a flurry of interest then, but if you look at most transplant stories they are about babies who are waiting for heart operations and do not have a donor. Those are tragic cases—and in many cases they are resolved positively—but they are a very small minority of the need. I cannot remember the last media report I saw on the idea of a middle-aged person dying. Interestingly, having produced my report there was a flurry of interest, and I was very interested to listen to some of the phone-in programmes that followed interviews which I gave, with patients who were on dialysis for long periods of time talking about how restricted their life was and how miserable it was. Those sorts of stories just do not get out into the public at all. If the media did pay more attention to this, I think there would be much, much more public pressure for something to be done about the shortage of organs. I am told that in some of the other European countries there is a lot more education in schools about this. I do not have any hard and fast evidence but talking to certainly one of the researchers who has done some work on what happens in other European countries she made the point that the general public level of understanding is much higher, and I would guess that it is very, very low in this country. It is always easy to say, “There should be more education in schools” but then we have problems of a crowded curriculum and so on and so forth, but I do think the health component of the school curriculum could be looked at to see whether this could be incorporated. Turning to the situation of ethnic minority populations: you are right—and you will be familiar with the statistics—about 25% or so of people on the transplant waiting list are from black or ethnic minority groups and 2% of donors are from those same groups. I would guess there are some cultural barriers and distaste, possibly, for donating organs. I think a different form of awareness and education would be needed, tailored to the attitudes and beliefs of those communities, if we are going to increase the donation rate from them.

Baroness Young of Hornsey: You say that as though you are not sure. Is that because you personally are not sure whether there is research? Has research been carried out in that area?

Sir Liam Donaldson: I do not think there has been particularly good research carried out yet in that area. We can check on that and come back to you.

Ms Norman: It is something the Taskforce agreed needed further work.

Baroness Young of Hornsey: Is there any knowledge about whether that pattern is repeated internationally, that, where there are significant ethnic minority groups, there is this reluctance to come forward? Or is it something that is peculiar to Britain? Or do you not know?

Ms Norman: I do not know. I am sorry. Across Europe I do not know.

Sir Liam Donaldson: This is not directly related to your question because it is a wider context, but when I was producing the recommendations following Alder Hey we had several meetings with the faith groups, because we expected big resistance over trying to change the legislation, and there was really very little strong feeling about it—the Jewish community being the exception, I think, where there was a strongly held view. Certainly many of the other faith and cultural groups were quite keen on the idea of organs and tissues being used to help others, but that was in relation to people who had had post-mortems. We were not talking about transplants.

Lord Trefgarne: It is a particular problem with some faith groups.
**Q70 Lord Trefgarne:** Who have not very readily responded to our requests for views on this matter. Is there a difficulty with some faith groups? I think you have referred to the Jewish faith.

**Sir Liam Donaldson:** Yes.

**Q71 Lord Trefgarne:** Is the Muslim faith group content with all this?

**Sir Liam Donaldson:** Certainly when we spoke to them in the earlier context they pointed to interpretations of the Koran which were supportive of the idea of donation. But then different Muslim scholars sometimes take different positions. Certainly the representatives we spoke to were very positive about it all.

**Q72 Lord Trefgarne:** Although most of the faiths do not seem to have a difficulty, nonetheless in some of these faiths they do not come forward.

**Sir Liam Donaldson:** Yes, which is why I think we probably need more research into the attitudes and beliefs and to see whether it is purely a lack of awareness or whether there are some more fundamental objections.

**Q73 Lord Lea of Crondall:** Is there not a paradox? You have a huge gap in supply and demand and I wonder why there is not slightly more direct public service advertising. When HIV/AIDS suddenly became a big thing, on a lamppost in Farnham there was a big poster saying, “Don’t die of ignorance” and I remember one of my friends in the pub saying, “I didn’t know you could die of that” ha-ha, but you did go in for direct advertising to fill the gap. Is the gap because people are too lazy to do it a donor card, or, like me, they have not got around to it? Is it because people are squeamish? It is strange. If the public opinion polls are saying that we ought to move in the direction of presumed consent, why is there such a big gap? Or is it just that people do not realise there is a gap?

**Sir Liam Donaldson:** I think people probably realise there is a gap because there are different recruitment campaigns undertaken periodically. I think it is just that people do not get around to it mainly.

**Ms Norman:** I would add: all of the above and a certain degree of apathy.

**Q74 Lord Lea of Crondall:** It is not easy to do. I do not know how to do it. What do I do?

**Sir Liam Donaldson:** You can just register on the website of UK Transplant.

**Q75 Lord Trefgarne:** You can still carry a card, can you?

**Sir Liam Donaldson:** Yes, you can.

**Ms Norman:** You can register at doctors’ surgeries.

**Q76 Chairman:** The Committee has demonstrated its ignorance I wonder when the last time was that government had a really strong TV campaign, like the smoking campaign or the drink driving campaign.

**Ms Norman:** We have tried to drip feed—which is a way we think we can get the best message across. Rather than a big, major campaign, we drip, drip, drip, to get the message across that way. I think there is evidence that if there is big media coverage, people will go to the website, they do register. As Sir Liam said, when the report was published a lot of people registered on the organ donation site.

**Sir Liam Donaldson:** Within 48 hours of my report, about 30,000 people registered.

**Q77 Chairman:** Maybe that is something we should be exploring.

**Ms Norman:** When Holby City covered a transplant in their storyline about 18 months ago, if you remember, there was quite a lot of interest then.

**Chairman:** We are demonstrating that it is probably ignorance and not squeamishness that stops people coming forward.

**Q78 Lord Wade of Chorlton:** What views do you have about the need to make much more explicit for potential organ donors the basis of defining the point after death at which organs may be taken from them?

**Sir Liam Donaldson:** I am not sure there is a problem of the public or the relatives of somebody who is dying fearing that the organ may be taken before they are pronounced brain dead. The greater problem really is an awareness amongst the staff in the hospitals, both in the intensive care units and in the accident and emergency departments, of the need to pursue consent wherever possible.

**Ms Norman:** UK Transplant has done an audit of every death in intensive care since 2003 and they have tracked where we are losing potential donors. That audit is probably worth having a look at and I can certainly provide it to the Committee. Before they even get to being asked, we are losing. I think there is an issue around working with the clinical staff but also with the relatives.

**Q79 Lord Wade of Chorlton:** There must be an understanding now in the medical profession as to when you say somebody is dead. What is the basis of that? Is it being brain dead or when your heart stops beating? I am not a medical man, so I do not have a clue how you do this.

**Sir Liam Donaldson:** For somebody who is in a coma, basically, in intensive care, there is a whole range of criteria—and we can send you them—on how you
define brain death. For somebody who is admitted to an accident department after a car crash and they are pronounced dead, it would be a conventional medical examination to determine whether there were any signs of life. That group is a more difficult group to get a viable organ from because you have to move very, very quickly to perfuse the organ and make sure it is viable. In the case of somebody who is in a coma, when you pronounce them brain dead the organ continues until the last minute to have its blood supply and it is well preserved and it is a healthier organ to transplant.

Q80 Lord Trefgarne: May we have an answer, please, to Lord Wade’s question? When are they dead?
Sir Liam Donaldson: I would not like to give you all the criteria in detail now.

Q81 Lord Trefgarne: You are a doctor, Sir Liam, are you not?
Sir Liam Donaldson: Yes, but I would not want to get it wrong. I do not have the exact details in front of me. I am not an intensive care specialist but there are strict criteria laid down for brain death that have been very, very carefully worked out and we can send you those.

Q82 Lord Wade of Chorlton: The way you are answering the question suggests that there is a certain amount of doubt and I do not see how there could be.
Sir Liam Donaldson: No, there is no doubt whatsoever. There is no doubt. There is a form of medical examination and tests that go on, and criteria are laid down which are reviewed from time to time.

Q83 Lord Wade of Chorlton: There is no question then that organs for transplant are taken out of anybody until they are pronounced properly dead.
Sir Liam Donaldson: No, absolutely not.

Q84 Lord Wade of Chorlton: And there is a clear definition of how you come to that decision.
Sir Liam Donaldson: In both cases, in the case of people who are so-called “heart-beating donors” and in the case of those who are “non heart-beating donors”.

Q85 Lord Lea of Crondall: Chairman, would it be useful to have the answer to another question which is certainly puzzling me. There must be something time-sensitive about some organs and not so time-sensitive about other organs. On the one hand, we are talking about minutes and how long it takes and so on, and then you have processes of consent which can go on for hours or days or something. Presumably there must be big differences. A few minutes ago you mentioned trafficking in organs, so there must be organs that you can put in a fridge for 10 days or something. I am probably getting this hopelessly wrong, but are there different degrees of time sensitivity according to different organs? Why is an organ time sensitive?
Sir Liam Donaldson: Essentially there are three clinical situations in which you can retrieve an organ and transplant it into somebody else. There is the situation with the heart-beating donor, and that is somebody who is in a coma and they are pronounced brain dead. Under the present legislation, if you are seeking consent from relatives or family on that, then you would start to address that with them when it was obvious that somebody was not going to recover. You would be then in a position to have the consent at the point at which they were pronounced brain dead. The organ would be taken out freshly and transplanted into somebody else very quickly. It would be in a good state because it would usually have been very well perfused: whilst the person’s brain was dead, their heart would still be beating. That is the first situation. The second situation is where a living donor has agreed to give an organ. Let us say a close relative has agreed to donate one of their kidneys: again that is a favourable situation as far as the quality of the donated organ is concerned, because one person giving the organ would be in one operating theatre and the relative receiving the organ would be in another operating theatre, perhaps next door, and the organ would be removed and it would be well perfused and then it would be transplanted quite quickly. The third situation, which is more difficult as far as the quality of the organ is concerned, is that of the non heart-beating donor. Let us say somebody who comes into an accident and emergency department after having had a heart attack or after having been in a car crash and they are pronounced dead on admission to the accident and emergency department: there you have to rely on the fact that the relatives are in attendance, and you do not just have to tell them that their relative has died but at the same time you have to ask them whether they would be willing to give permission for consent for their organs to be used for transplantation. That has to happen quickly. In that situation, when the organ is taken out there is not necessarily the recipient lying anaesthetised in the operating theatre waiting to receive the organ, so you then perfuse the organ with fluid to try to keep it going and you call in the potential recipient as quickly as possible, and so there is a time interval there. Sometimes the organ is going to be transported to another hospital in another part of the country, in which case it is preserved, usually on ice, with preservation fluid and so on. That is the situation where there is potential for the organ to deteriorate and its blood supply to be compromised, so-called ischemia. In that category of non heart-beating donors, we have another problem,
which is that, because of the shortage of organs, people are becoming donors after their death when they may not have been very well. They may have had a number of chronic diseases where their organ is of poorer quality. They may be a drug addict, where their organ quality is compromised. There is concern, also, not just about the shortage of organs but about the quality of organs, particularly in that category of the non heart-beating donors.

**Q86 Chairman:** All you have just said—and many of us have had the benefit of the background reading and we are grateful to you for elucidating that—simply demonstrates again the time factor. I would like to go back to something Ms Norman said earlier about losing many organs because of the clinicians’ lack of intervention. Does the Spanish model—which we have become familiar with—deal with some of that, because the complications you have just described clearly affect all the timings in a busy hospital where people are thinking of a million other things, not least the emotional impact on the relatives of the loss of a loved one, at the same time. It is structural.

**Sir Liam Donaldson:** It is partly structural and it is partly training of staff. In the situation I described, where you have to tell somebody about the death and ask permission, it is an awkward situation for somebody to handle. I remember as a junior doctor having to do that and I had had no training whatsoever. It is a bit better these days, but it is a situation where it is easier to tell them about the death and sympathise with them and leave it at that than it is to go on and ask for consent.

**Q87 Chairman:** Is this why having a specialist co-ordinators in hospitals and a team around them makes such a difference?

**Sir Liam Donaldson:** Yes, I think it does. They are trained to deal with those situations. Whether that alone would boost the supply of organs is what you are here for really, what you are talking about.

**Q88 Lord Kirkwood of Kirkhope:** Sir Liam, I would like to ask a quick question about research and information because I think it is important that the Committee should understand everything that is in the Government’s mind in that department. Before I do, I cannot resist asking you a little bit about how you felt your 2006 Annual Report *The Waiting Game* was received by ministers. Presumably, you are an experienced hand in the department: you have seen secretary of states come and go, and presumably you have some weight in helping ministers allocate political priorities. Did you think there was an adequate response to the very powerful piece of evidence that you had put in the public domain in your *Annual Report 2006*?

**Sir Liam Donaldson:** I think ministers are entitled to take time to consider a recommendation like that and they were also waiting for Elisabeth Buggins’ *Taskforce Report*, so I think it is reasonable of them to have taken time to consider it, and they have asked for the subject to be looked at. The last controversial recommendation I made in an annual report was for smoke-free public places and workplaces, and that caused a lot more controversy. It was hugely more controversial.

**Q89 Chairman:** But you got there.

**Sir Liam Donaldson:** In the end, I think it helped that public opinion changed on that. I think it changed because the subject was kept in the public domain.

**Q90 Lord Kirkwood of Kirkhope:** Reassure me about this, because you said earlier that the press are not interested much. You got the flurry of activity, rightly, after *The Waiting Game* was published, and then you seemed to slip into the drip, drip, drip approach. The press are not that bothered. 1,000 people are dying each year. Can you reassure us that you are personally committed to knocking on Mr Johnson’s door regularly? You slightly worked around the question about priorities that was addressed to you by saying that it is partly NHS priorities. Of course it is. Everything is partly NHS priorities. What priority is there in the department and with your staff in terms of making this a key issue, so that you get the same success in this area as you did with smoking?

**Sir Liam Donaldson:** The declared department policy prior to my report was not to support the idea of opt-out. Because it was debated at the time that the Human Tissue Act was passed and there was a Government whip on it and, therefore, if they had been in favour of it then it would have been done in a different way.

**Q91 Lord Kirkwood of Kirkhope:** Is there a change of political heart now, do you think?

**Sir Liam Donaldson:** To an extent. They have said they would like to look at it and they have tasked the Taskforce with looking at it and they could have just ignored it. I have made other recommendations that have not necessarily been acted on in earlier annual reports, but not as major as this issue or the smoking one. But I think they are giving serious thought to it. I cannot tell you what is in ministerial minds. There is a degree of inscrutability about ministers.

**Q92 Lord Kirkwood of Kirkhope:** That is an incontestable statement. You can reassure the Committee, can you, that this is a live issue, under active consideration by the professionals in the department?
Sir Liam Donaldson: Yes.

Q93 Lord Kirkwood of Kirkhope: And the ministers are being left in no doubt about what the importance of this subject is in terms of making progress in the immediate future?

Sir Liam Donaldson: I absolutely assure you about that. As far as my own commitment, I am strongly committed to this. I do not make recommendations about things that I think are not well-founded or not sensible or likely to be totally unacceptable to the public. I think this is one where I feel passionately. I do not like to think of people in these numbers dying. Where lives can be saved, I am always active to try to persuade and influence.

Q94 Lord Kirkwood of Kirkhope: Thank you for that answer. I am very reassured. Perhaps I could turn briefly to the question of research and knowledge. You have dealt with stem cells in your earlier answers. Would it be possible to compile a list of things that are actively in consideration or decent pieces of research—and some of it social as well as scientific—in terms of some of the cultural stigmas and taboos that there are around? I am always frightened of complacency. The drip, drip, drip approach to life sometimes takes a long time, and in the long run we are all dead.

Sir Liam Donaldson: We can write to you with a comprehensive list.

Lord Kirkwood of Kirkhope: Thank you very much. That would be very useful.

Q95 Lord Trefgarne: Many years ago I had the privilege of being junior minister for what was then called the DHSS. The Chief Medical Officer was someone called Sir Henry Yellowlees and he was brilliant at beating up ministers to get their priorities right. You might take a leaf out of his book.

Sir Liam Donaldson: Okay. Thank you very much. I wrote a history of the Chief Medical Officers, My Lord Chairman—with myself kept out of it—three years ago and I did give an account of how things sometimes get decided. It is fascinating to look back on history and see how some decisions were taken and how the Chief Medical Officer might have influenced those. I will send you a copy.

Q96 Lord Trefgarne: I dare say Sir Henry features in your book.

Sir Liam Donaldson: He does, yes.

Q97 Chairman: We are very grateful for the influence you have brought to bear here. We asked the European question earlier, but, just before we go, because we are really looking at an EU dimension, do you have anything else to say about the way we should be looking at the way the EU confronts this issue?

Sir Liam Donaldson: No, the categories I identified or the levels at which the EU could become involved, I would not want to modify that earlier answer, thank you.

Q98 Chairman: We hope you have influenced us enough for us to be of some influence in this area when we bring our report, because that may be another opportunity, once the evidence is gathered, for this issue to come to the fore again. You may want to talk to some members of the Committee again at that stage. Could I thank you both very much for coming and answering, at an angle, if you like, the questions that have been put to you.

Sir Liam Donaldson: Thank you, My Lord Chairman. Perhaps I could add that, before I came across, I was in a meeting with Lord Darzi and he advised me where the defibrillator was kept! I am relieved that I have not had to use it.

Chairman: We are all relieved that Lord Darzi is now on the front bench and can leap over benches—he knows how to use the machinery and will save lives!

Supplementary memorandum by Sir Liam Donaldson

DEPARTMENT OF HEALTH AND RESEARCH COUNCIL FUNDED RESEARCH

DEPARTMENT OF HEALTH

The Department’s goals for NHS research and development are set out in Best Research for Best Health—a new national health research strategy. The strategy document was published in January 2006 and its implementation is well underway. That implementation includes the strengthening of pre-existing research programmes, and the introduction of new funding streams. The first of the two clusters of research activity concerned with organ donation and transplantation described below belongs to an established research programme (the Health Technology Assessment programme). The second is a product of the new Biomedical Research Centres set up to drive the development, testing and uptake of new and better ways to prevent, diagnose and treat ill health.
1. Health Technology Assessment Programme

1.1 An evaluation of the costs, effectiveness and quality of renal replacement therapy provision in renal satellite units in England and Wales (Roderick) 178 pages, Volume 9, number 24.
Original project title: An evaluation of the cost-effectiveness and quality of care of renal replacement therapy provision in satellite units.
Chief Investigator: Dr Paul J Roderick, Reader in Public Health, Public Health Sciences and Medical Statistics, University of Southampton.
Publication date: July 2005

1.2 A systematic review and economic model of the clinical and cost-effectiveness of immunosuppressive therapy for renal transplantation in children (Yao) 178 pages, Volume 10, number 49.
Chief Investigator: West Midlands Health Technology Assessment Collaboration (WMHTAC), University of Birmingham
Publication date: December 2006

1.3 Clinical and cost-effectiveness of newer immunosuppressive regimens in renal transplantation: a systematic review and modelling study (Woodroffe) 194 pages, Volume 9, number 21.
Chief Investigator: West Midlands Health Technology Assessment Collaboration (WMHTAC), University of Birmingham
Publication date: May 2005

1.4 The clinical and cost effectiveness of pulsatile machine perfusion vs. cold storage of kidneys for transplantation retrieved from heart-beating and non-heart-beating donors (Wight) 94 pages, Volume 7, number 25.
Original project title: The clinical effectiveness and cost effectiveness of preservation systems for retrieving kidneys from beating and non-heart beating donors.
Chief Investigator: School of Health and Related Research (ScHARR-TAG), University of Sheffield.
Publication date: September 2003

1.5 Evaluation of molecular techniques in prediction and diagnosis of cytomegalovirus disease in immunocompromised patients (Szczepura) 176 pages, Volume 10, number 10.
Original project title: Evaluation of molecular techniques in prediction and diagnosis of cytomegalovirus (CMV) disease in immunocompromised individuals.
Chief Investigator: Dr Diana Westmoreland, Consultant Virologist, Department of Medical Microbiology and Public Health Laboratory, University Hospital of Wales
Publication date: April 2006

2. Biomedical Research Centres

2.1 Cambridge BRC: Improving Outcome in Transplantation Research Theme.
This theme is aligned to the internationally renowned multi-organ transplant unit based at Cambridge University Hospitals NHS Foundation Trust (CUHNFT). The two major problems in transplantation are a severe shortage of human organs and tissues for transplantation and graft rejection along with the side effects of non-specific immunosuppression. The overall aim of this theme is to address these two problems. We aim to maximise patient access to organ and tissue transplantation and to improve outcome after transplantation by reducing post-transplant morbidity and graft loss.
The specific aims are to:
— improve organ allocation through better understanding the influence of MHC gene products on transplant outcome;
— evaluate novel targets for therapeutic intervention in vascular injury associated with transplantation;
— test new immunosuppressive agents for their ability to modulate alloimmunity and improve transplant outcome;
— evaluate novel approaches for optimising organ preservation and assessing organ function and viability before and following transplantation; and
— develop the use of human embryonic stem cells as a source of cells and tissue for clinical transplantation.

2.2 Guy’s & St Thomas’ Hospitals NHS Foundation Trust / King’s College London BRC: Emerging Diagnostic and Therapeutic Approaches in Organ and Cell Transplantation Research Theme.

The number of life-saving or life-enhancing solid organ transplants (heart, lung, kidney, liver, and pancreas) exceeds 25,000/year in the US and UK. However the success of transplantation is plagued by a shortage of donor organs (enough for one in four eligible patients) and high rates of graft failure (4–10% per annum) beyond the first year of transplantation. Moreover, intensive use of therapy to prevent rejection is associated with life-threatening complications, including a 20% risk of cancer. Advances are thus needed to reduce the burden of failures, in particular to prevent reperfusion damage and early rejection episodes, which together reduce the half-life of kidney transplants by about 50%. Given the high initial (£54,000/patient) and maintenance (£10,000/year) costs of transplantation, the current failure rate of 2,700 transplants (out of 9,000) over five years in the UK equates to an estimated waste of £250 million for kidney transplantation alone.

Based on several outstanding programmes of pre-clinical and clinical research and one of the largest patient cohorts in Europe (eg 150 kidney and 150 liver transplants/year, largest living donor programme in UK, hepatocyte and islet transplant programmes), we propose to deliver improvement in graft half-life though better control of the inflammatory and immune response, aided by application of genetic markers that predict and interpret the outcomes of transplantation and development of new imaging techniques for visualising the inflammatory response in transplant organs. Specifically we propose the following aims:

— to apply membrane targeted inhibitors of complement to the prevention of reperfusion damage, and so reduce the burden of graft failure through non inflammatory injury and immune stimulation;
— to promote long term graft acceptance through tolerance induction protocols using cell-based therapy;
— to develop new imaging techniques that enable complement inflammatory activity and the cellular immune response to be visualised in whole organs; and
— to develop biomarkers in the innate and adaptive immune system that help to predict and interpret the outcome of transplantation.

2.3 Imperial College Healthcare NHS Trust Imperial College London: Renal Medicine and Transplantation Research Theme.

The overall aim of our programme is to pursue translational and clinical research in key areas of renal medicine and transplantation. We run a renal laboratory group of around 40 clinical and non-clinical researchers, whose work is integrated with the Imperial College London broad strategic research theme of Immunity and Inflammation. We work closely with researchers in the Immunology Department. Our basic research is directly linked to our translational research programme through six multidisciplinary clinical research groups. These are based at the West London Renal and Transplant Centre (WLRTC) at Hammersmith, which is the largest centre for renal disease in Europe. This gives us a tremendous opportunity to develop our translational research over the next five years. Our specific objectives include the following:

— to understand disease mechanisms and develop diagnostic and therapeutic approaches in glomerulonephritis and diabetic nephropathy;
— to investigate the causes and development treatment for renal cystic disease and renal carcinoma;
— to increase the donor pool and improve the outcome in renal transplantation; and
— to improve the outcome and quality of life in patients on dialysis.

MEDICAL RESEARCH COUNCIL

The Medical Research Council (MRC) is one of the main agencies though which the Government supports medical and clinical research. The MRC is an independent body funded by the Department for Innovation, Universities and Skills, via the Science and Innovation Group.

The MRC’s portfolio of transplantation research is largely addressed through the Infections and Immunity Board and focuses primarily on mechanisms of rejection and tolerance. The MRC has recently funded the new MRC Centre for Transplantation at King’s College London, directed by Professor Steven Sacks. The Centre,
one of six new translation research centres, has been awarded £2 million over five years to investigate a range of issues in transplantation including better preservation of donated organs. Although this award is not directly linked to DH activity, the Centre is embedded within one of the NIHRs Biomedical Research Centres and has significant clinical links. Prof Sacks also holds an MRC Research Grant which has recently been renewed at a level of £1.4 million for a further five years.

Current grants relating to transplantation total £7,872,875, comprising nine awards with an annualised spend of £1.9 million.

Relevant projects are as follows:

- Dr M Cobbold, University of Birmingham—The development of cellular therapy for the correction of CMV-specific immunodeficiency after stem cell transplantation (1/7/03–30/6/08 £550k)
- Dr K Suzuki, Heart Science Centre, London—Role of cell transplantation in treating heart failure (August 03–July 08 £775k)
- Dr A Dorling, Imperial College, London—Targeted inhibition of coagulation—an anti-inflammatory approach to prolonging organ graft survival (3/10/07–2/10/08 £171k)
- Dr S Nicholls, University of Bristol—Corneal graft rejection in the inbred minipig (1/3/07–28/2/09 £250k)
- Professor P Moss, University of Birmingham—Adoptive T cell immunotherapy therapy for adenovirus infection in transplant patients (1/9/06–31/8/09 £160k)
- Dr K Y Shiu, Imperial College, London—Defining the pathophysiological role of B cells and the therapeutic potential of anti-CD20 in chronic renal allograft rejection (1/9/06–31/8/09 £64k)
- Professor H Waldmann, University of Oxford—Therapeutic Immunoregulation (1/1/05–31/12/09 £2.0 million)
- Professor S Sacks, Kings College, London—Targeting the complement system in transplantation (1/1/07–31/12/11 £1.4 million)
- Professor S Sacks, Kings College, London—Emerging diagnostic and treatment approaches in organ and stem cell transplantation (1/4/07–31/3/12 £2.08 million)

In addition, the MRC funds a large ongoing programme of transplantation biology research (£854k in 05/06) led by Professor Elizabeth Simpson at the MRC’s Clinical Sciences Centre in London.

**ECONOMIC AND SOCIAL RESEARCH COUNCIL**

The Economic and Social Research Council funds research and training in social and economic issues. The ESRC is an independent organisation that receives most of its funding through the Department for Innovation, Universities and Skills. A budget of £181 million (2007–08) funds over 2,500 researchers in academic institutions and policy research institutes throughout the UK and supports more than 2,000 postgraduate students.

ESRC research in the area of organ donation and transplantation includes:

- Transplantation and the organ deficit in the UK
  Dr Anne-Maree Farrell
  University of Manchester
  01/10/06–31/03/08
- Xenotransplantation: risk identities and the human/nonhuman interface
  Professor Mike Michael
  Goldsmiths College
  01/01/01–30/06/03
- Medical device governance
  Dr Alex Faulkner
  Cardiff University
  01/06/02–31/07/04
- Childhood cancer tissue donations
  Professor Mary Dixon-Woods
  University of Leicester
  29/04/04–28/02/07
Using simulation modelling in the management of liver transplantation
Dr J Ratcliffe
Brunei University
01/04/98–31/05/99

Spaces of stem cell science: exploring processes of transnational research
Professor Stephen Wainwright
Kings College London
01/03/07–31/12/08

Processes, dynamics and problems in translation: a comparative study of stem cell innovation in the UK
Dr Alison Kraft
University of Nottingham
01/04/07–31/03/09

Haemotopoietic stem cells: the dynamics of expectations in innovation
Dr Paul Martin
University of Nottingham
14/10/04–13/10/07

Quality of life as an innovative health technology
Dr David Armstrong
Kings College London
09/04/01–01/05/03

Measuring preferences regarding equity and variations in health
Professor Peter Smith
University of York
01/03/99–31/08/01

Mapping stem cell innovation in action
Dr Clare Williams
Kings College London
01/11/04–31/10/06

UK Transplant—part of NHS Blood and Transplant—also commission research.
“Barriers to organ donation within the general public”—published March 2003, conducted by RBA Research
“NHS staff attitudes to organ donation”—published Dec 2004, by Research Quorum
“Attitudes and barriers to organ donation, and best communications routes to reach black and minority ethnic communities (BME)”—published May 2006, by Connect Research & Consultancy Ltd.

NHS Blood and Transplant have also conducted a number of short polls, including “How well do you know your partner’s wishes”, and “The value of sight” survey. The results of both these surveys have been used to help develop news releases for specific public relations activity for example the 10th anniversary campaign and the 100th anniversary of the first successful cornea transplant.

December 2007

Further supplementary memorandum by Sir Liam Donaldson

INTENSIVE CARE SOCIETY

GUIDELINES FOR ADULT ORGAN AND TISSUE DONATION
Prepared on behalf of the Intensive Care Society by the Society’s Working Group on Organ and Tissue Donation.
CONTENTS

1. Basic organisation
2. Criteria for organ donation
3. Approaching the family
4. Certification of death by brain stem testing
5. Clinical management of the potential heart beating organ donor
6. Controlled non heart beating organ donation
7. Last offices and follow-up
8. Revision date
9. Members of the Intensive Care Society’s Working Group on Organ Donation

ACKNOWLEDGEMENT

The Society gratefully acknowledges funding from UK Transplant. This funding covered the travelling and other expenses involved with the meetings of the working group.

The Guidelines in full can be found at http://www.ics.ac.uk/icmprof/downloads/Organ%20%26%20Tissue%20Donation.pdf
26 INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE

THURSDAY 13 DECEMBER 2007

Present Gale, B
Howarth of Breckland, B (Chairman)
Lea of Crondall, L
Morgan of Huyton, B

Neuberger, B
Trefgarne, L
Young of Hornsey, B

Memorandum by UK Transplant (on behalf of NHS Blood and Transplant)

The House of Lords EU Select Committee has called for evidence in the light of the intention by the European Commission to develop an EU Directive on Organs for transplantation. The following 17 bullet points summarise the issues on which the Select Committee seeks evidence, and each bullet point is followed by the proposed response.

1. EU-WIDE SHORTAGE OF ORGANS AVAILABLE FOR TRANSPLANTATION

It is clear that there is a severe shortage of organs in every EU state (with the possible exception of Spain). Spain has 35 deceased donors per million population (pmp), whilst most other EU states have donor rates in the range 12 to 23 pmp. The figure for the UK is 12.8 pmp. There are currently over 8000 patients in need of a transplant in the UK. The transplant list rose by 8% last year, with approximately 1000 of those patients accepted for the transplant list dying each year before a suitable organ becomes available. Thousands more patients who would benefit from a transplant are not placed on the transplant list as a result of the shortage of organs and it is difficult to define the true need for organs for transplantation. The pool of heart beating donors is likely to reduce further as changes in the management of severely brain-injured patients (e.g. decompressive surgery) result in fewer patients who progress to brain stem death. Some of these patients will fail to recover and, at some point, treatment is likely to be withdrawn. Such patients may be potential non-heartbeating organ donors (NHBOD) and NHBOD programmes should be expanded to capture this potential.

2. ORGANISATION OF ORGAN DONOR AND TRANSPLANTATION SYSTEMS

The Spanish success is clearly the result of an integrated and systematic approach to organ donation which has been replicated in northern Italy and several South American countries. Whilst few have achieved the Spanish donation rate, all have seen a major increase in donation. It is of absolute importance for states to have a national organisation with responsibility for the donation system. The key components of a successful donation system are:

— A clear legal framework for the diagnosis of death by neurological tests (brain death) and a legal and ethical framework for donation after cardiac death;
— Commitment from all hospitals with critical care facilities to ensure that all potential organ donors are identified and notified to the donor co-ordinator network. Donation must be seen as an integral part of end-of-life care for all suitable patients;
— A well-structured national donor co-ordinator network, including an individual with responsibility for organ donation in every hospital with critical care facilities;
— Support from the general public for donation. In Spain, the families of 83% of potential donors agree to donation as compared to only 60% in the UK;
— Efficient and fully-resourced organ retrieval teams;
— Accurate data to monitor all steps of the process and robust performance management;
— High level political commitment.
3. RAISING PUBLIC AWARENESS OF ORGAN DONATION

The public has a key role to play in the promotion of organ donation. Whilst it is encouraging that research shows that 90% of people in the UK express their support for organ donation, the reality is that four out of every ten hearts, livers, kidneys and other organs that could be donated and transplanted are lost because the donor’s family refuse permission (see above). This is not a consequence simply of the law (see below). Even in the UK, following the introduction in September 2006 of the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 which both give absolute primacy in law to the wishes of the individual (if known), it is acknowledged by the Human Tissue Authority Codes of Practice that organ donation may not be appropriate if the family is implacably opposed. Much has been done in recent years to promote organ donation in the UK, in particular introducing the NHS Organ Donor Register (ODR) which currently has almost 14.7 million people who have registered their wish to donate their organs after death. This figure is rising by approximately 1 million per year, but still represents less than 25% of the population. Much more work is required to identify the most effective way to promote public awareness, and even more importantly public acceptance of organ donation. This in turn needs to be supported by adequate funding of a high-profile, national campaign. This might go some way towards addressing the discrepancy between the large numbers of individuals who claim to be supportive of organ donation and the actual number who register as donors. The variation in relative refusal rate across member states is also an area for action informed by the outcome of studies in this area (e.g. the collaborative requesting study in the UK).

4. USE OF ORGAN DONOR CARDS, INCLUDING THE IDEA OF A EUROPEAN ORGAN DONOR CARD

The NHS Organ Donor Register (and its predecessor, the donor card) have proved to be very useful vehicles for the promotion of organ donation to the public. However, there is little direct evidence that donor cards or registers have an effect on actual donation. There are those who question whether any card or register can provide enough information to people who want to register their wishes to ensure that their consent to donation is informed and valid (in the general rather than the legal sense). These concerns could be magnified by the introduction of a European donor card. It is not clear whether any such card could sit easily alongside national systems (particularly those states with presumed consent legislation) or would be expected to replace them—a sure recipe for confusion and muddle. The key question relates to the status in law of a European card or a register. It may be more effective as a simple record of the wishes of the individual. As proof of legally valid consent, however, it could raise major anxieties about its use, not least amongst the public, with the possibility of negative impact on the level of willingness to sign up for donation.

5. USE OF VOLUNTEER LIVING DONORS

Living donor kidney transplantation has been established in the UK for many years, as is the case in most EU states. The number of such transplants has more than doubled in the UK in the past five to six years to approximately 700 per year. The process is well regulated by the Human Tissue Authority. Living donor liver transplantation is relatively new to the UK, and the numbers are very small, but is more common in other EU states (particularly Germany). There are clear national and international professional guidelines on living donor transplantation and the care of the living donor.

One area where EU co-operation may be of interest is in so called paired donation whereby one live donor-recipient pair who are not matched exchange a kidney with another pair. These patients are more likely to find a suitable exchange when there is a large number of pairs in the pool. The system came into operation only recently in the UK and more experience is needed, but there could be additional benefits from international co-operation in the future.

6. ENSURING THE QUALITY AND SAFETY OF CROSS-BORDER ORGAN DONATION WITHIN THE EU

The various Organ Exchange Organisations within Europe (not all of which are within the EU) have met annually in a semi-formal way for many years and there are proposals to establish future meetings in a more formal way. Few organs are exchanged across national boundaries (with the exception of the seven countries that take part in the Eurotransplant Foundation). There would be considerable merit in a more structured approach to ensure that appropriate information is always available to make an informed judgement about the risk-benefit analysis inherent in organ exchange between EU states and to harmonise the documentation, transport and traceability requirements. Additionally, consideration should be given to standardisation of the diagnosis of death by neurological and cardiovascular criteria across the EU. This would prevent national differences in diagnosis impeding cross EU co-operation in organ donation.
7. **Ethical Issues relating to Organ Donation and Transplantation**

Donation and transplantation raise profound ethical issues that are the subject of much debate at an international level. The (international) Transplantation Society and the World Health Organisation are both very active in this field. However, the translation of ethical principles into a legal framework is equally important and this could be an area of potential interest to the EU states. There is, currently, considerable anxiety in the UK about the legality of some parts of the donation pathway, most specifically relating to non-heartbeating donors. To some extent these anxieties stem from unintended consequences of the Mental Capacity Act 2005 which places absolute priority on “the best interests” of the patient without defining that term—specifically, it is important to establish that organ donation is in “the best interests” if the patient and their family wish this. These difficulties must be resolved. It is equally important that due care is given to any potential harmonisation of the legal and ethical framework for donation across the EU to avoid any further unintended or unanticipated difficulties.

8. **Health and Social Welfare Benefits of Organ Transplantation**

There is overwhelming evidence that, for appropriate patients, life expectancy is considerably longer after a kidney transplant as compared to the alternative treatment—dialysis. There is also clear evidence that quality of life is improved. For most other forms of organ failure, the only alternative to a transplant is early death. For all organ transplants, 85-95% of patients will be alive and well one year after the transplant, with survival at ten years in the range 50-80%, depending on the type of transplant. Moreover, regardless of the nature of the healthcare system and the funding mechanism, it is considerably cheaper to provide long-term care for a patient with a functioning kidney transplant than to provide dialysis. Increasing kidney transplantation has the possibility to save millions of pounds in the UK and the EU-wide savings could be very significant indeed.

9. **Medical Risks of Organ Transplantation**

These relate very largely to the need for lifelong immunosuppressive drugs to prevent rejection of the transplant. There is much active research into possible means of minimising or even avoiding entirely the need for such drugs and there could be considerable benefits if the EU were to play a role in funding and co-ordinating such research on an international basis.

10. **Illegal Trafficking in Organs**

There is almost universal acceptance of the principle that to buy or sell organs from living donors is not acceptable. Many EU states (and other countries) have incorporated this principle into national law—in the UK, through the Human Tissue Acts. Whilst there is little or no good evidence of organ trafficking within EU states, there is concern about past or present activity within several of the newer eastern European states and to an even greater extent about recent practice in India, Pakistan, China, the Philippines and South Africa. Most of these countries are now seeking to prohibit organ trafficking. A small number of UK residents continue to travel abroad each year to have a kidney transplant from a paid donor, who then return to the UK for long-term follow-up and treatment. The EU clearly has a role in maintaining vigilance to ensure that organ trafficking cannot and does not occur within member states.

**Other Issues of Relevance to the Commission Document:**

11. **Organ Donation and Transplantation from a Faith-based Point of View**

National leaders of the six major faiths in the UK—Christianity, Judaism, Islam, Hinduism, Buddhism and Sikhism—have all explicitly endorsed organ donation and transplantation. However, differences of opinion exist amongst local faith leaders across the country, a situation exacerbated by a blurred distinction between faith, culture and ethnicity. There is a clear and urgent need for local leaders to use their considerable influence to promote support for organ donation in their communities, particularly given that opinion at grassroots does not always reflect the official view of the faith.
12. **Organ Donation and Transplantation from the Point of View of Population Sub-Groups within the UK**

There are considerable problems relating to organ donation and transplantation stemming from the culturally and ethnically diverse population of the UK. Patients of Asian or African-Caribbean origin are three to four more times more likely to develop kidney failure and need a transplant than their white counterparts. Moreover, the frequency of certain blood groups and tissue types differs between people of different ethnic origin, making it difficult to find a well-matched kidney for black and minority ethnic (BME) groups. Unfortunately, for a number of reasons, organ donation from the BME population is lower than from the white population. This is due, in large part, to the lower rate of consent for donation (60% if the potential donor is white, 25% if the donor is of any other ethnic origin). As a result, whilst 23% of patients waiting for a transplant are of BME origin, they comprise only 8% of the general population. There is also a marked variation between different areas of the UK, related to the ethnic make-up of the population in different areas.

13. **The “Presumed Consent” Approach for Identifying Organ Donors**

Of all aspects of organ donation, presumed consent (or opting-out) generates probably more debate and controversy than any other. However, there is virtually no evidence to confirm that presumed consent legislation is associated with an increased donor rate, and there is some evidence to demonstrate that the legislative framework has little or no impact on the donation rate in different countries. The architect of the uniquely successful Spanish model, Dr Rafael Matesanz, is firmly of the view that the key factor in this success is the systematic approach to donation in Spain, rather than the legislation. The debate often centres only on the potential to increase organ donor numbers. The impact of presumed consent is, of course, wider and the possible effects on the relationship between critical care clinicians and their patients/relatives should not be underestimated. The primary role of these clinicians is to provide support to patients with the expectation of survival and organ donation is only considered when further treatment options are unavailable or inappropriate. The public currently understands and accepts this situation and has faith that their physicians always act in their best interests (rather than those of a potential organ recipient). Ensuring that this faith is maintained is critical. Any debate on changes to the legislation should carefully consider this issue.

14. **Arrangements for Taking into Account the Views of Relatives about Removing Organs for Transplantation from a Deceased Donor**

The relatives of potential organ donor must always be involved in the donation process, and this involvement is almost identical whether there is presumed consent or opting-in legislation (as in the UK). In order to ensure the quality and safety of donated organs, it is necessary to obtain not only a full medical history of the donor, but also his/her social history, the use of intravenous recreational drugs and sexual activity. In practice, these requirements can only be met through a detailed discussion with the donor’s relatives. This is best achieved by fully-trained donor transplant co-ordinators and it is essential that there is a robust national network of co-ordinators with the time and expertise to obtain this information in a sensitive manner. It should also be noted that the relatives have a de facto veto over donation so that if they are unwilling to provide the necessary information to ensure quality and safety, donation cannot proceed. These discussions take place in exactly the same way in Spain (which has opting-out legislation) as in the UK (which has opting-in legislation) and this reinforces the view that the legislative framework is peripheral to the need for a national organisation to ensure a systematic approach to organ donation.

**The Need for an EU Role in this Field—the Commission’s Argument is that it is Needed for Three Main Reasons:**

15. **To Promote Co-operation between Member States in Order to Share Expertise and to Expand the Size of the Potential Donor Pool in Each Member State**

Most EU states face broadly similar challenges, but have approached the need to promote organ donation in a variety of ways. There would clearly be advantages to greater co-operation in the sharing of experience and the more general introduction of best practice. The scientific and clinical communities internationally share knowledge and expertise regularly and constructively. Such co-operation between EU member states on organ donation and transplantation has been developing through projects such as Alliance-O, but there would be clear benefits to extending this collaboration. Good information, in a standardised format, on the identification and referral of potential donors and the consent rate for donation is one of the many areas where
accurate and comparable data are essential. It would also be of value to ensure a more standardised training programme for donor transplant co-ordinators, with training being recognised and transferable between EU states.

16. To Provide a Cross-border Framework for the Organisation of Organ Donation and Transplantation, with Harmonised Rules that would Provide EU Citizens with Higher Standards for Organ Safety and Quality than can be Assured by the National Legislations of Member States Acting Separately

The EU has, in recent years, introduced directives covering blood, tissues and cells to provide assurance on quality and safety standards. Organ donation and transplantation also require considerations of quality and safety, but there is one fundamentally important difference. The supply of blood, tissues and cells can be maintained whilst applying the highest levels of quality and safety, whereas the supply of organs does not currently meet the demand and across Europe thousands of patients die each year because an organ is not available. For some patients—particularly those with sudden fulminant liver failure—death will be inevitable within hours if a liver is not available for transplantation. The risk-benefit analysis of a suitable donated organ is therefore completely different from the risk-benefit analysis associated with blood, tissue and cell donation, and will itself vary with the clinical needs of the individual recipient. In other words, the risks associated with a given organ may be deemed unacceptable for one recipient (who can wait for a so-called better organ), but entirely acceptable for a second recipient for whom the almost inevitable alternative, if the organ is declined, is death. In the UK, there is clear guidance on the risks that may be associated with donated organs, but a recognition that the final decision as to whether to transplant a particular organ must rest with the clinician, the patient and the patient’s family. Whilst it would be helpful to have an EU-wide common data set of information about the donor and the organ, in order to allow informed decision-making, it would be essential to guard against excessive priority being given to safety and quality that could reduce further the number of organs that can be transplanted.

A further area of concern is the impact of the European Working Time Directive (EWTD). By its very nature, organ donation is totally unpredictable and donor co-ordinators and surgical retrieval teams must be available at all times. Most organ retrieval procedures take place outside working hours and the transplant operations need to take place within hours of retrieval to ensure that the organs are viable. The surgical staffing of retrieval and transplant teams (which frequently involve the same team of surgeons) is under serious threat from full implementation of the EWTD. Whilst this is most pronounced in the case of heart and lung transplantation, other organ transplant programmes are also affected.

17. To Enable More Effective Action Across the EU to Fight Illegal Organ Trafficking

While illegal organ trafficking is not perceived to be a significant problem within EU states at present, it is essential that vigilance is maintained. This is most effectively achieved through the appropriate legal and regulatory framework within each state—as currently exists within the UK. Increased co-operation between the regulatory authorities would ensure that the position does not deteriorate in the future.

October 2007
Examination of Witnesses

Witnesses: Mr Chris Rudge, Managing and Transplant Director, UK Transplant, Mr Gareth Jones, Director of Scientific Development and Bioethics, and Ms Triona Norman, Transplantation Policy Lead, Department of Health, examined.

Chairman: Good morning. We are very grateful to you all, particularly Ms Norman who has been with us for two sessions, one after the other, for taking the time and trouble to come and talk about what we see as a very important inquiry and I am sure that is true from where you stand particularly. The issues that arise from the Commission’s proposals arouse quite a lot of public interest and we recognise that not only is it of interest but also of public sensitivity. Again, working where you are, that will come as no surprise. We are taking evidence on a number of aspects of existing and developing UK policy on organ donation. Today’s evidence from you on the work of the organisation UK Transplant and of the Department of Health’s Organ Donation Taskforce is of particular importance in all of that. We have our Special Adviser with us, Professor Bobbie Farsides, who I understand you will know. Perhaps I should state now that she is a member of the Organ Donation Taskforce that will be discussed this morning. We have another declaration too.

Baroness Neuberger: My brother-in-law James Neuberger is deeply involved in transplantation. I see you all nodding, so you obviously realise that.

Q99 Chairman: We have a scheduled hour until 11 o’clock for the session. I should remind you that the session is open to the public and will be recorded for possible broadcasting and webcasting. A transcript is taken of the evidence and put on public record in printed form and on the parliamentary website. A few days after this session, your office will be sent a copy of the transcript to check for accuracy. Please advise us of any corrections as quickly as possible. You may submit supplementary evidence after the session to clarify or amplify any points made during your evidence or to answer any questions that may not be reached today. Please could you start by stating for the record your names and official titles. After that you are very welcome to make an opening statement; otherwise you can move straight into the questions.

Mr Rudge: My name is Chris Rudge. I am the Managing and Transplant Director of UK Transplant, which is part of NHS Blood and Transplant. I was a transplant surgeon myself for 30 years before doing the job I now hold. I would like to make an opening statement.

Mr Jones: Good morning. I am Gareth Jones from the Department of Health. I am the Director of Scientific Development and Bioethics and organ transplantation is one of the areas that falls within my remit.

Ms Norman: Good morning. I am Triona Norman. I am the Department of Health Transplantation Policy Lead.

Q100 Chairman: Mr Rudge.

Mr Rudge: I would like to make three very simple points very quickly that will come as no surprise to this Committee. I am sure. The organ donor rate and therefore the transplant rate in the United Kingdom is poor and it is static: it has not really changed for ten years or more. The waiting lists of those people waiting for an organ transplant is rising and the gap between the number of people waiting for a transplant and the number of organs that becomes available is increasing. That results in at least 1,000 patients a year who are on the waiting list for a transplant dying before a suitable organ becomes available. The third point is slightly more complex. The number of people who we can demonstrate are on the waiting list for a transplant is a very poor reflection of the number of people who would benefit from a transplant. Most transplant units limit the number of people who are put on the waiting list to an approximation of the likely number of organs that are going to be available. That is particularly true of the heart transplant and the liver transplant programmes. There are probably thousands more patients a year—it is unquantified, but it is in the thousands and probably the tens of thousands—who would benefit from a transplant but are never placed on the waiting list. As you said in your introduction, My Lord Chairman, this is a very, very important question to us and I am grateful to you for taking the time to listen to us.

Q101 Chairman: We will start by looking at the role of the Organ Donation Taskforce. We need to learn more about this. Although we are going to have oral evidence later on from the Chair of the Organ Donation Taskforce, could you begin by describing for us the composition of the membership of the Taskforce and how it goes about its business? In relation to the initial remit of the Taskforce to make recommendations about how to increase donor and transplant rates in the UK, would you please outline the key issues that the Taskforce has considered? While we understand that the precise nature of the conclusions and recommendations in the first report of the Taskforce will be confidential until it has been published, can you describe for us in general terms the main thrust of the report and the principal ideas it puts forward for improving organ donor and transplant rates in the UK?
Mr Jones: I would like to thank the Committee too for inviting us and giving us the opportunity to talk to you and help you with your inquiry. As Chris Rudge has outlined, there is a recognisable problem here in the UK with donor and transplantation rates. Health ministers were sufficiently concerned to get up this Taskforce in 2006 with the remit of taking stock of progress in terms of our success in these areas, trying to identify the specific barriers to the donation of transplantation and, of course, making recommendations on how we can improve the situation. They asked Elisabeth Buggins to set up a Taskforce with the relevant expertise. The Taskforce had its first meeting at the end of 2006 and they have met nine times, up until September this year. The composition of the group ensured that all of the key areas of expertise and interest were represented: transplant surgeons, intensive care specialists, patient representation, NHS management, donor liaison, nurse interests, people with an ability to bring to the discussion the issues around diversity and also media interest. We are very grateful for the time, energy, knowledge and expertise that the members have brought to this task. They have done a lot of very, very good work and the report, as you know, is currently with health ministers. They did not just rely on the expertise around the table. They recognised very early on that other countries have better success rates than the UK—we do not do well against other Western European countries—and so they took evidence and advice from a number of people: Rafael Matesanz from Spain who led for 15 years the development of the Spanish model; Frank Delmonico from the USA, another example of a successful model; and Jeremy Chapman from Australia who is chair of an Australian taskforce looking at similar issues. They were enormously helpful to the group in being able to bring to the discussion areas where certain steps they had taken in their countries had been found to significantly improve the rates of donation and transplantation. In broad terms, the Taskforce recognised very early on that they needed to address the systemic issues: the capacity and capability within the system; what they could do to improve the way that things were done. They looked at structures, roles and responsibilities and how the thing works in practice at each stage. They also recognised a number of fundamental things: first of all, that, although it is a local activity, in essence it is a UK-wide service. Also, they were asked specifically to look at all of these issues within the current legal framework. They were not asked, for example, to look at presumed consent or opt-out or other issues which might not be possible within the current legal framework. They looked at funding: Is the funding appropriate? Is it in the right place? They looked at what makes people want to donate? There is, seemingly, a very high degree of public support for donation—90% of the population, we are told, support the principle—but in practice only 25% of the population are on the Organ Donor Register. There is the issue around black and minority ethnic populations, which are significantly under-represented on the Organ Donor Register and yet are disproportionately more likely to require a transplant. They were looking at all of these factors—the legal issues, the ethical issues—and the practical issues: What could they recommend that they felt would make a significant difference? The report, as I say, is with ministers at the moment and we are looking forward to publication and a government response early in the New Year. I think they have done a terrific job: I was at many of the meetings and I think what they have produced will be an extremely worthwhile report and a real contribution to this area.

Chairman: Thank you very much.

Q102 Baroness Neuberger: You have answered part of what I wanted to ask. In September the Secretary of State asked the Taskforce very specifically to consider the opt-out question. I do not know if that has all been included in the report which is going to come out early in 2008 or whether that is going to be an additional piece of work but, either way, it would be very interesting for this Committee to know what the precise issues are that have been considered over that question. If it is not coming out with the report in early 2008, can you tell us when that is going to be ready?

Mr Jones: It was not included in the original remit. The Chief Medical Officer, who gave evidence to you recently explained that his annual report this year had within it this proposition for presumed consent or opt-out scheme. The Secretary of State and health ministers recognised that although the Taskforce had the right people to look at presumed consent—because they have amassed this expertise and looked at the detail of the issues—the nature of the question of opt out is different. It is not looking at what we can do within the existing framework; it is a separate issue, there are sensitivities around it which we all recognise, and therefore the Secretary of State in September asked the Taskforce to take it on board as a separate task. They are now looking at what additional expertise they will need to draw on in order to answer questions. There are a lot of issues to consider: What do we mean by consent? And there are practical issues: How would it work in practice? Would it make a difference? Some other countries have a presumed consent regime and some would claim that it has made a difference. What is the public attitude to some of these issues? I think they have quite a difficult complex task and they recognise that they need to augment their membership with people who can help them answer some of these questions.
They are looking at research that has already been done in some of these areas and making sure they learn from that, and it is very possible they will have to consider some new work where there are gaps in that. I do not think they have a definitive timetable at the moment. It will not be part of the main report of the Taskforce when it comes out early in the New Year but I think they are very much seized of the need to provide an answer as quickly as possible.

Q103 Baroness Neuberger: I think we knew it was not going to be in the original report but I wanted to get that on the record. You say they are expanding their membership or thinking about expanding their membership. When is it likely that they will at least have their membership established and be ready to start work on this question? If you cannot tell us when it would finish, at least it would be quite nice to know when it is going to start. 

Mr Jones: They have already met to talk about how they will handle it. The membership of the taskforce itself will not significantly change because they now have a dynamic as a group: they work well together and they have a shared understanding of the issues. The likely approach is going to be that they will set up a number of groups to look at each individual area for example, if there are practical considerations, getting the right sort of group of people together to thrash that out. The work will begin shortly in the New Year. They have pencilled in a series of dates for work to progress fairly quickly. I would not want to predict on their behalf how much time they will need for the work. Perhaps when Elisabeth Buggins speaks to you, she will have a better idea.

Baroness Neuberger: We can press her a little on that as well. Thank you very much.

Q104 Lord Trefgarne: If presumed consent is eventually decided upon as the right policy, will that mean legislation?

Mr Jones: My understanding from our legal advice is that, if implemented in the way that we currently understand it, we will need to revisit the Human Tissue Act. I think the Taskforce will want to look at: What do we mean by consent? What are the various models of presumed consent or opt-out that you might look at?

Q105 Lord Trefgarne: To take an organ today without consent is against the law.

Mr Jones: My understanding is it is. That is correct.

Q106 Lord Trefgarne: You have no idea which law, I suppose.

Mr Jones: The Human Tissue Act.

Chairman: We would like to talk a little about the role of UK Transplant and Lady Morgan is going to lead into this area.

Q107 Baroness Morgan of Huyton: First of all, could you briefly outline the main functions of UK Transplant so that we are all clear about those, but, probably more importantly, could you describe for us what you think you would need to change in order to move us nearer to the Spanish success rate. What changes do you think would have to happen? To what extent are you comfortable that the stakeholders in the field would think that UK Transplant was the right organisation to take on a larger role, a new role?

Mr Rudge: The current roles and responsibilities of UK Transplant I can summarise very briefly. There are five main responsibilities. It is a UK-wide NHS organisation responsible for holding the lists of all the patients who are waiting for a transplant. There are approximately 7,500 names of patients actively waiting today for a transplant. We have a role in allocating organs once they are donated. That falls into two parts: agreeing what the rules should be as to how you decide who gets the organ but then also implementing those rules. We work very closely with the transplant community and with the Department of Health in defining, if you like, the rules for allocating organs, and then we have—24 hours a day, seven days a week—a duty office managed by people who are notified of every organ donor in the country, the whole process as it follows through and then the allocation of the organs. The details differ a bit, depending on whether it is a kidney, a heart, a liver or a lung, but, in principle, we allocate the organs. The third thing we do is to collect data. We collect data about every single organ donor and every single organ recipient and we collect data about the recipients for the rest of their lives whilst the transplant is working. We are following up on people who have had transplants for 20 years or more. We get a report every year on them. We receive about 100,000 forms of information each year on the total range of things that we do. The fourth thing we do is to use that data. We use the data to inform clinical practice, to inform what the right allocation arrangements are, but we use it increasingly as a monitoring and oversight organisation. In the last two or three years we have developed some very sophisticated ways of monitoring the results of individual transplant units, both in terms of comparing one unit with all the other units but also trying to identify as early as practical if an individual unit’s results are deteriorating. That is monitoring and oversight. The fifth role—and this is a little limited—is that we do have responsibility to promote organ donation. That falls into two headings. The first is to the public. We have—and you would expect me to say this—a limited budget to promote organ donation, for publicity to promote the Organ Donor Register, but we also have a certain amount of money that we use to invest, to give to transplant units and...
others within the NHS to try to increase organ donation. That has been in place now for about five years. There are three strands of it. Two have been extremely successful—the number of non heart-beating donors has risen, the number of living donors has risen and continues to rise—but the number of heart-beating donors—and they are really the bedrock for many forms of transplantation—has been falling slowly but steadily.

Q108 Baroness Morgan of Huyton: Why has that fall happened?
Mr Rudge: That is really the essence of everything the Taskforce has looked at. There is a wide range of things to do with the explanation. It is primarily related to the practice within intensive care units. One of the things I have not mentioned which we have established at UK Transplant is the Potential Donor Audit, so we have information on every single patient in the UK who dies in intensive care. The starting point is: Could they have donated their organs or not? At each possible stage of the process we can identify whether the right things happened or did not happen, so we can answer your question in quite a lot of detail. My Lord Chairman, there is a UK Transplant Activity Report—and I can very happily leave this copy and provide as many more copies as you would like—in which you will find a breakdown of the figures I have just described in the Potential Donor Audit. It shows that potential donors are not subjected to the brain-stem death tests on every occasion; they are not considered as an organ donor: nobody thinks about it; they are not referred to the co-ordinator network; that the right potential donor is identified; that every donor is subjected to the brain-stem death tests on every occasion; 40% of families, when they are approached, do not give consent—and so it goes on. There is a lot of detail in there.

Q109 Lord Lea of Crondall: You might not have this figure at your fingertips but you did mention, Mr Rudge, that you have had a modest budget for public information and advocacy of people signing up. If you happen to know what the size of that budget is off the top of your head, it would be interesting to know. If you cannot today, could you give us a note on that question, and maybe the related question, if you have the information, as to what sort of budgets other European countries throw at this.
Mr Rudge: All the information is available. I could give you an approximate answer now but I would prefer to give you an accurate answer, and I will certainly do that for you. I do not know if that information is available elsewhere in Europe but, if it is, I will try to find it for you.

Q110 Baroness Gale: This might seem a strange question but it is one that intrigues me: you are a UK-wide organisation but, as you know, health has been devolved, for example, in Wales. Are there any implications in that? I have not heard any calls for this to be devolved to Wales but, as you know, there are lots of calls from the Welsh Assembly to have further measures devolved to Wales. Is this all in harmony, so that there are no problems with it? I do not think there should be but I would be interested to hear from you.
Mr Rudge: I meet regularly with colleagues in the Department of Health in London but I also meet regularly with colleagues in Cardiff, in Edinburgh and in Northern Ireland. Part of our funding comes through the devolved administrations and I think it works very well. I think it has to work on a UK-wide basis. If a patient were dying today in Plymouth, the only available liver that could save that patient’s life could be in Aberdeen or Inverness or Caernarfon. Unless you have a UK-wide organisation, it is not going to work, so we have to preserve that emphasis.
Mr Jones: The Organ Donation Taskforce including representatives from each of the four countries and four sets of health ministers are considering the recommendation collectively.

Q111 Baroness Morgan of Huyton: Could we return to the question of where we go next.
Mr Rudge: Yes, I would love to answer your second question: Where do we go next? Could I answer your final question first: my view on whether stakeholders would support the idea that UK Transplant or NHS Blood and Transplant (our parent authority) was the equivalent body. I think there would be very wide support. The Taskforce considered this and was unanimous in the view that the promotion of organ donation is a UK-wide responsibility and that NHS Blood and Transplant/UK Transplant should take a wide role. I think that will not be a major problem. What would the steps be? During the work of the Taskforce over the last six months there has been a lot of work carried out within NHS BT to try to anticipate the recommendations of the Taskforce and to try to identify the likely steps that we would need to put in place. So work has been done, and when the Taskforce is published I think we will be in a reasonable position. Could we carry on and change things? The key is in the assumption that appropriate funding will be made available. If that were satisfied, yes I do believe UK Transplant/NHS BT has the potential to expand its role. I think we need to focus on the gaps that identify partly what I have told you about and partly other evidence that has been sent into the Taskforce. We need to make sure that every potential donor is identified; that every donor is referred to the co-ordinator network; that the right co-ordinators are there with the right training and in the right number and with the right amount of time—it is all to do with the Spanish model really—and that the organ retrieval process, the surgical retrieval of organs is optimised. There is a whole series of steps.
Each step can be improved. Do I think it can all be done? Yes, I do.

Chairman: We are fascinated by all this but our real remit is to look at how the Commission’s interest affects a lot of what you are doing and what our view is on that. Lord Lea is going to move into the European area.

Q112 Lord Lea of Crondall: Would you be able to give us a broad view, to begin with, on the description of the issues relating to organ donation and transplantation which is given in the European Commission’s Communication and its accompanying impact assessment? Do you agree with the Commission that there is a need for an EU-level role in this area in addition to the activities of Member States and, if so, why do you take this view?

What re-assurance can you offer to those members of the medical profession who feel that such an EU role might bureaucratisate procedures to too great an extent and inhibit the full application of clinical experience and judgment?

Ms Norman: I am aware that you took evidence from Eduardo Fernandez-Zincke a couple of weeks ago. I have read the transcript and Eduardo obviously set out his stall, so to speak—very well and in a foreign language, which is amazing. Perhaps I could give the UK view on that Communication. I have been working with Eduardo now for about five/nearly six years and in answering this question I can draw on my experience of taking through the Tissues and Cells Directive, which was published in 2002, which we have recently transposed into UK legislation and implemented. The Communication identifies three broad areas. Obviously we need to address the shortage of donor organs across Europe. Some countries obviously have higher donor rates than the UK but we are all agreed that nobody has a surplus. We all need to improve our donor rates. We also need to look at the quality and the safety of organs procured and transplanted, to ensure that we have a harmonised approach and common standards across the EU, so obviously the Communication addresses that. The third point is addressing the trafficking of organs. Eduardo said in his evidence that he did not see this as a big issue in Europe but obviously we are aware—and Chris may again call upon his greater knowledge on the ground, so to speak—that people from the EU go outside the EU to procure organs. That is something that the EU is aware of, but obviously we need to make sure that trafficking does not happen in the EU. We need to make sure that we keep an eye on it. I think it is true to say that every EU country has laws in place to make it illegal in their own country to traffic organs—and here, the Human Tissue Act is very clear on that. Broadly speaking, the EU Government supports the Commission Communication. It is very much in line with what Europe wants to do: we obviously want to increase the number of organs procured and we want to ensure the quality and safety of the organs we procure and we transplant. We do have some reservations about an organ Directive, which we have shared with the Commission over a period of time, because we know that an implementation of the Directive does not come without some cost and it could draw resources away from what we see as the prime focus, which is tackling or increasing the numbers of donors/the organs donated. We need to ensure that any Directive is at a minimum, that it does not gold plate what we are trying to do. We need to ensure that it achieves its purpose, that it sets minimum standards. Obviously Member States can implement to higher standards but we want the minimum within a Directive, we do not want to gold plate. Obviously we must continue to respect subsidiarity: Member States must be left to make their own decisions around how they organise their health services, and they are very clear about that. We do understand that there are clinical concerns around over-bureaucracy. If we look at the model of the Tissues and Cells Directive, every tissue establishment has to be licensed—indeed, the Human Tissue Authority representatives are sitting behind me today—and it costs in the region of £8,000 to do that, so there are costs. Obviously they have to make sure they meet the requirements of the EU Directive, so that could have some costs, and I do understand that. Also, clinicians want to be able to use their own judgment about a particular donated organ and how they use it and the recipient who receives it. They would want that respected within the Directive, so obviously that is something we are negotiating with other Member States. In summary, I would like to say of the five years I have been working in Europe that I have found it a very positive experience. I am not sure whether that is because of the field or whether we have been very lucky with the people who come to it, but I have made some very good friends across Europe, some good alliances, and certainly have used the knowledge and expertise in other countries to help me take forward work in the country. I do not know if Chris wants to add anything to that, because obviously he is very involved in the European side as well.

Q113 Chairman: That was extremely helpful but it would be useful to know exactly what you see as gold plating and what you see as value added in relation to what would be in a Directive. If you cannot answer that now, that would be really a very useful thing for us to have later because that is what we are trying to look at.

Ms Norman: It is difficult for me to answer that perhaps on the organ Directive because we do not have the text of one yet and we are still in that sort of
pre-publication phase where we are looking to see what could go in the minimum standards. Perhaps I can draw on my experience of the Tissues and Cells Directive to give you an example where there was creeping gold plating—which we tried to bat out—to try to get every single detail included within the Directive, rather than perhaps looking at, for instance, a risk-based approach, allowing clinicians to make their own judgment perhaps about some of the clinical standards.

Q114 Chairman: We are familiar with that kind of creeping.
Ms Norman: I think that is something we will need to look at very closely with this negotiation. As negotiations unfold, I might be able to give you some more evidence of that but at the moment it is still at a fairly early stage.

Q115 Lord Lea of Crondall: One of the ideas put forward in the Communication is that it might be helpful to introduce a European organ donation card. How effective do you think this might be in increasing the willingness of the general public in the UK to identify themselves as a potential donor of organs after their death? Before we hear from Mr Rudge, perhaps I could say what an impressive piece of evidence you have given us. It is very clear. Thank you for it.
Mr Rudge: As far as the European donor card is concerned, all I am going to do probably is to repeat my written evidence to you. The key question is: What would be/could be the status of a European donor card? As a simple publicity gesture, I think it is possibly harmless. I am not even certain about that, because I think it would confuse people between our donor cards and our Organ Donor Register, but, at best, it is harmless. If it were to carry any form of legal authority about donation, I think that would be a recipe for chaos and confusion because all the European states have different legislation. We have just discussed that we have in this country an absolute requirement for clear and explicit consent before organs are removed. Austria has a rule which has a principle you are stating and I would absolutely agree with it that you are dead.
Q116 Lord Lea of Crondall: This is the problem we are confronting, I suspect. If I go to Spain and I am on the register here, I assume if the donor card is in my wallet that they say, “This chap’s okay, just to whip out his kidneys.” Is that not the position at the moment?
Mr Rudge: No, because in law the donor card in this country is an expression of your wishes and it is legally valid consent. You have consented by carrying a donor card. It is different in different legislations. I think it would be confusing. I think it would confuse people. I do not think they would know whether they were living in their legislation or somebody else’s legislation. Would they carry a donor card if it was meant to be an opting-out donor card, or if opting in? I am sorry, I just feel it would be confusing.

Q117 Lord Lea of Crondall: This is probably going to the heart of our inquiry. Is it not also possible to tell that narrative totally the other way around? A lot of people travel—I think 20 million a year or something around Europe—at least once a year and so on, and would they not presume, if they were killed in a car accident in Spain, that this was a blockage in them being able to help somebody? Prima facie there is a need to make some progress in making that less difficult. Why do you just put all the emphasis on causing confusion?
Mr Rudge: I do not think there is a problem there that needs to be solved.

Q118 Lord Lea of Crondall: My kidneys could be whipped out just because I have a UK donor card. I thought you said that was not true.
Mr Rudge: No, I am saying that what happens in Spain is that your family would be approached because you were dead.

Q119 Lord Lea of Crondall: I do not have a family—but that is another story.
Mr Rudge: Somebody would be approached on your behalf and asked to establish your wishes and your wishes would be carried out. I just think that a donor card is too explicit a statement of what could be completely different legislative frameworks.

Q120 Lord Lea of Crondall: In my case, I have a donor card and we are members of the EU. In the European Commission document—which, if I may say, so is rather well written, carefully considered, has some very good benchmarks in it—is there not going to be some *prima facie* advantage—not being just dog in a manger about it—of seeing how it can be endorseable like my driving licence? My driving licence is not *ipso facto* a European driving licence but it has a European validity, has it not?
Mr Rudge: I can happily go along with the view that your views, as represented in this country, should equally be valid in any other European country. That is the principle you are stating and I would absolutely go along with it. I cannot go along with introducing yet another way of recording your wishes. We already have a very good way of recording wishes in this country. People know about it. Fifteen million people have put their name on the Organ Donor Register. Why confuse them with yet another thing.
Lord Lea of Crondall: I am sorry, but we need analysis of what we would do to make it work.
Q121 Chairman: With respect, Lord Lea, we are going to have to move on because time has moved on and we have a lot to cover. I think Mr Rudge is suggesting that we are not at that stage in terms of different European legislation in different countries and that the wishes you might have expressed might not be the ones you find are being carried out if you find yourself in another country.

Mr Rudge: I think there is a risk of that.

Q122 Chairman: We have not reached that stage in Europe yet.

Mr Rudge: I think there is a risk of people perceiving that that is thought to be the case.

Q123 Chairman: And perception is a large part of what is going to happen.

Mr Rudge: A very large part, yes.

Chairman: Could we move on to Lady Gale.

Q124 Baroness Gale: My question is on improving the supply of organs for transplantation. Bearing in mind the much higher organ donation rate there is in Spain than there is in the UK, what is your view of the relative importance for improving the supply of organs for transplantation of (a) improving organ donation and transplantation services and (b) switching from a system of opting in to opting out or presumed consent? If improvements are to be made to organ donation and transplantation services, what new requirements do you think there should be for professional training?

Mr Rudge: Spain does have an organ donation rate that is unique in the world. Nowhere else in the world comes close to matching the Spanish donation rate, although Northern Italy and one or two other areas of South America have made quite marked improvements in recent years based on implementing the Spanish model. What is more important than what I think is what Rafael Matesanz thinks. Rafael was the architect of the Spanish model. He was appointed in 1989 and in 1989 Spain had the same organ donation rate as this country did. Now it has a donation rate that is three times greater. I have worked very closely with Rafael Matesanz. I write chapters with him. I have the embarrassing difficulty of speaking at meetings immediately after him, so he describes the Spanish success and then I have to describe the UK’s failure. Rafael would say himself, and has said in writing and in public, that it is the Spanish system and structure and model that is important and not the law. The law in Spain was exactly the same in 1989—when they had the same organ donation rate as we did—as it is today. The changes that have occurred in Spain, the threefold/two-and-a-half-fold increase in organ donation in Spain, have occurred without changing the law. They occurred because Rafael changed the system. He did all the things I mentioned earlier. He changed how they identify potential donors and notify them to the co-ordinators—the right number of co-ordinators in the right way, with the right amount of time and the right experience—and everything else I have already mentioned. There are one or two other comments, while we mention Spain. I would emphasise this point that I believe it is the structure rather than the law. Spain pro rata has three times as many intensive care beds as we have in this country and it has three times as many donors pro rata. Spain has three times as many organ donor co-ordinators as we do in this country and it has three times as many organ donors. I do not think those two things are a coincidence. I think the law clearly plays a part. I would not for a second understate that but I do not think anything will be achieved until the system is right and I do not believe we have the right system in this country.

Q125 Chairman: You are painting a very clear picture that structure plays a very important part. I am going to move on now because time is moving on.

Mr Rudge: Perhaps I could very quickly say, My Lord Chairman, that there is a great need for training. I think it is already available and can be improved and implemented. I do not think it is a restricting factor.

Chairman: Lady Young is going to deal now with organ trafficking.

Q126 Baroness Young of Hornsey: You have already alluded to organ trafficking. How serious do you think the problem of organ trafficking is across the EU? Do you envisage that there is a role at the EU level to monitor and combat any growth in the problem of organ trafficking? If it is not a substantial problem in the EU, do you see any other issues arising out of donation tourism and/or cross-border donation? I think organ trafficking is a horrible thing. It is very disgusting and desperate and so on are unacceptable and provide a strong framework for other countries to work within. It is essential that we do not drop our guard because I do believe organ trafficking is a horrible thing. It is very important for countries to have appropriate...
legislation and appropriate monitoring systems to ensure that it is not happening. The experience varies across the EU. Obviously some of the more recent countries have had less experience of this sort of legislation and these sorts of monitoring processes. I think the EU can play a role in spreading good and correct practice, both in legal terms and in structural terms, to monitor what happens.

Q127 Chairman: What about this distinction between tourism and trafficking?
Mr Rudge: I think we could spend a long time discussing whether there is a difference or not. Some patients from this country travel to other countries for a transplant quite legitimately and properly because that is where their families come from. I have worked for many years in the East End of London where there are very large Bangladeshi and Pakistani populations. Those patients who are resident in this country have families in Asia and they travel to Asia to have a kidney transplant from their brother or sister or mother and father, and that is all right and proper. I do not really call that transplant tourism. I call that right and proper, good medicine, but it happens to be patients from different countries having a transplant.

Q128 Chairman: We have heard of people arriving in this country and then having to have treatment for what are poor quality organs. Do you have any evidence of that? What are the consequences of it?
Mr Rudge: I have a limited amount of hard evidence and I have some personal experience. The hard evidence is that UK Transplant asks all the transplant programmes in this country to register with us the patients who have originated in this country, gone abroad for a transplant and then returned to this country for their follow-up care. We receive between 20 and 30 registrations a year. I cannot guarantee that that is comprehensive, because I do not know of the patients who are not registered with us and we have no way of enforcing that, but I believe it is pretty reasonable. Twenty or 30 patients a year go abroad, have a transplant and come back to this country. The outcome for those patients is marginally less good than it is for patients who have a transplant in this country but not dramatically so. But of course I am only referring to those patients who go abroad, have their transplants, survive and then come back to this country. I do not have any information about individuals who go abroad and have an unsuccessful transplant and perhaps die and therefore do not come back.

Q129 Chairman: It is not a huge problem.
Mr Rudge: It is not a huge problem. Personally I see these patients in the clinic that I do in the Royal London Hospital every Tuesday morning. They do very well actually, if the truth be known. The problems associated with this sort of transplantation are real but they can be exaggerated.

Q130 Baroness Young of Hornsey: The next question is about raising public awareness and ethical concerns about organ donation. To what extent do you think that measures to increase public awareness and knowledge could be effective in getting more people willing to place themselves on the register? Which measures do you think might be the most effective?
Mr Rudge: Awareness of organ donation amongst the public is crucial. There are currently nearly 15 million people who have put their name on the Organ Donor Register and that number is rising by over one million a year, but of course it is still only representative of 25% of the population. As with everything, there is a lot that can be done without spending enormous amounts of money on advertising but large amounts of money spent on advertising are important. I think we need to make it easier for people to put their names on the Organ Donor Register. We are forever trying to come up with ways of making it easier. People can put their names on when they have a driving licence, when they change their general practitioner, when they get an Advantage Card from Boots, and in a wide range of other ways, but we are always looking for more ways of making it easier. Media interest undoubtedly has an effect. It has a short-term sudden effect. Sir Liam’s report and the publicity surrounding it in the summer had an effect. I think we need to work more with schools. UK Transplant and NHS Blood and Transplant launched a schools educational pack in September this year called Give and Let Live. That has been made available to secondary schools. About 1,000 schools so far have taken up that offer and I think more are doing it all the time. I think it is a very wide-ranging question and there is not one answer. I think every possible way of raising awareness of organ donation and the need for transplantation has to be grasped. Some of that can be done relatively easily, some requires money.

Q131 Lord Trefgarne: We are anxious to ascertain in the course of our inquiry the expert’s view on when death occurs and therefore after which it is proper to take the organ. We did talk to Sir Liam about this last week but we would be grateful to hear your view, particularly as you yourself have been a transplant surgeon. Are there any circumstances when we do not take an organ, even from a consenting patient; for example, very ill patients?
Mr Rudge: Yes. The criteria for the diagnosis of death, either by brain-stem death tests or after the heart and respiration have ceased, are crystal clear. They are published in the intensive care society guidelines and the Academy of the Royal Medical
Colleges is about to update their existing guidance on the diagnosis of death. I do not believe there is any uncertainty about knowing whether somebody is dead or not.

Q132 Lord Trefgarne: Would we understand that documentation or some of it? Could we see it? Mr Rudge: I can provide it for you. It is technical. Let me answer your question in another way. In practice it is really the family of the organ donor who have to be satisfied the person is dead. They understand that. They say to me, “He died two days ago when his car hit the tree.” They know the person is dead. But increasingly they are being taken along to the bedside when the tests that are carried out are being carried out. They see the body not breathing when it is disconnected from the ventilator; they see that the eyes are dead; they see that there is no response to anything. It is like looking at a doll. Families see that and families understand that that person is dead.

Q133 Chairman: Does that answer your question? Mr Rudge: It is a short answer because of time.

Q134 Lord Trefgarne: I accept what you say about that because I had the same with my mother back in the summer. She was too old but she wanted to give her organs.

Mr Rudge: The answer is that there are clearly criteria that allow organs to be suitable or not suitable. It depends on the organs. Age is one of them. Things like HIV, CJD, cancer, other infections may or may not make the organs suitable or not.

Q135 Baroness Young of Hornsey: There is an important question on this issue of the mismatch between the supply and demand of organs particularly for black and other ethnic minority groups. I am wondering why there is that mismatch, because it is so significant. What is it possible to do in terms of preventative work with those communities? What is it possible to do in terms of working with those communities to lower that disparity? Are there issues across the EU with other ethnic minority groups and what actions, in general, do you think could be taken to address this situation? I am aware of the time, so perhaps if we are not able to address this all today you could write in.

Mr Rudge: I certainly will. Perhaps I could give you three or four little bits of information and then Triona may want to say something also. At the moment 23% of the people who are waiting for a kidney transplant are from black and minority ethnic backgrounds; approximately 8% or 9% of the population are from that background and only 3% of organ donors come from that background. There is a clear mismatch. Why are so many people on the waiting list for a transplant? Sadly, the incidence of kidney failure is three or four times greater in patients from an Afro-Caribbean, African or Asian background than it is amongst Caucasian patients, so the need is three or four times greater. That is an absolute problem, because, even if the donation rate were the same amongst the groups, the need is three or four times greater. However, it is even worse than that because the donation rate is low. It is low because if the potential donor is—and forgive me for being so simplistic—white, 35% of the relatives refuse consent for organ donation. If the potential donor is from any other background, other than white, 75% of the relatives refuse consent for donation. There are not enough donors from those groups and there are far more patients who need transplants from those groups, so the gap is enormous.

Q136 Baroness Young of Hornsey: Why are there so many more instances of kidney failure? Is there a quick answer to that or is it very, very complex?

Mr Rudge: It is complex. It is the subject of a lot of work and a lot of research and a lot of thing in preventative medicine in particular. There is a group in north-west London who are doing all sorts of things out in the community, trying to get people walking down the street to have their blood pressure measured or their urine tested for protein.

Q137 Baroness Young of Hornsey: Is it blood pressure? Lifestyle?

Mr Rudge: It is blood pressure and diabetes.

Q138 Lord Lea of Crondall: Presumably under the opt-out possibility there is a reduction in this mismatch of people saying, “I don’t want my kidney to go there.” Would that be logically an inference you would draw? How would the scheme work if that would not be a reasonable inference?

Mr Rudge: I am sorry, I am not entirely sure I understood your inference.

Q139 Lord Lea of Crondall: The inference being that the difference between 25% who say, “I am happy for my kidney going to a white person” but 75%—

Mr Rudge: No, I am sorry, I did not say that.

Q140 Lord Lea of Crondall: What did you say then?

Mr Rudge: I said that if the donor is white, 35% of the families refuse permission for those organs to be transplanted into anybody. If the donor is not white, 75% of the families refuse permission for the organs to be donated into anybody. It is not the recipients I am talking about; it is the donors. It is permission from the relatives.

Lord Lea of Crondall: I am sorry. Thank you for making that clear.
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13 December 2007 Mr Chris Rudge, Mr Gareth Jones and Ms Triona Norman

Chairman: That does move us into some of the issues around this which are about faith groups. Lady Gale wanted to ask some questions because we have had some difficulty getting responses.

Q141 Baroness Gale: What can you tell us about the concerns of individuals about organ donation and transplantation—possibly associated with faith-based beliefs—that might lead them to oppose organ donation by themselves or their relatives? How do you think that these concerns could most effectively be addressed?

Mr Rudge: There are six major faiths in this country: Christianity, Judaism, Islam, Hinduism, Buddhism and Sikhism. I have worked with UK Transplant to produce some leaflets, so the official position of those six religions is that organ donation is a good thing and they believe followers of those faiths should donate their organs. The problem is translating that into practice at a local level. I am not sure whether this is strictly speaking a faith-based decision or a wider culturally based decision but, as I have emphasised, the families of patients from ethnic minority groups—and that is not necessarily the same as faith groups but there is obviously an overlap—do not give permission for organ donation. So it is a local cultural phenomenon rather than a formal position of the faith. I intended to bring those six leaflets with me but I will happily provide them to you if they would be helpful, because they set out very clearly the views of those faith communities.

Baroness Young of Hornsey: I think we have a copy.

Chairman: Yes, we have a note, thank you.

Q142 Baroness Gale: Are people of faith less keen than the general public on organ donation? I would have thought it would be in the general population that the relatives of somebody who died would not be too willing for their organs to be used.

Mr Rudge: I do not know that there is any evidence to answer your question about the faiths of donors or the faiths of their families. There is a broad trend which everybody looks at and nobody understands that organ donation rates and consent rates for donation appear to be higher in the Southern European Roman Catholic countries than they are in the Northern European Protestant countries. It is a very broad generality but it does seem to stand up quite clearly.

Q143 Chairman: Has the Taskforce looked at this? Is this something that will be subject to their report, do you know?

Mr Jones: No, I do not believe it is. But I think they do generally acknowledge that more work needs to be done around these variances between culture, faith, ethnicity.

Q144 Chairman: It seems to be a very crucial area and one where other countries in Europe might have something to add to give us. That takes me on to the last question about research and information. I know Mr Rudge said in response to Lady Young’s question that there was a lot of research going on in a variety of areas and we are interested in your views on new research and the improvement of information. However we have come really to the end of the session. I am going to have to ask you if it would be possible for you to let us have this in writing. We do think this is crucially important. Indeed, it might be better to have it in writing because I assume there is quite a lot you would want to give us and that would be very valuable. Do you mind if I do not ask you that question at this moment and ask for that in writing?

Mr Rudge: We would be very happy to give you that.

Chairman: Thank you very much. That has been an extremely helpful session. You have reinforced some of our knowledge and what we have heard before, which is always important, and you have taken us into new areas and that has given us more food for thought. We are beginning to distil some of the questions that we do not have answers to. Thank you very much indeed. We wish you well in what you are trying to achieve.

Supplementary memorandum by Chris Rudge, Managing and Transplant Director, UK Transplant

The UK Transplant “Communications” budget is approximately £1.3 million in 2007–08. Net of pay costs etc, this amounts to approximately £873,000 for campaigns and publicity.

In addition, during 2007–08, NHSBT provided an additional £1 million, non-recurring, for a one-off mail-drop campaign.

It has not proved possible to identify comparable figures from other European countries, I’m afraid.

18 December 2007
Supplementary memorandum by the Department of Health

Thank you for your recent emails following up the evidence given to the EU Sub-Committee G Members on 13 December on the Government’s thinking on the nature of a European directive on organ donation and transplantation safety that would be appropriate and would add value to national provisions across the EU.

As Baroness Howarth and the other Members of the Committee will know, on 31 May 2007 the EU Commission adopted a Communication on organ donation and transplantation. This Communication proposes future activities across the EU in the field of organ transplantation. The Communication concludes that an appropriate and flexible European legal framework could be an adequate community response to meet the mandate provided in Article 152 (4) (a) of the Treaty.

On 6 December 2007, the European Council adopted conclusions on organ donation and transplantation. The Council recognised the importance of having high standards with respect to the quality and safety of organs for transplantation, in order to ensure a high level of protection for patients throughout Europe. It invited the Commission to continue its work under the proposed action plan aimed at increasing the availability of donor organs and, in consultation with the Member States, to continue its examination of the need for an EU framework on quality and safety for human organs. It also invited the Commission to coordinate, promote and strengthen the cooperation between the Member States on organ donation and transplantation, on the basis of agreed objectives and priorities. The Community has already adopted Parliament and Council Directives on quality and safety standards for blood and for tissues and cells.

At the time of writing, the Commission has not published proposals for an Organ Directive. It is likely, however, that in light of the extensive therapeutic use of human organs for transplantation, quality and safety standards will be identified in order to prevent the transmission of diseases. For example, a Community framework could set quality and safety criteria with respect to the procurement and traceability of human organs across the Community. These standards would help ensure that human organs are of comparable quality and safety across the EU and could facilitate exchanges of organs across borders. Like the Blood and Tissue and Cells Directives, the establishment of standards would help reassure the public that human organs procured in another Member State carried identical basic guarantees as those obtained in their own country.

It is recognised that the severe shortage of organs donated for transplant remains the main challenge that EU Member States face. Waiting lists are increasing faster than organ donor rates. Clinicians recognise that the risk-benefit ratio is different for organ transplantation than for tissue and cells procured for human application. The overall benefits of an organ transplantation are high and broadly more risks can be accepted than with blood or most tissues and cells based treatments. In this context the clinician has an important role in deciding whether to accept organs for transplantation.

We must therefore ensure that requirements contained within a legislative framework do not impose a disincentive to donation. However, experience obtained through the negotiation, transposition and implementation of the tissues and cells Directive indicates that there are a number of measures that could be considered by Member States to improve the quality and safety of organs. These include:

Competent Authorities—National Competent Authorities have played a key role in ensuring the quality and safety of blood, tissues and cells. For example, in the UK, the Human Tissue Authority has been instrumental in establishing systems for the licensing of tissue procurement, testing, storage and distribution, based on common quality and safety criteria. Any introduction of a similar system for organs would need to be discussed with stakeholders to ensure an appropriate level of regulation.

Procurement—Pre-transplant evaluation of potential donors is an essential part of solid organ transplantation. This evaluation must provide enough information to undertake a proper risk-benefit analysis by the transplant team. Risks and characteristics of the organ must be identified and documented to allow allocation to a suitable recipient. In the UK we need to be clear about the level of detail that should be included with a framework document and how compliance would be monitored.

Traceability—It is recognised that any transplant system must ensure traceability from donor to recipient(s). The system must also have the capacity to detect and investigate serious or unexpected adverse events. As organ donors are often tissue donors, it will be vital that the introduction of quality and safety requirements for organs complements existing systems for tissues and cells.

UK Ministers have considered the Commission’s Communication and summary of the impact assessment. They believe that the proposals are broadly in line with policy across the UK to increase the number of high quality and safe organs available for transplantation. However, concerns remain about the level of detail that will be included within any Directive and compatibility with current arrangements and operating principles. Ministers recognise that implementation of a Directive would incur additional costs of regulation, such as inspection and licensing with the majority of the costs falling on the public sector. Many member states,
increasing the supply of donor organs within the European Union: evidence

including the UK, already have high quality systems for the identification, testing, procurement, allocation and distribution of organs procured for transplant. In the UK, we will seek to negotiate quality standards that add value but not unnecessary cost, to enable appropriate investment in initiatives to increase the number of organs donated for transplant.

The Committee will be aware that on 16 January 2008, Health Ministers across the UK accepted the Organ Donation Taskforce’s 14 recommendations to increase organ donor rates. Copies of the Report have been placed in the Library of the House. Alternatively it is available on the Department of Health’s website www.dh.gov.uk The recommendations include: the establishment of a UK Wide organ donor organisation as part of NHS Blood and Transplant; a strengthened network of dedicated Organ Retrieval Teams available 24 hours a day; and a doubling of the number of front line donor coordinators (about an extra 100 donor transplant coordinators) working with donor hospitals and families to facilitate donation. All parts of the NHS will be encouraged to embrace organ donation as a usual, not an unusual event and donation activity in all Trusts will be monitored. Electronic on-line organ offering systems will be developed to improve the allocation of organs and all clinical and nursing staff likely to be involved in the treatment of potential organ donors will receive mandatory training in donation and regular update training.

Taken together, the Taskforce recommendations draw heavily on the successful Spanish system—the country with the world’s highest organ donation rates. The Taskforce believe that their recommendations, if implemented, could increase organ donation rates by at least 50% over five years—a potential 1,200 extra transplants each year. Hundreds of additional people will see their lives saved or dramatically improved. This significant investment in the infrastructure of donation in the UK will see UK rates rise to match some of the more successful countries in Europe and elsewhere.

May I reassure the Committee that the UK will continue to work with key stakeholders in the UK to ensure an appropriate input into the development of Community guidance or legislation. This will include representatives from NHS Blood and Transplant—responsible for matching and allocating organs in the UK and for auditing outcomes; the Human Tissue Authority—the Competent Authority for the licensing of tissues and cells procured and stored for human application and clinicians from the Transplant community. We are also making arrangements to meet with UK MEPs to discuss organ donation in the UK and the preferred content of the Directive and Action Plan.

6 February 2008
THURSDAY 24 JANUARY 2008

Memorandum by the Jeanette Crizzle Trust

As discussed, I have written for you below a summary which I hope is helpful for you to include as a further piece of evidence to reinforce the need to continue with the current “Opt In” policy.

Our 2007 report can be found on our website http://www.jeanettecrizzletrust.org/default.asp?page=229

In addition, we should like to highlight, based upon all the evidence we collected in 2006 and 2007, the following key points:

1. The Government agreed, in accordance with our April 2006 proposal, to allocate tax payers’ money to launch an education programme with the object of raising donor levels in the long term.

2. If this is successful, in twenty years from now, every person in the UK under the age of thirty will have all the necessary facts to do with donation, enabling them to make an informed decision with regard to joining the NHS registers.

3. Our 2006 report to Rosie Winterton, former Health Minister, suggested that an education programme in schools would lead, in the long term, to an increase in the number of donors.

4. Our 2007 report suggests that the overall awareness of the question of donation in England is currently limited.

5. There is a possibility that if an “Opt Out” principle became UK law, a significant number of the general public would “Opt Out” without having the full facts and merely in accordance with their personal opinions. This might then undermine the taxpayers’ investment in the education programme, the whole purpose of which was to increase national donor levels in the long term.

6. Attempting to launch the “Opt Out” principle in 2007/8 would not provide the Government with the opportunity to see the benefit, if any, of the education programme.

As discussed, I should be more than prepared to make an oral presentation if required and should you require any further information please do not hesitate to contact me.

1 November 2007

Memorandum by Kidney Wales Foundation

1. The Kidney Wales Foundation welcomes the opportunity to provide evidence on the vital issue of organ donation and transplantation. This invitation comes at a most opportune point as we have launched our People Like Us Campaign. “People Like Us” is a radical patient centred vision for kidney services in Wales with a view to making Wales a world class provider of renal services. Over 400 people (and we believe much more) are waiting for a transplant in Wales and a crisis in organ supply faces Wales as demand increases year by year. Our campaign aims for a new transplant strategy based on: introducing legislation in Wales and UK for presumed consent; working with partners to deliver a substantial increase in donors; and delivering a new dedicated transplant unit for Wales.

2. The Kidney Wales Foundation (known for many years as KRUF) was established in 1967. In its 40 year history it has, through a thriving fund raising base, supported many aspects of kidney patient care in Wales including transplantation. In addition Kidney Wales played a major role in getting an organ donor card attached to the new driving licence and was instrumental in setting up Lifeline Wales—a computer register of people willing to be organ donors in the event of their death. Our current People Like Us Campaign aims to demonstrate the need for improved services for kidney patients in Wales and is championed by those patients themselves. The evidence we present below is informed by the experiences and views of those in Wales who live with kidney disease every day.
3. We concur with the view in the communication from the Commission of the European Communities: Organ Donation and Transplantation that organ transplantation offers excellent results for patients. For those with kidney disease renal transplantation provides the most successful and cost effective treatment for established renal failure. However, in Wales a relatively low number of people are receiving transplants as a consequence of three inter-related factors:

— lack of availability of organs;
— lack of capacity to undertake transplantation; and
— sub-optimal organisational arrangements.

4. The Policy Statement and Renal National Service Framework For Wales produced by the Welsh Assembly Government in the Spring 2007 states that up to 10,000 people in Wales have renal disease and it affects all age groups. The incidence of renal disease is rising and seems likely to do so for the foreseeable future.

5. The demand for renal transplantation in Wales is provided in Figure 1 and this is projected to continue rising. In terms of provision there is one transplant unit in Wales based at the University Hospital of Wales in Cardiff which serves South Wales. Patients in North Wales receive their transplants in England which is also where all paediatric transplantation takes place. The current level of transplants is far lower in Wales than might be anticipated as demonstrated in Figures 2 and 3.

6. The current level of organ donation in Wales is too low. Many people wish that on their death their organs be used to save the lives of others but have not opted in to the current system. Kidney Wales endorses the suggestion by the Chief Medical Officer for England and the campaign by BMA Wales for a system of presumed consent. Even with improved conventional donation rates the case for presumed consent remains a strong one to vastly increase the availability of organs to meet growing demand.

7. There has been relatively little empirical evidence on the impact of presumed consent on donation rates. However, a study by Abadie and Gay of Harvard and Chicago Universities (2005) have conducted a study to examine this across 22 countries who have introduced presumed consent systems over a 10 year period. The study found that presumed consent had a positive and sizeable effect on organ donation rates of some 25%–35% higher on average in presumed consent countries.

8. Kidney Wales proposes that the law on consent for organ donation be changed and that for purposes of disease treatment Welsh residents are presumed to be organ donors on death unless:

— they have opted out;
— they cannot be identified;
— the persons place of residence cannot be identified;
— the wishes of the deceased can be proven to be contrary after relatives have been contacted; or
— immediate relatives object.

9. The Welsh Assembly Government (WAG) current has no powers over organ donation and in Wales we have yet to have a public debate about the viability of a presumed consent scheme. We believe the WAG has a duty to encourage a wide ranging debate on this morally complex issue. Moreover, we believe a National Assembly for Wales member or the WAG itself should bring forward the appropriate legislative framework to draw down to the National Assembly the power to determine how organ donation is facilitated in Wales. Once this happens an Assembly Measure could be debated and passed to facilitate Presumed Consent in Wales.

10. Kidney Wales Foundation as pioneers in the development of organ donor cards would positively endorse the proposal of a European donor card. This, we believe, would contribute to increasing the number of organs available. We would welcome further work to examine the potential for reciprocal organ donation arrangements across Europe. In Wales patients currently sometimes receive organs from Spain and discussion on how this might be developed should be taken forward.

11. We recognise the very difficult issues associated with the trafficking in organs and of patients travelling to, often less affluent countries, to receive organs. However, from a patient perspective of despair and personal anguish we believe it is important not to judge those who feel they have no other option. Kidney Wales believes that the way to avoid this challenging practice is to develop a transplantation system for Wales that meets demand.

12. The general organisation of transplantation services in Wales is sub optimal and needs to be improved. In the past NHS Wales has relied on UK Transplant (UKT) to manage its donor campaigning. UKT is an operating division of NHS Blood and Transplant, which is an England and Wales Special Health Authority with a key role to ensure that donated organs are networked and allocated fairly. UKT also manages the National Transplant database and maintains the National Organ Register. Although the WAG works with
UKT to identify Welsh specific campaigns Kidney Wales believes that UKT does not have a significant enough presence in Wales and the level of dialogue between UKT and the WAG appears to be minimal. In 2006–07 just one meeting was held between WAG and UKT.

13. NHS Wales has set a strategic target that 725,000 people in Wales should be registered as organ donors by March 2008. However, there is little evidence of how this objective will be achieved. No budget agreed for 2007–08. In particular the amount of funding provided by the WAG has not been sufficient to ensure this change. In 2004–05 and 2005–06 just £35,000 per annum was allocated and although this rose in 2006–07 to £55,000 this was as a result of a specific one-off leaflet campaign. This must be placed in the context of an overall budget for the health service in Wales of around £4.5 billion.

14. Kidney transplantation in Wales is also being held back by a lack of facilities. There is a clear need to develop the Renal Transplant Unit in Cardiff. Cardiff and Vale NHS Trust, which runs the University Hospital of Wales, has presented to Health Commission Wales (the body that commissions specialised health services in Wales) a draft business case to develop the unit but we have yet to see any real progress on this.

15. Transplant provision for children in Wales also needs to be significantly improved. Clinical governance dictates that as result of the relatively low incidence of renal disease in children compared with adults optimal care of children with complex renal disease should be managed from a single centre in Cardiff. This further supports the case for a developed Renal Transplant Unit located in the University Hospital of Wales.

16. We believe that a small country like Wales in Europe can be better served on renal health issues. We would like the Committee to consider the following:

— Firstly, a UK and European wide call for a change in legislation on presumed consent.
— Secondly, how organisations like UKT work effectively with charitable organisations in Wales and other regions on promotion and awareness.
— Thirdly, that all UK and European regions have a fair amount of allocated funds to spend on donor awareness.
— Fourthly, a European Donor Card be activated and enabled as soon as possible while waiting for a Directive on presumed consent.

5 October 2007

Figure 1

PATIENTS FROM WALES (WELSH POSTCODE) LISTED FOR A RENAL TRANSPLANT BY REGION OF RESIDENCE

North Wales

<table>
<thead>
<tr>
<th>Age</th>
<th>Organ listed</th>
<th>Active</th>
<th>Suspended</th>
<th>Total</th>
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<tbody>
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<tr>
<td>Adult</td>
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<tr>
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Mid and West Wales

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<td>94</td>
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<td>21</td>
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INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE

South East Wales

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<tbody>
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<tr>
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<td>5</td>
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<td></td>
<td>kidney/pancreas</td>
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<td>1</td>
<td>3</td>
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<td>Total Adult</td>
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<tr>
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Figure 2

ADULT TRANSPLANTS THAT TOOK PLACE IN AND FROM WALES FROM 2004 TO 2007 (MARCH)

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<th>Liverpool</th>
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<td>2006–07</td>
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</tbody>
</table>

Figure 3

WELSH PAEDIATRIC TRANSPLANTS TAKING PLACE IN ENGLAND

<table>
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<th></th>
<th></th>
<th></th>
</tr>
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<tbody>
<tr>
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<td>7</td>
<td>5</td>
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</table>


Memorandum by Patient Concern

SUMMARY

1. Patient Concern is concerned about the shortage of donor organs and wishes to see more active methods taken to recruit potential donors. However, we are equally concerned about push towards the coercion of an opt-out policy and any suggestion that organ donation, which should be a generous gift, should be regarded as an obligation.

2. We campaign against the introduction of a presumed consent system but support all efforts to spread awareness and increase the donor pool.

PRESUMED CONSENT

3. Presumed consent is no consent at all. It relies on inertia and ignorance to achieve a desired goal. In the UK we have fought hard, over the last 15 years, to achieve a situation where informed consent is recognised as an essential foundation of health care. The force of organ donation propaganda must not be allowed to undermine this important principle.

4. When comparing the systems adopted in various countries it is necessary to take account of the value placed on personal autonomy from country to country. UK Transplant has taken the view that an opt-out system could damage patient confidence in the transplant system.

5. An opt-out system, dispensing with the need for explicit consent, runs counter to the Department of Health’s “Good practice in consent” and the principles underlying the Mental Capacity Act 2005, which aims to maximise each individual’s capacity to make their own informed decisions. The BMA’s enthusiasm for an opt-out system shows an unfortunate tendency for the medical establishment to abandon explicit consent when they fear that not enough people are willing to do what they believe is the “right thing”.
increasing the supply of donor organs within the European Union: evidence

6. The Alder Hey scandal has left a deep rooted suspicion of organ removal in the UK, resulting in the Human Tissue Act 2004, which aimed to restore trust and confidence in the medical profession. The issue of presumed consent was fully debated in Parliament at the time and was rejected.

7. Expediency, the need to combat the shortage of donor organs, is not a sufficient reason to overturn all the ethical issues accepted by Parliament at the time. It may sound like an easy option but could be counter-productive.

8. The transplant service in the UK is renowned for its openness and transparency, due in part to the fact that consent has always been an integral part.

9. Supporters of an opt-out system point to the discrepancy between the number of people who declare themselves willing to donate organs in opinion polls and the number who sign up to the donor register. But giving a “feel good” answer in the street is very different from facing the reality of the process, so it cannot be assumed that a “yes” in these circumstances represents a considered decision.

10. The soft option: If the so-called “soft option” on presumed consent, where organs will not be removed if relatives voice objections, is followed, relatives are likely to come under psychological pressure, at a time when they are most vulnerable, simply because the patient did not get around to opting out.

11. The hard option: The hard option, where relatives objections are not taken into account, may have meant, in Austria, that almost everyone who needs a kidney transplant can obtain one, but it has no place outside a totalitarian state. Our bodies are not the property of the state, either in life or death.

Taking into Account the Views of Relatives

12. Claims that an opt-out system is advantageous to relatives because it “relieves them of the burden of making a decision” is insulting. Some 20% of bereaved relatives report that they were never asked about the possibility of organ donation, which suggests that many doctors find the task too onerous. Four out of 10 bereaved relatives who are asked about donation in the UK refuse.

13. The success of the organ donor programme in Spain, the only country where there has been a year on year rise in organ donors over the past 10 years, is often held up as an example of the opt-out system. However the law on opt-outs was changed in 1979 and only showed a marked impact when transplant coordinators were introduced into every intensive care unit (ICU) in 1989. These coordinators monitor possible donors in the ICU—a questionable practice which might lead to patients perceiving that they will be more valuable as a set of spare parts than as a seriously sick individual. But they are also highly trained in approaching and explaining to relatives. Surveys indicate that a high number of relatives change their mind from an initial “no” once the process has been properly explained.

14. The Human Tissue Act laid down that if anyone has indicated their wish to donate an organ after death, the donor’s wishes take priority over the views of relatives who may object. Patient Concern supported this change as it fully accords with the principles of patient choice. However, doctors are unwilling to wave the law in the face of grieving relatives, so this change has had little effect. Perhaps part of the problem here is that insufficient emphasis has never been laid on the need for willing donors to discuss the issues with their family.

Obstacles to Donation

15. UK surveys always show a sizeable majority willing to donate organs, though only one in four registers their willingness. This indicates that giving the “feel good” or politically correct answer in the street is very different from facing the reality of the process. The 2006 European Commission 12 survey showed that though 60% of students favoured the idea of donation, this dropped to less than half in those aged 55 and older—in other words, those more likely to see this as a reality in their lives.

16. The focus on the positive aspects of organ donation has failed to recognise and deal with the fears that may prevent many people from signing up.

Some of the arguments are as follows:

— Brain stem death, when someone’s heart and lungs are still working, is not death in the ordinarily understood sense—nor is it death in any universally accepted neurological sense. It is part of the dying process and at such a time, the medical duty of care should be concentrated on the “dying” patient and not with any third party.

— In the UK, organ removal may be performed when the body is paralysed but not anaesthetised. This may be so that the organs can be harvested in the best possible condition but whatever the reason, it leads to the impression that the recipient is more important than the donor, as no one can
In the absence of a feeling, the Royal College of Anaesthetists and many in the patient movement believe that full anaesthetic should be mandatory, to obviate any risk of suffering.

Some doctors and patients believe that the tests used to ascertain brain death—notably the crucial apnoea test—may induce rather than diagnose brain death and thus some patients may be deprived of recuperative treatment too hastily.

The concept of brain death and brain stem deaths are not universally accepted. In countries where they are accepted, methods of making the diagnosis and the number of doctors required to certify this condition vary. Given that, once organs have been harvested, there is no way back, this is a matter for grave concern.

The emphasis placed on cost savings and benefits in the EU document (EN50) may only serve to confirm suspicions that a seriously sick person has far less value than a potential organ donor.

**Increasing the Donor Pool**

17. In Patient Concern’s view, the government and medical community could make far more vigorous efforts to encourage organ donation within the UK:

- Ensure that there is a simple and direct system within doctors’ surgeries, hospitals, pharmacies, blood donation centres etc for signing up the to donor register—not simply handing out donor cards.
- “Payments by results” for putting certain categories of patients on drugs etc has proved very successful within the NHS. Perhaps it would be productive to pay for numbers of patients signed up to the donor register.
- Fund special training is needed for those who approach bereaved relatives about the possibility of organ donation—but consider that having these same people identifying potential donors may be counter-productive.
- Offer relatives the option of seeing the brain stem death tests performed, preferably with the support of the specially trained individuals.
- All organ should be harvested under full anaesthetic.
- When the regular campaigns to persuade people to carry donor cards and sign up to the register are launched, emphasise that it is essential to discuss your choice with relatives.

**Oral Evidence**

Patient Concern would be pleased to elaborate on these issues orally if required. Patient Concern has given oral evidence to the Shipman Inquiry over two days, the Joint Scrutiny Committee of the House of Lords and Commons on the Mental Capacity Act and the Health Select Committee of the House of Commons on electronic patient care records.

18 September 2007

**Memorandum by the Patient Liaison Group RCSEng**

*The Patient Liaison Group RCSEng is particularly interested in the issues raised by “Presumed Consent” and how to make the public better informed about organ transplantation.*

******

**EU-Wide Shortage of Organs**

*Supply side*

Greater awareness, understanding and trust in the system drawn up among members of the public, may well encourage more donors to come forward.

If the system were an “opted in” one, this would have a dramatic effect on the potential supply of donated organs.
increasing the supply of donor organs within the European Union: evidence

There is a need for an overarching “Eurotransplant” with representation from EU countries that will investigate organ donation, looking at best practices and create a EU-wide legal framework. In the UK particularly, the shortage of ITU beds must be addressed urgently.

The issuing of drivers licence and other essential documents could contain a legally binding clause to fill in the section as to whether there is agreement to transplantation or not. Currently this often comes as a separate optional form, which is inevitably never returned.

**Demand side**

Presumably alongside transplantation work, there is currently funded research going on into alternative therapies to transplantation?

Where particular shortages are identified among ethnic/religious groups then a more concerted campaign should be organised e.g. dialogue with leaders/priests and the need to target this group in a campaign, which highlights the benefit to their particular community. Earlier identification of renal/liver/heart failure through improved medical training, screening/funds for testing— injection of EU funds to those areas. This could diminish the numbers at “end stage” organ failure. Better management of diabetes and early identification.

**Organisation of Organ Donor and Transplantation Systems**

In order to increase public trust it is crucial that QA and procedural differences between the approaches adopted by individual Member States towards organ donation are reduced by establishing legally binding regulations and effective Quality Assurance.

On this basis, Option 3, as outlined in the Impact Assessment document would be the ideal option.

This can be done through EU Legislation, standards of compliance and regulations over procedures when a patient is in ICU and due to die, and in setting up a structured system of waiting list for donors. Medical training is also the key to incentivising clinicians. EU funds and facilities should promote the exchange of expertise and best practices.

Whilst an increase in NHBDs may be a short-term solution, the aim should be to increase the pool of brain stem dead heart beating donors. It would be ideal if there was a uniform system of organisation of organ donation and transplantation across the EU.

In the UK there is a need for Clinical Champions in every hospital, which has an ITU. It would be best if this person was independent of the transplant team and also independent of ITU and UKTS but maintaining relationships with all three.

**Raising Public Awareness of Organ Donation**

Trust in the reliability/safety of the system is crucial. Without this the public will not engage with it. It is vital to communicate with the public. If consent is presumed because people are automatically opted in, then if that consent is to be “informed” consent, it must be mandatory for the NHS to inform every member of the public. Health professionals could visit schools and higher education institutes to explain what is meant by presumed consent and something of the procedure.

Primary care could be the source of far more information about transplantation and donor procedures, when routine checkups etc are done information could be given to patients. Posters and leaflets could be posted in all A&E depts and hospital waiting rooms. Health professionals could be trained to explain the procedures to patients. National Blood Transfusion service for example, could provide leaflets and information.

Case studies of patients who have benefited from transplantation should be made more accessible to the public.

TV could be used to make appeals.

This must not be “one-off” advertising but a concerted long-term drive. Danger of bad publicity via TV programmes. Public are easily influenced by the media.
use of organ donor cards, including the idea of a European organ donor card

This is a useful idea, as it would result in a reliable register of donors. Again the biggest hurdle remains inertia by people to sign up if the system involves having to opt in.

Information held must be accurate and easily accessed—time is of the essence. National register seems a good idea for the public and clinicians when in urgent need of a donor. A register would be needed if there were an automatic “opted in” system, so that the NHS could record those who had “opted out”. This register could be used like an electoral roll, with those listed asked at regular intervals if their details are still correct. This in turn would inform people of the donor system and provide an opportunity for them to opt out if they so wished.

use of volunteer living donors

This is problematic in countries where success rates of transplantation are not good. Living donor transplantation should only be used where the rates of success justify this and thus standards of expertise will need to be raised Europe-wide before rules on this are formulated.

Altruistic organ donation should be clearly explained. If there were enough deceased donors, altruistic non-directed organ donation would be superfluous. If procedures to increase the number of deceased donors progresses, then the need for living donors should decrease.

ensuring the quality and safety of cross-border organ donation within the EU

This is vital and procedures agreed should be made legally binding.

ethical issues relating to organ donation and transplantation

These must be taken into account, especially in a system, which plans to use the “presumed consent” approach. There must be no risk of the public seeing themselves as becoming the means of providing “spare parts” for clinicians keen to save another life. There may be a fear that given a dying patient in intensive care and a patient in urgent need of an organ, the survival chances of the former could be compromised if organ donation took priority. Separating out the responsibilities very clearly of those who provide declaration of death of the patient (and care for them in their last days) from those who evaluate the patient for donation is essential and would reduce this fear.

The “heart beating donors” issue is a difficult one and the public will need reassurance on the ethics of it as well as greater clarification about how it is defined. Issues related to the diagnosis of brain stem death must be transparent, with clear guidelines and nothing left to clinical judgement. Public education on understanding of brain stem death as opposed to cardiac death is important.

health and social welfare benefits of organ transplantation

Information should be far more freely available to the public on these issues, so that decisions as to whether to become a donor and not opt out are informed decisions.

medical risks of organ transplantation

Prevention of spread of diseases via transplantation and screening are very important and standards must be set that are common to all countries.

It is very important to establish the consistent reporting of adverse reactions in an organ donor/recipient. Must at all costs avoid loss of public trust.

illegal trafficking in organs

More public awareness of the issues will raise the number of donors coming forward, which would in turn reduce the levels of trafficking.

Greater availability of organs should go some way to helping solve this. Nothing can be done about those who go outside the EU for trafficking in the LDCs.

Also essential to tighten up controls on those obtaining organs from patients illegally.
QUESTIONS, WHICH MAY ARISE IN RELATION TO ORGAN DONATION AND TRANSPLANTATION FROM A FAITH-BASED POINT OF VIEW

There are cultural and religious considerations which will need to be explored, reflected upon and an action plan drawn up to tailor-make the awareness campaign and promote the desire to donate in the different cultural areas of the EU.

There is a need for a Department of Health sponsored major symposium, bringing together representatives of all religions and faiths within the transplant and ITU community. This would be extremely beneficial and allow the various faiths to put forward their point of view on brain stem death and organ transplantation and for the transplant community and ITU community to dispel any myths.

THE “PRESUMED CONSENT” APPROACH FOR IDENTIFYING ORGAN DONORS (UNDER WHICH A WILLINGNESS TO DONATE ORGANS BECOMES THE DEFAULT POSITION AND PEOPLE WISHING TO OPT OUT FROM THIS NEED TO MAKE THIS KNOWN)

How does the suggestion of presumed consent square with the recent Human Tissue Act, where consent of the individual is given primacy?

How will the consent of the individual be safeguarded?

The patient must be aware that he/she is automatically “opted in”, otherwise it is not “informed” consent. If the patient did not know that they are automatically opted in, then they have not consented to it. It is therefore mandatory for the NHS to have informed every member of the public of this opted in situation.

At what point in their life is it proposed that an individual is automatically “opted in” to this system?

How would the crucial understanding of an automatically opted in system be assured for people with low IQ, or those with a poor understanding of English?

If presumed consent is to be adopted, then opting out must have a transparent procedure for implementation and be thoroughly understood as an individual right.

If a patient is to be part of a presumed consent, then they must know exactly what they are consenting to. It is therefore important that adequate literature is provided as far as presumed consent is concerned. It must not be made difficult for people to opt out. Ideally, the electoral roll could be used. Regular checks of the electoral roll are made as far as local elections are concerned and there could be space on the forms, which are returned to indicate that you wish to opt out.

Those countries with legally automatic “opting in” approaches will presumably have potentially greater availability of donors—the supply across the Member States could become unbalanced. This would encourage “donor tourism”.

Not sure whether in an automatically opted in system, that patients would necessarily agree to their organs being used outside the UK. Would the system allow for this? Would donors feel that they could specify where and to whom their organ should go?

These are all issues that the Patient Liaison Group is particularly concerned about.

THE ARRANGEMENTS FOR TAKING INTO ACCOUNT THE VIEWS OF RELATIVES ABOUT REMOVING ORGANS FOR TRANSPLANTATION FROM A DECEASED DONOR (BOTH UNDER THE PRESENT SYSTEM OF “OPTING IN” OR UNDER THE “PRESUMED CONSENT” SYSTEM FOR IDENTIFYING DONORS)

If presumed consent applies, does that mean that no family confirmation is needed?

In an “opted in” system will the family have no say? What about confrontation between family and clinician at the deathbed? There surely must be some allowance made for this?

If relatives have the final veto, a presumed consent system could become unworkable.

VIEWS ON THE NEED FOR A EU ROLE

To promote cooperation between Member States and particularly for funding and facilitating exchange of expertise.
TO PROVIDE A CROSS-BORDER FRAMEWORK FOR ORGANISATION OF ORGAN DONATION AND TRANSPLANTATION

This is necessary in order to make sure that the QA, screening and clinical procedures are of the highest possible standard throughout the EU.

5 October 2007

Examination of Witnesses

Witnesses: Mr Roy J Thomas, Executive Chair, Mr Raj Aggarwal, OBE, Chair of Trustees, Kidney Wales Foundation; Ms Lesley Bentley, Lay Chair of the Patient Liaison Group, Royal College of Surgeons England; Ms Elizabeth Gibb, Trustee, and Mr Philip Hollobone, a Member of the House of Commons, Trustee, Jeanette Crizzle Trust, examined.

Q145 Chairman: Good morning. We are extremely grateful to you all for coming and giving evidence to this Committee. I know some people have travelled some way to be here and we do appreciate that. There are some very important issues arising from this inquiry. I would remind you that the focus of this Committee is on the European dimension. I say that because there has been so much going on across the whole front in terms of organ donation and we began this inquiry some time before that came into the public eye. You need to remember that is our particular focus, which is pretty important in itself. Thank you too for your very helpful written evidence, which we have all had and read, as well as information from Patient Concern. They were not able to attend today but they will give us further written evidence, after this session. I have to give you some housekeeping points. I remind you that the session is open to the public. There is a verbatim transcript taken of your evidence and this is put on the public record in a printed form and on the parliamentary website, so there will be wide circulation of your evidence. A few days after this session a copy of the transcript will be sent to your office for checking. It is important that you check that for accuracy and send it back as quickly as possible as there are tight timetables for our Committees. If you think we have not covered everything during the session, you can to submit supplementary evidence to clarify or amplify any point. However, we hope we are going to cover quite a lot during the time we have here today. There is a quite important point: because we do value everything you say, we would ask you to try and speak up and speak clearly. It is quite helpful if people speak as I am, as if they are in a public session, rather than as though we are having a conversation. It just makes it easier and we can then get it on the record more clearly. Could you start, when we do start, by stating your name and your official title? That is for the record. We have to do that for the record. Then we will ask you at that point about opening statements and we will move into questions. Could you begin by stating your names for the record?

Mr Thomas: Good morning, my Lord Chairman. It is a privilege to be with you all this morning and to give evidence to you following our written submission. May I introduce myself? I am Roy Thomas, Executive Chair of Kidney Wales Foundation. I have on my left the Chairman of Trustees, Raj Aggarwal. As I say, we are delighted to be here today.

Ms Bentley: My Lord Chairman, thank you very much for inviting me to give evidence to this Committee. I am Lesley Bentley and I am Lay Chair of the Patient Liaison Group of the Royal College of Surgeons England.

Mr Hollobone: I am Philip Hollobone, Member of Parliament for Kettering and also a trustee of the Jeanette Crizzle trust. I am standing in for Adam Crizzle, who is the founder of the trust, and I am accompanied by Beth Gibb, who is behind me, who is another trustee.

Chairman: Thank you. Before we do opening statements, the thing I have to do at this point, now we know who you are, is ask if any Members have any interests to declare?

Baroness Neuberger: It is a slightly bizarre one but my brother-in-law is a transplant specialist, particularly in livers. It would be awful if you did not know that.

Baroness Gale: My interest is I am a patron of Kidney Wales Foundation.

Q146 Chairman: Are there any other declarations? I must explain that Professor Farsides is our specialist adviser who helps us with any technicalities as we are a lay Committee and she is a member of the Department of Health Organ Donation Task Force. Mr Thomas, you were going to begin with an opening statement.

Mr Thomas: Kidney Wales Foundation has been in existence since 1967 and we have a proud history, including lobbying Prime Minister Margaret Thatcher in the Eighties to put donor card applications in driving licences. As you know, the DVLA sits in Swansea in South Wales. We were successful in that and established Lifeline Wales in the 1980s with Manchester University, which then was a new registry online. Computers were then in a different age. To mark our 40th year last year we launched a high-profile public campaign from patients which was called “People Like Us” and I would like to talk about that further, if I may, this morning. From the research prepared in Cardiff for
this Committee today, we have found that a record number of people are listed for kidney transplant in Wales, with a dramatic 16.2% increase on previous year’s figures. In total, since 2001 there has been a 44.1% increase in the number of people listed for kidney transplants in Wales from 284 people in 2001 to 431 in 2007, and that is at the end of December. This compares to a 36.9% increase in the same period for the UK. There are many reasons why we are here today, particularly for patients, and I would like to describe what we have been doing in Wales.

Q147 Chairman: Can I just remind you that we will have read all your papers so anything that you say we would like to be supplementary to your papers because all Members will have read your documentation.

Mr Thomas: I will leave it at that.

Ms Bentley: My Lord Chairman, I would like to make a statement because patient groups vary in structure and role and I just wanted to clarify what we are exactly so that you know our remit. The Patient Liaison Group at the Royal College of Surgeons works to bring patient concerns to the attention of College and provide lay input to numerous policy-making committees. It is made up basically of 12 lay members and six surgeons. The lay members are either patients, surgical patients, or carers of a patient. They are volunteers who are non-medical and they do not represent any organisation. Their views are their own as individuals, so we are a group of individuals with a patient perspective. The PLG therefore provides the collective lay view from individuals who bring a patient perspective to their response. We make considered responses based on patient experience and this will be reflected in the answers given to the Select Committee.

Mr Hollobone: The Jeanette Crizzle Trust was set up to encourage greater awareness of the possibilities of making blood, organ, bone marrow and tissue donation following the death of Mrs Jeanette Crizzle and the Trust’s view is that greater awareness of donation can be facilitated through an education programme.

Q148 Chairman: Thank you very much indeed. We are going to move into the questions. You have seen these questions in advance. However, I should just tell you or warn you that Members can ask any supplementary questions of witnesses. We are going to address these and I understand you have decided who is going to take the lead on which question. The other Members may then want to add. Can I just say, please will you add, or disagree if you disagree. What we want to avoid is repetition. If your lead member has given a view, then we would like any additional information to add or be a point of disagreement, if there is one. Is that helpful? Then we can move on. I am just going to begin by reminding you of something that you all really know, that the European Commission’s Communication was published against the background of a major shortage of organs across the European Union. I do not need to say that to your kinds of groups; that is your concern but the UK is less well-placed than some other countries, with a donor rate of 12.8 million a year compared with 35.1 million in Spain, for example, and we have heard a good deal about the Spanish system. All the patients’ organisations that we have heard from agree on the shortage of organs available for donation and that this needs to be addressed. So the question which you have is that, as a representative of patients who may need to receive a transplanted organ, what do you see as the major obstacles to sufficient organs being available for transplant within the UK? We will then later come to the EU issue.

Mr Hollobone: The view of the Jeanette Crizzle Trust is that a large number of people are aware of organ donation but that awareness is not translating itself into people actually coming forward to register their interest as a donor. I am registered as a bone marrow donor. I also have the NHS donor card but, as we all know, far too few of our fellow citizens go down the route of actually getting themselves on to the register. I think there are a number of reasons why people are not taking that next step. People are afraid of the potential consequences. Bone marrow donation, for example, is a painless procedure but if you stop most people in the street and say “Do you think bone marrow donation is a painful or painless procedure?” I think most people would take the view that it probably could be quite painful, could be quite time-consuming, could be debilitating over a period of days. People misunderstand how relatively straightforward it can be to be a bone marrow donor. The Trust takes the view that if we are to get more people to bridge that gap between being aware that donation is possible and actually registering as a donor, the important thing is to educate people. The Trust has had success in persuading the Government to launch what is called the “Give and Let Live” donor education awareness programme which is being launched across sixth forms across the country. Our worry is that there is not enough commitment by the Government to that programme but were there sufficient commitment, it would mean that in 10 or 20 years’ time every sixth former in this country will have been briefed about how easy it is to become a donor and the benefits to the greater good of the community by them so doing.

Q149 Chairman: Do either of the other witnesses want to add to that or take a different perspective?
Ms Bentley: I agree with the points made. Also, in our society in particular, there may be a culture of reluctance to talk about death and the emphasis in society is on actually remaining youthful and putting it off. Education is fine, and then you have to encourage a culture which finds it easier to discuss the issues that are obviously going to be very important when that decision has to be made. I think too it is extremely traumatic for relatives currently if they are in a position where they are asked if their deceased relative can give their organ. That is a very difficult thing and may hinder the number of organs that are currently given. The other thing is the medical framework: is the medical framework adequate to actually make sure that potential donors are found? In other words, are there enough intensive care beds, transplant surgeons? Are doctors trained to see the potential which arises? Are there enough transplant coordinators? I think it is a combination of things.

Mr Thomas: I would just like to quote from last week’s Organ Donation Task Force to answer that, which said “Currently organ donation is not adequately performance-managed or funded. Key elements such as organ retrieval and donor transplant coordination are heavily reliant on a variety of ad hoc arrangements.” I think that captures it very well. It went on to give full support to address the main reason that the Trust have identified for donors not coming forward to register, which is lack of information. The main reasons that we have discovered why people are not translating their awareness of donation into becoming donors themselves are, in order: lack of information, not a high personal priority, “I am frightened to do it”, and “Concerns over health risks for me”.

Q151 Baroness Gale: My question is related to the quality and safety standards of organs for transplantation. What are your views on the issues from a patient’s perspective of the benefits of an EU Directive on organ quality and safety, and how would you think the benefits of the imposition of high standards of quality and safety should be balanced against a possible reduction in the supply of organs for donation?

Ms Bentley: If there is to be an EU pool of donors and organs, it is essential that there are the highest possible standards set and agreed for quality and safety of organs. As patients’ trust is crucial in these things, I think patients would want that to be the case. That is extremely important. Of course, the ideal aim must be to get the most high-quality organs for patients. The EU Directive would make this more likely to happen. The issue that you would have with the public possibly is that they would need to be reassured that how that Directive was actually implemented across states was uniform, so they felt that the same standards were actually on the ground being reached in the different Member States. The important thing for patients too in this is that the safeguards of quality and standards are set for the whole route of the organ, so it is how the donor is screened, wherever that might be in the EU; how the organ is actually removed; how it is preserved; and how it is transported before it then gets to the recipient. As long as the public or the patients would know there are high standards of quality and safety for each of those stages, they would be more likely to support something like that given that it is coming possibly from a different place.

Q152 Chairman: Can I just ask you a question about that? We have had witnesses who have been concerned about the possibility of what they call “gold-plating” because there are so many people who are desperate for organs that they will go to other places anyway to achieve this. How do we get this quality standard with enough organs and at the right quality levels so that we do not exclude what is possible and available rather than the absolute perfection?

Ms Bentley: I think there has to be a baseline of quality and safety below which it is either dangerous or unadvisable to go but there must be room for clinical judgement to be made because there will be patients who will have maybe a rare tissue that is difficult to match and their likelihood in any situation of finding an organ is going to be hard. They may well, having talked to their clinician, be prepared to accept a marginal donor, a less than the highest
quality organ, in order to get some quality of life as a 
result, and I think that must be available for patients. 
In terms of safeguarding it so it is not an abused 
thing, it is going to be very difficult across the EU for 
reassurance to be given to patients that clinical 
judgement will be as reliable or the same across 
Member States. I think that might be a real issue. The 
only way—and this is just a lay suggestion—would be 
that if you have that baseline, that sort of gold 
standard, it has to be documented if any exceptions 
are made to that—that may well be a way round it—
that could be monitored and would then be looked at 
in the context of organ donation generally but that 
clinical judgement is very important to patients and 
may be vital to some transplant patients.

Q153 Lord Lea of Crondall: It is something I have 
not thought about, but now is the moment, I think. 
You mentioned a hypothetical conversation between 
the patient and a clinician. Would you be happier, 
given facts on the ground, “This is your only chance”. 
sort of thing, to have not a substandard organ but did 
you say an organ from a marginal donor? I cannot 
imagine that conversation. How wide can that 
conversation go? I did not know there were 
organ that could be coming their way.

Ms Bentley: No, I am not talking about the donor at 
all but the quality of the organ.

Q154 Lord Lea of Crondall: How wide could that 
conversation go? I did not know there were 
conversations on this point that you are making 
between a patient and a clinician about the particular 
organ that could be coming their way.

Ms Bentley: I am just thinking in terms of if a patient 
has a lot of difficulty in finding an organ, it may be 
suggested to them that they could consider having an 
organ that was maybe less than the highest quality organ.

Q155 Chairman: You did say it was probably a very 
specialist area.

Ms Bentley: This would be all part of the consent 
between the doctor and the actual transplant patient. 
That was the context in which I was saying it. 
Nothing to do with the donor, where it came from, 
but the actual quality of the organ as it would affect 
that patient. They check for transmissible diseases, et 
cetera. It is on that level.

Q156 Lord Lea of Crondall: So it is a category of 
organ that you could be offered or a standard of 
organ that you could be offered. It is not a question of 
someone saying “We have got an organ on the 
shelf here”?

Ms Bentley: No, I am not a doctor so I cannot 
really—

Q157 Lord Lea of Crondall: I am very much a 
layman, as is very obvious.

Ms Bentley: I am just mentioning it as the clinical . . . 
If the doctor suggested there was an organ available 
for a patient that maybe did not meet all of the 
standards, the patient would then have the flexibility 
to talk it through with the doctor.

Q158 Baroness Neuberger: Can I perhaps just tease 
it out a little bit further? I think you are making a very 
interesting point. Where there is obviously the 
discussion between the very specialist doctors in 
teams and potential patients and there is a shortage of 
organs, wearing your hat, chairing this committee, 
have you looked at questions about how one might 
standardise any of that, given that is part of the 
clinical relationship, really hard?

Ms Bentley: No, we have not looked at it in detail.

Q159 Chairman: Could I ask if either of the other 
witnesses want to add to this?

Mr Hollobone: I would like to make a contextual 
point, my Lord Chairman. I think the view of the 
Jeanette Crizzle Trust would be that in large respects 
this is an issue because there are not enough donors. 
If you make people aware of how straightforward it 
is to become a donor and what the benefits are of 
being a donor, and you increase the number of 
potential donors, this issue in effect solves itself 
because there will be more donations out there to 
which people have access. The reason that the Trust 
was established was that Mrs Jeanette Crizzle, who 
died of leukaemia, was not able to find a suitable 
bone marrow match.

Q160 Chairman: I suppose the question is, where 
there are not enough donors, would it be useful to 
have some common, not maximum, standard? I 
thought Ms Bentley made a very important point 
when she said that documentation when that has to 
be achieved differently would be a useful standard. 
As this may be a European standard, because it is to 
do with safety and that is a European issue, do you 
think that would be helpful?

Mr Thomas: I think it would be helpful but, at the end 
of the day, I think it must rest with the clinician, the 
patient and the patient’s family. That discussion we 
were having earlier with Lord Lea has to be put in 
context, and indeed, in Wales we have had kidneys 
from Spain and they have proved to work very well 
for our patients, I should add, and we were pretty 
much delighted and the patient receiving it was very 
delighted in January 2007. We have had that 
experience and it has been a good one.

Chairman: Thank you very much indeed. Can we 
move on then to models of consent?
Q161 Baroness Perry of Southwark: Could you tell us what you think about the current consent processes for organ donation in the UK and what do you think about proposals for a move to opt out or presumed consent? When you answer that, could you perhaps tell us what evidence you are aware of that support your views on the issue.

Ms Bentley: My Lord Chairman, may I preface this by saying first, as a patient liaison group, our first concern must be for those patients who are dying because there are insufficient transplant organs available, therefore it is crucial to find a satisfactory way of raising the number of potential donors. Just putting it in context further, if a system of presumed consent—and I will come to the current one—was found to be the crucial factor in achieving the end aim of providing more organs, it might have to be considered. However, for us and our group the issue of informed consent for both the potential donor and for the transplant patients is also extremely important and a system of presumed consent would compromise this. Ideally, we would look for a system like we have now, where you have to opt in. Looking at the current system, obviously, we have a relatively low level of donor volunteers. It seems to us that insufficient effective action has been taken to make the most of the current voluntary opt-in system, one that is based on the principle of individual informed consent. To us, it would seem logical therefore to improve the current system within the current opt-in framework. A lot has been mentioned earlier about education and we think this is vitally important because we feel there does not seem to be an appreciable understanding of the donor need problem or the processes of becoming a donor or the process of donation generally. Therefore it would be premature to suggest a system of presumed consent before ways had been found of improving the effectiveness of the current system. The background is lack of awareness but I also feel there may be a combination of factors leading to this problem of the number of organs and there needs to be a look at the transplantation process. That may have weaknesses, such as I have mentioned: transplant units, transplant doctors, transplant coordinators, medical training on the identification of donors and ITU beds. That, we feel, needs to be looked at as well to make sure that that is actually functioning effectively. We feel that if the public are not made fully aware of the consent procedure itself, as we have it now, and its ongoing potential, then ignorance and inertia will mean insufficient potential donors will register. We also feel that some of the possible routes to organ donor registration seem to occur rarely as a prompt to the public. So completing a driving licence application, registering with a new GP, Boots Advantage card, applying for a European health insurance card—they happen fairly rarely, and completion of the relevant organ donation questions does not seem to be compulsory. The public need to be more aware of that. Do you want me to go on to presumed consent?

Q162 Chairman: Yes, please.

Ms Bentley: Basically, given that, given that we do not feel the maximum has been made out of the system that we have at the moment, it would be premature to move to a system of presumed consent, given that you will have a background of the public who are unaware of donation generally and of the issues, never mind presumed consent, and a medical system that may not be working to full capacity in terms of actually taking that on board. If you moved to presumed consent and if that did increase initially the number of organs available, you may not actually have the capacity within the hospital system to deal with it, which means you would instantly lose or run the risk of losing patient support. This system is asking such huge questions that you really do need patient and public trust and support in all this to go with you, so it would be better to build up that awareness and only if, even after that, there were not enough organs coming forward, you then discussed the option of presumed consent. That would be more constructive. If presumed consent was suggested, we would have a lot of concerns because we do feel informed consent is of vital importance to patients. It is central in the GMC’s Good Medical Practice and the Human Tissue Act, which is only newly implemented. We just feel it is so important. We feel it is a difficult situation: if someone does not know that they are opted in, how can they know that they can opt out? Even that choice may in theory be denied. There must be no risk of the public seeing themselves as providers of spare parts by default for clinicians keen to save another life. That may be an interpretation, however unfair. It would have to be very important to ensure the separation of decisions made in critical end-of-life care for those made by transplant surgeons thereby guaranteeing that all such decisions are made irrespective of any transplant potential of the dying patient. I think too the public, as was mentioned earlier, as well as knowing how to become a donor, need to know what it means for a recipient. What does it mean to be on dialysis? They die when they do not get an organ. They need to know something about the process, they need to be spoken to about what does death mean, how it is defined, what is brain stem death, what is a non-heart beating donor. If the public had some idea of what all these things meant, they would understand it, they would know what questions to ask to be reassured, and they would feel more brought into the process. I think this needs to be
done. The other query would be what age you would be opted in; we would be really concerned about what that was, and then what the roles of the relatives would be in the last analysis.

Q163 Baroness Perry of Southwark: Ms Bentley, obviously your committee has thought about this very carefully.
Ms Bentley: Yes.

Q164 Baroness Perry of Southwark: Have you taken wider evidence? Do you know what evidence exists to support your views?
Ms Bentley: For some of this, we actually got the research report done for the Jeanette Crizzle Trust on the background awareness, which gave us a lot of information, as did a lot of your accompanying documents and also the initial report from the Organ Donation Task Force on the medical framework and the readiness for actually coping and having capacity. The wife of one of our lay members did have a transplant some years ago, so we have knowledge of that, and one of our surgeons on the lay group is a transplant surgeon, but we are just 12 people making those views and I stress that those are our views.

Q165 Baroness Perry of Southwark: I did hear one recipient on the radio saying very passionately that what mattered to her most was that the organ she had received had been voluntarily given and she felt that gave her a relationship with the person and she would have hated to have had something that had just been taken from somebody without their consent.
Ms Bentley: Absolutely. I think that is very important.

Q166 Chairman: That is extremely clear. Do either of the other witnesses want to add to that?
Mr Thomas: I would like to disagree profoundly with what has been said. We in Wales—and we are supported by the BMA in Wales, who have been lobbying for this presumed consent change in legislation for some years—have been arguing for the last six or seven months for a position on presumed consent. Indeed, as we have a devolved government, we are actually reviewing it with the National Assembly for Wales and the current Minister of Health and Social Services, Edwina Hart, in our view has been very brave in coming out publicly, as did the Prime Minister some week or two weeks ago, and giving a personal view, and so has our First Minister and indeed the other leaders in the Assembly. One of the key issues is education but also we have actually asked—and you have seen it in our written evidence—the Minister for a consultation with the public. We believe that is essential. The Minister has taken on board that challenge. We believe that in educating the public you have to have a discussion and a dialogue with them. Unfortunately, we have some issues with the top down approach of the Task Force that actually puts recommendations out there, and I must say, I have much praise for the Task Force report that came out last week because it has been very honest and it actually exposes weaknesses in the system that we have in the UK. I share the concern that perhaps the system might not be able to cope, because we have some excellent transplant coordinators in Cardiff and I know the demands they have when they are working 24-hour shifts. But I also know the demands of patients because we meet them every day. I have a 43-year-old man from Bridgend, who last year went to the Philippines with a BBC camera crew for three weeks, seeking a kidney. It brings it home to you when you have him perhaps on the phone every month discussing his position. Mark Schofield is pretty well known in Wales for wanting to have a kidney so he can get on with his life with his children. That perhaps is the extreme end but we would prefer to have transplants in Wales, not in the Philippines, or in the UK, because we do not support that, obviously, but we do not actually support some of the remarks of UKT, who in the evidence given to you have been lobbying, it seems to us, against presumed consent. That concerns us because it is not a matter for a government agency to actually put a view. It is for a government agency to go out there and help expose the issue and actually get the debate going. That is a concern. Looking at evidence, and there does not seem to be reference to, and we put it in our written submissions, the Harvard University, well respected John F. Kennedy School of Government, the Abadie and Gay paper, The Impact of Presumed Consent Legislation, which looked at 22 countries over a 10-year period, so it is quite an in-depth study and I think it is worth reading. They did actually come out with the fact, having looked at all the determinants, that presumed consent legislation did have an effect. I know UKT has submitted something quite different and the architect in Spain, who has obviously given evidence to the Task Force, believes that the system is the important issue. Of course it is; the system is bound to be important but you need that overall consent to have organs of high quality available. We are concerned that there is danger of fear from the public but there are people dying and so we have to also look at that. A thousand people will be dying this year. We have to take account of that while we intellectualise on these things today.

Q167 Lord Wade of Chorlton: Why do you feel so convinced that the general public would automatically accept, in their present knowledge
and understanding of these issues, if presumed consent was suddenly confirmed by the Government as the way forward? I take an example of the situation in Alder Hey a few years ago, where the smallest samples were taken from children that had died, and the parents knew that they had died, yet when they found out that their parts had been taken without their permission, there were riots in Liverpool. Just put a position where suddenly somebody... We are not dealing with people who understand all these things. Take my own point of view. If someone had asked me 30 years ago, I would have said, "No, I don’t believe in this. It's a lot of nonsense. You are ill, you die and we are all dying all the time. We can’t solve all these woes," and I would not have even known or thought about it. As you become more involved in these issues, you learn a lot more about it but if you were to ask the majority of 30- or 40-year-old people in this country, they would not want to be involved in these sorts of activities. I must admit that my views are much more akin to the lady who said that before we can bring in presumed consent, surely we have to educate the public about the implications of it and understand much more about the need for it and the impact of it. Do you not agree with that or do you believe we can suddenly impose this on the public?

Mr Thomas: Lord Wade, I agree with the education position wholeheartedly. We are a small country in Wales and most of the population is in the southern part of the country. It is not the size of the South East or London but we can get out and discuss matters in a far more confined way. Why am I convinced? I can only, from my experience, look at patients who have been desperate—and I have met them over several years. I had a little 14-year-old, who Baroness Gale took around your Lordships' house just before Christmas in November, who went on the list on 29 November and had a transplant in Bristol—because our children are transplanted in Bristol from Wales—on 30 December. The relief to that family, having gone through all those years of desperation, is a huge message. I agree with you that perhaps not everybody is touched or understands the position but if we do not start organising ourselves, and I think perhaps in the smaller regional parts of the UK you can do that, because that is the US model, and I believe that not-for-profit organisations should be doing it, not government, by the way. I think UKT do a fine job but sometimes it is Big Brother and sometimes the voluntary sector and the charitable sector can help in that debate, whereas government is seen as in a different context.

Q168 Lord Wade of Chorlton: If you have presumed consent, it would have to be legalised. You cannot just say you have presumed consent because an organisation like you say we are going to have it. The government would have to pass a law to make presumed consent an acceptable activity.

Mr Thomas: Absolutely, Lord Wade, and that is what we have been lobbying for.

Lord Wade of Chorlton: Voluntary organisations cannot decide to do it.

Q169 Chairman: Mr Thomas, could I just ask you a supplementary question here? I probably should have declared my interest as a trustee of Little Hearts Matter. I did not because we have not reached the stage where our children can be transplanted but it will come. These are hypoplastic left heart syndrome children. I say that because you see the position I am coming from, which is that I actually at the moment do not have a view either way and I am listening carefully to the evidence. One of the things you did say is that you are a small country in Wales, a country many of us know and love but, in order to have the right number of organs, depending on type and referencing and all of those things, the Welsh community is going to have to look more broadly. This is why we, as a European Committee, are looking at the European dimension of the whole issue. Therefore, if you solve it in Wales and it is different in another country, what are the issues going to be for some of your patients?

Mr Thomas: That is a very good point. Wales is part of the European Community. That is not a glib point but we are, and, for example, on smoking, Wales was at the forefront of the banning of smoking. Again, it got round the pubs and clubs of the valleys, and there was a consensus that smoking is harmful. It was not the case 20 years ago. If I was sitting here then, I would be booed in the gallery for saying that. We are and we will continue to try and change the legislation in Wales and I think, to answer your question, from the point of view of patients, and I mentioned Spain earlier, a patient would receive, gladly receive an organ from Spain. So Wales as a region, and I am sure there are other parts of the UK, would very happily hook up with other parts of the European community to look at these issues, particularly the patients who are waiting, and there are over 400 in Wales waiting and I can assure you that some of them are very desperate.

Q170 Baroness Neuberger: In a way, we have covered part of my question. We have been looking at high rates of refusal in the UK and there is some evidence that they are particularly high in some ethnic minority groups. You were talking particularly, Ms Bentley, about how the system
works and the extent to which there needs to be more explanation and more discussion with possible donors. Perhaps it is a question really for all of you but to what extent do think that it really would help if the system were changed sufficiently that doctors or transplant coordinators or whoever else were both willing and indeed had the opportunity to explain the issues much more to relatives of potential donors? I think we would also like to know about other ways of improving the position other than presumed consent, so other ways that the system as it stands could be improved. I think it is worth saying that one of the key pieces of evidence is that in 20% of cases or so it appears that the possibility of donation is not raised at all with relatives, and that is clearly something that I think would concern us.

Mr Thomas: I would like to bring the Chairman of the Trustees in on this, certainly on the ethnic side. He is trying to convert me to Hinduism very easily as an Anglican and I would be delighted actually because we share a lot of things in common. Family refusal is what we are talking about here. The most commonly reported reason from the coordination team that we have in Wales for declining organ donation that has been reported to us is because the family member felt the need to protect the body of the deceased. Families sometimes do not want to relinquish the guardianship of the body. That is a big issue. They want to keep it intact and do not want it to be interfered with. We heard from my colleague on the right on that. The other reasons that we have come across, because we have a very open relationship with the transplant coordination team—in fact, we erected a memorial for donor families in Cathays Park in Cardiff in October, when we had a thousand families from across the UK come to Cardiff for the memorial unveiling that we had. The other factors include circumstances at time of death, obviously. People needed to have time to come to terms with the death of their relative, especially if the death was sudden or their body looked normal. Lack of knowledge is a key point. Some people have said to us that they did not have enough information about what organ donation involves, and that is clear and we heard that earlier. The donation discussion—issues have been raised with us around the timing and sensitivity of discussions between relatives and healthcare professionals. A doctor is not always the best person to deal with it. That is why we have our coordinators and we welcome the task force recommendation of 100 more. We are hoping they are all in Wales, of course. Witnessing the observable ending of life is a big issue, and some people have said that they needed to be present when the relatives' heartbeat stops.

Q171 Baroness Neuberger: I think that is particularly common for some faith groups and some cultural groups. There is clear evidence of that.

Mr Thomas: I would like to bring my Chair of Trustees in on the faith group now but if I may put to the Committee something that we have researched in advance of this Committee, the Journal of Advanced Nursing have a report on this from the University of Southampton, and it is worth looking at for your Committee, where they put adverts—I am not sure of the Committee is aware of this—in newspapers asking for those families who at that time did not fulfil the wishes of the deceased and how it felt for them. It is quite a useful summary.

Q172 Chairman: Maybe you could give us the reference.

Mr Thomas: I will. Can I bring my colleague in?

Q173 Chairman: Can I just ask if any of the other witnesses want to come in on this?

Ms Bentley: Just to say—it is probably an obvious statement—that it is an extremely traumatic time, obviously, for relatives to make a major decision on organ removal. I agree it would be ideal if someone could explain to them and that would probably help them to ease it but, again, if they are given more information that they already came with through better education, that may well then be a good issue.

Mr Aggarwal: I am the Chairman of Kidney Wales Foundation and a trustee as well. Thank you for giving me this opportunity to say a few words. Leaders of all six major faiths in the UK—Christianity, Judaism, Islam, Hinduism, Buddhism and Sikhism—have all explicitly endorsed organ donation and transplantation. Even in Wales differences of opinion exist among local faith leaders, although it is not a major issue. There is a clear and urgent need for local leaders to use their considerable influence to promote support for organ donation in their communities, particularly given that opinion at grass roots does not reflect the official view of the faith. This is because some groups are suspicious of government at a local and national level. Groups are concerned at the heavy hand of government, of EU matters, with the top-down approach. It is well documented that there are considerable problems relating to organ donation and transplantation stemming from a culturally and ethnically diverse population and the same is true in Wales. There is terrific variation between different areas of Wales but the concern we have is communication and trust within these patient or donor groups. Government, especially UKT, needs to communicate differently with these groups,
perhaps through religious leaders, priests. I think these priests are very important at the last resort, during the last few days. They can give a lot of counselling, a lot of advice and a lot of support and I think their views are very strongly taken. Generally, I feel with the ethnic community it is just a question of awareness. There is not much difference basically between all these communities. I think they are all very generous. It is a question of awareness, education, training, support, and I think exactly the same applies all over the UK.

Ms Gibb: I am Elizabeth Gibb, and I am a trustee of the Jeannette Crizzle Trust, with special responsibility for the ethnic minority and hard-to-reach groups. I am also a trustee and health lead for Welwyn Garden City, Hatfield Black and Multi-ethnic Group and the hard-to-reach group. Because of where I sit in the BME family, as it were, I work through the BME networks so that in Welwyn Garden City, when the presumed consent came out, that was an immediate trigger for me to alert people that this was here and what they needed to know. That went immediately down the cascade, so then I went up to London, to Notting Hill Gate and into Suffolk and Norfolk—it was out of area a bit but that is why. My experience in BME work was with a medical background and when I was in London for the Notting Hill riots, specifically as a health lead but also a community lead. We have just started some research, and I have brought this copy as far as it has gone for your Lordships, because it is not complete but the work that is coming through is very interesting. I am not at the top; I am at the bottom. I know the imams, I know the church leaders, I know the community workers and, because they know me and this is the secret, is it not? They know the face; they will talk to you and listen to you as an equal, not as a top-down. Some of the remarks that have come back have been incredibly interesting, and I would recommend this, although it is incomplete.

Q174 Chairman: Could you give us the key points?
Ms Gibb: Yes. The problem is, or at least what I am beginning to see is that people are in their little boxes. The doctors are in a little box, the community workers are in a little box, anybody else, the church leaders, I am in a little box, and it is trying to bring these together, in which I did succeed to a certain extent. They are willing. I agree with everything you say. They are not against organ donation. This came through very, very strongly. They are very caring, very responsible. They sat down and hashed out these but they do not like presumed consent, and if you go down the presumed consent road, my feeling is—and it is a personal feeling—that you could lose a lot more ethnic minorities.

Q175 Chairman: Could I ask you one question?
One of the things we have learned in the Committee is that the vast majority of the community give the impression that they are in favour of consenting. The problem is they do not act upon it, particularly so in the minority communities. What we are looking for is what would be the trigger to help us to encourage those communities to come forward more? That is really what I think we are all looking for, how we actually ensure that more donors come forward from the ethnic minority community. Everyone has good will; it is action that is the problem.

Ms Gibb: Take away “ethnic minority” and “hard to reach” and think “people”. I have only put this in here because I am coming here for the ethnic minority. I think people: people who have opinions, people who want to learn, so you need education, you need a cascade of information. What I come across all the time with BME groups is “But I never heard about that.” There are language barriers, there are isolation barriers. There is at the moment a certain degree of increasing racial barriers. When they can get down to the nitty-gritty, they are responsive but they will not act on uninformed consent.

Chairman: That is really helpful. That is the piece of evidence we were really wanting you to say.

Baroness Young of Hornsey: Thank you very much for what you have said and I am very interested in the research you talked about and I would be keen to see what that is about. I absolutely take your point about people rather than always categorising and dividing people up. Nonetheless, there are three factors which mean that what we currently call black and minority ethnic people are seriously affected: there is the high proportion on the register, there is the higher rate of refusal from relatives, and there is also a lower proportion of black and minority ethnic people on the donor registers. Those three factors combine to make it a particularly acute issue for a specific grouping within our society. One of my questions is that people tend to collapse black and minority ethnic into faith groups as if that is the only determining factor and I am very interested to see if that might be something that we can knock on the head and look at it as people, people with specific physiological and medical needs. That is one thing I would like to hear your comment on. The other thing I have been trying to get at but nobody has been able to identify so far is the extent to which other groups that are marginalised, either within this society or within other European states, also have a lower rate of giving consent for organ
Q176 Baroness Morgan of Huyton: My question really is about, how you feel you have managed to place organ transplantation in the social and political world how far you are getting it up the agenda, and obviously, in relation to the specifics of our inquiry, to what extent the EU involvement is going to be a help or not or do you think it is not going to have much impact? What do you think the implications of that will be? Are there any countries, regions or groups within Europe that you know have been particularly successful at actually moving the agenda on the issue?

Ms Gibb: This is quite complicated; you might have to remind me of some points. I have been very successful, so successful that I have challenged myself as to whether I need to go into it more deeply and put more checks on it. You have to be aware that the BME groups are now setting up their own charities to educate their own people. This is very dynamic and it is being cascaded down the network. One group is starting up. There is a national one, so they are going along that. Most of the inter-racial groups, minority groups, tend to get together. It is not just black people and Asian people. I come across Chinese, German, refugees, Afro-Caribbean, Africans—and remember, Africa is a large country. There are a lot of nationalities in there, and in the Caribbean—Spanish, French, American, New Zealand, because they are ethnic minorities if there is only a few of them, and they tend to get together. So yes, it is cascading out. The education, even though it is very early, is beginning to show results. So that is going on. I agree with Lord Wade that it is actually essential; the only way forward is focused to actually up the number of donors, and the more targeted the campaign, the more effective it is. You think you have more chance if it is Welsh-focused to actually up the number of donors, and you think you have more chance if it is through the BME networks. I suppose in the back of my mind I am very struck since the large cancer charities merged by how effective their national advertising is. It is very personally based. It makes you jump up. It is very much about people. Do you think there is any role for a much bigger campaign that is not local in fact to get the issue up the agenda or are you saying it should all be locally focused or network focused?

Ms Gibb: I think it is both. For instance, I managed to get traveller clan leader to come to one of my meetings. You would probably not have found a traveller easily in a national campaign. You need the two levels, because one will complement the other. If you have language difficulties . . . If I could interject this for a moment, one of the things that caused tremendous hilarity in one of my meetings was a doctor on the television saying “Of course,
every person will be told about this before it becomes law,” whereupon I lost the meeting. They just collapsed, because if you have language barriers, you are sensory deprived, you are isolated, you are a refugee, you are an economic migrant, and even if you belong to the black and multi-ethnic community, and certainly travellers because they are travelling, you do not get this information. There again, I am only a little cog but, as a lead in that area I can cover a lot of people because I can link with the traveller work, I can link with different charities. I think it is working locally, working nationally, working together, with everybody that is involved in the field.

Mr Thomas: I endorse that. It is the national, the local, the political will, whether the Prime Minister is in favour of it. All these things are taken into account when the discussion is there over the kitchen table, which unfortunately does not take place at the moment, on death. We are looking at a local campaign and I think charities are essential here. The British Heart Foundation did a great job, I think, in terms of smoking, and they were given money by, as I understand it, the Department of Health. We have taken a similar line with our Health Minister in Wales. If I may be rude about the civil service for a minute, they are not very good at putting adverts together, we would suggest. Also, when you go to the television companies with your card rate, you find that they will be thinking government is a bottomless pit but when we go to ITV or whoever these days, at least we think we can get a better negotiating stance. I think that was true of the British Heart Foundation. Also, you keep your money tight. I am not saying that NDPBs are not accountable of course but at the same time, we could work far better together. One of the things I would like to stress to UKT, if they are listening, here is that perhaps, instead of just spending, which they have done, £42,000 in Wales in 2006 and meeting the Assembly once in a year, they should actually see what they can do in regional parts of the UK.

Chairman: I am going to stop you there simply because I do want Lord Lea to press the European dimension a little more, which we are still trying to get you to answer.

Q178 Lord Lea of Crondall: Can I link it to a linked question in a sense? In a pub the other day somebody said, “You’re in Parliament, aren’t you? What is all this? Taking all our organs?” I said, “No, et cetera,” and all that. I must say that the biggest thing in the last 20 years that has been done to raise awareness is what the Prime Minister said. I do not think there is any doubt about that. No-one would have asked me in the pub otherwise, I do not think.

Secondly, I said, “What is your take on it” and he said, “Well, I’m dead. They can have what they like, can’t they?” I did not go into detail: “Does your family know that?” and all the rest of it but the implication was “I’m not going to do anything about it” so we are trying to look for a halfway house between doing something which does not perhaps go as far as the opting out issue but nevertheless . . . My question is on the European organ donor card. In the Commission’s Communication, and I am sure you have seen what it is all about, it would help raise public awareness and make it easier to identify people willing to donate organs after death. The organisation UK Transplant told us however that in their view such a card would be confusing for people and could not operate effectively across the EU because of the different forms of consent in place in each country. So there is the paradox which relates, if I may say so, to what we have been discussing in the last 20 minutes. You have to square that circle. Could somebody comment on that?

Ms Gibb: I had some Spanish and French in my group, so it is very small, but the issue they raised was that different countries within the EU have different transplant regimes, and they did not think it would work. They said “Why can’t we just have a card which says yes or no and carry it with us because the other is too complicated?” Their feeling was that they also would not be happy carrying one if they were travelling across Europe and going through another country that had a different . . . Do not ask me why because I have no idea but they had reservations within themselves. In the group, out of 275, there were only about 11 European people, so it is very low but they had their own doubts about it because they cannot see it sitting comfortably with other countries. They came from different countries.

Q179 Lord Lea of Crondall: Sorry, we are talking at cross purposes here. I am in France on holiday and I am killed. That is one situation. The other one is a Europe-wide scheme so we have roughly parallel opt-in, opt-out arrangements, backed by a card. Would be we talking about a difficulty if it is just that I am in France and my own driving licence on the one hand. Obviously, there is no difficulty about that. Can you just elaborate a bit on why a Europe-wide voluntary card would be a problem?

Ms Gibb: I do not think they felt it would be easily transferrable, but as I am not a European—

Q180 Lord Lea of Crondall: What do you mean, you are not a European?

Ms Gibb: Living on the continent of Europe. I am a Scot so I am not European. What they felt was if you are French or Spanish, it may not be easily
Mr Roy J Thomas, Mr Raj Aggarwal, OBE, Ms Lesley Bentley, Ms Elizabeth Gibb and Mr Philip Hollobone

carried across. That is what they were trying to say to me. I have not explained it very well.

Q181 Chairman: One of the things we have heard is that people have views which are difficult to carry through about who they do and do not want to give organs to, and that is something ethical committees I know have strong views on.

Mr Thomas: Can I answer Lord Lea, if I can. There are two issues—you are absolutely right—the card and if you die on continental Europe. There is some evidence that in Spain, when people have died, they asked British tourists whether they would give their organs, and the evidence there is that they have had a far better success rate of convincing British tourists or British people to actually give their organs. We know there is a different refusal rate in the UK as opposed to Spain, to answer the question on the European dimension. My own view on the card, shared by my colleagues, although not all of our trustees, I should add—there is one dissenting surgeon, who I respect enormously—is that the more access, the more cards we have, the more demonstration that people are prepared to give, the better. I know I am coming from that side and I would say that, wouldn’t I, but that is important and it also demonstrates that there is a need. Whether you have one register, which is the third point you were bringing into it, is something else, because I am then defeating my argument about locality and the local side of things. We are in Europe, we should be looking over the borders and we should be looking at best practice. Indeed, that is why I think the evidence today is essential and what we are bringing is benchmarking. One of our key things is that we have a world-class renal service in Wales but you cannot have a world-class renal service if you just stick to the UK. You have to look outside, indeed, to the United States, for example, where again they do things locally, not nationally, and it is a bit bottom-up more than top-down.

Chairman: Thank you very much indeed. We have run over time. I hope we have not detained you too long. That is simply because we have found your evidence so useful and interesting and I am sure the whole Committee will join me in thanking you again for your very useful and helpful contribution.

Baroness Young of Hornsey: I am sorry to interrupt you. A couple of questions I asked were not able to be addressed due to time. Is it possible to have some written response to those?

Chairman: If we could, it would really be helpful. I apologise. I thought they would run through and of course they did not and we have not had a chance to come back. Unfortunately, we never cover all the things we want to, so we may drop you a note and ask a further question, because we do not expect you to keep it in your heads, just to reassure you of that. Ms Gibb, we were trying to get you to answer it and we had to move on far too quickly. I apologise for that. Thank you very much for your evidence. As you have heard this morning, we have heard some extraordinarily complex issues. We now have the benefit of the Task Force document but we are ploughing on, trying to look at the European dimension on the basis that the Commission may well take another step forward in this, and that will have implications for the UK—and even Wales and Scotland! Thank you very much indeed.

Supplementary memorandum by Patient Concern

Patient Concern regrets being unable to attend the evidence session on 24 January and is grateful for the opportunity to answer the questions asked at the session.

Q1. What do you see as the major obstacles to sufficient organs being available for transplant within the UK? 

In simple human terms: inertia, lack of information, reluctance to contemplate death. The fact that over 2,000 people joined the donor register within three days of Sir Liam Donaldson’s announcement that he now favours presumed consent indicates how much can be done to overcome these obstacles.

We noted that in an earlier session of this committee some noble Lords were asking how to go about joining the register and if it was a difficult process. If members of the committee, who have some expertise in the area, feel the need to ask such questions, it is hardly surprising that a large section of the general public remain in ignorance.

The Bishop of Southwark, speaking on Thought for the Day on BBC Radio 4 related his difficulties in replacing a lost donor card, when he was told by various agencies that they “hadn’t seen one for years”. That is our experience too.
Increasing the Supply of Donor Organs Within the European Union: Evidence

Patient Concern has a small advisory board and no member of it has ever been asked, at a doctor’s surgery, hospital or blood donor unit, if they had thought about organ donation. Why not? We incentivise doctors to test for hypertension etc, why not for ensuring that patients have the full information about organ donation?

A powerful message about the need for blood donors has been running on TV for some time. We cannot remember when the last such push towards organ donation took place.

A further obstacle is mistrust. The scandal of Alder Hey and other hospitals in the UK shook confidence in the medical profession in the area of organ donation and goes some way to explaining why we have performed so poorly in the last few years.

We have no way of knowing what proportion of patients have serious doubts over the concept of brain stem death (see Melanie Phillips’ powerful articles in the Daily Mail and Spectator) and how many are inclined to the view that a patient cannot be truly dead while the heart is beating and blood circulating, so that it is actually the act of removing organs that brings about death. Tests for brain stem death vary between countries and it is a matter for some disquiet that a patient might be “dead” in one country but not another. Following Melanie Phillips’ articles several stories emerged of people who had been classed as brain stem dead but who subsequently recovered.

Gordon Brown’s idea that hospitals will be rated according to the number of donors they produce is likely to fuel the suspicion that some people will be more valuable as donors than as sick patients.

We suggested a number of possible practical ways of boosting the donor rate in our submission and others have added to them. We are very disappointed that the Donation Task Force, after a year of work, did not take the opportunity to draw up a list of their own.

Q2. What are your views on the issues from a patient’s perspective of the benefits of an EU Directive on organ quality and safety, and how would you think the benefits of the imposition of high standards of quality and safety should be balanced against a possible reduction in the supply of organs for donation?

Patients must be confident that standards of quality are maintained and an EU standard would be useful and reassuring. It should be neither a “minimum”, as the medical establishment has suggested, nor “gold-plated” as they fear. It should be possible to agree on safety and quality criteria covering every stage including procurement, preservation and transportation while still leaving room for clinical judgement.

There have been recent reports in the UK press that organs from drug addicts etc are being used. If this is happening it is essential that the outcomes are strictly monitored and the results shared openly with patients. However, we agree with the Jeanette Crizzle Trust that questions over quality arise because of the scarcity of donor organs. If the government shows genuine commitment to tackling this problem, that should cut down the need for clinical judgement on marginal organs.

According to recent figures from UK Transplant over 3,500 organs are lost each year in the UK because potential donors are not identified, relatives are not asked or families have refused.

Q3. What you think about the current consent processes for organ donation in the UK and what do you think about proposals for a move to opt out or presumed consent?

Presumed consent would turn us from volunteers into conscripts—unless we register as conscientious objectors. Those who feel they have to opt out, for whatever reason, may fear discrimination. Over the past few weeks, when I have been upholding the principle of explicit consent (while at the same time supporting all efforts to boost the donor pool) I have been met with such a level of personal abuse and vitriolic insults that I have become convinced that their fears are well founded.

Such a system would make the term “donation” redundant. A donation is something freely gifted, not taken by default.

Supporters of the presumed consent system seem to hail it as a magical quick fix and the success in Spain is constantly quoted. They fail to mention that Sweden, where a presumed consent system has been in force since 1996, has a lower donation rate than the UK. The reasons behind Spain’s increasing donation numbers have been covered in the submissions so I shall not repeat them.

There has been powerful “special pleading” amongst the submissions and in the media coverage from groups representing those needing transplants. Naturally feelings run high and those who are suffering find it hard to appreciate that there are ethical considerations on the other side. I admit that if I had a relative dying from heart disease I might support presumed consent, from an emotional standpoint. That does not make it right. If I had a kidnapped relative, I would probably call for the ransom to be paid—but it still would not be right.
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We cannot allow the needs of a small minority to undermine the rights of the majority to make a conscious decision on what happens to their bodies after death. Noting the UK Transplant figures, it should be possible to meet their needs without a change in the law.

When the Human Tissue Act was being drawn up, after the Alder Hey scandal, Sir Liam Donaldson said: “Patients and relatives need to be in control. They need to know exactly what they are consenting to”. He has recently performed a U-turn. The Human Tissue Act came into force in 2005 and has done a great deal to restore confidence in the medical profession. Altering the Act in a fundamental way at this very early stage risks damaging confidence in both the medical profession and the government.

The BMA has long supported a change in the consent system. We are concerned that while the BMA supports presumed consent for organ donation they oppose this same system for uploading patients’ records to the electronic data base. This contradictory position might lead patients to suspect that “ethics” for the BMA are influenced by what is best for doctors.

The Organ Donation Task Force report makes the point that many medics are concerned that carrying a donor card or even joining the donor register does not meet the normal standard of informed consent. This standard would be completely jettisoned by a presumed consent system. The imperative is to ensure that people are aware of the issues and the processes of transplant. This will convince many people that donation is the right way for them, while there may be others will find that more knowledge discourages them from offering this gift—but it is the only ethical way to go.

Suggestions of a mandatory choice have been made during the submissions. This would be preferable to presumed consent but the prospect of prosecuting/fining 20 year olds (or for that matter 80 year olds) who do not wish to make a decision on what happen to their body after death is extremely uncomfortable. The suggestion of three possible choices might be considered: (1) yes to organ donation, (2) no to organ donation, (3) the decision is to rest with the family when the time comes. If these options were attached, say, to the census, then everyone would have the choice to reconsider every few years in the light of events.

Q4. Why do you think family refusal rates are high within the UK, particularly within certain ethnic minority groups? To what extent would the situation be improved if doctors/transplant coordinators could spend more time explaining the issues to relatives of potential donors?

It is always difficult to come to terms with the death of a loved one and even more difficult to contemplate donating organs from a person who is breathing, with blood circulating and limbs moving.

Spanish co-ordinators report spending as long as 18 hours with a family, giving them time to come to terms with the idea, helping them to work through their feelings about it. Too often, in this country, families are approached by a busy doctor who may have no training in this particular area. A great deal depends on the timing of the request and the amount of support given to the family.

While we would all accept that we have no use for organs once we are dead, many people cannot bear the thought of their loved ones being mutilated, “messed about”. The reverence with which we treat a dead body, the viewing at the funeral home, the elaborate burial ceremonies, indicates a deep feeling for the sanctity of the body which prevents some relatives from giving permission for donation.

It is vital not to add to the burden of bereavement with any suggestion of undue pressure on families of potential donors or any consent law that would leave those who feel they must refuse, for whatever reason, with feelings of guilt.

One of the reasons frequently given for refusal is that the family don’t know what the deceased would have wanted. Future publicity campaigns should emphasise the importance of anyone willing to donate discussing this with the family, long before the occasion arises.

We might expect that among ethnic minorities, who are more likely to need a transplant, awareness would be higher and this would lead to more willing families, yet 70% refuse requests for donation. We need more research on the reasons for this: is it lack of information, alienation from the main body of society, or are there religious and cultural barriers that need understanding? Perhaps we need to make much more effort to involve community leaders in an education programme.

The point was well made by Ms Gibb, from her experience, that the idea that everyone would understand a change in the consent system — those with learning difficulties, non-English speakers, travellers etc. — is laughable. Among these groups we believe that a change to presumed consent would cause confusion at best and resentment at worst.
Q5. How has your organisation managed to place organ transplantation on the social and political agenda? To what extent is the EU involvement going to be a help or not or do you think it is not going to have much impact?

Patient Concern is a generic “watchdog” organisation whose aim is patient choice and empowerment. Since the issue of presumed consent has come to the fore we have had the opportunity, through many media interviews and requested articles, to emphasise the current problems and suggest what could be done about them. It has been obvious from the response that widespread education of the facts of transplantation is desperately needed.

We have in production the tenth leaflet in our series of “patient survival guides” which will deal with organ transplantation. These leaflets attempt to give an “insider” view which goes far beyond the standard handouts and enables patients to weigh up pros and cons before making decisions.

Any initiatives taken by the EU, if given sufficient publicity, should succeed in the essential raising of awareness. The directive on quality and safety is one example. It would be helpful if the EU made it a priority to ensure that member states standardise training of transplant coordinators according to best practice. Another positive step would be standardising tests for brain stem death to include electro-encephalography and arteriography – which would raise the bar in countries like the UK and ensure that “dead” does not mean different things in different countries.

Q6. What is your view about the desirability of a European donor card?

The launch of a European donor card would undoubtedly raise awareness of the issues, which would be an undoubted plus. With this in mind, it might be worth starting a high profile debate among member states: yes or no to a European donor card?

Beyond that, we see little point in the possession of another card and accept UK Transplant’s point that it could even be confusing. When the legislation in member states varies so much, it might be difficult for patients to understand just what they were agreeing to.

February 2008
INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE

THURSDAY 7 FEBRUARY 2008

Present
Eames, L
Howarth of Breckland, B (Chairman)
Kirkwood of Kirkhope, L
Morgan of Huyton, B

Neuberger, B
Perry of Southwark, B
Wade of Chorlton, L

Memorandum by Professor Gurch Randhawa

Gurch is Professor of Diversity in Public Health at the University of Bedfordshire. He has spent many years researching issues relating to diabetes, kidney disease and transplantation amongst minority ethnic groups. He pioneered research in the UK examining cultural and religious influences toward organ donation amongst South Asian groups, with a grant from the King’s Fund. This research has been pivotal to the Department of Health South Asian and African Caribbean organ donor campaigns. He is currently a member of the Department of Health’s Organ Donation Taskforce commissioned by the Minister of State for Health Services. He is a recipient of numerous grants from organisations such as the Department of Health, Kidney Research UK, Big Lottery Fund, and King’s Fund. Professor Randhawa has presented an earlier draft of this submission to the European Platform on Ethical, Legal and Psychosocial Aspects of Organ Transplantation (ELPAT) at its conference 1–4 April 2007, at which there is consensus that the recommendations made within the paper need to be addressed at European level as well as UK level.

1. INTRODUCTION

1.1 I have written and researched extensively on the different organ procurement systems operating within the EU and how public awareness concerning organ donation may be raised (Randhawa, 1999). My European-wide analyses demonstrates that where co-operation exists between countries in sharing organs, there is a more efficient use of scarce transplant resources (Randhawa, 1998a). I will, however, for the purposes of this submission focus on the salient issues relating to faith and ethnicity within the UK.

2. BACKGROUND

2.1 South Asians (those originating from the Indian subcontinent) and African-Caribbean communities have a high prevalence of Type 2 diabetes: recent studies indicate a prevalence rate four times greater than Whites. It has been reported that 20% of South Asians aged 40–49 have Type 2 diabetes, and by the age of 65 the proportion rises to a third (Raleigh, 1997). A further complication is that diabetic nephropathy is the major cause of end stage renal failure [ESRF] in South Asian and African-Caribbean patients receiving renal replacement therapy [RRT], either by dialysis or transplantation. Nationally, this higher relative risk, when corrected for age and sex, has been calculated in England as 4.2 for the South Asian community and 3.7 for those with an African-Caribbean background (Roderick et al, 1996). Data from Leicester, shows that South Asians with diabetes are at 13 times the risk of developing ESRF compared to “White” Caucasians (Burden et al, 1992). Thus, not only are South Asians and African-Caribbeans more prone to diabetes than Whites, they are more likely to develop ESRF as a consequence.

2.2 Importantly, the South Asian and African-Caribbean populations in the UK are relatively young compared to the White population. Since the prevalence of ESRF increases with age, this has major implications for the future need for RRT and highlights the urgent need for preventive measures (Randhawa, 1998a). The incidence of ESRF has significant consequences for both local and national NHS resources. The National Renal Review estimated an increase over the next decade of 80% in the 20,000 or so patients receiving RRT and a doubling of the current cost, about £600 million a year of providing renal services (Raleigh, 1997).

2.3 Kidney transplantation is the preferred mode of RRT for patients with end-stage renal failure. There are currently over 5,500 people on the transplant waiting list in the UK—the majority waiting for kidney transplants, but substantial numbers also waiting for heart, lung, and liver transplants. However, a closer examination of the national waiting list reveals that some minority ethnic groups are greater represented than others. For example:

— one in five people waiting for a transplant is from the African-Caribbean or South Asian communities (table 1).
14% of people waiting for a kidney transplant are South Asian and over 7% are African-Caribbean (table 2) even though they compromise only 4% and 2% respectively of the general population.

one in nearly 10 of all cornea transplants carried out in the UK help a South Asian person gain their sight again (table 3). South Asians require a cornea transplant for keratoconus at a younger age (under 30) than white people (table 3).

South Asian people are also more likely to need a liver transplant. While 4% of the UK population are South Asian, Asian people comprise 6% of the liver transplant list (table 4). This is because viral hepatitises—Hepatitis B & C—that can lead to liver damage and liver failure is more prevalent in the South Asian population.

Just 1% of people registered on the Organ Donor Register are South Asian and 0.3% of people registered are African-Caribbean (table 5).

1.2% of people who donate kidneys after their death are South Asian and 0.7% are African-Caribbean (table 6).

South Asian and African-Caribbean people have to wait on average twice as long as a white person for a kidney transplant. White patients wait on average 722 days, Asian patients wait 1496 days and Black people wait 1389 days (table 7).

one in eight people who died waiting for a transplant in 2006 was of African-Caribbean or South Asian origin (table 8).

2.4. The situation is clear, there is an urgent need to address the number of African-Caribbean and South Asian patients requiring a kidney transplant otherwise the human and economic costs will be very severe. In the short term, there needs to be a greater number of donors coming forward from these communities to increase the pool of suitable organs (Randhawa, 1998b; Exley et al, 1996a). In the long term, there needs to be greater attention on preventive strategies to reduce the number of African-Caribbeans and South Asians requiring RRT. The latter can only be achieved if we begin to address the problem of poor access to services for minority ethnic groups (Randhawa, 2003).

3. Improving Access to Services

3.1. The Diabetes National Service Framework highlights the importance of access to services, in particular to meet the needs of minority ethnic groups (DoH, 2002b). The Renal Services NSF also focuses on “renal disease complicating diabetes” and emphasises inequalities experienced by minority ethnic groups (DoH, 2004). However, there is evidence that knowledge of diabetes and its complications is poor among South Asians and African-Caribbeans (Nazroo, 1997; Johnson et al, 2000). Preliminary evidence also suggests that quality of health care for South Asians and African-Caribbeans is inadequate and compliance poor (Johnson et al, 2000; Raleigh, 1997). There is also a low-uptake of hospital-based diabetes services, with growing evidence that South Asians are subsequently referred later for renal care, and are more likely to be lost to follow-up (Jeffrey et al, 2002). Late referral may reduce opportunities to implement measures to slow progression of renal failure, or to prepare adequately for RRT, adding to morbidity and mortality.

3.2. The World Health Organisation (WHO) study group on diabetes notes that resources should be directed to improving the quality of preventive care in primary care settings and to public health interventions for controlling diabetes. Education, early diagnosis, and effective management of diabetes is important for safeguarding the health of susceptible populations and for long term savings for the NHS (Raleigh, 1997). Most encouragingly, recent studies from the US and Finland have demonstrated that modest lifestyle changes can reduce the risk, by more than 58%, of developing overt Type 2 diabetes in susceptible groups (DPPRG, 2002; Tuomilehto et al, 2001). Furthermore, various interventions, such as tight blood pressure control, effective use of angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor (ATR) blockers, and tight blood sugar control can significantly delay the progression of diabetic nephropathy (UKPDS, 1998; Feest et al, 1999; Brenner et al, 2001; Cinotti & Zucchelli, 2001; Lewis et al, 2001; Lightstone et al, 2001).
3.3 Recommendation 1: “Reducing Inequalities” is a Cross-Cutting Theme in a Number of UK Government Health Policy Working Groups—Diabetes NSF, Renal NSF, CHD NSF, and the Organ Donation Taskforce. There should be Active Collaboration between the Respective NSF “CZARS” to ensure the Best Use of Resources so that Future Rates of Renal Failure and Heart Failure are Reduced among Black and Minority Ethnic Groups

4. Improving Transplantation Rates

4.1 Unfortunately, the transplant option may be medically and economically favourable but in reality is not as forthcoming due to constraints around the severe lack of donors from the African-Caribbean and South Asian population. This could be attributed to two main reasons—a lack of awareness concerning organ donation and transplantation; and potentially low referral rates to the Intensive Care Unit (Exley et al, 1996a; Darr & Randhawa, 1999). It must be stressed that these factors are not unique to the African-Caribbean and South Asian population and have relevance to other members of the UK’s public. Furthermore, it is extremely important to recognise that the African-Caribbean and South Asian communities in the UK are heterogenous and thus it is important to familiarise oneself with the demographics of the local population (Khan & Randhawa, 1999).

4.2 Increasing awareness of the need for organ donors among the African-Caribbean and South Asian communities

4.3 Unfortunately, very little research has been devoted to this area. The relatively few studies which have been carried out, consistently show that African-Caribbeans and South Asians are supportive of organ donation and transplantation, but are simply not aware of the specific needs for organs from their community (Exley et al, 1996a; Darr & Randhawa, 1999; Hayward & Madhill, 2003; Alkhawari et al, 2005; Davis & Randhawa, 2006; Morgan et al, 2006). These studies, however, do not identify what would motivate these communities to come forward as potential organ donors. Pertinently, Titmuss (1973) famously viewed the NHS which had been created in the post-war period as a vehicle for institutionalising altruistic practices, notably the voluntary “gift” of blood to strangers represented by the transfusion service. More recent advances in medical technology have made new forms of bodily tissue donation possible, including organs, gametes, eggs, stem cells, embryos, etc. The limitation of Titmuss’s analyses was an implicit assumption that all individuals would feel a belonging to “society” and would therefore wish to contribute to a “societal problem”.

4.4 Within the main South Asian religions namely, Hinduism, Sikhism and Islam, the concept of gifting to assist society is a highly-valued virtue, “Sewa”, “Sewa”, and “Zakat” respectively. This issue needs careful examination within the context of an increasingly diverse UK population.

4.5 Recommendation 2: Research is Required to Identify What Would Make the “Gifting of Organs” Relevant to a Multi-Ethnic & Multi-Faith UK Society

4.6 A growing amount of literature has shown that the role of religion has been known to play an important part in the decision to donate organs (Randhawa, 1998c; Hayward & Madhill, 2003; Alkhawari et al, 2005; Davis & Randhawa, 2006). The religious beliefs of the major faiths of the UK’s African-Caribbeans and South Asians namely Islam, Hinduism, Sikhism, Buddhism, and Christianity have been scrutinised in the literature. None of the religions object to organ donation in principle although in some there are varying schools of thought. What is interesting, however, is that the position of one’s religion is used by many people in informing their decision as to whether to donate or not (Randhawa, 1998c). This has been highlighted in several studies conducted abroad (Callender, 1989; Kyriakides et al, 1993; Spina et al, 1993). Unfortunately, this issue has not been prominent in research carried out in the UK but the findings of a pilot study to examine the attitudes towards organ donation and transplantation among a cross-section of the UK’s South Asian population have shed some light on the matter (Randhawa, 1998c). It was found that far from being a barrier to organ donation, the respondents were more supportive of donation and, transplantation, in general, when they were aware of the position of their religion with regards to these issues. This highlights the importance of education and raising awareness among the South Asian public (Exley et al, 1996a; Darr & Randhawa, 1999).

4.7 In recent years, the Department of Health and UK Transplant have produced a range of educational material (including leaflets, posters, and videos) in the main South Asian languages to increase awareness of transplant related issues. Additionally, materials have been produced that set out the position of each religion regarding organ donation. However, current evidence shows that further thought is required to the dissemination of this literature among African-Caribbean and South Asian populations Unit (Exley et al, 1996a; Randhawa, 1998c; Darr & Randhawa, 1999). Namely, care needs to be taken in specifying the target
population, selecting the persons who will communicate the campaign appeal, designating the methodology of appeal delivery, and deciding upon the content of the appeal. There are indications from pilot work in the UK and research overseas involving minority ethnic groups, that appeals for African-Caribbean and South Asian donors may be more effectively communicated by employing a grassroots, community networking approach Unit (Exley et al, 1996a; Darr & Randhawa, 1999; Khan & Randhawa, 1999).

4.8 Recommendation 3: There is a Need to Identify How Best to Engage Local Religious “Stakeholders” with Agreed Religious Opinion

4.9 Recommendation 4: Furthermore, There is a Need to Identify How Best to Encourage Religious “Stakeholders” to Engage with Their Local Community Concerning the Issue of Organ Donation & Transplantation

4.10 Low referral rates to the Intensive Care Unit (ICU)

4.11 The vast majority of organs are procured from ventilated patients in the ICU who have suffered some form of cerebrovascular accident (Gore et al, 1992; Randhawa, 1997). Thus, an important point to consider is whether African-Caribbean and South Asian patients are reaching the ICU so that the may be considered to be potential donors. It may be that the African-Caribbean and South Asian population are simply not dying of the relevant cause or being referred to the ICU rather than an unwillingness to become donors (Exley et al, 1996b).

4.12 Again, there is very little research in this area. Gore et al (1992) carried out a comprehensive audit of all ICU deaths in the UK and the suitability to become organ donors. However, the main drawback to this study was that the ethnic group of patients was not recorded. A pilot study in Coventry was carried out which sought to determine admission rates of South Asian and non-South Asian patients to ICUs (Exley et al, 1996b). The results indicate that South Asians were less than half as likely to be admitted to an ICU than non-South Asians. These findings have serious implications, as it indicates that there are less instances where the health professional has an opportunity for making a request for organs from South Asian families. Another important finding of this study was that the rates of referral from the ICU to the transplant unit were the same for South Asians and non-South Asians, as were subsequent donation rates (Exley et al, 1996b) Thus, the results of this preliminary study suggest that lower rates of organ donation among the South Asian population are related to the initial low admission rates to the ICU. Related to this, there is preliminary evidence emerging to suggest that the number of brain-stem deaths are lower among minority ethnic groups. It is acknowledged that the more recent work of the UK Transplant led Potential Donor Audit may have begun to address these issues. However, presently there is no firm evidence to support the view that access to ICUs is equitable across all ethnic groups.

4.13 Recommendation 5: Identify Whether Black & Minority Ethnic Groups have the Same Likelihood to Become Potential Organ Donors as their “White” Counterparts

4.14 The Potential Donor Audit has highlighted the fact that families and friends of African-Caribbean and South-Asian potential donors are more likely to withhold consent for donation to take place than for white donors. Indeed, the refusal rate for non-white potential donors is 69%, compared with 35% for white potential donors. UK Transplant have previously commissioned research to identify why families refuse a request for organ donation. However, this research did not include non-white families.

4.15 Recommendation 6: Commission Research to Understand Why Non-White Families Have a Higher Refusal Rate than White Families

5. Looking to the Future

5.1 There has been substantial recognition of the need to improve organ donation rates among minority ethnic groups in the UK as evidenced by the plethora of initiatives led by UK Transplant (table 9). Many of these initiatives are recognised to be at the forefront worldwide in the development of culturally-competent organ donation education materials. However, the success of these initiatives has been limited by the lack of a focussed strategy that brings together the various strands of a multi-faceted problem that would lead to a coherent implementation plan. It is hoped that this submission contributes to beginning and shaping this process not only in the UK but for many other countries also who have a multi-ethnic and multi-faith society.
5.2 On a final note, it is worth noting that debates concerning organ donation and ethnicity are relatively new and are limited by the quality of data available not just in the UK but also worldwide. In future, it is imperative that data is collected on a wide range of variables including age, ethnicity, social class, gender, and religion. The potential interaction of these variables will be an important area of research in future to identify potential organ donors.

5.3 **Recommendation 7: Donor Data and Organ Donor Register Data should Collect Age, Ethnicity, Social Class, Gender, and Religion. The Potential Interaction of These Variables should be Analysed to Inform Future Strategies**

5.4 It is only when these issues are addressed adequately will we begin to see a transplant service that truly meet the needs of a multi-ethnic and multi-faith population within the UK.

**References**


### TABLE 1

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<th>pancreas</th>
<th>kidney/pancreas</th>
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<th>lung(s)</th>
<th>heart/lungs</th>
<th>liver</th>
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<td>%</td>
<td>#</td>
<td>%</td>
<td>#</td>
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<td>92.9</td>
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<td>6</td>
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<td>TOTAL</td>
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<td>97</td>
<td>213</td>
<td>88</td>
<td>276</td>
<td>89</td>
<td>37</td>
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Source: UK Transplant, 2007
INCREASING THE SUPPLY OF DONOR ORGS WITHIN THE EU: EVIDENCE

TABLE 2

% REGISTERED (INC SUSPENDED) ON LIST FOR A KIDNEY (INC KID/PAN) TRANSPLANT IN UK AS AT 31 DECEMBER 2006, BY AGE DECADE AND ETHNIC ORIGIN

<table>
<thead>
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<th>Asian</th>
<th>Black</th>
<th>Chinese</th>
<th>Mixed</th>
<th>Other</th>
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<td>0.5%</td>
<td>0.9%</td>
<td>0.7%</td>
<td>0.0%</td>
<td>8.3%</td>
<td>0.8%</td>
<td>0.0%</td>
<td>0.5%</td>
</tr>
<tr>
<td>10–</td>
<td>1.7%</td>
<td>1.9%</td>
<td>1.3%</td>
<td>1.2%</td>
<td>0.0%</td>
<td>0.8%</td>
<td>0.0%</td>
<td>1.7%</td>
</tr>
<tr>
<td>20–</td>
<td>6.9%</td>
<td>8.1%</td>
<td>6.8%</td>
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<td>8.3%</td>
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<td>16.7%</td>
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<tr>
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Source: UK Transplant, 2007

TABLE 3

CORNEA TRANSPLANTS IN THE UK, JANUARY 2005–DECEMBER 2006, BY ETHNIC ORIGIN

<table>
<thead>
<tr>
<th></th>
<th>White</th>
<th>Asian</th>
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<td>4.0%</td>
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<td>1.1%</td>
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Source: UK Transplant, 2007

TABLE 4

NUMBER REGISTERED ON LIST FOR A LIVER TRANSPLANT IN UK AS AT 31 DECEMBER 2006, BY AGE DECADE AND ETHNIC ORIGIN

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<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>287</td>
<td>20</td>
<td>8</td>
<td>1</td>
<td>0</td>
<td>17</td>
<td>333</td>
</tr>
<tr>
<td>%</td>
<td>86.2%</td>
<td>6.0%</td>
<td>2.4%</td>
<td>0.3%</td>
<td>0.0%</td>
<td>5.1%</td>
<td></td>
</tr>
<tr>
<td>pop %</td>
<td>92.1%</td>
<td>4.0%</td>
<td>2.0%</td>
<td>0.4%</td>
<td>1.1%</td>
<td>0.4%</td>
<td></td>
</tr>
</tbody>
</table>

Source: UK Transplant, 2007
increasing the supply of donor organs within the European Union: evidence

TABLE 5

% REGISTERED ON ORGAN DONOR REGISTER AS AT 31 DECEMBER 2006, BY REGION OF RESIDENCE AND ETHNIC ORIGIN

<table>
<thead>
<tr>
<th>Region</th>
<th>White</th>
<th>Asian</th>
<th>Black</th>
<th>Chinese</th>
<th>Mixed</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eastern</td>
<td>97.9</td>
<td>0.8</td>
<td>0.2</td>
<td>0.1</td>
<td>0.9</td>
<td>0.2</td>
</tr>
<tr>
<td>London</td>
<td>89.8</td>
<td>4.8</td>
<td>1.9</td>
<td>0.4</td>
<td>2.5</td>
<td>0.6</td>
</tr>
<tr>
<td>North West</td>
<td>98.1</td>
<td>0.6</td>
<td>0.2</td>
<td>0.1</td>
<td>0.8</td>
<td>0.1</td>
</tr>
<tr>
<td>Northern &amp; Yorkshire</td>
<td>98.4</td>
<td>0.6</td>
<td>0.1</td>
<td>0.1</td>
<td>0.7</td>
<td>0.1</td>
</tr>
<tr>
<td>South East</td>
<td>97.9</td>
<td>0.7</td>
<td>0.2</td>
<td>0.1</td>
<td>0.9</td>
<td>0.2</td>
</tr>
<tr>
<td>South West</td>
<td>98.7</td>
<td>0.3</td>
<td>0.1</td>
<td>0.1</td>
<td>0.7</td>
<td>0.1</td>
</tr>
<tr>
<td>Trent</td>
<td>97.5</td>
<td>1.2</td>
<td>0.2</td>
<td>0.1</td>
<td>0.9</td>
<td>0.1</td>
</tr>
<tr>
<td>West Midlands</td>
<td>96.3</td>
<td>2.0</td>
<td>0.4</td>
<td>0.1</td>
<td>1.0</td>
<td>0.1</td>
</tr>
<tr>
<td>Wales</td>
<td>98.8</td>
<td>0.3</td>
<td>0.1</td>
<td>0.1</td>
<td>0.6</td>
<td>0.1</td>
</tr>
<tr>
<td>Scotland</td>
<td>99.0</td>
<td>0.3</td>
<td>0.1</td>
<td>0.1</td>
<td>0.5</td>
<td>0.1</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>99.3</td>
<td>0.2</td>
<td>0.0</td>
<td>0.1</td>
<td>0.4</td>
<td>0.1</td>
</tr>
<tr>
<td>Total</td>
<td>97.3</td>
<td>1.1</td>
<td>0.3</td>
<td>0.1</td>
<td>1.0</td>
<td>0.2</td>
</tr>
<tr>
<td>Population %</td>
<td>92.1</td>
<td>4.0</td>
<td>2.0</td>
<td>0.4</td>
<td>1.1</td>
<td>0.4</td>
</tr>
</tbody>
</table>

*only where ethnic origin is specified
Source: UK Transplant, 2007

TABLE 6

KIDNEY DONORS IN UK, JAN 04–DEC 06, BY DONOR TYPE AND ETHNIC ORIGIN

<table>
<thead>
<tr>
<th>Donor type</th>
<th>White</th>
<th>Asian</th>
<th>Black</th>
<th>Chinese</th>
<th>Mixed</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deceased</td>
<td>2,165</td>
<td>27</td>
<td>16</td>
<td>8</td>
<td>15</td>
<td>3</td>
<td>2,234</td>
</tr>
<tr>
<td>%</td>
<td>96.9%</td>
<td>1.2%</td>
<td>0.7%</td>
<td>0.4%</td>
<td>0.7%</td>
<td>0.1%</td>
<td></td>
</tr>
<tr>
<td>Living</td>
<td>1,486</td>
<td>97</td>
<td>61</td>
<td>6</td>
<td>5</td>
<td>23</td>
<td>1,678</td>
</tr>
<tr>
<td>%</td>
<td>88.6%</td>
<td>5.8%</td>
<td>3.6%</td>
<td>0.4%</td>
<td>0.3%</td>
<td>1.4%</td>
<td></td>
</tr>
</tbody>
</table>

Source: UK Transplant, 2007

TABLE 7

TIME ACTIVELY REGISTERED ON LIST FOR KIDNEY TRANSPLANT, UK

<table>
<thead>
<tr>
<th>Ethnic origin</th>
<th>Average wait median (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>722</td>
</tr>
<tr>
<td>Asian</td>
<td>1,496</td>
</tr>
<tr>
<td>Black</td>
<td>1,389</td>
</tr>
<tr>
<td>Other</td>
<td>948</td>
</tr>
</tbody>
</table>

*based on registrations in 1998–2000
Source: UK Transplant, 2007
Increasing the supply of donor organs within the European Union: evidence

Table 8

Patients dying in 2006 whilst on list for a transplant, UK

<table>
<thead>
<tr>
<th>Ethnic origin</th>
<th>Kidney</th>
<th>Pancreas</th>
<th>k/p</th>
<th>Heart</th>
<th>Lungs</th>
<th>h/l</th>
<th>Liver</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>212</td>
<td>—</td>
<td>9</td>
<td>24</td>
<td>50</td>
<td>7</td>
<td>81</td>
<td>383</td>
<td>85.5</td>
</tr>
<tr>
<td>Asian</td>
<td>34</td>
<td>—</td>
<td>—</td>
<td>3</td>
<td>—</td>
<td>—</td>
<td>8</td>
<td>45</td>
<td>10.0</td>
</tr>
<tr>
<td>Black</td>
<td>10</td>
<td>—</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>1</td>
<td>12</td>
<td>24</td>
<td>2.7</td>
</tr>
<tr>
<td>Chinese</td>
<td>3</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>3</td>
<td>0.7</td>
</tr>
<tr>
<td>Mixed</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1</td>
<td>2</td>
<td>0.4</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>—</td>
<td>1</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1</td>
<td>3</td>
<td>0.7</td>
</tr>
<tr>
<td>Total</td>
<td>261</td>
<td>—</td>
<td>9</td>
<td>29</td>
<td>50</td>
<td>8</td>
<td>91</td>
<td>448</td>
<td></td>
</tr>
</tbody>
</table>

Source: UK Transplant, 2007

Table 9

Work already done or supported by UK Transplant

2000— A multi faith symposium organised by Donor and transplant professionals aimed at the eight major faiths in the UK supported by the Department (Lord Hunt). And senior religious leaders (Bradford 250 delegates from all major faiths

2001— Arranged a debate for Muftis and Imams in the Muslim school. Unable to go forward with this project due to political reasons

2002— Appointment of project worker by UKT, to look at organ donation and ethnicity. Leaflets and booklet produced another seminar (in Birmingham 200 delegates)

2003— UKT take over running of all Black and Asian donor campaigns developed by the Department of Health using Black and Asian celebrities to highlight the importance of organ donation and transplantation

2005— Developed training for Donor Transplant Co-ordinators and clinicians (Hospital development, Breaking bad news) with a significant component of the training applied to cultural differences

2006— Research into attitudes of Ethnic minority groups to organ donation run and commissioned by UKT

2006— Developed cultural guide for Health Care Professional as aid for use in interviews when speaking to families with differing and diverse cultural backgrounds

Source: UK Transplant, 2007

Memorandum by Dr Magi Sque and Dr Tracy Long

1. Introduction

1.1 We favour the Third Level Option of European Union (EU) intervention that promotes active coordination between Member States (MS) on organ quality, safety and availability as well as minimum harmonisation on quality and safety, plus initiative on organ trafficking.

1.2 We have responded to issues on the following:
   — illegal trafficking in organs;
   — EU-wide shortage of organs available for transplantation;
     — The presumed consent approach for identifying organ donors,
     — The arrangements for taking into account the views of relatives about removing organs from a deceased donor (both under the present system of “opting in” or under the “presumed consent” system for identifying donors).
   — raising public awareness about organ donation;
     — use of organ donor cards, including the idea of a European organ donor card.
   — Organisation of organ donor and transplantation systems.
1.3 European Union (EU) intervention to address the issues that concern organ donation and transplantation is welcome; particularly in addressing the shortage of organs, developing a rigorous and orchestrated response to organ trafficking and in strengthening the harmonisation of quality issues. We would support the development of a Coordinating or Regulatory body that would facilitate donation and transplant activities among Member States (MS). It would be necessary for this body to also consider EU appropriate donation and transplantation Research and Development. Many of the ideas highlighted in EU Council document 9843/07 were issues of discussion at the recent conference in Rotterdam, 1-4 April 2007, which launched The European Platform on Ethical, Legal and Psychosocial Aspects of Organ Transplantation (ELPAT) http://www.elpat.eu/platform.html. ELPAT is attempting to provide a structure through which the complex issues that concern organ transplantation can be discussed by drawing on European expertise in the legal, ethical and psychosocial aspects of organ transplantation. ELPAT aims to map and resolve complex differences between MS by formulating European guidelines reflecting the ethical, legal and psychosocial aspects of organ transplantation. ELPAT’s goal is to be a link between the European Union, the Council of Europe and European Society of Organ Transplantation thereby benefiting all the individuals within MS in need of a transplant operation.

2. ILLEGAL TRAFFICKING IN ORGANS

2.1 The ELPAT conference in April 2007 ended with delegates asked to vote on a number of resolutions; among them a resolution regarding organ trafficking. Organ trafficking appears to be impinging on EU borders, notably in the Eastern European countries of Moldova and the Ukraine, which should be of concern to MS. Evidence for this is drawn from Council of Europe Parliamentary Assembly Doc. 9822, 3 June 2003, “Trafficking in organs in Europe”, Report Social, Health and Family Affairs Committee, Rapporteur: Mrs Ruth-Gaby Vermont-Mangold http://assembly.coe.int/documents/workingdocs/doc03/edoc9822.htm

Point 12 and 13 from the document, Trafficking in organs in Europe states that:

12. “While prohibition of organ trafficking is legally established in member states, most countries still have legislative loopholes in this domain. Criminal responsibility in organ trade is rarely clearly specified in national Criminal Codes. Criminal responsibility should include brokers, intermediaries, hospital/nursing staff and medical laboratory technicians involved in the illegal transplant procedure. Medical staff who encourage and provide information on “transplant tourism” should also be liable. The medical staff involved in follow-up care of patients who have purchased organs should be accountable if they fail to alert the health authorities.”

13. “Member states have a common responsibility to deal openly with this problem nationally, but also through multilateral co-operation at the European level—bringing together Ministries of Health, Interior and Justice.”

The resolutions agreed at the ELPAT conference supported these initiatives and stated that: “This congress condemns without reservation any practice that subverts or violates a potential donor’s human rights or that involves coercion or deception.”

(a) The transplantation of organs and tissues from executed prisoners should be universally banned by law.
(b) The practice of organ and tissue trafficking should be universally banned.
(c) Every effort should be made to discourage potential recipients from seeking trafficked organs and tissues.
(d) Health care professionals should be banned by law from facilitating organ and tissue trafficking (ie referring a patient to a foreign transplant service known to be involved in trafficking).
(e) Governments should be encouraged to carry out the necessary surveys to quantify organ and tissue trafficking.
(f) Health insurance providers must not facilitate, financially or otherwise, activities that directly or indirectly promote trafficking in organ transplants. (G Danovitch, R Sells, Rotterdam, 2007).2

Collective action across the EU could help stop exploitation of individuals for the purpose of illegal organ trafficking.

1 ELPAT is funded by a grant from the European Union. ELPAT is based at Erasmus MC University in Rotterdam, Jan J.V. Busschbach and Willem Weimar, Erasmus University Medical Centre, Rotterdam; Bernadette Haase-Kromwijk, Dutch Transplant Foundation, and Michael Bos, Health Council of The Netherlands, are funding members; Leonieke Kranenburg, Marian van Noord are ELPAT secretariat. ELPAT working group members will be experts in the field in Europe. The membership is currently being invited.

2 Statements a-f above resulted from Workshop 1, Commercialisation and Trafficking.
3. EU-wide Shortage of Organs Available for Transplantation

3.1 As pointed out in EU Council document 4 June 2007 9834/07 ADD1 (9834/07) organ shortage is the dominant problem in the field of transplantation. Organ and tissue donation require the participation of society for their full development and could not exist (under present ethical and legal standards) without the support of the public. This support is fragile because deceased organ donation is an emotive issue and depends to a large extent on public trust in the professionals who are making decisions about the life or death of a critically injured family member. With regard to donation from the deceased it appears that no matter which legislative system is in place in MS ie “presumed consent” or “opt-in” the potential for donation is discussed with the bereaved family and their consent or lack of an objection sought before organ donation can take place. So theoretically whilst “presumed consent” allows organs of the deceased to be donated, if that is what the deceased in life had wished and documented, in practice the principle that prevails is that of family agreement or consent. One of the greatest barriers to donation is the refusal of bereaved families to give consent for donation to take place.

3.2 It must be noted that there is no “evidenced” link between an indicated support for organ donation and an agreement to donate when faced with the sudden death of a family member (Sque et al 2006). The suddenness of death and their status as newly bereaved may well impact decision-making by relatives about organ donation. Also due to the low numbers of people who die in circumstances that facilitate donation potential donor families are unlikely to have any role models for their behaviour. Families of potential organ donors are first, bereaved families, and need to be supported by staff educated to work with bereaved people.

3.3 Whilst there may be an assumption that the public is familiar with the process of donation Sque et al (2006, 2007) have shown that donation was declined because bereaved family members did not possess sufficient information about donation nor were their needs recognised at the time of the request (eg they did not know what the process of donation involved; did not understand how autopsy and donation worked together; did not understand how death was certified by brain stem criteria; thought only a tiny minority of bereaved relatives did not donate). There remains enormous scope for public education.

3.4 Sque et al (2006) in a UK-based study recently challenged the notion that the most important reason for relatives agreeing or declining donation in knowledge of the deceased person’s wishes, as most families reported a wish to protect the integrity of the deceased person’s body even if it meant the deceased’s wish to be an organ donor was not fulfilled. This decision made by participants to decline organ or tissue donation appeared to be made in the context of deeply distressing concerns related to the “cutting up” of the body. Concerns about dissection may have some value in explaining why, in populations where there is broad awareness of the benefits of organ transplantation, refusal rates remain high as reflected in the figures gained when EU participants were asked about donating a family member’s organs, 23% would not (9834/07 p23). Unfortunately the research does not give the reasons why EU participants would not donate.

3.5 Research suggests, that many donations are denied because families will not give consent, even if they knew in life the potential donor wished to be an actual donor (Dodd-McCue et al 2006, Sque et al 2006). Adjusting practice to support donor’s rights moves health professionals’ communication mission from requesting donation to one of informing or supporting a choice previously made by the potential donor. Dodd-McCue et al’s research provides evidence that indicates that families are not negatively affected by strict enforcement of “donor designation”. Within its limits the research upholds that donor designation can lead to positive results for families as well as organ recipients. Even with laws however, ie “presumed consent” in place, in a number of MS, to support the choice of the deceased, disparity exists in practice. The challenge for health professionals in MS is to how to help families reconcile their repugnance for dissection (Richardson 2007) with the benefit of donation to the waiting recipient.

4. Raising Public Awareness about Organ Donation

4.1 Donor relatives have an important contribution to make in sustaining donation rates both in the educational role they play within their own communities and the formal roles they sometimes adopt, to help educate health care professionals, and bereavement support groups. Magi Sque was advised (verbal communication) that, in the USA, for every donor, approximately 1,000 people will receive informal donation education. Families for instance appear motivated by what their deceased family member achieved through donation, illustrated by the heroic status which is attributed to them due to their ability to save life or give life and to have that achievement appreciated, valued and not forgotten (Sque and Payne 1996, Sque 2007). Thought therefore needs to be given to the way organ donation is promoted so that the contribution of the donor and their family is celebrated and the donor’s achievement is appreciated, valued and not forgotten. Furthermore continuing to articulate organ donation within a “gift of life” discourse does not reflect the depth and complexity of the process more aligned to “sacrifice”, and is therefore not an adequate framework for
understanding what is important for families faced with a donation decision (Sque et al 2006, in press 2007). Meeting their needs may be an effective way of improving donating rates across the EU.

4.2 Information regarding the possibility of organ donation should be fundamental to all areas of EU health care systems and not left until individuals are at the death bed. The function of public education therefore should be to enhance awareness of organ donation to the extent that when the question of organ donation is raised the idea is neither foreign nor intimidating to the grieving family but simply reminds them that other lives hang in the balance of their response.

4.3 Sque (1996), Sque et al (2003) has shown it is helpful to families of the deceased to have concrete evidence of the wishes of the deceased with regard to organ donation. It may be feasible for some MS to maintain organ registries. For other MS unable to maintain a registry the use of a donor card may be appropriate: in light of this there should be widely available to the public. The issue is that many people who carry a donor card or are on an organ donor registry often do not know what is involved in the donation process (Sque et al 2006). Organ registries may be more amiable as they require less “work” and one only has to register once. It should be possible with the right technology for MS to access each other’s registries.

5. **Organisation of Organ Donor and Transplantation Systems**

5.1 **Staff development**—Any successful organ donation and transplant system must begin with an effective workforce that is knowledgeable about all aspects of the donation process and the benefits of transplantation. Nurses and doctors are the people charged with the crucial responsibility of identifying and caring for potential donors, a key area to increasing donation rates. Collaboration between MS in sharing best practice could enhance all areas of practice. Models and systems of care need to be assessed and best practice elicited and implemented.

5.1.1 Organ donation needs to be considered as part of good end of life or bereavement care, coordinated with other health initiatives, such as the End of Life Strategy (UK) and public initiatives. Across the EU the police, rescue services, funeral directors need to be integrated with the health system as their practice has the capacity to impact donation rates.

5.1.2 There is also work to be done with health professionals examining their own feelings about donation. Research has shown that nurses who are often the main supporters of families are no more informed about organ donation and transplantation practices than the general public (Sque et al 2000). Few nurses have attended a donation operation and many have concerns about the care and treatment of the organ donor. Positive role models are needed in clinical practice. An educated EU workforce could lead discussions in the field: be it during potential donation encounters or while carrying out their roles as health educators in the public arena and who can separate grief reactions and donation reactions. This depends on the integration of bereavement theory into health professionals’ education related to sudden death and organ donation. These subjects need to be mandatory in all pre-qualifying programmes for doctors and nurses.

5.2 **Harmonising systems**—Organ donation system needs to be adequately resourced across the EU. Harmonisation of practices across MS such as non-heartbeating donation, paired and altruistic donations, and expanded criteria donors, would provide a greater pool of organs for MS. This needs to involve expansion and commitment to the non-heartbeating donor programmes in Accident and Emergency Departments, general wards as well as ICUs. An expansion and commitment to the non-heartbeating programme may help families to donate who wish to be with the deceased and witness the observable ending of life, represented by the cessation of the heartbeat, which is important to some (Sque et al 2006). Greater EU collaboration could provide a greater pool of data for unusual events than would be as possible within individual MS and for resources for “organovigilance”.

5.2.2 The focus on public education and agreement, education and support of health professionals must be balanced by a rigorous audit of the number of potential donors in each MS, and stringent reviews of the number of donated organs, which are not retrieved for transplant operations. Personal communication has indicated that a large number of hearts were not retrieved within the UK for the years 2003–06, contributing to a fall in the number of heart transplant operations. If the public in MS is to be confident that their agreement to donate is important this must be reflected in the efforts made to retrieve organs. All aspects of the health care system that presents obstacles to increasing organ donation (eg intensive care bed provision and admission policy (Briggs et al 1997)), and shortage of transplant staff (Statham 2006) must be addressed.

5.2.3 The EU must also look to reduce the type of lifestyle illnesses for which organ transplantation is the only effective therapy. Organ donation and transplantation should be placed within a wider arena of a holistic health awareness that includes lifestyle choices in relation to diet, risk related health behaviours and exercise.
INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE

References

25 September 2007

Examination of Witnesses

Witnesses: PROFESSOR GURCH RANDHAWA, Director, Institute for Health Research, University of Bedfordshire; DR MAGI SQUE, Senior Lecturer, and DR TRACY LONG, Senior Research Fellow, School of Nursing and Midwifery, University of Southampton, examined.

Q182 Chairman: Good morning and welcome. We are absolutely delighted that you are going to give the time to us this morning. We have had a lot of witnesses; we are struggling with a lot of issues and I am sure you are going to be able to help us with some of them this morning. There are some housekeeping things I have to say to you; I have to say them every time someone comes into this room. Thank you for your written evidence. This has been circulated to the members of the Sub-Committee so you will not have to repeat at great length your written evidence because we expect everyone to have read that, but of course you may want to refer to it. We have with us Professor Bobbie Farsides who is our specialist adviser for this inquiry. I have to remind you that the session is open to the public and will be recorded for possible broadcasting or web casting. A verbal transcript will be taken of your evidence. It will be put on the public record in printed form on the parliamentary website. A few days after this session you will be sent a copy to check for accuracy. We do advise you that if you want to change anything you will let us know rapidly. The speed of turnover of these things is pretty prompt. At the end, if we have not got through everything or you think there is something we have not covered you can submit supplementary evidence. The acoustics in this room are very difficult so it is helpful if you could try to speak as though you are in a public place. We would be grateful if you would do that otherwise we will not get what you have to say on the record and it is important. When we start can we ask you, for the record, to state your name and official titles and then, only if you wish to, make an opening statement? After that we will go into questions. Professor Randhawa: I am Professor Gurch Randhawa; I am Director of the Institute for Health Research at the University of Bedfordshire. Dr Sque: I am Magi Sque and I work as a Senior Lecturer at the School of Nursing and Midwifery at the University of Southampton. Dr Long: I am Tracy Long and I am a Senior Research Fellow at the School of Nursing and Midwifery at the University of Southampton.
Q183 Chairman: As you do not want to make an opening statement of any kind, we will move straight into the questions. I am going to begin by talking about Professor Randhawa’s work relating to ethnic minority groups. We have looked at your written evidence and some of the work you are doing for the King’s Fund. What we would like to ask is if you would describe for us your views on the issues affecting organ donation rates among South Asian and African-Caribbean ethnic groups in the United Kingdom. What further research do you think is needed to investigate these issues and to develop ideas for improving organ donation rates amongst these groups? In what ways do you feel that involvement of the European Commission could help with this work? Just to remind you, we are not, like the task force, doing an investigation into organ donation but particularly looking at how Europe and the European Commission can help with this work.

Professor Randhawa: Can I begin by unravelling a lot of those issues and start with the first concept which is that there are a lot of underlying issues that we need to be aware of concerning the different ethnic groups who live in this country. The first point I would like to stress is that we are actually ahead in this country in policy terms as we do collect ethnicity data, so the very fact that we do know where we in relation to variation in organ donation and transplantation rates in the UK is a good thing and I would stress that in terms of Europe-wide all the other major European countries do not even collect ethnic data. Although it is quite distressing to hear about the different issues affecting ethnic groups at least we have a base line and move on from that. In terms of the key issues, as I have stressed in my written evidence, 20% of the waiting list in this country for people waiting for a transplant are made up of non-white communities. Clearly that is in far greater proportion than how they make up the UK’s population. The really important issue which we need to focus on is the fact that those communities only make up 1% of donors and, because of issues around tissue type and blood group matching, the need for organ donors from those ethnic communities is actually very, very urgent. What we are going to find is that as those populations are much younger at the moment than the rest of the communities in this country the rates of diabetes and high blood pressure at the moment do not seem to be going down. Sadly it looks as though the rates of kidney failure will continue to increase in those communities so the demand will actually go up. The current problems we see in dialysis units across the country, especially in inner city areas, are actually going to get a lot worse before they get better unless we address the two fundamental issues. One is around how we are going to increase the number of organ donors amongst those communities and secondly—which I think is far more important—how are we going to stop the need for transplantation amongst those communities by preventing ill health in the first place.

Q184 Chairman: How do you think Europe can help in this?

Professor Randhawa: I think the first thing Europe can do is that if across Europe we understood that it is really important to collect ethnicity data that would be a massive step in the right direction. Dr Sque and I were at an event in March in Rotterdam where there was a European platform and I have to say that at that event there still was not appetite amongst the major European countries to collect the data. They simply do not have the focus that we have in the UK around equity, around the need for equality in the system and the need for making sure that everybody has an opportunity to benefit from transplantation. I think if we could get a Europe-wide understanding that we do need to collect different ethnic data and then begin to understand how different sections of the population either benefit or not from transplantation we would then hopefully see, on the back of that, Europe-wide strategies on how you are going to deal with the problems. At the moment I would say that the UK is at least ten years ahead of any other country on how to grapple these issues due mainly to government policies such as Our Healthier Nation, Tackling Inequalities in Health: A Programme for Action—all of which have given significant prominence to the need to reduce health inequalities.

Q185 Baroness Morgan of Huyton: Could I ask about preventative strategies and what is the relative importance between increasing the number of donors and preventative strategies? I think from what you said in answer to the first question you place greater priority on reducing demand for the need for transplants—for preventative strategies—than financing increasing efforts to increase the number of donors.

Professor Randhawa: If you were pushing me into making a choice that is what I would say. Our key concern at the moment is that increasing the number of organ donors is a very complex issue and I am sure my colleagues will talk to you about societal issues around death especially among certain minority ethnic communities. A lot of the work I have done has shown that if you want to get people to think about death and think about giving organs, think about burial and ritual rights, you have actually got to go into those communities and really tackle this face to face. That is going to take a long
time. In the meantime, if we do not deal with the preventative issues then the NHS will go bankrupt trying to deal with the dialysis problem that will occur. Wearing my other hat as a chair of a PCT I know that we have to deal with ensuring that certain population groups do not get to the stage of kidney disease. We have not published this yet but I am currently leading a study funded by Kidney Research UK which is a three year study where we are tracking South Asian and white patients from the day they are diagnosed with diabetes to the day they end up with kidney disease to see what is going on. Early data from that study is showing that even though these patients for a number of years have now been ill with diabetes the South Asian patients, for one reason or another, have not understood that the diabetes could lead to further complications. They do not appear to understand the significance for them as a community of having diabetes. I know it is confusing, but one of the things that we are suggesting to them in terms of how we grapple this issue with them is that I think we have to be far more assertive and say to them that actually diabetes is their cancer for them as a community. It is the illness that is leading to deaths for them whereas cancer is not so prevalent in their community. The irony is that they understand cancer very well, even though it is not very prevalent, and they know it is associated with death, but they are not making the same connection with diabetes leading to kidney disease. That is where we are at with that study. I do think we have to do something. If you look at places like London, Leicester, Birmingham, Bradford in some of those units now over 50% of their patients on dialysis are non-white. Given that they are a younger population at the moment as those populations get older we have a huge problem. Why I think Europe-wide we could really do something about this, if you now look at recent migration into countries like Italy, Holland, Belgium, Norway, France, Germany and Spain although they do not collect the statistics we do know it is the same communities at the same very young ages who are now beginning to suffer the same illnesses. They could potentially learn a lot from what we have done in the UK.

Lord Wade of Chorlton: I would just to follow that up. I have been diabetic for the last 40 years and I am still fit and well because I inject myself with insulin every day. Why can everybody else not do that? What you have suggested to us is that this problem is much more a question of not treating diabetes than it is of organ transplants because if everybody that you are saying has diabetes now is going to end up having an organ transplant that is a much greater issue in itself. Is the underlying problem dealing with the people with diabetes and, if so, I do not quite see why that cannot be dealt with more effectively?

Q186 Chairman: Before you answer that, I have a question that links into Lord Wade’s question so perhaps you can answer them together. I think this is the first time we have had the connection so clearly put between the prevention and the organ donation. You did mention Spain and we have been told about Spain’s huge success in organ donation. Would you know anything about their preventive programme?

Professor Randhawa: Yes, I can talk about that as well. Firstly, obviously diabetes is mainly related to kidney failure. It is worth pointing out that for South Asian communities there is a higher demand for liver transplants and cornea transplants as well so it is not just kidney failure that is affecting the ethnic communities. In terms of diabetes, you are absolutely right. We do need to find a way of getting all of UK society to think about how you manage chronic conditions. Again, if I can put my PCT hat on for a minute, what we have done in this country at the moment is borrowed a lot from self-care models from the US which, I might add, have been tried and tested on predominantly white, middle-class people who can afford private insurance. They have not been tried and tested amongst the very diverse population from very different socioeconomic groups in this country. I think there are questions to be answered about whether the self-care models we are implementing in this country are appropriate, which is why I think that the studies—not just the one I am involved with but also others—about how you engage those communities in thinking about these chronic conditions, asking them, “If you were to play a role in managing this condition, what would it be?” are so important. I do not think you can underestimate the scale of that question because a lot of these communities come from countries where you actually take no role in self-care. They are used to a health service in which you hand yourself over to a physician who, the majority of the time you are paying for, and they do everything for you. Conceptually we are trying to achieve something very huge by engaging patients in a more active role in their care. The prize is huge if we can get there but I think we have to understand how much resource is required if we really want to engage the public with preventative action. You are absolutely right, if we can get that right we should be able to deal with at least kidney failure and diabetes failure.

Q187 Lord Wade of Chorlton: Following on from that, I think this is an important part of what we have to try to draw attention to. Better facilities to deal with these long term chronic illnesses would be an effective way of reducing the number of organ transplants that are needed in the first place.
Professor Randhawa: I agree, but I think what we have to be very careful about is then ensuring that the self-care programmes and actually caring for people around chronic disease management are culturally specific. We are not there in this country.

Q188 Baroness Neuberger: I used to chair an NHS trust and I have a great deal of sympathy with what you are saying. Can you comment at all on the extent to which within Europe there are some of the same problems about the expectation, that when you hand yourself over to a physician it is all done for you so even in European terms—which is really what we are here for—thinking about a self-care model that really involves people, given their specific cultural backgrounds, is quite difficult to do. Presumably that is part of your work.

Professor Randhawa: Absolutely. I think one of the things that European countries are now grappling with is that once you overlay issues around ethnicity, culture and social class then the whole concept of self-care gets quite complicated. Depending on those variables an individual’s approach and mindset to thinking about self-care is going to be quite different. One of the things we recommended Europe-wide is that surely when we are thinking about organ donation and engaging with communities around organ donation, at the same time we should be telling them that disease prevention is their priority. One of the things I have been privileged enough to be part of is something that UK Transplant and the Department of Health are doing at the moment, which is a series of community based campaigns asking people to donate their organs the “Can we Count on You? Campaign”. One of the criticisms we were actually getting—quite rightly—from certain communities was, “So let me get this right. We have never seen you before and now you are telling us that our communities are dying and you need our organs. Where were you when we had the diabetes and high blood pressure and kidney failure?” We took that on board and now in certain parts what we are trying to do is when the transplant coordinators go and deliver these campaigns at the same time they are bringing along primary care trust colleagues and diabetic nurses. The one I witnessed was fantastic. They had the diabetic patient, an Asian man who talked about what it is like to be diabetic. They then had a renal patient talking about what it is like to have renal care. Each of them talked about how these conditions are preventable but also manageable. They then had someone who was on the transplant waiting list and they also had a family who had agreed to give one of their loved one’s organs. So they got the whole picture on that day and essentially the message was, “You can manage these conditions but the consequence is that if you don’t you’re going to need a transplant and, by the way, you’re not likely to get a transplant because there are not enough of these families coming forward”.

Chairman: We are going to have to move on now because of the time, fascinating as it is.

Q189 Baroness Morgan of Huyton: To what extent do other groups—other than defined by ethnicity—have particular issues, particularly for example socio-economic status? When you look at low donation rates amongst certain ethnic groups, is that just because of ethnicity or is that exaggerated because of socio-economic status? Are there any other issues, for example age or gender or anything? Professor Randhawa: I personally think it is the whole gambit of all those issues. I think ethnicity in isolation does not influence whether you become an organ donor or not. The only reason we have focussed on it is because we actually have some data at least to give us an idea of which communities to focus on. When you look at the people who do choose to become organ donors it is influenced by the amount of information they have been exposed to, their ability to understand that information (which again is influenced by their levels of education and social class) and one of the things that we are lobbying very hard in this country now is for UK Transplant to collect data on the postcodes at least (because they have that) and make known to researchers who has agreed to sign the organ donor register so that we can start to analyse that and explore whether there are any postcode differences on who chooses to become a donor or not and then start to understand why that is. We could analyse the records of the families who have agreed to become organ donors and we are pushing that to be a Europe-wide issue, that you need to understand people’s levels of education and their likelihood to want to read this kind of information and make those kinds of decisions.

Q190 Baroness Perry of Southwark: Could you please describe what is known about the extent to which people take account of the position of their faith group to which they adhere in informing their views on their own or their relatives’ organ donation? To what extent do you think that low organ donation rates amongst some groups in the UK can be ascribed to the way in which individuals choose to interpret the thinking on organ donation of the religious group to which they adhere? Professor Randhawa: I have personally been involved with two studies, one involving South Asian communities and another one involving African-Caribbean communities exploring those very issues. Both studies found the same thing that where people know what their religion’s position is on organ
donation they are far more likely to use that information to make a positive decision. If people do not know the position of their religion they are more likely to say no. It is not that the religion is blocking them, it is the fact that they do not know what their religion’s position is. I think one of the consequences of that is that although UK Transplant have produced some superb material setting out the position of each religion on organ donation I am not sure how—and I welcome advice—but we do need to work with the various religious institutions in this country on how they are going to communicate that message and position to local levels so that the person on the street, if they walk into the local church, temple or mosque and say, “What is the position of my religion?” the person does not say, “I don’t know” or, which is even worse, says something which actually is not correct and potentially misinterprets the religion. Sadly I have known that to happen; I have been on a few visits where people are adamant that “This religion does not support organ donation” and I am sitting there saying, “This leaflet is suggesting this” and they simply say, quite rightly from their point of view, “That leaflet must be wrong”. That must be very confusing for a lay person seeking advice from a local faith leader.

Q191 Chairman: Information, community involvement and community communication are the things you are talking about.
Professor Randhawa: Yes, but I think in the context of religion the various religious organisations and the way they are structured have a huge role to play in disseminating that information and getting some kind of consensus. At the moment there is not consensus in faiths, which is very confusing if you are a member of the public having to make a very difficult decision.

Q192 Lord Eames: My questions are about family permission and suspicion that they do not want to give that permission; how do we overcome that? How do we address concerns of that nature and, particularly as we are concerned about the European dimension to all this, do you know of any issues that involvement of the European Commission could help to overcome some of these difficulties? It is really grouping together the question of getting permission from relatives for the donation of organs.
Dr Sque: I think before we actually look at the way we get organs it is very important to set the context in which the request for organ donation does arise. I think we have to realise that we are dealing here with bereaved families of potential donors and both in the United Kingdom and across Europe they are absolutely critical to the organ donation process because they will normally be asked either whether they agree with organ donation or will give consent or in fact have a lack of objection. They also have a very important role in providing medical and social information about the donor which could impinge upon the donation going forward. I think we also have to realise that we are not only dealing with bereaved relatives but the requests for organ donation are most likely to arise out of situations of very sudden, unexpected and untimely deaths. Also it happens in a very provocative and emotional environment. All the evidence has told us that these types of bereavement tend to be more difficult than ones that are anticipated. Certainly these relatives are at a very high risk of having complicated bereavements. That has cost implications, of course, to the National Health Service in following up these families. Family members are generally in a situation where they have very little time to adjust to the loss and they will struggle with the enormity of the events that are unfolding around them. We have no evidenced link between indicated support for organ donation and agreement to donate. When a family is faced with a sudden death their status as newly bereaved may in fact place specific demands upon them that will impact on their decision making. We do know that donation rates have risen month on month in agencies in the United States that have followed a successful system redesign for approaching families about donating organs. This process has been through the Organ Donation Breakthrough Collaborative which has clearly shown the importance of focussing first on a family’s bereavement issues before any approach is made about donation. However, what I would suggest to you is that even in their grief our studies have indicated the importance that is attributed by families to being asked to consider organ and tissue donation. Suggesting in situations of donor suitability that organ donation should be discussed with relatives and should form part of really high quality, end of life and bereavement care. It should not be seen as anything special or different; it should be the usual rather than the unusual. Donation does need to be incorporated into other end of life initiatives such as the one that is being run by the Department of Health at the moment on the End of Life Strategy. Combining organ donation in assessment tools, for instance the Liverpool Care Pathway, which is a clinical gold standard for caring for people who are dying, has been associated with a substantial increase in donation from families. That has been particularly shown in an ICU in North West England. Healthcare professionals should feel very confident and know that relatives are most likely to be grateful to them for approaching them to ask about organ donation. We know from our studies, for instance, that relatives...
are not offended: it does not increase their distress; they did understand that health professionals have a responsibility to ask: and, they are sympathetic to health professionals that are tasked with this discussion, as they realise it must be very difficult for them. I would want to say that it is actually unethical not to offer the choice of donation to a family because it is not necessarily something that they will think about at this stage of their bereavement and most families want to honour the pre-mortem wishes of a loved one, even if they find it is difficult for them. If we deny a family that opportunity then that ability to fulfill the wish of their loved one is lost. We know also from families that donation can sometimes bring them what they often see as, “some comfort”, in their grief. It also provides the opportunity for the donor to achieve something truly incredible and this is really, really important because it is a way of leaving a profound and poignant legacy of life which not only provides a better quality of life for the recipient but the benefits ripple out beyond their family and the community. Families can find a source of esteem and pride in that achievement from which, at the time, might have been perceived to be a rather unremarkable life. There was a situation in one of our studies where a young man had spent most of his life in prison and his mother actually said that his disease, he had asthma, was always much better controlled when he was in prison because once he came out he tended to neglect himself. He died of an asthmatic attack and his wife said that she thought her husband had not achieved much in his life and that was why she agreed to donation because this could have been his real achievement. So relatives are actually motivated by what the donor can actually achieve and they receive an appreciation and reciprocity on behalf of the deceased. This is what I believe subsequently brings them some solace in their grief. It is not about what the donor gives away but it is what they are actually able to achieve.

**Q193** Chairman: Dr Sque, does that mean that you have a view about opt-in and opt-out and the way relatives are dealt with in opt-in and opt-out?

*Dr Sque:* Yes, I believe that relatives need to be involved. All the relatives that we have spoken to in our studies over a number of years now have all expressed a desire to be involved in the discussion about organ and tissue donation. I would suggest to you that there should continue to be an opt-in system.

**Q194** Chairman: Do you have a view about how the European Union can influence some of the thinking on this? I notice in one of the papers you talk about an organisation called ELPAT that is working.
have a much better developed end of life care strategy, even if it has not been published yet?

**Dr Long:** The USA model, the Breakthrough Collaborative, has got some key features within it but there are also some key features from areas within Europe that I think would benefit UK thinking in relation to this. The key features from the USA model are that the individual who is in very early contact with the bereaved family is a knowledgeable, motivated, positive about donation, family focussed, very skilled individual. They are skilled in the following kind of areas. They know all the information that the family member is actually going to require but it is not just about giving information; it is about confronting these fears that individuals have in relation to this, the fears that Magi has already described to you. There are concerns such as: “Is my relative really dead? Are they going to be treated with dignity? Are these organs going to be used?” You need an individual who does not wait for those questions because family members frequently cannot raise them; they find it a bit uncomfortable raising those issues. You need someone who will say, “Some people have these concerns, is that an issue for you?” You also need a skilled individual who can deal with the family dynamic. Frequently you may have one individual who says, “No, no, no” and yet the actual next of kin, the closest member or the person whom the deceased would expect to make a decision on their behalf, their voice is lost. So you again have to have an individual who can confront that issue and also investigate a no response, not just leave it, which is what tends to happen at the present time.

**Q197 Lord Eames:** All this has to be done in a very limited period of time.

**Dr Long:** At the moment it does in the UK because unfortunately we do not get in contact with the right person at the right time. It tends to be left until the end and is all a bit of a rush. In America, because they use clinical triggers to prompt contact with organ coordinators early, they can then have very detailed conversations with the intensive care team, learn about the dynamic of the family, what is going on, what do we need to think about in relation to ethnicity? What do we need to think about in relation to the actual critical injury? We need to have those discussions and decide who is going to say what to whom and in what way? They have shown clearly that having a specifically trained individual, we will call them a donor coordinator, it does not have to be a nurse, it does not have to be a doctor; in Spain many of them are medics, in the UK and in America they are mainly nurses, it is about these key features that this individual has to have which influences consent rates, but not only that, it is not just about consent rates, it is also about families being satisfied and confident with the decision they have made because they also become community advocates for donation.

**Q198 Chairman:** I wonder how typical that kind of good model is? Anecdotes are sometimes quite helpful and I spoke to a woman at the weekend whose husband had died and he had a donor card. She said yes to donation despite her distress. She was in the hospital for 24 hours without anyone explaining to her anything that was happening to her or her husband. How typical is that and how much do we have to do to change from that to the kind of system that you have just described?

**Dr Long:** It is typical and that is unfortunately because there is such a shortage of donor coordinators in this country. However, not only that, we are only just really developing a model of in-house coordinators, which again is a feature of the Spanish model, where you have somebody who can do exactly what I have just described immediately. They are involved straight away; they are part and parcel of all the areas within a hospital that may have donation, because of course it is not just the intensive care units and accident and emergency departments where donation can happen, and therefore you can have this individual involved in all those areas. In-house coordination is a very good model from Spain and also in areas of the UK where it is happening. The other essence of the USA model which is also being implemented in the UK is collaborative requesting where you have a donor coordinator and the intensive care team showing a cohesive face to the family, going together. The actual conversation about death having happened is separated from the donation request and that is facilitated if you have collaborative requesting. Early trials in Oxford where this is carried out have already shown an increase in donor consent rates. Of course consent rates do not always lead to donation, but consent rates have gone from 35% to 75%, so again that is a model. If I could briefly refer to one other model, a new role which is developing in Belgium in accidents and emergency units and is called the “social nurse”. The social nurse is there as a patient and family advocate in resuscitation areas where the voice of the family and the individual is often lost because of the intensity of that situation. The social nurse is there to liaise with the family, or be with them through that difficult time and to make sure that their voice is heard in whatever situation. As the Taskforce has recommended that it is a good idea that two coordinators are always available, we would suggest that the social nurse role would be a good model for one of the roles within donation so that that person can focus on the family while the other coordinator is focussing on making sure that
the organs are as good as they can be if they go forward for transplantation.

Q199 Lord Kirkwood of Kirkhope: If the question that we are considering is, “Can you increase donation rates by increasing public awareness?” I am trying to find some measure of priority that each of you would give to that and can I ask each of you to give me an estimation on a scale one to ten, low to high, how important increasing public awareness is to increased donor rates for organs?

Dr Long: Ten.
Dr Sque: Ten.

Q200 Lord Kirkwood of Kirkhope: Okay, that is a result. How do you do that? Let me give you an example. We get the papers and this question is being asked of us in a European context and we must not forget that. The kind of thing we get is the Commission documents, advice to Parliament and the rest, and let me just quote a sentence you might be interested in. They say, “The most cost effective means of increasing public awareness to donate seems to be improving the knowledge of health professionals and the media about transplantation issues because both positive and negative messages can affect the public’s willingness to donate.” The European way of doing this is getting the health professionals. Part of that is what you have already been saying but it conflicts a little with Professor Randhawa’s important evidence that he gave in writing which really means going down below that, getting into streets and communities and working with networks. How do we pick our way through these different models?

Professor Randhawa: I think this goes back to the fundamental point that across Europe the demography of all the European countries is rapidly changing and the way people get their information now as a society is changing; we are all using the internet far more often, we are all using our social networks be that via the internet or whatever very differently. For certain communities, for example, the faith community could be their way of getting information. If I can focus specifically on the South Asian community, you cannot underestimate the power of celebrity. In India or Pakistan if a top cricketer, regardless of their views on anything, says something on whatever, rightly or wrongly the vast majority of the country does it. I am not saying it is right what they do. The private sector has tapped into that clearly because now Pepsi and Coca-Cola are all queuing up to get the cricketers and the Bollywood stars et cetera to follow them. I do not think you can underestimate the power in certain communities of these alternative ways of reaching out to them. Obviously the media then has to have a role.

Q201 Lord Kirkwood of Kirkhope: The dilemma for us is how to persuade the European Community to go for Pakistani cricketers.

Professor Randhawa: It goes back to economics, I am afraid. Across Europe now they are beginning to see a huge investment required for dialysis beds. Across Europe we cannot sustain that level of investment; the NHS certainly cannot. I think if people know that and then realise that we need some urgent action, and we know that leaflets in different languages do have a place but they take a lot longer and you can actually reach people a lot quicker, then next time those countries are here playing cricket or the Bollywood stars are here you can get them; they do not even have to say anything, they just wear blue ribbon with the heart and be photographed with it or start a debate, but we need to move people on and we have to use the financial argument. I understand that is how governments tend to operate; if something is going to cost them they tend to take action.

Q202 Lord Kirkwood of Kirkhope: It is interesting you mentioned the internet as well.

Dr Sque: I would like to turn to the everyday end and just remind the Committee of the sorry state of public information about access to the NHS Organ Donor Register and donor cards. It became clear during the witness statement from Sir Liam Donaldson that information was clearly not easily available to inform people how to apply for registration on the NHS Donor Register or even if donor cards were still being used. I think that what we need to do is to increase registration on the NHS Organ Donor Register and also to not forget about donor cards because we know from our studies that concrete evidence of a person’s wish to become a donor is very important to the family. The Organ Donor Register in some ways can seem a little bit removed because they have nothing concrete and tangible in their hands. I wanted to share with you the really sorry state of this very low key but important public information reported in a paper “I want to become an organ donor—can you help?” from a study carried out by MacIver and Parrott in Manchester. What MacIver did was to go around to 110 GP surgeries and 112 pharmacies in Manchester and asked for information about organ donation. The results were actually quite staggering: in 85 cases 76% of pharmacy staff were unable to give any advice whilst 41% of GP surgeries could not offer leaflets or written information about organ donation.

Q203 Lord Kirkwood of Kirkhope: Is that available? It would be very useful to have those statistics.
Dr Long: I would like to add that again we can learn some lessons from Europe because in Belgium and Spain in particular organ donation is part of school education and therefore if you begin to influence children at an early stage they will at least begin to have these kinds of discussions. In fact in one study again carried out in the UK where there had been some educational input it showed that a week later at least half of those children had been home and had that discussion with their parents and raised the issue of organ donation within the family environment where they had a discussion. Most European countries are ten years ahead of us in education in schools; it is very disparate in this country. Again there is that issue to be thought through and that could go right across the board. Having the right kind of person there available for children to bring questions to means that they can then go home and be family informants as often children are very important family informants for some of the ethnic groups.

Chairman: So what you are really saying is that whatever great big public awareness television programme might be put out—which is one of the thoughts people have—unless you actually have it at grass roots level, where families can get information from people they know and spread it, it will not make a difference. That is what you are really telling us and that is what Lord Kirkwood was drawing attention to, the professionals and the people on the ground need to know. Lord Wade?

Q204 Lord Wade of Chorlton: I would like to explore this whole issue of presumed consent with you. If you feel that is an ethically correct way to go, how are people likely to react to it and what are some of the issues that might be in some of the ethnic groups towards presumed consent and how might they be adjusted to in a different way or can you make exceptions? That is what we would like to explore with you.

Dr Long: I would argue that it is unethical to presume someone’s consent to such an emotive procedure—as opposed to seeking their informed consent which of course would come from that. I am going to base that on a couple of points. The main reason is that the UK public we know are poorly informed about this particular issue of organ donation and also that although we have seen quite a bit of publicity about support for presumed consent the sample size on which that support is based is very small. If you could bear with me for a minute I would just say that the arguments to support presumed consent tend to fall under the following: the feelings that the majority of the UK public actually support organ donation; the concern that the wishes of the deceased will be overruled by family members; the impact that this legislation has had in other countries on their donation rates and also a wish to relieve family members of a difficult decision at a time when it is problematic for them. I would like to suggest that in relation to the majority of the British public actually being supportive of organ donation we have a couple of studies. One study carried out in 2003 by UKT showed that 90% of 1,206 people were actually supportive. The follow-on study done by the BMA and YouGov in 2007 showed that 64% of 2000 people were supportive of organ donation. We know those figures because 40% refused so that means on average 60% are supportive. However, 62% of that group actually said they would go with presumed consent. So they have an intention but 26% only of that group are on the Register; 23% nationally are on the Register. There is no evidenced link between an intention to be a donor and the actual action that is part of that. I feel that one of the reasons for that is the fact that when the topic of organ donation is raised there are certain concerns we have already detailed those in relation to how we feel about post-death procedures which come through and people are also concerned about aligning themselves with that in this rather informal way. Our research has shown that family members need concrete and discursive knowledge of what their family members actually want to happen to their body after death. I think that is important. The second argument that the wishes of the deceased are ignored is actually not well-evidenced either because in the majority of the cases the family members support the wishes of the deceased when they know them, when they have concrete or discursive knowledge of that. Again that is not very well supported. The issue around other European countries having better donation rates who have this legislation, is not a clear cut issue. In Spain they have had this particular legislation for over ten years but they had the same donation rates as we do now, at that time, before they put in the re-design of the system from the top to the bottom.

Q205 Lord Wade of Chorlton: Just to clarify that, what you are saying so far as Spain is concerned is that it was not the presumed consent that increased the organ donation, it was the re-organisation of their systems that created the extra organ availability. There was clear evidence to that effect. Dr Long: Absolutely, without question. Also the fact that in a survey carried out in Spain with these citizens 53% of 2000 people stated that presumed consent was “an abuse of authority”. Basically they were against presumed consent and in the same study they indicated that Spanish families felt that if their wishes were not asked, they would be more likely to decline organ donation. Other evidence from France, from Portugal and from Norway is
that health professionals if I can be so bold as to say it ignore the legislation; they will always defer to the family, they will always ask the family. Their view is that when they are dealing with these families at this time the trust relationship is the most important thing. Therefore I think it is very important that we do bear that in mind. There is a very clear indication with the increasing figures in America and also in Italy that it is the change to the system that has actually made the legislation unnecessary in many cases.

Q206 Lord Wade of Chorlton: Professor Randhawa, do you have anything to add on the ethnic issue?
Professor Randhawa: I think in this country we are trying to move to a more cohesive society so on that basis I think it would be setting a very unhelpful precedent if we then allowed certain groups to opt-out of any form of legislation. I just do not think that would be helpful. I think one of the things I am sure Professor Bobbie Farsides has briefed the Committee about is that the Taskforce has been asked to look at the whole issue about different consent models and one of the things I have been asked to lead on is the different cultural and societal views on different consent models. What we are doing as part of that process is engaging with different faith and cultural groups on how they would perceive different consent models, including presumed consent. Regardless of what consent model we have in this country, unless the public perceive it as being a positive step you are in danger of making organ donation actually regress rather than progress in this country, so we must take the public with us. I think that has got to be fundamental to what we do.

Dr Long: Could I possibly add two other points into that? We again could look at other European Member States and look at some of the things they do. In the Netherlands where they have 40% of the population on their Register they have a model where their Register accepts an explicit agreement, disagreement or decision to be left to a relative. The researchers there feel this encourages individuals to register their wishes because they know that they are safeguarded, that there is a definite “Yes”, there is a definite “No” or that they can actually allow the decision to be made by the relative some time in the future. That again fits in with a lot of the models that we are talking about. To add one more thing, following the Organ Retention investigation and in response to what Bell has called “societal expectations” a decision was taken that a process of explicit informed consent should underpin all post death procedures [including post mortem, organ donation, tissue donation and anatomic dissection] and this concept is fundamental to the Human Tissue Act [2004]. Moving away from this stance could be seen as a desire by the Government to negate the rights of the individual for the benefit of the state. I think that is a damaging message to go out.

Q207 Baroness Perry of Southwark: As you know, the EU Directive is going to deal with a cross-border framework for the organisation of organ donation and transplantation and an action plan for strengthened cooperation between Member States. How would you describe the benefits of those proposed EU level actions for citizens across the EU and, more specifically, for us in the UK? What disadvantages do you think there might be?
Dr Sque: I think that this proposal could actually be instrumental in helping us to standardise the quality and safety of organs to what I would call the level of the best. This would actually be imperative if there is to be more cross-border transport of organs, and then of course this would actually benefit our UK population. I think the potential increase in the cross-border EU organ donation and transplantation would be welcome for trying to match difficult to match donors and this could benefit our UK ethnic minority groups as well.

Q208 Baroness Perry of Southwark: Do you not think there is a danger of gold-plating, making it so difficult that a lot of organs which could be useful might be discarded?
Dr Sque: If directives are enabling rather than restraining then I think they can be helpful. I think there is a fine balance to be struck there, yes. Also I think harmonising practices across Member States such as for non-heartbeating donation, paired and altruistic donations and expanding criteria donors could potentially provide a greater pool of organs for the Member States and also augment the programmes in the United Kingdom. We might actually have difficulty in having successful programmes if we go this alone. I think it could also be helpful in collating data about transplant outcomes for recipients and particularly for living donors because we do need to continue collecting information in that area. We could more quickly accrue data about unusual cases and this of course would help to provide better evidence for the United Kingdom transplant programmes. It could also be instrumental in coordinating and quickly and effectively disseminating best practice across Europe and this could also benefit our donation and transplant programmes. As I said previously, Europe could help particularly maybe with the financial end of things; as Professor Randhawa has said public education does have an economic cost to it. They could help with that for transplantation across Member States which would also help within...
the United Kingdom. At a European level there could be help to influence health policy to reduce life style choices and behaviours that actually precipitate the need for transplantation and this again could be beneficial to the UK population. Also, as I said, providing resourcing for an organ donation system across our Member States. Certainly some of the disadvantages would be that if any directive was constraining rather than enabling and also was without cultural sensitivity because I do think it is important that we bear that in mind across Europe. I think there is also a danger of a two-tier system developing where you might find that there are countries that feel a pressure to be donor countries and others to be seen mainly as recipient countries. There is potential for a lack of transparency in the allocation of organs and at the end of the day this could in fact waste precious organs.

Chairman: That takes us very nicely to the other difficult area which Lord Wade is going to ask about, which is about organ tourism.

Q209 Lord Wade of Chorlton: How serious do you think this question of organ trafficking and organ tourism is? How serious do you think that the problems of these activities within the EU and particularly the UK actually are?
Dr Sque: Can I just say that I condemn without reservation any practice that actually subverts or violates a potential donor’s human rights or involves coercion or deception of any kind. What I would say to you is that we have little evidence at the moment about organ trafficking and tourism, certainly in the United Kingdom and across Europe. We need to bear in mind that we have human trafficking going on in European countries and if we have human trafficking there is also the danger that organ trafficking could become problematic. I think there is a very important role here both for individual countries and for Europe to be alert and to practise surveillance for these particular issues. I also think that it would be very helpful if transplant units collected data about patients who are going abroad and coming back with kidneys. That has a cost implication for the National Health Service as many of these organs are not well-matched when they are transplanted abroad. We need to know about that cost as well and I do not think we have very good data at the moment.

Q210 Lord Wade of Chorlton: How can we deal with that? What can one practically do to stop that happening?
Dr Sque: I think that certainly both within in the UK and at European level there would need to be very strong legislation against it. At the moment the criminality is not clear. Are we going to say that we would bring a case against a doctor, for instance, that had supplied a patient with information that they could take abroad in order to get a kidney? I think that needs to be looked at in legislative terms both within Member States and across Europe.
Chairman: We are going to have to stop there; we have run over time. Your evidence has been utterly fascinating. I can see from my Committee members that if I allowed them to we would go on all morning listening to you and I am only sorry it is my job to make sure we finish in a timeframe otherwise I would have wished to ask further questions and go on listening to you. We are very grateful for you coming and giving us the benefit of your knowledge. There are one or two bits of research you have mentioned; will you please make sure that we do have the references and the research if necessary. If there is anything you think you have not covered in your wonderfully comprehensive coverage which has been fascinating, do let us have that too. Thank you very much indeed.

Supplementary memorandum by Professor Randhawa

In response to Lord Wade’s Q210 in 7 February transcript
Although trafficking of organs is illegal and should be condemned, it is important to recognise that as there is such a dire shortage of transplant organs in this country, patients and their families often feel that they have no choice but to seek organs from another country. If the alternative is imminent death, then these people feel that they have made the right choice for them even though it could involve the donor organ being obtained from an illicit source. The only way to stop this practice is to ensure that there are enough organs available in the UK and throughout Europe.

February 2008
90 INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE

Supplementary memorandum by Dr Magi Sque and Dr Tracy Long, School of Nursing and Midwifery, University of Southampton

DR SQUE’S AND DR LONG’S WORK RELATING TO THE FAMILIES OF POTENTIAL ORGAN DONORS

Q. What further research do you feel is needed to investigate these issues and to develop ideas for encouraging more relatives to agree to organ donation? In what ways do you feel that involvement of the European Commission could help with this work?

We need to increase the evidence to enhance donation rates as there is very little work done with families, health professionals or the public in UK and Europe. Therefore we need studies at UK and European levels. The purpose of these studies would be to inform best practice. I feel strongly however that we need to get our house in order in UK and make organ donation a research priority and get a number of large scale studies commissioned urgently; particularly in areas that will illuminate the recommendations of the Organ Donation Taskforce and underpin its implementation. We have provided a list of studies that we believe to be priorities (Please see Appendix 1).

The European Commission must make organ donation a health priority and must commission and fund research in individual Member States and EU projects. The Commission needs to establish an EU coordinating centre eg Ethical, Legal and Psychosocial Aspects of Organ Transplantation [ELPAT] based at Erasmus University, Rotterdam. A similar organisation, the Gift of Life Institute in Philadelphia mission states: “The Gift of Life Institute aims to increase organ and tissue donation rates by providing the most innovative, evidence-based training, and consulting services required to enhance the skills, expertise, and practices of donation professionals worldwide.” An EU Co-ordinating centre would oversee and work with Member States on:

- Research and development.
- Dissemination of best practice.
- Education and training.
- Exchange of best practice.
- Conferences and publications.
- Data storage and analysis.
- Source of information.

ELPAT, funded by a grant from the European Union, is based at Erasmus MC University in Rotterdam. It is attempting to provide a structure through which the complex issues that concern organ transplantation can be discussed by drawing on European expertise in the legal, ethical and psychosocial aspects of organ transplantation. ELPAT aims to map and resolve complex differences between Member States by formulating European guidelines reflecting the ethical, legal and psychosocial aspects of organ transplantation. ELPAT’s goal is to be a link between the European Union, the Council of Europe and European Society of Organ Transplantation thereby benefiting all the individuals within Member States in need of a transplant operation. It is the first real attempt to get EU experts in the field and with similar interests working together.

CHALLENGES FOR HEALTH PROFESSIONALS IN HELPING FAMILY MEMBERS OF POTENTIAL ORGAN DONORS

Q. What arrangements do you think could be most effective for helping the families of potential organ donors to overcome their concerns and to agree to the donation of organs from a deceased relative? What evidence can you describe to us from across the EU or elsewhere in the world about the effectiveness of the arrangements you suggest?

At a National level the present lack of a cohesive system for making organ and tissue donation a priority within the NHS is the main barrier to increasing donation rates.

The lack of a cohesive system is hindering the efforts of health professionals who are striving to change this situation. Changes within the present day NHS, poorly informed and trained staff, and a poorly informed public, are undermining their aim of providing the best possible service to potential donor families and thereby increasing the donation of both solid organs and tissues.

Most of the barriers within the NHS have been clearly identified in the Organ Donation Taskforce report as well as being placed in front of this committee by earlier speakers. By implementing the recommendations of the Taskforce the foundations will be laid for a service that helps health professional’s support bereaved family members to reach decisions about organ donation that they have confidence in and feel satisfied with.
INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE 91

Preparation and training of health professionals

Those who are in the front line of organ and tissue donation should have mandatory training, which is centralised and standardised. Training that is based on the best evidence and not personal preference. It is essential that tissue and blood donation are also fully integrated into this training as both of these activities are reducing within the UK, and yet are greatly influenced by the intervention of knowledgeable, positive and skilled health professionals.

On a wider scale all training for health professionals, must address organ and tissue donation. This is in place in countries such as Norway, Belgium, France, Portugal, USA and Australia. In these countries organ and tissue donation is part of the curriculum at undergraduate and post graduate, or post registration levels. Issues underpinning organ and tissue donation are embedded in ethical working practices and end of life care modules.

RAISING PUBLIC AWARENESS OF ORGAN DONATION ISSUES

Q. How important do you think that raising public awareness about organ donation and transplantation issues will be in seeking to raise the level of organ donation rates across the UK as a whole; and among particular sub-groups of the population? Please would you describe how you think such awareness raising could most effectively be carried out

Increasing public awareness about organ and tissue donation is crucial in seeking to increase donation rates in the UK and Europe as organ and tissue donation can only exist with the participation of society and the support of the public. This support is fragile because organ donation whether deceased or living is an emotive issue and depends to a large extent on public trust in the professionals who are making decisions about the life or death. Due to the low numbers of people who die in circumstances that facilitate donation potential donor families are very unlikely to have any role models for their behaviour.

Unlike a number of European countries the public in the UK [and USA] were not given the opportunity to be involved in the discussions concerned with setting up laws and defining under what conditions organ donation could take place. A questioning British public now needs to understand that organ donation is something they may be asked about as part of being involved in a health system; or at the death bed. Therefore they need non-crisis information to develop trusting relationships with health professionals and to be able to make informed choices at the bedside.

Information regarding the possibility of organ donation should be therefore be fundamental to all areas of UK and EU health care systems and not left until individuals are at the death bed. The function of public education should be to enhance awareness of organ donation to the extent that when the question of organ donation is raised the idea is neither foreign nor intimidating to the grieving family but simply reminds them that other lives hang in the balance of their response.

The circumstances of loss and bereavement associated with organ donation are culturally challenging, especially the post mortem procedures on the body. There is a need for public information and education about the procedures surrounding donation and transplantation, ie the concept of death certified by brainstem testing; brainstem testing; the nature of the donation operation (ie it is a careful surgical operation) and, the appearance of the donor following the operation, and the possibility and process of donation after cardiac death; the propriety of the donation operation; the disparity in need for organs and organ availability.

Donor relatives have an important contribution to make in sustaining donation rates both in the educational role they play within their own communities and the formal roles they sometimes adopt, to help educate health care professionals, and bereavement support groups. Sque was advised that, in the USA, for every donor, approximately 1,000 people will receive informal donation education. Meeting the needs of families involved with donation may therefore be an effective way of improving donating rates across the EU.

Support for the donor families should start at the bedside of the donor and be continued for as long as the need exists. One of these special needs is that it is important for the family to be cognisant of the difference a transplant made to a particular recipient’s life, so they can “picture” their donor’s achievement.

Donor families wish this achievement of their donor to be recognised, valued and not forgotten. A number of strategies have been used to promote this on a personal level such as: thank you letters from transplant coordinators and recipients, updates on recipients’ progress, remembrance cards sent to the family on the anniversary of the death and donation. On a public level in some areas there are commemorative thanks giving church services and the British Organ Donor Society has access to an avenue of lime trees in Wimpole Park in Cambridge, which can be adopted in the memory of a donor or recipient, while Donor Family North is developing a commemorative quilt.
In the USA there are memorial gardens. An example of a memorial to organ and tissue donors is the granite memorial which stands on the main walkway into the entrance of the Jackson Memorial Hospital in Miami. This is not only memorial to donors but acts as a tool of public education. Miami had one of the highest rates of donation in the USA.

Are there other ways [such as a books of remembrance in hospitals] that could help families realise that the gift from their loved one is appreciated, valued and not forgotten? We probably need something of national significance. The bottom line is, and as suggested by the Organ Donation Taskforce, that we need research with families to help us understand the best way to acknowledge their donor and their families’ generous decisions.

All promotion advertising should stress the importance of discussing donation with family members or the person expected to make decisions following death.

It might be helpful for charitable organisations and UK Transplant to work together to promote awareness about organ donation.

20 February 2008

Appendix 1

The following list sets out a programme of UK and European research into issues underpinning organ donation and transplantation to be considered for urgent commissioning.

Family care driven:

— A prospective, ethnographic observation study needs to be carried out to further our understanding of the minutiae of the dynamic interaction at the time of the approach and discussion about organ donation, both in UK and cross Member States.

— An exploratory study investigating families’ experiences of being asked about donation after cardiac death.

— Large scale study of families who refuse donation in UK recruiting from all 250 intensive care units using Potential Donor Audit [may pick up ethnic minority groups].

— A comparison across Member States about why families agree and deline donation.

— A study to tell us how we can honour donors and their families both privately and publicly.

Health professionals driven:

— Health professionals across Member States own knowledge, attitudes and organ donation behaviour—to assess need for further education especially if working across borders, will need a well informed work force.

— An exploratory study investigating health professionals’ experiences of donation after cardiac death.

— To investigate the culture of organ and tissue donation within (x number) of NHS Hospital Trusts and factors that influence the donation process [we must not forget that there may be differences between the nations of the United Kingdom].

Public awareness driven:

— More research is needed exploring the “cultural” views of death and what is acceptable in post death procedures. Comparative research from countries across Europe would increase knowledge of reasons for refusal, which research suggests is influenced by personal beliefs, values, and interpretation of religious teachings and folklore.

— Evaluation of an educational programme, about organ donation, for school children in the first year of secondary education.

— The role and influence of children and young people on the donation discussion and decision-making [the role of children and young people in the organ and tissue decision-making process has been an unexpected finding of our previous work. It has specific consequences for the provision of information aimed specifically at children, the impact of children on families’ and health professionals’ behaviour, and the bereavement support needs of children].
Theoretical driven:

— The genesis of the beliefs that individuals and families bring to the donation discussion has received scant review. By eliciting these beliefs a greater understanding of the barriers to organ and tissue donation could be established. Identifying these beliefs may also further illuminate the concerns raised by families in relation to the organ donation operation and its association with any potential disfigurement of the deceased.

— Research designed to further enhance the understanding of the complex processes underpinning donation decision-making is urgently needed. In particular there is a need to explore the importance of the “gift of life” and “sacrifice” discourses to the decision-making process. Such research should include those families who choose not to donate as well as those who do. The extent to which timing of information may influence whether the positive sense of the donation process as a “gift of life” is more powerful than the potentially negative construct of “sacrifice” also requires examination. This calls for a qualitative study where these factors can be discussed in detail with participants.

— Notions of what constitutes death in the 21st century: The case of organ and tissue donation—a project to explore health professionals’ attitudes, beliefs and knowledge about death declared by neurological criteria and non-heart beating criteria. Targeted groups would be health care professionals working in intensive care, accident and emergency, the ambulance and rescue services.
Increasing the Supply of Donor Organs within the European Union: Evidence

Thursday 21 February 2008

Memorandum by the British Transplantation Society

Overview

1. The British Transplantation Society (BTS) is pleased that the Commission is showing this interest in organ transplantation. We believe this is entirely appropriate because transplantation has a very high level of success in improving the life expectancy and quality of life of many EU citizens but the extent to which citizens can benefit is at present limited to a significant degree by problems that can reasonably be addressed by organisational change. In many cases, this change will be most appropriately implemented at governmental level and there is benefit to be gained from the cooperation between different governments and governmental bodies throughout the EU. In other areas, governments have potentially useful contributions to make in supporting research into the factors affecting organ donation (and organ failure and replacement, in general) and implementing strategies for improving public awareness, with a view to increasing donation. This too is an area in which the EU can have an impact. Research work in this area undertaken across the EU may have greater impact at lower cost than the aggregate of smaller, nationally based research.

Organ Quality and Safety

2. The Commission document rightly places great emphasis on minimising the risks of the transmission of infection and cancer by transplantation. They are correct that increasing organ sharing will increase such risks. However, the BTS feels that the risks are small and the procedures that would have to be put in place to minimise these risks will require relatively little effort. Inappropriately onerous restrictions could result in more deaths on the waiting list than might occur following the transplantation of higher risk organs.

3. The BTS heartily endorses the framework for quality and safety of organ donation and transplantation and the measures outlined in section 3.1. However, we are concerned that the burden of ensuring the quality and safety of organ donation and procurement will be great. It includes many factors discussed in both the Commission’s Communication (COM(2077)275 Final) and the Impact Assessment (SEC(2007)704), such as the transmission of infection and malignancy. However, there are other areas of quality and safety that have not been emphasised, such as the quality of the retrieval process: Were organs damaged at retrieval? Was the retrieval undertaken in a way that will maximise the utility of all organs to be used? We believe this should be coupled with stratagems to increase the number of organs being donated as this is likely to be most effective and efficient in using resources. We will return to a proposed mechanism below.

4. An additional factor in improving quality is maintaining a high level of experience by ensuring a level of activity in a transplant unit such that the unit and each practitioner has sufficient ongoing experience to maintain their skills. The number of centres in different EU countries varies. We suggest the EU use this opportunity to maintain quality by considering minimum activity levels.

5. It would similarly be valuable to consider the quality of the training experiences available throughout Europe. A training standard in transplantation surgery has very recently been established and this could be considered for other professions.

6. Finally, safety assurance of professional performance requires some consideration of manpower provision and service delivery.
ORGAN TRAFFICKING

7. The BTS shares the concern of the Commission about organ trafficking. It has the potential for corruption and has safety implications. We agree that EU countries are rarely the destination of the transplant tourist. Hence, we think there is limited scope for its prevention by the EU. The best response to transplant tourism is to improve the supply of organs within the high quality, regulated health care systems of Europe so that the incentive to travel abroad is greatly reduced. We believe that the enthusiasm for participating in transplant tourism will fall if the waiting time for organs is significantly reduced and the prospect of being transplanted feels realistic. We believe this is not currently the case which is why patients are prepared to take risks.

ORGAN SHORTAGE

Research potential

8. The biggest problem amenable to intervention at governmental level is the shortage of organs. We agree that there are many different reasons for this. We believe that within any member country there may be more different reasons than exist between countries. This underscores the value of an EU-wide approach to considering this problem. Factors such as ethnicity, country of origin, religion, level of education and socio-economic class have all been shown to affect attitudes to donation. The BTS believes there is value in undertaking research across national boundaries to determine common themes in attitudes to organ donation to inform public policy responses. We believe this is particularly important in the area of public awareness of organ donation and transplantation. Indeed, we believe there is an underemphasised level beyond “awareness”, namely public “perception” and inclination to support organ donation. Research has shown a disturbingly high level of mistrust of the medical establishment which has an effect on inclination to consent to donation. In addition, understanding of cultural and religious values is important in designing approaches to increasing organ donation. This need for research is underscored by the Commission’s own concession (in the Impact Assessment accompanying the COM(2007)275 final, SEC(2007)704), that the differences in donation rates are “not easy to understand”.

European Donor Card

9. The BTS has concerns about the wisdom of a European Donor Card. We believe that maximum acceptability will be achieved by aligning donation with something with which the public most closely identifies. It may be that national or supranational identity may not be the most appropriate medium of identification in this context. For example, in the US, the Orthodox Jewish community has developed their own card, which deals explicitly with some of the concerns of their own community. This may represent a more effective model. Having said that, a mark of EU support may add to the value of cards that are primarily more locally affiliated.

10. This touches explicitly again on the issues of the impact of faith, ethnic backgrounds, country of origin, and socio-economic backgrounds as areas for further research. The BTS feels that these are all crucial factors impinging on attitudes to donation which probably are more important than nationality. Hence, they must be the subject of close attention in attempts to develop donation.

The Organisation of Donation

11. Whereas the number of centres performing recipient transplant operations will be relatively small, and thus relatively simple to police, if there is to be a real increase in the number of organs for donation, every acute hospital in every country has to be involved as a source of donors.

12. In our comments above on organ quality and safety, we stated that we were concerned that the burden of ensuring the quality and safety of organ donation and procurement would be great. Similarly, we believe that increasing the number of organs donated will also require the commitment of a large number of professionals at many different centres. We believe that systems should be developed in parallel to develop local processes that both ensure the generation of large numbers of donors and the maintenance of the high quality and safety of those donated organs.

13. Donor care needs to be considered from an early stage. Recipients will be dependent on clinical and laboratory evaluations undertaken by a large number of professionals. The task of assuring uniformity and quality is thus huge. The BTS believes that it will be possible to design detailed guidelines, but ensuring their implementation is a responsibility that will have to be devolved. Experience from countries such as Spain has suggested that if responsibility is devolved to an individual of high enough seniority and influence within his
increasing the supply of donor organs within the European Union: Evidence

institution and if there is a financial benefit (or at least no financial disincentive) to donate, then this local delegation of authority is likely to be most effective. We also believe that central to the effectiveness of this process is the completion of the audit loop, also undertaken at a high level, to reward institutions that have generated high numbers of donors and demonstrated high levels of quality and safety in those organs.

14. For these reasons we agree with the proposal that a flexible system of decentralisation for procurement and centralisation for promotion of donation and organ distribution is desirable. We would add, however, that a centralised quality assurance for procurement with significant incentives and disincentives for failure needs to be part of that system. This might mean that the promotion of organ donation and evaluation of the effectiveness of such activities by local health care bodies would be included in the criteria by which a trust is evaluated. Money might follow success and external assessment of processes be triggered by failure.

15. The BTS agrees with the sentiment that a major issue to be tackled is the loss of donors due to lack of evaluation, referral or discussion with relatives. We believe that this will be greatly assisted by the process described above, of setting in place a high level of audit and incentivisation of hospitals to maximise the number of donors being generated locally.

16. It is currently unclear which interventions are appropriate before death to maintain organ health. The law needs to be clarified in this area for the benefit of both the public and critical care staff. In addition, pre-donation and post-brain stem death research need to be made easier to undertake.

17. One area of significant disparity within the EU is in the provision of intensive care facilities for potential donors and the approach to donor care. There is significant potential for a general improvement in practice following the sharing of experience between states.

18. Finally, all levels within the donor pathway need to be considered. The Commission’s Communication gives very little attention to the intensive care community. The training and practice of these professionals and the provision of adequate facilities in this sector needs to be incorporated into any consideration of the organisation of an organ donation service.

Consent

19. UK law has only recently changed to move the focus of consent directly to the donor himself. However, operationally, the family retains an important role. At a practical level, they may be the only source of information about the deceased’s preparedness to consent to donation. In addition, it is very difficult to use historical evidence of consent to ignore the implacable opposition of the deceased’s relatives. In practice, they could say the deceased underwent a last minute change of heart on consent. We believe this is likely to be true whether the consent is actual or presumed.

Donation after Cardiac Death

20. The BTS feels that the Commission has given insufficient emphasis to the development of donation after cardiac death. This is discussed in some detail in the Impact Assessment, but not in the Commission’s Communication. This is a labour intensive approach which would be culturally unacceptable in certain parts of the EU. However, it could make a significant impact on the issue of organ shortage and, we believe, should be given more prominence. Data suggest that it is still potentially cost-effective and we would encourage the Sub-Committee to press for more detailed consideration of this approach as an additional string to the bow of increasing organ donation.

Living Donors

21. In view of the proven beneficial outcomes of live donor programmes and the very low level of donor risk, the BTS strongly supports their expansion throughout the EU. In particular, altruistic unrelated organ donation, including “paired” and “pooled” donations, non-directed donation, and the development of programmes for higher risk transplantation, such as blood group-incompatible transplantation and the transplantation of HLA-sensitised patients, should be encouraged. This is likely to require additional funding. The BTS has developed Guidelines in some of these areas of practice which have been widely recognised as useful aids in practice.

22. All member states should develop appropriate protocols to eliminate the possibility of undue inducement or coercion and ensure informed donor consent. However, given the continued, and growing, overall organ shortage, the urgent need to expand cadaver donation remains unchanged.
Recipients who are difficult to transplant

23. An additional benefit of sharing between EU countries which is discussed in the Impact Assessment, but is insufficiently emphasised in the Commission’s Communication, is the potential value of organ sharing between EU countries for potential recipients who are difficult to transplant, for example because of HLA sensitisation. Even in a country as large as the UK, UK Transplant has found it difficult to develop the practice of paired donation. This would be greatly improved if the pool of potential participants could be expanded.

Role of the EU

24. The BTS agrees that EU-led cooperation is essential in preventing organ trafficking and could be helpful in facilitating the exchange of expertise on safety, organisation and expanding the donor pool. We also feel that a centrally defined minimum standard for assessment would be useful. We are not convinced that there is yet a role for a Europe-wide unified single organ sharing scheme.

25. An additional important role for the EU will be in raising public awareness of organ donation.

October 2007

Examination of Witnesses

Witnesses: Dr Anthony Warrens, Reader and Honorary Consultant Physician, and Treasurer, British Transplantation Society and Mr Keith Rigg, Vice-President, British Transplantation Society, examined.

Q211 Chairman: Welcome. We are very grateful to you both for coming. We are looking very much to hearing your evidence and will, of course, have read any submissions you have made. I have to do some rather boring housekeeping points, and I have to do them out loud for the record. The nice thing is to say that we do have Professor Farsides, our adviser, helping us here today. I have to remind you that the session is open to the public. As you can see, we have got masses of public here this morning, but it is recorded for possible broadcast, so you will have to remember that we are very much on record. A verbatim transcript will be taken of your evidence and this will be put on the public record in the printed form and on the Parliamentary website; so we are very transparent in the open this morning. After the session you will get a copy of the transcript to check for accuracy. Can you advise us on corrections as quickly as possible? Things here move very rapidly from one bit to the next and we would like you to have the opportunity of corrections if you have any. If you feel at the end we have not got through everything, you can send us supplementary evidence—we are always grateful for anything that will help us with what we are doing—amplifying points or telling us things that we have not had a chance to get through. These rooms are not easy. You may think that we have got a PA system; in fact they are not wonderful. Unless you address us, as I am trying to, as rather semi-public, we will not hear you and we do want to hear what you have to say to us. If you could keep your voices and your heads up as much as possible, we will try and do the same and we will then be able to hear what you have to say. When you begin, although we have got your names here, we have to ask you to state your name and background for the public record, then I will ask if you want to make a short opening statement and then we will move into the questions. Although you have been advised of the questions, you know that members can ask others if they so wish. They may not ask all the things you might expect, partly because we have had a lot of witnesses, but I think you will find we will cover a lot of ground. Would you begin by stating your names for the public record and then letting me know whether or not you want to make an opening statement?

Dr Warrens: My Lord Chairman, I am Anthony Warrens; I am a consultant renal physician at the Hammersmith Hospital where I have a specialist interest in the management of the transplant recipient; I am also an academic at Imperial College, where I am a Reader in renal medicine and immunology. I am also a trustee and Treasurer of the British Transplantation Society and I prepared the submission, obviously, after consultation with my colleagues, the other trustees and the Council of the British Transplantation Society so that the information you had represented the feelings of the senior member of the Society. Finally, I am a member of the Advisory Committee on Safety in Blood, Tissues and Organs. After Mr Rigg has introduced himself, I am happy to make a short opening comment.

Mr Rigg: Good morning. My name is Keith Rigg; I am Vice-President of the British Transplantation Society and I am a consultant transplant surgeon at Nottingham University Hospital. I am also a member of the Human Tissue Authority.

Q212 Chairman: Thank you very much indeed. Dr Warrens, would you like to make your brief opening statement, remembering that we have had your documentation?
Dr Warrens: I think all I wanted to do is just focus the conversation at the beginning on the fact that we are talking about a situation of real human suffering for a large number of people who do not have the opportunity to have organ transplants. One of the great attractions of my area of medicine is that I see people on a regular basis whose lives are transformed. Their quality of life on dialysis is often very poor and even days after their transplant operation, they come into my clinic and say, “I have been given my life back.” The sad thing is that there are so many people out there that do not have that opportunity because we have got an insufficient supply of organs, and so I think it is very gratifying to those who are involved in this field to see the Government, Parliament and the European Commission taking an interest in what we believe is very important. My message is simple: for every new donor that we find, we can give our recipients approximately 56 extra years of life.

Q213 Chairman: We are all aware of the UK Transplant Report, but we are very much focused on the European Union issues and how that whole scenario can help. We have to get a baseline of what happens in the UK to understand it, but we really want to focus on how the European Union can help. As you know, they have had the Directive, which concentrates on the quality and safety of organ donation, and then the formulation of the action plan to strengthen co-operation on organ donation between Member States, and you have said somewhat about that, Dr Warrens, in your evidence. What we would like to know is what are you views on the benefits that action at EU level on organ donation could have for citizens across the EU and, more specifically, for UK citizens, and what disadvantages do you think there might be, as our job is to scrutinise Europe on behalf of UK citizens?

Dr Warrens: My Lord Chairman, I think there are tremendous opportunities with the interest that has been taken at a European level to help the patients both throughout Europe but also in the UK by the pooling of expertise. As I am sure you are very aware, our donation rate in the UK is significantly lower than many other countries in Europe and, therefore, there is a lot we can learn from how they have managed to increase their donation rate. It is interesting, if you look at the change in donation rates, we were on a par with countries like Spain and Belgium perhaps five years ago, but now they have raced ahead of us; so there are things that we can do to find out and improve our services locally. We can learn about how they have organised their services, how they have communicated to the citizens of their country the importance of organ donation. I think that is something that we need to give some focus to in this country, as has been highlighted very nicely in the excellent document that was published by the Organ Donation Taskforce in January of this year. We believe there is also a general requirement to increase public awareness in the UK. These are the positive sides: co-operation, information exchange, improvement of systems based on what other countries have done. I am less convinced that there is a role for organ sharing or having a supranational organisation as a general way of distributing organs to recipients throughout Europe, because I think that is something that currently we do well in this country. I think UK Transplant is a first-class organisation that has got very high level buy-in from professionals who are active in the transplant world, and so I feel that is an area that perhaps we would be able to help some of our sister countries in Europe with, information exchange. I know you have already heard from Mr Chris Rudge, who is the Managing Director of UK Transplant, and his organisation makes a very major contribution. I think that would be my feeling: it is information exchange rather than supranational organisation that will move us forward.

Q214 Chairman: Certainly we have heard from some of the witnesses about their anxieties regarding the possible bureaucratisation of the work, and the medical profession really feel that the EU could add a dimension of gold-plating that would make it more difficult for some services to be developed. Do you have a view about that and any experience from which to form a judgment?

Dr Warrens: I would generally agree with that view. Services, where possible, are better developed locally, and I think it would be hard to find a model that would be easily applied to all the different Member States of the European Union. I think we should cherry pick the things that we can do well by sharing information and by sharing best practice, but I think if there is the potential for, as you have already said, excessive bureaucratisation if we were to impose a system where we actually have something that works very well in the UK.

Q215 Chairman: Before I move on to Lord Lea, I am involved in children’s services in relation to Hypoplastic Left Heart Syndrome children. We therefore know about other children through the Heart Federation. Recently a child received a heart from Spain which actually saved her life, not a child with Hypoplastic Syndrome but another child. How do you see that kind of co-operation if you do not see a register?

Dr Warrens: That already happens, as you have already said. There are situations where we do share organs. We were relatively recently offered a kidney from Spain. I think you have highlighted the important area where we can effectively co-operate,
and that is in the area of difficult transplants, patients who are difficult to find a match. That may be because of the disease they have got or the nature of their immunological status, for example. Somebody who may have high levels of antibodies is one example, to a molecule that is very common in the UK population but may be less common, let us say, in sister countries in Eastern Europe. So there is the potential for helping those people, and, I think, if we develop services focused on the people with particular problems in the UK then we may help them, but overall, the system, I think, has a number of pitfalls that you have already implied.

Q216 Lord Lea of Crondall: I think that last reply was very helpful to me because I was beginning to wonder whether we were, talking at cross purposes about the European structure which will just run the thing. I do not think anyone was suggesting that. I think you used the expression you are less convinced about organ sharing or a European structure for organ transplants. You will perhaps tell me where I have written that down wrongly, but the essential question follows on from what you have just said. You have given us in your evidence a very interesting example from the group who are difficult to transplant, for example, Human Leucocyte Antigen sensitisation, is that right—Dr Warrens: That is right.

Q217 Lord Lea of Crondall: ---and the increased pool of potential participants that this would generate could help the practice of paired donation, which has been found difficult within the UK alone. Then, paradoxically, in some ways, you say, “We are not convinced there is yet a role for a Europe-wide unified single organ sharing scheme.” Is that not comparing apples with oranges? Within the spectrum of one to ten you want information sharing, which is number one, but for some purposes you want numbers three, four, five six and seven and yet you have got to have some rules about reciprocal arrangements around all of that; so it is not just something that is number one in some across the board way, is it?

Dr Warrens: No. I think you are absolutely right. There are situations, and they happen now, as you have said, where we do share organs and, therefore, to have a background framework in which we can be sure that the level of safety of organ transfer is high enough to meet our standards is important. What I am talking about is where all organ transplants went through a supranational sharing scheme is a situation that I think many of us in the profession would be worried about; it is a situation where we might end up losing time, losing organs because of the excessive bureaucratisation of it, but at a specific, particular difficult transplant level, it may very well be an attractive option to try and develop. Does that clarify?

Q218 Lord Lea of Crondall: It is a big step forward, but it is not totally clear me, therefore, which bits of the EU paper do you agree with and which bits do you not agree with: because you are knocking down the EU paper do you agree with and which bits do you not agree with: is not what is their paper, is it?

Dr Warrens: I felt it was implied by the paper.

Q219 Lord Lea of Crondall: Which bit of it is that then?

Dr Warrens: I do not know that I am going to be able to give you chapter and verse. Mr Rigg was going to talk about pooling. Perhaps if he wanted to address that answer I will see if I can find it.

Q220 Chairman: Would you like to come in?

Mr Rigg: Yes, I do. To come back from what Anthony was saying, I think we recognise that for the majority of people, within an organ sharing scheme within one country such as the UK, there are enough people waiting to actually match those organs. One of the concerns, if you start to share between more countries, is the actual time that is involved, the so-called ischemic time. There is only a finite storage time for organs and, therefore, if you increase the transport times, that then means that the organs can become unusable, and so I think we would recognise that the outcomes are far better when we are able to transplant organs a lot quicker. For kidneys, for example, there is good evidence to show that, if we are able to transplant them within 20 hours, then they are more likely to work both in the short-term and in the long-term. Once you start to talk about sharing those within a wider geographical area, there is therefore the risk that those organs may not work as well. What Anthony was referring is that there is a group of patients who are far more difficult to find a suitable organ for, whether that be a deceased donor organ or a living donor organ, and for that small group of patients, therefore, it may be advantageous to dispel the geographical reasons: because you then have the choice of either not getting a transplant at all or getting one from elsewhere, accepting that the outcomes may not be quite as good because of the longer transport times. Coming on to the specific incidence of paired donation, this is something that has been allowed into the Human Tissue Act which we had not been able to do in the UK prior to that. In the living donor context, say, there is donor A and recipient A who would like to be able to donate to each other but they are biologically incompatible and, therefore, at the moment could not go ahead with live donation, and then another couple, donor B and recipient B who, again, are in a very similar situation. What the paired donation scheme allows is
for the donor in pair A to donate to the recipient in pair B, and vice versa. When we talk about pooled donation, it is where there is more than two in the chain. It does get very complex, and logistically it is quite difficult to put into practice. This has been allowed in the UK since September 2006, but up to now only two of these transplants have gone ahead. That is partly because the British are always slightly more reticent about new things and it takes a little while for new schemes to come on board and there are always those at the vanguard who would like to be first and others who would like to see how it goes first. I think what Anthony was saying was that within a wider European pool, for example, and you could argue this in France and Belgium which are quite accessible, if there was a larger pool, then there would be the possibility of matching more people in this way. This would still be a very small proportion of the overall number of living donors. Last year the number of living donors in the UK was nearly 700, and so we are talking about a very small proportion of that.

Chairman: Lord Lea, you may want to come back, but can I pursue this bit with Lady Gale bringing her question in, because she wants, I know, to ask about quality and safety and one of the issues, of course, is whether there should be a framework of safety. Do you want to come in here, Lady Gale?

Q221 Baroness Gale: I wonder, could you describe the views of the British Transplantation Society regarding the seriousness of the risks of transmitting disease if the number of organ donations is increased and organ sharing across EU borders becomes more frequent? What form of EU regulation in this area would you find the most helpful and what, if any, inappropriately onerous restrictions do you think should or could be avoided?

Mr Rigg: I think there are two things to say, just to put it into context. First of all, the risks of transmitting disease, either an infection or a malignancy, are actually very low because of the systems that are in place within this country. There are very strict regulations in terms of donor assessment to be sure that the donor has not had previous diseases. There are also strict regulations on what infectious diseases a donor may have had. There are various tests we do to ascertain whether somebody has had exposure to HIV or hepatitis, for example, before and then there is a traceability process so that there is a very clear system in place. Therefore, the risk of transmission is actually very low, but we can never say that it is not there, because sometimes you do not know, even on blood testing, even on close questioning. So, there is a very small risk, and we would always have to explain that to the patient. The second thing to say, as we have already hinted at, is that the number of organs that we receive in this country from Europe is actually very low in the grand scheme of things. There is the occasional kidney that cannot be placed within Europe and there may be perhaps a slightly higher proportion of livers and hearts where the actual recipient pool is lower. So it is very important (and I think this is one of the things that is important in the European proposals) that there should be minimum standards that all countries should stick to so that at least one can gain some assurance that an organ that you are receiving from another country meets the same standards as you would expect from our own country. One of the concerns from the transplant community is that the baseline or the precautions that are already in place are pretty robust, and I am not sure that we would see the need for that to be increased. It comes back to the bureaucratisation: actually if it came to a place where transplant units needed to be licensed, where there needed to be more paper work, I think this would add unnecessarily to what is already a pretty safe scheme where there have actually been very few adverse events. We have a system that is working very well, and I think we would want to see those best practices incorporated into a European framework but without making it overly bureaucractic.

Baroness Gale: My Lord Chairman, before I ask another question, could I ask you, should I have declared an interest before I asked my question?

Chairman: You probably should have done. Perhaps you could declare it now.

Q222 Baroness Gale: My interest is I am a patron of Kidney (Wales) Foundation. Could I ask you, are there any cases of infections after a transplant, and are you saying that, even if we got all this regulation, there would not be many organs coming from EU countries? Would we be able to manage in the main?

Mr Rigg: On the whole, I think all countries within the European Union have more people waiting for a transplant than there are organs available. I think even in Spain, where they have the highest donation rate, they still have people on their waiting list. I think in the main we would, I am sure, within any allocation system, allocate to those within that local geographical area. We obviously have UK Transplant in this country. In Europe there is Scandia Transplant and Euro Transplant, which may cover a few of the adjacent countries, but I think there is a lot to be said for those smaller regional allocation sharing schemes, partly to come back to what I said before about minimising the transport times. I think even if there were to be a combined European view on this, I think there would still be only a small proportion of organs that were shared. That might be different in perhaps some of the newer Member States, who have very low donation rates and very low transplant rates, perhaps some of the
Eastern European countries, I suspect that we would not necessarily be able to help those because we are quite far geographically from them and, therefore, any sharing is likely to be within those countries nearby, such as Spain, France, Belgium or even Germany.

Chairman: We are still trying to pursue what value the EU could add. I think, Lady Perry, you are going to pursue this. Lord Lea started this one and we are still pursuing what value it can add.

Q223 Baroness Perry of Southwark: Yes, indeed. In your submission you did point to at least one omission, as you saw it, in the Directive, which is the quality of the retrieval. I was amazed to learn that apparently sometimes you waste an organ because the retrieval has not been efficiently or safely carried out. Do say something about that, and are there other areas where you feel that the Directive could be expanded to include more than is currently there? Dr Warrens: With respect to safety, I would say that is the major issue that we felt was missing. The other area that I think would be very important to promote on a European-wide basis is research. I feel I also ought to declare an interest here in that I am research active. I am interested in mechanisms of increasing organ donation, and so I would say that, would I not? But, I do believe that there is a lot that we can learn from our sister countries throughout Europe, because the factors that make people less enthusiastic to donate, I am sure, cross national boundaries, but by increasing the number of people from whom we glean information, we will learn what those factors are and put in place the most appropriate way of trying to respond to them. I would like to say from the start, I do not think that the results of that research always has to be that everyone will agree to donation. It may be that, for entirely appropriate, personal, religious, cultural, ethical issues somebody is disinclined to support donation. I think our responsibility is to make sure that the decision they are making is an informed one, and by understanding what their concerns are, I think we are in a better position to help that process of informing them and the step before understanding what those concerns are is research, and so I am very keen to see at a national and, indeed, supranational level, the promotion of research into the issue of what inhibits people from participating in organ donation.

Q224 Baroness Perry of Southwark: This would be social science research and not medical research? Dr Warrens: Yes.

Chairman: We are going to come back to research again, but could I take you back again to the EU Directive and really pursue it again. I know Lord Eames wants to ask some questions about practitioners in this, but what do you think the Directive could bring? From the documentation we have had from the EU, in their view, what value could they add in terms of safety or sharing?

Q225 Baroness Perry of Southwark: I think we would like you to be specific about what you would like the Directive to say about safety and retrieval, for example, standards in retrieval, and also, now you have mentioned this kind of research, what could the EU do or say in their Directive that would help that? Dr Warrens: I will talk about research and I shall let Keith talk about retrieval, since he does retrieval as a surgeon and I do not as a physician. I think social science research is exactly the right phrase. We need to understand the structures of the communities, and I mean the smaller communities to which people identify, within which their opinions are formed. What are the processes that allow the formation of those opinions, what are we succeeding in communicating and what are we failing in communicating? What are the anxieties that people have about going ahead with donation or permitting one of the members of their family who has died to become a donor?

Q226 Baroness Perry of Southwark: That would not, however, be in the content of the Directive, would it? It would be the EU in another of its personas in its sponsoring of research topics and programme?

Dr Warrens: Sure. The development of the criteria for sponsoring research follows on from policy directives and, in the context of the conversation we are having today, I would like to see in a document such as this that discusses policy actions at EU level a comment that says: it is very important for the EU to recognise the need to increase our knowledge in this area and it would be an appropriate place for EU funding to be given to research. I know that would then have a knock-on effect on the criteria that the funders of research use to decide how to disburse their moneys.

Q227 Baroness Perry of Southwark: And retrieval? Mr Rigg: So far as retrieval is concerned, the retrieval of organs from deceased people tends to be an out-of-hours activity and, therefore, is often unpopular, it has often been done by perhaps the junior members of the team and, I think, as the European Working Time Directive increasingly bites, it then becomes increasingly difficult to deliver that in the context of also trying to deliver the rest of the services. Perhaps I can talk about what we are trying to do in the UK first, because that then has a context to what is happening European-wide. I think we have recognised within the UK that there has been a problem. I chaired a UK Transplant working group five or six years ago, which has subsequently been taken on by the British Transplantation Society, to look at what the problems were and what some of
solutions might be. I think some of the solutions are actually highlighted in the recommendations from the taskforce, but it is trying to have dedicated multi-organ retrieval teams, maybe ten to cover the UK. That would be their job for that period of time. So, they were not involved with routine elective work, their commitment was to the team, they were properly trained, they were properly resourced, the teams were dependent on no one from the donor hospitals, they would take the surgeons, the nurses the anaesthetists with them and, therefore, they would be able to respond in a timely way. We believe in this country that, by implementing that, that will provide a much safer way of providing organ retrieval, both in terms of the quality of the organs that are removed but also in causing least disruption to the donor hospitals: because intensive care units are under increasing pressure for their beds as well.

The last study that looked at organ damage was about seven or eight years ago now, and that showed that about 14% of organs were damaged during retrieval, although I should say that most of those items of damage could be repaired and only a very small proportion were actually discarded and not used; but I think it does show that it is a stressful operation, it is done out of hours often with inadequate assistance for the operating surgeon, and it can be a difficult procedure and, therefore, to have dedicated teams who are trained is very important. I think there are steps to put this in place, and we hope that that part of the taskforce, we hope that all parts of the taskforce recommendations, will be implemented, but from a surgical point of view, I have great hope that that will take place. As far Europe is concerned, I think there can be standards of training and standards of competency in delivering these services. I think retrieval services are delivered differently in different countries and I think some of the recommendations that have been put forward in this country have been implemented in other countries, I think, but in the majority of countries they have not and, therefore, to have a European-wide Directive that says: these are the standards for training, these are the standards for competency, and there is already a European transplant exam which has donation and retrieval as a module, is perhaps one way forward, but, again, to have something from the EU Directive that actually applies to all states means that there is a good standard, not just for the country in which the organs are removed and most likely will be used. There is also that assurance that if the organ is coming from another country it will be of a quality that you will be ready to use. For some of those organs, the livers or the hearts, that come from Europe, often if it is retrieved in mainland Europe, then one of the surgeons from this country will go out, and vice versa, if a liver or heart is being retrieved in this country to go elsewhere in Europe, then the European surgeon will come, because surgeons at the moment do not necessarily trust other surgeons to do things in just the way that they would like. Therefore, I think that some standardisation and some trust and acceptability is very important and I think this is something that the Directive, or at least the action plan, could address.

Baroness Perry of Southwark: Very quickly to follow up, the conditions you have described, the after hours work and not a sufficient team to back-up, is that true for living donors or simply for the—

Chairman: Can I hold you there, Lady Perry, because we are moving into some areas that we are going to come to.

Q228 Baroness Perry of Southwark: I wanted to confirm what he said about the—

Mr Rigg: It is deceased donors only. Living donors are done during the day by experienced consultants.

Chairman: Thank you I can see Lady Perry’s anxiety there! Lord Eames, this touches on the question you wanted to ask. I would like to come to research immediately after, because it fits in.

Q229 Lord Eames: It touches very much on what I have been thinking about. Can I say, first of all, how helpful your presentation has been? We have had many presentations, but I have found this one particularly helpful, just as a personal aside. Gentlemen, with the avalanche of EU directives, there is one that perhaps impinges very much on what you have already said this morning, and that is the one which concerns working times. It brings me to ask the rather pointed question whether or not, in the light of all that, you feel that there is su—

Chairman: I wanted to point out that it is deceased donors.

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Dr Warrens: Perhaps I could start and I am sure Keith will contribute. I would seek to reassure you that this is something that the profession is very aware of and over the course of the past 15 years you will have seen a contraction in the number of units that actually do perform transplants largely for that reason: because we recognise that, in order to maintain skills, you need to be doing a certain minimum number of procedures. The pressure to conform to directives limiting the number of hours any individual can work only increases the pressure to have a large number of transplants in one centre so that any one individual can maintain his or her skill-set. There was an important and influential report published by Sir Peter Morris, at the time he was
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Dr Anthony Warrens and Mr Keith Rigg

President of the Royal College of Surgeons, about exactly this issue, rationalising the number of transplants units, and we moved in that direction. It may be that, if the situation arises that we are required to conform to a number of other directives, we may move further in that direction. However, we have had a major problem with training junior transplant surgeons. Again, Keith is better placed to answer that than me, but I know that we have got over many of those problems and the problem is not as great an issue as it was perhaps three or four years ago, but I will pass over to Keith, as a surgeon.

Mr Rigg: One of the concerns for those of us who practise in one of the craft specialities, such as surgery, is that you obviously do need the experience and you can train someone to do an operation but that is the easy bit. The more difficult aspects are making the decision whether to operate or not and being able to recognise the complications afterwards. Those are the sorts of things that often do happen out of hours. One of the concerns is whether you can actually provide that training and that experience within a 48 hour working week. The thing is, we do not quite know that yet, and we do recognise that, as the training times have come down, we have obviously had to change the way in which we train our junior surgeons, but I think there is no doubt that the experience they come out with at the end is perhaps not as comprehensive as it once was. Whether this will be adequate or not I think remains to be seen. When we do get down to the 48 hour requirement in eighteen months time, whether the eight years of training will be sufficient, we do not know, but I think there are concerns and, therefore, when someone is appointed as a consultant they will need to be mentored very carefully for perhaps a couple of years before they are fully up to speed. Certainly within the area of organ retrieval, where it is out of hours, I think that comes back to the fact that we do need dedicated teams who are able to do that.

Although we say that in surgery, I am sure it is the same in other specialities as well.

Lord Eames: For the record, I was going to say that when my two sons, who are consultant surgeons, hear that this was the question I asked you, they will be horrified, but I will pass back.

Q231 Lord Lea of Crondall: Maybe Lord Eames’ sons would be horrified because they would know perhaps, would they not, that there is an averaging rule in the 48 hours. There was a time when junior hospital doctors, we all know, worked all the hours that God sends, and that was itself not a very bright idea from the health and safety point of view, and so there has been a general acceptance now that that this is the position. Of course you need to have more staff if you are going to have any hours limit, but when you say 48 hours, how exactly do you mean 48 hours is binding on this? It is not 48 hours in any particularly short period of time, is it? You are just talking about the amount of labour input that is needed extra because of the general average of 48 hours?

Mr Rigg: Yes and no. The European Working Time Directive, as far as I understand, averages out at 48 hours work per week, which by the time you have got to a night on call, for example, takes out 16 hours, which leaves you 32 hours for the rest of the week. Actually you have not got people there very often by the time you have covered the weekend, so we need to consider other ways of providing the service as well as the training. There are various ways, but if you increase the number of trainees, then you dilute the experience and you then have not got the consultant posts at the end of it for them to go into, so you then end up producing a large number of trainees with nowhere to go. There are other options of providing this service by people who are not trainees. There are no simple answers, and I think it is something that we are wrestling with, and I am sure we are not alone in the medical profession.

Q232 Chairman: We want to move on, but do we have any knowledge from Spain and Belgium as to how they have tackled the point? The issue is continuity, is it not, in this field?

Mr Rigg: Yes

Q233 Chairman: You have got to have someone seeing the thing through. Do we know whether they have cracked the Working Time Directive in relation to this?

Mr Rigg: I know in some countries the individuals choose to disregard it actually. They pay lip service and then just carry on doing what they have always done.

Chairman: Thank you. Because we have got into research, it seemed that it would be worth pursuing and battling this one out before we move on to the
other complicated questions about what is life and what is death, you know!

**Q234 Lord Kirkwood of Kirkhope:** I will deal with the easy questions first! My Lord Chairman, I concur with Lord Eames: I think this is a splendid four-page submission. It is concise, it is lucid and it is persuasive. I nearly spoil it all by saying “for something that is written by a doctor”, but I am being facetious. I did really both enjoy and learn a lot from the submission, but I wonder if you could clarify a sentence for me. I am interested in public awareness, because it is an important part of this whole inquiry and there is a sentence under organ shortage, research potential, where you say, “Indeed, we believe there is an under emphasised level beyond awareness, namely public perception and information to support organ donation.” Could you expand a little on that? That is the first time that has been suggested. I thought awareness was the target that we were aiming for, but you seem to be suggesting that actually we need to try and aim for something slightly higher than that.

**Dr Warrens:** I certainly do believe that. If I can refer to some of my own research here, I am currently undergoing a project, funded by the Big Lottery Fund through Kidney Research UK, in which we are doing some social science research with various communities in London. There are a number of ethnic and religious issues that appear to have an impact on the level of knowledge, but, over and above that, there is a recurring theme of alienation amongst certain communities from the medical establishment. This was something that seriously distressed both myself and my fellow researchers: that people feel that the process of organ donation is not something in which everybody is dealt with in an equitable fashion. Members of some communities fear that they would not be accorded the same level of care in order to preserve their personal health if they were seen as a potential donor. Clearly, I would want to put it on the record that, of course, we bend over backwards to pursue absolute equity of care for everybody, but it is clear that is not how it is perceived. There is perceived to be, and I think I cannot use an alternative phrase, a white medical establishment that discriminates with respect to organ donation against other communities and, horrified though I was, I think what we need to do is address that perception of how we behave.

**Q235 Lord Kirkwood of Kirkhope:** I think trying to explain to politicians that there is a disturbingly high level of mistrust in the medical establishment, which I think we know about, we know about disturbingly high levels of mistrust in this building—that is very interesting—but the key question going on from that is: you were saying in relation to social science research that is necessary to do it across border, and that is something that the European Union can do and that is important to the consideration of our report, but explain to me what you can gain from comparing social scientific surveys between Athens and Edinburgh? I can understand that drilling down into the reasons why people are resistant and getting awareness, if not perceptions, is what we are trying to do, but is Eastern Europe the same as the Southern Mediterranean countries? Would a cross-border piece of research be useful comparing north, south, east, west across a really wide continental spectrum of opinion? What would you learn that would not be better than spending a lot of money in Edinburgh for Edinburgh and a lot of money in Athens for Athens?

**Dr Warrens:** There may well be very great differences between Edinburgh and Athens, but poverty may bring with it shared perceptions or shared feelings of alienation and that is exactly the same in different parts of Europe. Immigrant status, be it to Germany or Spain, may bring with it the same feeling of alienation. Let me take one step back. I did a lot of work with the Muslim community and discovered that there are some strands within Islam which have a negative view of donation, but by no means universal, and we found this amongst some of the black community in London. So I asked the question, was this specific to black Muslims? We then started a small study in black Christians, and the fact is that there is a shared common cultural heritage from Africa that owes, we think, more to the experience in West Africa than it does to the Christian or Islamic traditions; and so we have already demonstrated, by looking at different groups that you would not think shared things in common, that it is possible to learn things from groups that appear to be rather disparate. That is one answer. The other answer is by getting larger numbers, by studying larger numbers of people, you get more information, and so that would be our principal argument in support of research across boundaries.

**Q236 Lord Kirkwood of Kirkhope:** The fairy godmother question about cross-border research: if you were only allowed one wish and you could have anything you liked in terms of European-wide cross-border research, what would it be?

**Dr Warrens:** I think I need to understand what it is that means that donation rates in the UK are so low but those in Spain are so high—having taken out the organisational factors (the Taskforce report has dealt with that very well indeed). We are hopefully going to move forward and build on that, but there are still going to be common factors. Even if, as Keith has said, we were to reproduce the figures that they have in Spain, we would still have a significant shortfall; so there is a gap there that we need to fill.
Q237 Baroness Neuberger: I have to declare an interest, which is that I have a brother-in-law who may be known to you, who is a physician specialising in transplants. It always seems a rather odd interest to have to declare, but there we are. Can I just proceed quickly on the research area, because I think we all feel we wish we had heard about this earlier on in this work, and pick up also what you have said about your work with the Muslim community? I completely accept your wish to conduct more cross-border research, but in the research that you have been doing with the Muslim community in this country, do you believe that the reluctance to be organ donors—this feeling that they are facing the white medical establishment—also exacerbated by something we do keep hearing about, which is the desire to target the South Asian community in order to get them to be organ donors because of the shortage? Is there another further exacerbating issue that we need to drill down into?
Dr Warrens: I am not quite sure I fully understand your question. Are you asking that the community is feeling that it in receipt of an unreasonable level of attention because of that?

Q238 Baroness Neuberger: Yes, because people want those organs?
Dr Warrens: No, I do not think that, because the information that we keep on getting is that, if organ donation so is important, why are we not hearing more about it? My GP tells me, or has leaflets about heart disease and making sure my cholesterol is all right and stopping smoking. Why is he not continuing to say, “Are you on the organ donor register?” (Again, on the subject of declaring interests, this is the subject of the grant proposal I have currently under consideration with the National Institute of Health Research.) No, I do not believe there is a feeling of victimisation at all. In fact, quite a lot of people, when they hear that there is an issue, when they hear that their community is particularly susceptible to diseases that will result in renal failure, are actually more thoughtful about it and are more prepared to consider it. That has been our experience.

Q239 Baroness Neuberger: That is very useful. Can I move on to what I am supposed to be asking you, which is about organ donation after cardiac death, and that is really important because in your submission one of the strong recommendations you are making to us is that we should press for more detailed consideration of organ donation after cardiac death in what the Commission itself does. What would be very useful to us, I think, is if you could set out your views on the potential ways of increasing the practice of organ donation after cardiac death and say to us what else you think we should be asking, because I think that is key if we want to really go and follow your suggestion. Can I add into that something that is not on the script, which is the question within Europe of the large prevalence of Catholics and the extent to which that has been a difficulty in some of the Commission’s own consideration, because that is where a lot of the negativity has come from? I can say that as a Rabbi!
Dr Warrens: The principal issue with donation after cardiac death is organisational, because it is extremely labour intensive.

Q240 Baroness Neuberger: Sure. It is not the ethical problem?
Dr Warrens: In my view, it is not. There are ethical issues but, in my view, the dominant factor is organisational. The reason we probably have not hit our heads on the ethical ceiling yet is because quantitatively it is a much smaller practice than donation after brain stem death. There were something like 150 donations after cardiac deaths in the UK in 2006 compared with over 600 after brain stem death, so quantitatively it is much less. The ethical issues may become more prominent if and when we do more. The problem with donation after cardiac death is that you need to have a team that is available who can preserve the organs very rapidly. Clearly, if you know it is likely to happen, then it is easier to plan than if you do not, but it is still not nearly as easy as a situation where somebody is maintained on cardio-respiratory support but is dead because their brain stem is dead. That clearly is a more elective procedure. So there is a major organisational issue. There are also areas of doubt as to what the legislative framework is for donation after cardiac death in the UK, and it will be very helpful, I think, for people who are practitioners in that area to have clarification about this. The Human Tissue Act moved that forward greatly when it came into force in 2006, but there are some areas that have left practitioners still without guidance, and it would be very helpful if Parliament and government were able to give guidance to my colleagues who are involved in that.

Q241 Chairman: Would you be prepared to write to us and say what they are?
Dr Warrens: I will speak to some of my colleagues within the Society about this and write to you. I am sure it would be useful to have your support in clarifying these issues.
Mr Rigg: Perhaps if I can just add, the Academy of Medical Royal Colleges have been working, as you know, on the code of practice for the diagnosis of death, and I am not sure what stage it has reached. There is the promise that it will be published very soon but there is no date yet set for this. There are going to be, hopefully, some clarifications within that. I know that there are people within particularly
the intensive care community in the UK who have concerns. It is really the time after the heart stops beating: how long you should leave it until it is safe to go ahead with removal of the organs. Again, this is very different across Europe. Some people say that two minutes is adequate, some people say five minutes, some people say ten minutes, and there is that level of concern there. I should also say that the EU document talks about increasing the number of living donors and extended donors, or extended organ criteria donors. I think we would probably say that donation after cardiac death is not part of the extended criteria donor; it is something separate. It may be that the European Union intended it to be included within that, but I think it does need to be specified because they are two different types of donor. Just to clarify, the extended criteria donor is somebody who has brain stem death but, because of other medical conditions they have, the organ may not be perhaps of as good quality as another one. Let us say, for example, if somebody who was 25 was unfortunate enough to have a head injury and died, then you would expect the organs of a 25-year old to be of good quality and to last for a long time in the recipient. If, however, the donor was 70, had a previous history of heart disease and then died of a stroke, then they would have an underlying disease that might mean that that organ may not last as long in the recipient. That is what we mean by the two types of donation after brain death, there is the extended criteria and then the normal one. Then there is donation after cardiac death, and to confuse things further, there are two categories: there is the controlled category, which is where the patient will usually die in an intensive care unit from cardiac death and there is the uncontrolled category, which is where somebody may be brought into accident and emergency having had a heart attack and the organs can be used. That happens very infrequently in the UK, and there is conflict between the Human Tissue Act and the Coroners Act about that which has not yet been resolved. It was certainly one of the issues that came out of the taskforce that coroners do have different perspectives in different in parts of the country, their own interpretation of the legislation is different, and that does cause issues for transplant co-ordinators and others.

Dr Warrens: I was just going to come back to the ethical and religious issues that you raised, which I think are important. I am sure you are right that there are some traditions that find it unpalatable to proceed with donation after cardiac death. My own view here would be that it is our responsibility to find out what people’s traditions are, to make sure that they are in a position to make an informed decision, without any coercion whatsoever and full respect given to whichever decision they take, and as long as that framework is in place, I think the pressure then is removed and those for whom it is culturally, ethically acceptable would then be in a position to proceed. I think the whole system, as it were, would benefit from basically opening up discussion, understanding what people’s views are, and it is not just the Catholic position. You said you are a Rabbi and I remember having a discussion with a Rabbi myself whose concerns were how long after the cessation of cardiac function does one have to wait before that defines death?

Q242 Baroness Neuberger: It should be eight minutes.

Dr Warrens: There are issues in many cultures, and I think what we need to do to get round some of the problems we were alluding to earlier of a lack of trust is make it abundantly clear to everybody that we wish to know what people’s views are, we wish to respect them, and in that context we can move forward and those who feel comfortable with participating in this will be able to do and I am sure the number of organs would increase. The last comment to make, because you asked me also about European dimensions, is that we have a lot to learn from Europe here because probably the leading centre in Europe for donation after cardiac death is Maastricht in southern Holland, which has led the way. Professor Kooststra there has done an enormous amount of work, so I am sure we have a lot to learn.

Chairman: Lord Eames, you wanted to ask a question.

Lord Eames: No, I was nodding in agreement.

Baroness Neuberger: Shall I follow up with living donors? They have given me these nice neat ethical issues that are so easy to answer, and I know that Lord Eames and I have been nodding to each other all the way along. You make the case very strongly for the expansion of living organ donation in the UK and throughout the EU. Could you, first of all—this for the record—describe what the advantages of living organ donation are and then could you also explain exactly for us what is meant by the terms “paired” and “pooled” donations and non-directed donation. I think we really do need to know why you feel so strongly that these should be encouraged.

Chairman: We mentioned this earlier.

Q243 Baroness Neuberger: We need to get it on the record.

Dr Warrens: It bears repetition anyway, does it not? Living donation is very successful. The outcome following living donation is better than the outcome following cadaveric donation, even if the living donor is not particularly well-matched. By definition, if you are performing a deceased donation, the donor was ill prior to donation: by contrast you only take a kidney from somebody who is well, and so you are using a very good quality organ and so the outcome from the
recipient are extremely small. There are data that demonstrate that the life-expectancy of kidney donors is actually better than the life-expectancy of age-matched individuals from the general population. That is because you only get to be a kidney donor if you have been screened and, therefore, all patients found to have medical problems are not considered further as donors. The reason I say this to patients is because it tells them the magnitude of the risk they are taking, which is extremely small. The risk of death we quote as 0.03%, which is approximately the risk of being run down in the street in a 12-month period as a pedestrian. But, while the risk is very small, it is not zero. There is also additional advantage for donors, because in the vast majority of cases they have an ongoing relationship with the recipient, and renal disease is not something you experience alone. The majority of donors probably are partners, and living with somebody who is on dialysis has an impact on your own quality of life and so there is an additional benefit for the donor in improving the quality of the life of their recipient. Retrospective studies of people who have been donors suggest that the vast majority of them are very pleased that they did it and, quite rightly, they feel good about themselves. As a physician, I find it a very humbling experience to see people who are prepared to put themselves through this sort of discomfort, and it is often no more than that, but altruistically. That was the first question about the advantages of donation. I have talked long enough. Shall I leave Keith to talk about “pooled” and “paired” again?

Q244 Baroness Neuberger: Yes, please.
Mr Rigg: Do you want the definition of paired donation again at this stage?

Q245 Baroness Neuberger: Yes, very briefly, so we have absolutely got it.
Mr Rigg: We have a pair who would like to be able to donate to each other, let us say pair A, but they are incompatible, and then pair B, who are in a similar position, would like to be able to donate to each other but, again, are incompatible. It is, therefore, possible through a matching system whereby the donor in pair A can donate to the recipient in pair B and for the donor in pair B to donate to the recipient in pair A. The modelling data would suggest that you probably need at least 30 to 50 pairs within a pool of patients, and that will mean that about 30% of those will actually get a successful transplant. Therefore, there is a minimum number within the pool. So it will not be the answer for everybody. I think we have calculated in the UK that if you look at all the people who are incompatible, either because of them being the wrong blood group or because of, going back to the HLA or the antibodies whereby people cannot donate, then we could probably increase the number of living kidney donors by between 50 and 100 (but, again, that does mean that everyone who is seen has to go into the scheme), and it has to be recognized that not every living donor pairing want to do this, because some really want to have a kidney from their loved one and do not necessarily want theirs to go to someone else and to receive one back from someone unknown. So it is not going to be the answer for everyone, but it is an option for a number of people who are currently difficult to transplant. Again, they have a successful scheme in the Netherlands. Certainly, in the introduction of the scheme in this country, we took on board some of what they were doing. Again, there is the opportunity to learn from other people within Europe and also for other countries within Europe to learn from those who are doing it. Alongside of that, the Human Tissue Act also allows for altruistic or stranger donation, which is where an individual decides that they have two kidneys, they only need one and they would very much like one of their kidneys to go to someone else. That is not something that many people would choose to do and, at the risk of stereotyping, I think we have found that those people who are most likely to do this tend to be middle-aged women whose children have grown up, and I think that perhaps shows the generous nature of that group, or maybe they are fitter, I do not know, but that tends to be what has happened. Again, it is not a large number and probably less than five or six people have done that, but it does increase the number of organs that are available.

Q246 Baroness Neuberger: You have mentioned the Netherlands for the paired donation, the absolutely altruistic. Is that more common in other European countries?
Mr Rigg: I am not sure exactly. I know in Germany it was permitted, but I think they may have stopped it. I think it is one of these things that, ethically, people do have some concerns about, because one of the things that has to be ensured in the work-up process is that there is no evidence of coercion or inducement, and one could argue that who in their right mind would give up an organ? It is different giving up blood or bone marrow but giving an organ that is not going to grow again, why would anyone choose to do that? One has to be sure that the reasons are right.

Q247 Chairman: Can I just clarify one further point. If pooling is so useful, why would it not be useful for the EU to have this wider pool and, if so, how would you see the EU carrying that out without increasing the paperwork (because I cannot say that word this morning!)
Mr Rigg: Again, part of it is around the transport times and that is one of the issues because one of the other advantages of live donation is that the organ is not out of the body for very long. In a traditional living donation it comes out of the donor and goes into the recipient more or less straight way or within a couple of hours. Within the paired donation scheme in the UK again you are putting that up to perhaps four to six hours. It you then start to expand that across Europe that time is potentially going higher.

Q248 Chairman: Presumably people could travel?
Mr Rigg: They can do. One of the other things is that there is a requirement for anonymity between both pairs beforehand. Let me explain that because there are some horrified faces! I think the concern is that if people know who they are donating to in terms of the other pair, they may say because of their colour or because of their age or whatever that they do not want to go ahead, so I think the reasoning is that before the donation goes ahead it is recommended there should be anonymity so there is no condition attached. That is part of the problem with logistics because, yes, potentially everyone could travel and go into the same hospital, but people do not necessarily want to travel to another unit and then it is very difficult to maintain that anonymity within one hospital where you have a defined number of wards where those patients are and a defined number of theatres so logistically it would be difficult but not impossible.

Q249 Baroness Morgan of Huyton: You have submitted evidence to us on donor cards and my understanding of what you said is that you are pretty hesitant about the notion of a European donor card and you are more interested, if anything, in going even more local than a national donor card. Then you raised the possibility of a local or community-based donor card with some sort of EU stamp of approval as a possibility. For the record, could you expand on those points.
Dr Warrens: I think it is all a matter of buy-in. We were talking earlier about people identifying with the services that they were going to be interacting with and I think people do that more naturally with something that is familiar. Therefore if you can introduce some sort of familiarity by virtue of it having recognisable authority or displaying features that are important to them, then it is something they are going to feel more comfortable about. That is why I feel we are going to get greater buy-in to a UK donor card than we would to something that was EU-wide. It may be that within local communities there are alternative ways of "kite-marking", as it were, a local system of donor cards. There is very little research on this, but I think there is the potential for doing it, if a local community has respect for a particular set of individuals whose authority they believe is something that is important to them before proceeding. If that individual were to participate in the local scheme, then I think it is more likely to win the affections and buy-in of the local populace than something that is imposed from a structure with which they do not identify.

Q250 Baroness Morgan of Huyton: Is that a presentational point or is that a reality in the sense of are you saying that you are against the notion of organisationally having a European-wide donor card or are you saying presentationally that it should be a locally presented card but that nevertheless could be organised on a EU basis?
Dr Warrens: I do not think it is just presentation because there may be local requirements for adaptation to different approaches. For example, there are communities who have problems with the definition of death on the basis of brain stem death criteria, and it may be that they would be prepared to sign a donor card that stipulated they would be donors, but only in the context of the cardiac death and not following brain stem death. If we were able to develop a system with enough flexibility to accommodate their wishes—and I think to a certain extent we could—then (i) we could communicate to that community that we have an interest in taking their concerns to heart and (ii) I think we would increase the number of donors, so that is what was behind the idea.

Q251 Chairman: It would be a pity if we did not ask for your views on opt-in and opt-out because, having heard what you have got to say, I think it would be very useful to know what your views are about that topic.
Mr Rigg: We did do a survey within the British Transplantation Society recently and we have done it a number of times. There was a small response and two-thirds of the membership were in favour and one-third were against, which is not that disparate from the views of the general population. I think we would have to say that as individuals we both have some concerns about it because we now have a Human Tissue Act which is based on consent and if you introduce presumed consent, there is concern that people may not have the knowledge. I think it is fair enough if there is extensive public information so that everyone knows but how you do that so that everyone in the population is aware, I do not know.

Q252 Chairman: The work with the relatives will still have to be done?
Mr Rigg: It would do and is that any different to what we have currently have?
Dr Warrens: In the situation of being faced with the implacable opposition of the relatives of somebody who has just died in your coronary care unit or intensive care unit, it is very difficult to disregard that, and those are the practical issues that the professionals who are involved in this have to face on a day-by-day basis.

Q253 Chairman: I think we have found that people say yes until they think about it! We have got one more question but I think we need not spend a long time because you have answered it and that is: do you want to say anything else about the organising of services or is there anything you particularly wish to pick out in relation to the Task Force report and particularly what you want to send us away thinking about in relation to organisation in Europe?

Dr Warrens: Just for the record, to reiterate, I think it is a first-class document and I think the idea of having a unified organ donor service within this country will represent a very great step forward. UK Transplant is a very good organisation and I am sure is the right place to house that. I suppose I would look to your good offices to push forward the implementation of that because I appreciate that there is many a slip twixt report and lip.

Q254 Chairman: Can you add anything to that?

Spain and Belgium certainly have given it consideration.

Mr Rigg: I think the report takes on board what is happening in Spain and some of the recommendations are based on those reports, so it important to be able to learn from each other and to learn from good practice, and I think there are aspects around quality and safety, as we have already said, where we can learn from each other. We would just emphasise that we would not want the extra bureaucracy. I think there are minimum standards for quality and safety and we all need to be able to maximise knowledge about organ donation so that people can make a choice and hopefully we can then meet the needs of the many people who are waiting for organs.

Chairman: Gentlemen, we are immensely grateful to you. We have not only learnt from you but enjoyed your presence and we would say thank you very much.

Supplementary memorandum by the British Transplantation Society

LEGAL AND ETHICAL ISSUES IN NON-HEART-BEATING ORGAN DONATION (NHBOD)

The summary issues are:

— avoiding conflict of interest when defining ongoing active support as futile;
— the ethics and lawfulness of any alteration to clinical care (including investigations and interventions) that is directed solely towards maintaining or improving organ viability; and
— working within an unambiguous and universally acceptable definition of death.

1. Decisions to withdraw treatment are made frequently on intensive care units when the goals of treatment are no longer achievable. Such decisions are always made in the patient’s best interests. If the patient is conscious (rare) the issues can be discussed with them directly but, if not, the decision to withhold or withdraw treatment involves liaison with all disciplines involved in the patient’s care as well as with the next-of-kin, in order to establish the patient’s values, beliefs and any expressed wishes. When carried out to the defensible standard defined by professional and regulatory bodies, and solely directed towards the best interests of the patient, such decisions constitute a mandatory discharge of professional responsibilities and are supported by established ethical and legal frameworks.

Once a consensus on the withdrawal of futile treatment has been reached and, if it is anticipated that death will follow within a short time frame, it seems reasonable to confirm the patient’s known wishes in relation to organ donation by review of the UK Organ Donor Register and by seeking the views from the next-of-kin as to the patient’s known or predicted position on organ donation. If this process is free from patient harm and the family are not exposed to time pressures or coercion, it is difficult to see how consideration of NHBOD at this stage can be perceived to be ethically or legally unacceptable. However, there are those who believe that, because such actions are not strictly in their patient’s best interests, they represent a conflict of interest for the practitioner and therefore fall outside current ethical and legal frameworks.

2. The ethical and legal issues are even less clear if it is necessary to make alterations in clinical care that are primarily directed towards maintaining or improving organ viability. The main issue centres on what measures a doctor could or should take in order to facilitate organ donation from a patient who is dying but not yet dead. In order to minimise warm ischaemia it is necessary, as a minimum, to maintain the potential donor on
the current level of cardio-respiratory support until such time as the surgical team has been mobilised and is ready to commence the retrieval process.

Interventions such as pre-mortem cannulation, drug infusion and efforts to restore a systemic circulation after the onset of asystole are performed in some countries in order to facilitate NHBOD. Such practices are extreme, play no part in any controlled NHBOD program in this country, are not endorsed in our national guidelines and are not defensible. However, it is accepted by those who support NHBOD that it is reasonable to manipulate the timing of withdrawal of treatment (and therefore the time of death), and to perform pre-mortem investigations, in order to facilitate NHBOD. What is less clear is what a practitioner should do if the patient’s condition deteriorates before withdrawal of treatment, whilst still awaiting mobilisation of the retrieval team. Is it reasonable to increase cardio-respiratory support and, if so, to what degree? How does this actually differ from the provision of cardiopulmonary resuscitation to a potential donor who suffers a cardio-respiratory arrest? Because of these questions, the opponents of NHBOD argue, not unreasonably, that the current UK position is fundamentally no different from that in other countries that allow more invasive interventions and that both are ethically, and perhaps legally, unacceptable. Their position is that current UK practice merely represents one end of an unacceptable spectrum of practice. The fundamental ethical and legal question is therefore, if cardio-respiratory support has been deemed to be no longer in a patient’s best interests, how can it be acceptable to continue or increase such support simply in order to facilitate NHBOD?

The answer might lie in the concept of “best interests,” and this has assumed a central role in guiding the actions of clinicians who care for incompetent patients. “Best interests” and “necessity” are the principles in law that govern the care of the incompetent adult and these have been incorporated into statute under the Mental Capacity Act. Although “best interests” need not strictly be limited to medical best interests, there is no explicit definition of this extension. None of the interventions necessary to facilitate controlled NHBOD, including the prolongation of the current level of cardio-respiratory support, are easy to accommodate under a narrow interpretation of “best medical interests.” For example, it is difficult to see how it can be in a patient’s medical interests to continue to be treated if such treatment has already been judged to be futile. However, if the concept of best interests is extended beyond the physical to include the broader wishes and aspirations of the patient, then an indication that the patient would wish to donate their organs after death, such as through registration with the UK Organ Donor Registry or discussion with the next of kin, is interpreted by some to authorise clinicians to take reasonable steps to facilitate donation after cardiac death, providing that the primary duty of care to the comfort and dignity of the patient is not breached. This expanded view of best interests easily accommodates prolongation, and possibly increase, of cardio-respiratory support to facilitate NHBOD, particularly if it receives the informed support of the next of kin. This is similar to the way in which clinicians readily grant requests to delay withdrawal of cardio-respiratory support to allow family members to travel from afar to attend the bedside.

This broader definition of best interests is used to support the ethical and legal basis of NHBOD but is declared to be spurious by opponents. In defence of this broader definition is its parallel with other aspects of healthcare where “best interests” is not limited to “best medical interests” but incorporates the patient’s wishes and beliefs when competent, their general wellbeing and their spiritual and religious welfare. Although there is a substantial view that this position is ethically defensible, there is no certainty that it is similarly defensible in law. This is one of the issues on which the Organ Donations Taskforce has called for urgent clarification.

3. The uncertainty as to when death can be legitimately confirmed is particularly relevant to NHBOD. Whilst this “uncertainty” is also used by opponents of NHBOD to highlight their concerns, it is my opinion that this issue is less open to ethical or legal challenge. Much attention has been given to the minimum period of continuous cardio-respiratory arrest that is sufficient to allow the diagnosis of death to be made with certainty and indicate the point at which organ retrieval can begin. A period of no less than five minutes has been recommended in the UK by the Intensive Care Society and this position will be supported by the Academy of Royal Medical Colleges when their guidance is finally published. A similar period has been recommended in North America by the Canadian Council for Donation and Transplantation, the US Institute of Medicine and the Society of Critical Care Medicine. The latter reviewed the published evidence of continuous observation of asystole, apnoea and unresponsiveness and concluded that an observation period of no less than two and no more than five minutes of observation was adequate to allow the confirmation of death.

April 2008
THURSDAY 28 FEBRUARY 2008

Present Gale, B
Howarth of Breckland, B (Chairman)
Kirkwood of Kirkhope, L
Lea of Crondall, L
Morgan of Huyton, B
Neuberger, B
Perry of Southwark, B
Trefgarne, L
Young of Hornsey, B

Memorandum by Dr Paul Murphy, Consultant in Neuroanaesthesia and Critical Care, Leeds General Infirmary, Member of the Department of Health Organ Donation Task Force

1. ORGANISATION OF ORGAN DONOR AND TRANSPLANTATION SYSTEMS

There is wide variation in the organisation and performance management of organ procurement systems. In comparison to the highly efficient systems such as those seen in Spain and Northern Italy, where the systematic identification of potential deceased organ donors is seen as “core business” to an institution (even though the absolute number of potential donors each year might be relatively modest), in other countries (for instance, the United Kingdom) it appears to a highly inconsistent affair, with no monitoring or sanction being applied to individuals or institutions that neglect the donation potential of their dying patients. Whilst it is the case that experts from Spain are frequently invited to advise lesser performing countries (both within the EU and elsewhere), it is similarly the case that no one would come to the UK to model themselves on us at the moment. A fundamental problem with current UK practice is the absence of engagement with senior clinicians and Trust managers to acknowledge and act upon failures in potential donor identification.

2. RAISING PUBLIC AWARENESS

Evidence for the sustained effectiveness of publicity campaigns is not convincing. However, efforts to increase public understanding of donation and transplantation are to be encouraged, particularly when incorporated into educational programs such as the National Curriculum. Engagement with black and minority ethnic (BME) groups is particularly important; in this respect, the miserable consent rates for donation seen amongst Black and Asian groups is simply but one example of how these groups travel through our healthcare system in a completely different fashion to majority groups.

3. ORGAN DONOR CARDS AND THE UK ORGAN DONOR REGISTER

3.1 The principle benefit of an organ donor card is that it is an objective record that at some time in the past the individual recorded a desire to donate in the event of their death, and that it is a record that close family members are likely to be aware of. Whilst I have never gone through a patient’s belongings in search of a donor card, when speaking to the family of a potential donor I would regularly enquire as to whether the individual had expressed a desire to donate, whether they had a card, whether they had signed up to the UK Organ Donor Register (ODR), made an advanced directive etc. The common theme of all of these approaches is that they direct the burden of decision making away from the next of kin and back to the individual, thereby maintaining the principle of patient autonomy as enshrined in the Human Tissue Act. In my experience, having a “pro-donation” conversation with a close family member or friend is a most potent way of recording one’s desire to donate in a way that the next of kin feel obliged and empowered to honour (even though it may add to their own burden of grief at the time).

3.2 Although experience with the UK ODR is more limited, anecdotal evidence suggests that knowledge that a patient has previously registered a desire to donate after death helps relatives who would have otherwise said “no” to donation give their consent. The ODR is different to the donor card however—whilst a donor card or a stated wish to donate is a tangible and more or less direct link between loved one and next of kin, the ODR is something brought up by someone else (doctor, transplant co-ordinator etc) and accessed by someone else. Some clinicians feel some uncertainties about when the ODR should be consulted (eg before death vs after death, without the family knowing or only with their knowledge and permission).
3.3 Registration with the UK ODR is officially recognised, according to the Human Tissue Authority, as consent for organ donation after death. However, the validity or quality of the consent associated with possession of a donor card or registration with the ODR has been questioned, because little information is presented on what it might mean to be brain dead,\(^1\) or how becoming a donor after cardiac death might necessarily alter the way in which you die.\(^2\)

4. The European Donor Card

I sense little enthusiasm for a European donor card. The usefulness of the donor card in the UK has been described to above, but as means of registering a wish to donate after death has been superseded by the ODR, access to which can be made either on line, by telephone or when completing various governmental applications. Serious consideration should be given to extending the electronic opportunities to register, particularly given the increasing access of the population to on-line services such as Amazon, e-bay, YouTube etc. However, I very much doubt whether the concept of European registration would receive much public approval, either in the UK or elsewhere. For instance, one of the many reasons for the very high rates of donation in Spain is the emphasis placed upon local donors for local recipients, ie a strong regional pride in what is happening in the local environment. This has some resonance with the strong support for donation (and recipient)-related issues that appears in the local and regional media in the UK. If anything, I think that the solutions for the UK lie in developing local pride (particularly amongst the BME groups) rather than what is happening in the local environment. This has some resonance with the strong support for donation and approval, either in the UK or elsewhere. For instance, one of the many reasons for the very high rates of donation in Spain is the emphasis placed upon local donors for local recipients, ie a strong regional pride in what is happening in the local environment. This has some resonance with the strong support for donation (and recipient)-related issues that appears in the local and regional media in the UK. If anything, I think that the solutions for the UK lie in developing local pride (particularly amongst the BME groups) rather than giving the impression that the benefit from any particular donation may extend not only beyond the local health care economy but indeed be diluted across national boundaries.\(^3\) EU initiatives would be better directed towards understanding why donation rates vary so widely across the EU, exploring ways of improving engagement amongst BME groups and defining ways of effectively disseminating the key aspects of successful programs across the whole of the community.

5. Ethical Issues Relating to Organ Donation and Transplantation

Real or perceived ethico-legal issues represent a significant obstacle to increasing the number of deceased organ donors in the UK. It is not clear to what extent such issues have been relevant in other member states (and if so, how they were overcome). Potential issues include problems with donor identification and attempts by the next of kin to place conditions on the allocation of organs from a loved one.

5.1 Many doctors are concerned about to what extent the principle of “best interests” allows the management of a patient’s death to be altered so as to maintain their potential to donate after death, and how such actions may place them at personal risk of a charge of conflict of interest. Specific examples include the following:

5.1.1 consider a patient in an A&E department who is deeply unconsciousness following a brain haemorrhage from which there is no prospect of survival. Is it ethical or legal to take the patient to an intensive care unit in order to perform brain death tests to thereby preserve the potential for heart beating organ donation, when otherwise—in the best interests of the patient—treatment would have been withdrawn in the A&E department?

5.1.2 consider a patient on an intensive care unit with a catastrophic head injury. His doctors are intending to perform brain death tests later in the day. Is it ethically correct to consider the patient as a potential donor before death is declared, and as a result contact the donor transplant co-ordinator and the organ donor register, knowing that if you leave it until after the tests have been performed the opportunity to proceed to donation might be lost?

5.1.3 for the reasons explained above, non heart beating organ donation requires the issue of donation to be considered before treatment is withdrawn and cardiac death occurs. Does this generate a conflict of interest for those caring for the patient in addressing the issue of donation before death? Is it ethical or legal to delay the actual withdrawal of care until such time as arrangements for surgical removal of the organs has been made, particularly since this might delay the admission of subsequent critically ill patients?

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\(^1\) There remain in the United Kingdom a handful of individuals who deny the concept of brain death, describing organ donation after brain death as the greatest deception of all and citing the fact that some anaesthetists may administer anaesthetic drugs during the organ retrieval process to support their arguments. Other clinicians express theoretical concerns that the current clinical tests of brain death cannot interrogate every single neuronal pathway, and cannot therefore declare that the whole of the brain is dead (even though there is absolutely no evidence of residual neurological function). Neither is there any evidence in the world literature to indicate that any patient has ever recovered from a diagnosis of brain death made using the UK criteria providing that the tests have been properly applied and interpreted.

\(^2\) Donation after cardiac death most commonly occurs after the planned withdrawal of futile life-sustaining therapies on an intensive care unit. In order for a donation to occur, a surgical team must be assembled (usually from another hospital), and only when they are ready can treatment be withdrawn. This inevitably means that the withdrawal of futile therapies has to be delayed by a few hours if a donation is to take place.

\(^3\) I recognise that this would not in any way be the intention of a European donor card; it may, nevertheless, send such a message.
5.1.4 The crucial point in the above seems to rest with the interpretation of “best interests”. Whilst some legal opinion has indicated that it should rest with that which is strictly related to the best physical interests of the patient, others suggest that it extends far beyond this to embrace the wishes and aspirations of the individual when competent, including a stated desire to donate after death. The Organ Donation Task Force has been repeatedly frustrated by the difficulties in obtaining persuasive and authoritative judgements on such matters.

5.2 Occasionally, potential donor families seek to place conditions on who should or should not receive the donated organs of their loved one. Since the principle of unconditionality is fundamental to the gift of donation after death in the UK, any proposal to limit, qualify or revoke it seems as if it should automatically be rejected. However, further reflection leads me to a rather more troubled position, because not only does our approach to securing donation after death rely heavily on patient autonomy and an extension of the concepts of best interests, but also because in life, directionality is fundamental to live related donor programs. It would seem then that in life a potential donor can considerably influence the destination of a donated organ, but in death have no influence whatsoever. There is, however, a crucial difference between conditionality and directed donation, in that the former seeks to deny the gift of donation to specific groups, usually on the grounds of race, creed, lifestyle etc, and frequently derives from beliefs that are morally repugnant, whilst directed donation in life occurs within the context of a specifically identified recipient whose interests and health are clearly important to the potential donor to the extent they are prepared to risk their own health or very existence to improve it. Such acts have considerable resonance with the general public who readily rejoice in such selfless acts (and similarly condemn occasions when individuals fail to make such an offering).

5.2.1 Consider then the case of patient lying brain dead on an ICU whose daughter lies critically ill elsewhere with acute liver failure whose only hope is a transplant. Currently the family do not have the right to direct a father’s liver to treat his dying daughter (despite it being inconceivable that he would not have wished to do so had he been able to be asked)? Is this right? Would it have made a difference if he had been being worked up to be a live related donor for her prior to his death?

6. Faith and Cultural Issues

All the major faiths in the UK have endorsed the concept of organ donation for the purposes of transplantation, although there is little evidence that this has had any impact upon the poor consent rates from BME groups. In part this is because it is a mistake to equate faith with culture—for example, it would be quite wrong to assume that the solution for African Muslim groups is the same as that for Asian Muslims just because their religion is the same. My general observation is that the rejection of the option of donation is but one example of the poor engagement and communication between clinical staff and the families of patients from BME groups throughout their illness—one of my colleagues interprets this as distrust of “white man’s medicine”. Others’ interpretations focus on an unwillingness to give, a lack of charity, amongst BME groups, although this would be quite wrong—within their communities they can often be incredibly generous to each other. Depressingly, there is little evidence, either from the UK or elsewhere, of interventions that have made a real difference, although learning from any examples of success within the EU should be considered as a matter of some urgency.

7. Presumed Consent and the Role of the Family in Decision Making

Although some high profile groups in the UK, most notably the British Medical Association, support presumed consent (ie opt out rather than opt in), the evidence that it makes a difference per se remains equivocal, mainly because its introduction is usually part of some broader initiative. The philosophy of donation after death in the UK is that of a gift, and the next of kin having the opportunity to honour that gift—my observation is the latter can often be a very powerful positive experience for the bereaved family. Occasionally it seems right to allow a family to overturn an individual’s desire to donate because their grief is too great and will be added to if their loved one undergoes surgical retrieval—if we are acting according to best interests we must assume that an individual would not wish to significantly add to the grief and hurt that the next of kin would be suffering. Opting out, in my opinion, devalues the gift and the altruism of the donor. Rather we should be rejoicing in the donation—the giving—and finding ways to get more people to translate their support of donation into registration on the ODR, and most crucially, having that conversation with their family.

4 October 2007

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4 With exception of Austria for instance, where the system of “hard” opt out denies the next of kin the right to over-rule a failure to opt out.
Examination of Witness

Witness: Dr Paul Murphy, Acting Clinical Centre Director, Leeds General Infirmary, examined.

Chairman: Good morning, Dr Murphy. We are grateful to you for coming. Obviously you bring with you a great deal of knowledge about intensive care units. Would you like to start by giving an opening statement?

Dr Murphy: My Lord Chairman, I am happy to go straight to questions.

Chairman: Perhaps we could begin by talking a bit about intensive care units across the European Union. Could you tell us how intensive care provision within the UK compares with other European Union countries and if this correlates at all with performance in organ donation.

Dr Murphy: Comparative data on the provision of critical care capacity across Europe is not that easily come by and that which is available has to be looked at with some caution, because what is intensive care in one Member State may not necessarily equate to the same provision or level of care in another. The data that is available—and it is most commonly expressed in terms of the number of critical care beds as a percentage of the total number of acute beds, say per 100 acute beds in a hospital—would suggest that the United Kingdom is relatively underprovided for.

Data on the intensive care website shows that the UK has around two-and-a-half intensive care beds per 100 acute hospital beds and that compares with, at the other end of the scale, Denmark, which has just over four intensive care beds per 100 acute hospital beds. If you correlate that with donors—most commonly expressed in terms of donors per million population per year—then you will find no relationship. Denmark has a lower donation rate than the UK, despite its apparently high provision for critical care beds. Spain has 3.2 ICU beds per 100 acute hospital beds and yet we are all well aware that it has a donation rate of three times that of the United Kingdom. In terms of critical care capacity or provision, my opinion is that there is little, if any, relationship. That is not to say that there are not differences in the way in which clinicians act in a hospital when dealing with a patient with the most life-threatening of intracranial emergencies like a brain haemorrhage; that is not to say there are not differences in the way those emergencies are managed that reflect in a differential, access or otherwise, to an intensive care unit and if you do not get into an intensive care unit, in all likelihood your potential to donate should you die is lost. Perhaps I can give the Committee an example of that. Imagine, if you will, a patient in an accident and emergency department with a very severe brain haemorrhage. It is judged—and there is no doubt or debate over this—that the patient will not survive from that brain haemorrhage but has not yet died. In some countries that patient would nevertheless go to intensive care—and by going to intensive care the potential to donate is preserved. In this country there is an emerging view that to take the patient to intensive care, whether there is a bed or not, would be futile because the patient is not going to survive and therefore why would we wish to put the patient through that process. There is an emerging suspicion amongst intensivists and amongst transplantation specialities that those patients are dying in an accident and emergency department or in a side room on a ward and their potential to donate is thereby lost. It is not about critical care capacity, it is about clinicians' decision-making over who should or should not go to intensive care.

Chairman: It is a management issue

Dr Murphy: I think so.

Chairman: We have heard that on a number of occasions.

Dr Murphy: It is a management issue and it is also—and we may come back to this—an ethical issue: Why did you take a patient to intensive care if you believed their condition to be futile?

Lord Lea of Crondall: If you say there is a suspicion emerging, what are the guidelines on this?

Dr Murphy: There are no guidelines.

Lord Lea of Crondall: Why not?

Dr Murphy: You know doctors perhaps as well as I and they tend not to respond well to guidelines over how patients should be managed. They tolerate targets badly enough; to tell doctors how they should manage a particular clinical condition they respond to very badly indeed.

Lord Lea of Crondall: Perhaps we could use some other word, benchmarks or some other word as to what can be done.

Dr Murphy: The Intensive Care Society has issued a statement in a more recent publication that to diagnose brain-stem death should be pursued wherever possible, because it is the diagnosis of death rather than the diagnosis of futility that requires the withdrawal of care. That is a long way off from influencing what happens at 2.00 am on a Saturday night in a busy A&E department, frankly.

Baroness Morgan of Hayton: Dr Murphy, is there no alternative to ICU that you can see. I can understand why clinicians would think the priority for the ICU bed is somebody who potentially is going to survive from something else—because we all know there is a shortage of ICU beds. Is there not an alternative that could be applied within A&E to help facilitate donation?
Dr Murphy: Increasingly we are trying to support accident and emergency departments to facilitate donation, and, indeed, there are examples of good practice in that regard around the country. But I am an intensive care clinician and I have to say that my personal view is that part of the job of intensive care is to sweep up and an A&E department is not a place to die really.

Q263 Chairman: Thank you, that is an important question. To get back into the European dimension, you mention that information is difficult to come by and you are given a picture of a range of different survival rates and provision. Would it be helpful if the EU tried to get some comparisons? Would that be useful?

Dr Murphy: It would be very useful to have comparative data on how different Member States and different medical professions within those states handle these very serious life-threatening emergencies. Anecdotally, I know from my conversations with colleagues in Spain that they do not withdraw care. The concept of futility is an alien one to them. They would manage a patient until brain death evolves on an intensive care unit. It would not occur to them to withdraw care in an accident and emergency department because a judgment of futility had been made.

Chairman: That is useful.

Q264 Lord Trefgarne: Dr Murphy has just been saying something crucially important. Is he saying that different management of certain very serious cases in A&E facilities, cases where the chances of saving life are almost nil, would result in a greater flow of organs for transplant in a circumstance where everybody knows there is an acute shortage?

Dr Murphy: Absolutely.

Lord Trefgarne: Dear, oh dear.

Chairman: We are straying into Lady Perry’s area. Would you like to pick up from here, Lady Perry?

Q265 Baroness Perry of Southwark: Dr Murphy, I was particularly interested in the section in your evidence about the ethical issues and I wonder if you could give us your view of the UK Transplant report which says that many potential organ donors are not subjected to brain-stem death tests and are not considered as organ donors. What evidence can you give us about the way in which cases suitable for organ donation are dealt with in ICU, as you have been talking about A&E. Perhaps you could separate that out, both after brain-stem death and in non-heart-beating cases.

Dr Murphy: Could I deal, first of all, with donation after brain-stem death. That is the standard model for donation and non-heart-beating donation is very much more a "work in progress" if I might describe it in that fashion. The Committee is obviously well aware, with the headline findings from the potential donor audit that were published 18 months ago. They indicated that there are between 400 and 600 patients every year who die on intensive care in whom the diagnosis of brain-stem death was likely, in the opinion of the auditors, but that diagnosis was not made. The paper did not really go into why that was the case. I have conducted my own sub-analysis of that group of patients. The biggest single reason why those patients do not go on to have their brain-stem death diagnosed is that they are physiological unstable, cardiovascularly unstable. To that I must add the rider that the clinicians also felt it inappropriate to correct that instability—and my experience is that it is easily correctable—to thereby allow brain-stem death to be diagnosed and thereby preserve the potential to donate in the event of brain-stem death being diagnosed. That was around 30% of those 600 patients a year. For an almost similar number, I could find no reason at all why brain-stem death was not diagnosed. Thereafter, there were quantitatively less important factors. Sometimes brain-stem death would not be diagnosed because the clinicians were already aware that the family would say no were an approach over donation to be made. Sometimes the clinicians were making a judgment over the medical unsuitability of that patient to be a donor. That is an important issue because there are very few absolute contraindications to donation and I would feel that, at the very least, a referral to an expert like the donor transplant co-ordinators should be made before such a judgment is made. As I say, the biggest reasons appear to be either, “I'm sorry, I don't know. I can’t give you an answer” or “There is cardiovascular instability.” This goes back to the ethical issues that are central to so many of these obstacles: to what extent can a doctor intervene to maintain a patient’s potential to donate when those interventions are in no way in the physical best interests of that patient but rather in the best interests of a third party; that is, a recipient down the line. What does “best interest” mean? Is it restricted to the physical or does it rather embrace much more about that patient and how they would want, as a person, their death to be handled, and would they wish donation to be considered as part of the end-of-life care pathway?

Chairman: That has significant implications for the whole opt-out/opt-in debate.

Q266 Baroness Perry of Southwark: Perhaps, drawing on that, could you tell us what the staff working in ICUs generally identify as the main obstacles to organ donation and what would be the impact of the introduction of a system of presumed consent?
Dr Murphy: I do not think there is any single answer to that. It may disappoint you to learn that not all staff in an intensive care unit really have donation on their agenda. It is not—which I think is a phrase used in the taskforce report—“core business”. It is not something that the intensive care unit has on its mind on a day-to-day basis. For some units, that is not surprising because the number of potential donors is relatively small. Some units may only see two or three potential donors a year—I see 30 or 40, so it is part of what we do most days, most weeks—so they perhaps do not have an opinion at all. Some of my more truculent colleagues would feel irritated. They feel that they are under pressure from the transplantation lobby in general and certainly UK Transplant in particular. They are under pressure to produce organs: “Don’t they realise that my patients have to die to be donors?” The more reasonable ones would point, first of all, to the refusal rate, a refusal rate of 40%. When we know that all the surveys in the street indicate public support of 80/85/90%, why is there such a gap between what people would want to happen to them and what relatives will allow to happen to them?

Lord Lea of Crondall: Could I check something which I have been worrying about for a bit now. Is there a confusion of nomenclature to some extent? In your opening remark, you talked about “donation rate”. On the face of it, that is not the same as the statistic about donor registration; it is what you might call the outcome of a donation rate in an intensive care unit. I mean, there is no obvious way in which the statistic that we have all been looking at; namely potential donors equals a registration card—

Chairman: What is the question Lord Lea?

Q267 Lord Lea of Crondall: What do you mean by donation rate?

Dr Murphy: From a unit or a national rate or both?

Q268 Lord Lea of Crondall: You used the phrase “donation rate” as I recall. I just want to know what you mean by that.

Dr Murphy: I guess that for an intensive care unit—and I am being vague because the data does not come back to intensive care units systematically, and certainly my chief executive and my medical director have no idea whether potential donors in my hospital are all being identified, what the conversion rate, what the consent rates would be—by “donation rate” I mean, first of all, how many potential donors are being missed, and, of those potential donors, how many are being truly considered to be donors: what percentage of families are being asked and what is the consent rate from those families. They all make up the conversion rate.

Chairman: We are going to have to move on because of the time, but that is a useful question, Lord Lea. Thank you.

Q269 Baroness Neuberger: I have to declare an interest to start because I have a brother-in-law James Neuberger who is deeply involved in transplantation, which you probably realise. In your evidence to us you describe “the miserable consent rates for donation” amongst black and minority ethnic groups. You also point out to us, very importantly, that there is a mistake around in the ether confusing the impact of faith and culture on people’s views on donation—and you take the example of South Asian Muslims and African Muslims. What do you and your colleagues really believe to be the reasons for low organ donation rates amongst some ethnic minority groups? Do you think socio-economic circumstance is part of it? What should we be doing about it?

Dr Murphy: I think—and this is not terribly helpful—that the donation rates from the black and minority ethnic groups are the biggest single challenge facing transplantation. That is a reflection of how difficult they are. As I think I said in my written evidence, the failure to gain consent for donation from the minority groups does not come in isolation. It does not come as a surprise to clinicians who work with patients from those groups in intensive care and, more commonly, their families because it is simply one facet of what is, by and large, often an unsatisfactory relationship between the healthcare professionals and the family. If there is one focus that generates the tension between those two groups, it seems to be about authority. Who has the authority to make seminal decisions about life and death, about the withdrawal of care and futility, about the diagnosis of brain death and what does that mean? Who has the authority to make those decisions? Is it the healthcare professionals—as they believe it is—or is it the family? It seems to be with many minority ethnic groups that that is the fundamental point of disagreement. Once that disagreement has been defined, it thereby defines the whole relationship that you have with that family. If at the end of the day the outcome is death, and then you approach the family with another request that involves a surgical procedure to remove organs, in the background to all that are different concepts over how the relative is handled in the immediate aftermath of death. I would point out that I am not sure ICU staff necessarily have enough knowledge about how the ethnic groups have different views on the aftermath of death and the disposal of the remains. I do not think we can take that as a given at all.
Dr Murphy: I am sure there are pockets, again, of excellence, but is it on the curriculum of intensive care medicine? Of course not.

Lord Lea of Crondall: To what extent have you benefitted from activity at the EU level around organ donation? How might action at EU level to strengthen the co-operation and the exchange of information between professionals working in ICU in different Member States benefit you and your colleagues in the future?

Dr Murphy: My principal role in the transplantation pathway field is in donor identification and donor management prior to organ procurement. That is my expertise. I recognise the importance of other aspects of the EU Commission’s report into maintaining a minimum quality of retrieved organs for transplantation, issues over organ trafficking. In terms of improving donor identification, improving the number of donors we identify in intensive care units and offer for donation, it seems to me that the biggest advantage from the EU is sharing experience from other Member States who seem to have got it right ahead of us. I would be lying if the organ donation taskforce were not heavily, heavily influenced by the work of Rafael Matesanz in Spain, the so-called “Spanish model.” I am not saying that we have taken the Spanish model off the shelf and just put it into a UK context—not at all—but we have been heavily influenced, not least because it shows what is possible if you put your mind to it.

Q270 Baroness Neuberger: I think you are right about that, incidentally. Speaking from a Jewish perspective, I think that is true.

Dr Murphy: I am sure there are pockets, again, of excellence, but is it on the curriculum of intensive care medicine? Of course not.

Chairman: You are saying that in the present state of people’s behaviour and their social understanding of this they are likely to respond to something they feel close to and therefore Europe and its use may be a little way off.

Dr Murphy: I think so.

Chairman: That is helpful.

Q274 Baroness Gale: I have an interest to declare, in that I am a patron of Kidney Wales Foundation. My question to you is on the Organ Donation Taskforce, of which you are a member. Could you explain how the changes proposed by the taskforce in their report that was published last month might help to ameliorate some of the problems we have discussed in response to previous questions?

Dr Murphy: The first thing I would say about the taskforce report—and maybe we were not clear enough about the philosophy behind it—is that it is about people. It is about focusing not on what doctors want to do, not on what nurses want to do, but recognising the right of a person to express a wish to donate in the event of their death—and that is what the Human Tissue Act is about, I think—and also recognising that most people who go on to donate, at the time leading up to their death are incompetent, and we have to therefore put in place the mechanisms to make sure that inquiry over donation is made in a systematic fashion. That is part of the Mental Capacity Act. That authorises and I think requires doctors to make that inquiry at the time of their patient’s death. The first thing to say is that it is about people, and I think that is a sea change in donation in the UK. The second thing to say is that there is nothing radically new in what we are recommending. All we are saying, I think, is that, where there is best practice, we would like that to be standard practice and we would like that to happen in every hospital and all of the time. These are the ways in which we think existing best practice can be delivered in every hospital and all of the time. We think—and I have alluded to it already—the hospital need to know what is happening, because, as I say, my chief executive and my medical directors do not know. You might be cynical and say, “They do not know because it is not part of a target and it is only targets that they listen to.” There is some truth in that, I think, but it has to be somehow performance managed. If it emerges that donors are being overlooked on this, then the best way to effect change is for those senior officers of the Trust to know about it, so we are recommending that the whole process of donor identification has to be performance managed. Some intensive care units do not see many donors.
A&E departments may miss donors. We recognise that there is a great need to support the clinical staff in this process, so we recognise the need for education and training, for identifying leaders, champions, clinical champions who will take on this role in their organisation and will be trained by us to do it. We also recognise that there are some other obstacles. We have alluded to some ethical legal problems that we must have resolved. There are issues from time to time with other agencies. The coroner from time to time will say no to a donation. The family have said yes, there is a suitable donor likely to donate five, six, seven organs and for some reason the coroner will say no or an investigating police officer will say no. It is the inconsistency in that regard that the clinical staff find so frustrating. The report, to me, is all about performance managing best practice into standard practice. It is nothing new.

**Chairman:** Dr Murphy, we are incredibly grateful. We are sorry we are going to move on but time is very short for us together. Thank you for helping us in this way. If there is anything else you want to let us have, do let us have it, but we have found your written evidence extremely helpful too.

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**Examination of Witness**

Witness: Ms Jayne Fisher, Chair, UK Transplant Co-ordinators’ Association (UKTCA), examined.

**Q275** **Chairman:** Ms Fisher, you have had the benefit of listening to the previous witness, which is helpful to us. We want to talk to you a bit about the role of transplant co-ordinators. We have had some descriptions of how that works here and how it works in other places. Would you begin by explaining how the role of a donor transplant co-ordinator is defined in the UK and how that role differs from those that you have seen in other EU countries where donation is significantly higher. What lessons can be learned from the transplant co-ordination models used elsewhere in the EU where they do achieve those better rates?

**Ms Fisher:** Perhaps I could first describe how the donor co-ordination service works in the UK at present. Historically, donor transplant co-ordinators have evolved from renal transplant units. This goes back to the early days of transplantation when really the only organs that were transplanted were kidneys. The donor co-ordinators are based in renal and often liver units. That means that we are based within usually a large teaching hospital and we cover a large region. Most donor transplant co-ordinator teams in the UK cover populations of between four to six million people, so geographically we can often be a long way away from the hospitals where potential donors are. At the moment, our role is multifaceted, in that some of us work in what we would describe as a dual role, so not only do we have responsibilities for potential organ donors but we have a responsibility for a recipient workload as well; that is, with the people who are waiting for a transplant of some form or another—although it has to be added that UK Transplant have addressed this over the last two to three years and that role is diminishing rapidly. I believe, personally, that it needs to be a completely separate role, so that either you are a procurement co-ordinator or a recipient co-ordinator. The donor co-ordinator in essence is the first point of contact for the ICU when they identify that donor. This one person will be on call, they will arrive at the hospital, if the family have not been spoken to at that point we will then speak to the family, discuss the option of donation, take a very detailed consent. We will do an assessment of the donor, looking at their medical background, their behaviour and their social history. We will then advise the intensive care unit on donor management; that is, as Dr Murphy alluded to, maintaining cardiovascular stability, to ensure that we can honour the wishes of that person and their family by retrieving as many organs as possible. We do all that, and then, within UK Transplant we start the allocation of the organs, set up a team of surgeons to come and retrieve the organs, accompany the donor to theatre and then deal with the last offices and the follow-up care with the family. That usually takes up to 24 hours. That is one individual doing all of that. As an association we would say that the present role is completely unsustainable for health reasons, Working Time Directives, and other relevant legislation therefore the role has to change. We always talk about Spain because Spain is the ideal that we all want to achieve, with those wonderful donation rates. In Spain, every intensive care unit has a transplant co-ordinator employed on it. UK Transplant have already looked at that option. Over the last two years we have seen the introduction of in-house co-ordinators. They have made a difference and the aim has been to get an in-house co-ordinator in every large neurosurgical unit within the UK. I think that has almost been achieved. In some areas they have had great success and in some areas it has taken a bit longer to see that success but I do believe that will happen. The other major difference with the Spanish model and the UK model, as we stand at the moment, is that the transplant co-ordinators in Spain are from a medical background. Personally, I think most donor transplant co-ordinators around the country would say, “I don’t believe that because that person is a medical professional makes any difference to the consent rates”. I do not believe every intensive care unit needs a donor co-ordinator but you do need somebody who has the knowledge and the
information to speak to that family and ensure that that family makes a truly informed consent. In the UK at the moment there are many families where that does not happen, where the families are not approached. A clinician makes a decision that this person is unsuitable for donation with no reference to a donor co-ordinator at all. Anecdotally, I have heard clinicians say to me, “The family was so upset, we couldn’t possibly have asked about donation.” The research has shown that asking that question does not make any difference to these families. They have already been told the worst outcome possible. The other thing I have found while completing the potential donor audit—and this has been reflected across the country with my colleagues—is that, although we have an organ donor register and, yes, we know that probably only 24% of the population are registered on that, we still go to intensive care units and we find people who could be potential donors who were registered on the organ donor register and still an approach has not been made.

Chairman: Lord Kirkwood, this has gone into your area.

Q276 Lord Kirkwood of Kirkhope: I am very interested in that very comprehensive answer, but remember we are lay people so we have to understand these things.
Ms Fisher: Sorry.

Q277 Lord Kirkwood of Kirkhope: You have made a very clear case, and it certainly came through in the taskforce report, that the 24-hour period after an event that could potentially lead to transplantation event occurring would involve a professional series of tasks that were really impossible to do because you are being asked to do things simultaneously, so one person can do this. I think you have just said that you believe that looking to the experience from Spain we are moving to a stage where every large neurosurgical unit would have someone who was able to do that. Does that mean that we are only getting to the stage where we are asking people to do the unsustainable work? If every large neurosurgical unit has an in-house co-ordinator are you saying that that means these in-house co-ordinators still have this unsustainable task?  
Ms Fisher: No,

Q278 Lord Kirkwood of Kirkhope: Could you disaggregate that for us and then I have a further question.
Ms Fisher: The in-house co-ordinator’s role will be somebody who is in the hospital every day, effectively working nine to five, so they will be on the hospital ward rounds, they will be identifying people who could potentially be donors. That person will have an on-call commitment, as it stands at the moment. The difference will be that they will call on the regional team and another transplant co-ordinator will come to the unit—so there will be two: one with the family and one doing all the management, so to speak, of the donor, and it is planned to have organ retrieval teams working around the UK and they will then come to that hospital at a certain point. Perhaps I could give you an example. You have the in-house co-ordinator and she is on duty until five o’clock. Her colleague, who is on call, comes to the hospital at one o’clock.

Q279 Lord Kirkwood of Kirkhope: That colleague will be called what?
Ms Fisher: That colleague would also be a donor transplant co-ordinator.

Q280 Lord Kirkwood of Kirkhope: They are all donor transplant co-ordinators.  
Ms Fisher: They are all going to be donor transplant co-ordinators, yes. There will be two people doing what one person is doing at the moment with the family and the donor management, and there will be then be a third separate person who will come and take that person to theatre for the organ retrieval.

Q281 Lord Kirkwood of Kirkhope: These could all be categorised as transplant donor co-ordinators.  
Ms Fisher: The first two categories will definitely be donor transplant co-ordinators. Whether the third person, who will be in the theatre, needs to be a donor transplant co-ordinator is being looked at and examined at the moment.

Q282 Lord Kirkwood of Kirkhope: To get to your Spanish ideal, where we understand that they do this better, how many extra staff personnel across the United Kingdom would you estimate you would require to get to that standard?  
Ms Fisher: I personally do not believe that in the UK there is need to have a transplant co-ordinator on every intensive care unit.

Q283 Lord Kirkwood of Kirkhope: I was hoping your answer would be a number.  
Ms Fisher: The taskforce have recommended that the present number of donor co-ordinators—at present we have about 100 in the UK—they are going to increase to 250.

Q284 Lord Kirkwood of Kirkhope: Is that enough?  
Ms Fisher: The taskforce have agreed that they will meet each year and the whole process has to be very widely audited. If at two and a half years past this point we have not seen an increase—we should see an increase within the first year, I do believe—that is the point we need to revisit it. I do not believe that having a co-ordinator on every intensive care unit will make that
difference because there are lots of hospitals that only see potentially two or three donors per year.

**Q285 Lord Kirkwood of Kirkhope:** If money was no object, how many would you need to do this gold-plated?

*Ms Fisher:* If money was no object, we should have a co-ordinator in every large teaching hospital and every large district general hospital who is looking at not only an intensive care unit potential but also the potential donors that are in the accident and emergency department.

**Q286 Lord Kirkwood of Kirkhope:** How many is that?

*Ms Fisher:* I do not know off the top of my head how many ICUs we have in the UK.

**Lord Kirkwood of Kirkhope:** For every ICU how many would it need, because we can find out how many ICUs there are.

**Q287 Lord Trefgarne:** There are about 1,000, are there not?

*Ms Fisher:* Yes, 1,000.

**Q288 Lord Kirkwood of Kirkhope:** So it would be a three figure number.

*Ms Fisher:* Yes.

**Q289 Chairman:** This may not be in Ms Fisher’s armoury of information. It may be information we want to achieve from whoever we see in the future because I think it is a very important question you have raised in terms of the resource allocation and the fact that we have heard from other witnesses that the British system is at the moment described as “chaotic” in terms of its management across. How we get from that chaos to what Lord Kirkwood is trying to get you to describe in numerical terms is something we need to pursue but we are probably pursuing you unfairly.

*Ms Fisher:* That is fine.

**Chairman:** Perhaps we could move on to Lord Trefgarne, who is going to ask you something you will know quite a bit about.

**Q290 Lord Trefgarne:** We have heard how many families are perhaps not even approached when it comes to the question of agreeing to a transplant and many families are not fully briefed and not fully informed and maybe make their decision in a situation of great distress and almost certainly not fully informed of the issues. What do the families express to you as an experienced practitioner in the area as their concerns when they are going to refuse to give consent or even for the reasons that they do give consent?

*Ms Fisher:* Families do give many different reasons for saying no to donation. My experience personally and talking to my colleagues is that one of the main concerns is a fear of mutilation. Again, this is why I would stress the need for experienced people to talk with families because somebody who has little knowledge of the process I believe could not give this information accurately. Often we will explore this with families and ask them: “You are concerned about mutilation, can you explain to us what you mean by that?” and they will describe that they do not want the body cut up and things like this. When we explain exactly what happens: “Yes, there will be one scar and that scar will be closed as per normal,” some families will change their minds. Other people give reasons of wanting the soul and the body to be intact, complete. Occasionally families do discuss concerns about potential recipients. A good example is somebody who may have been waiting for a liver transplant who has alcoholic liver disease. Some families may say they would go ahead and donate but they would not want to donate the liver. Mutilation is the big thing and, again, as we have already alluded to a lot of families from South Asian backgrounds particularly will say their religion forbids it.

**Q291 Lord Trefgarne:** I wanted to ask whether this reaction varied from different groups?

*Ms Fisher:* Yes, it does. Amongst the South Asian community, it is, “My religion does not allow this.”

**Chairman:** Lady Young, would you like to pursue this?

**Q292 Baroness Young of Hornsey:** That is an interesting point because one of the things we have heard is that we need to separate out religion from ethnicity in order to try to get to grips with this particular issue. I am interested that you say that because South Asia covers a huge range of different countries, different religions, different cultural traditions.

*Ms Fisher:* I know it was a rather sweeping statement.

**Q293 Baroness Young of Hornsey:** I know you have to speak in shorthand but, because it is such an important issue, we need quite a lot of clarity around it. I would also be interested in your view as to whether you think the socio-economic position of a particular grouping has an impact on their decision to donate or otherwise. For example, if we looked at white working-class in particular areas, would we find similar rates of refusal or similar issues coming up? The big question is how we address this for the future without stigmatising people. I am becoming concerned that if we float these statistics around, it makes it look like there are these BME people who want to take all the organs but they do not want to give any into the pool. I am sorry, that is a whole suite of difficult issues for you there.

*Ms Fisher:* I agree there is that danger. Can I address the socio-economic question first? This is a very interesting concept. I know UK Transplant were
looking at recording socio-economic class of donors. My experience has been that we always think, “Where do the donors come from? The middle-class white people?” My experience has been that that is not necessarily true and it is more likely to be the working-class families that say yes to donation. As far as the problems with donation from the ethnic communities, there have been lots of programmes, lots of initiatives, incentives. Nothing appears to have worked so far. I think we need to examine why. There is one particular group at the moment which has started a project with the Department of Health, the Policy Research Institute, on age and ethnicity. I know they have been asked to work with one of the sub-groups that have been formed following the taskforce. Their philosophy is to work with the community leaders within the communities and get right down to the grass roots. I think that is where we need to start. As I say, radio campaigns, television campaigns, newspaper campaigns, leaflet campaigns, nothing seems to make any difference. Talking to people from these communities and fellow healthcare professionals, they are aware and have said that there is this danger, as you say, of, “They’re taking all the organs but they are not prepared to donate.” I do not think it is as simple as that. We need to get together with these people and say, “Why do you not donate?” It is still not clear why they do not donate. The other thing we need to bear in mind is the fact that from the South Asian community it appears from the potential donor audit that there are not as many people from that community who get admitted to intensive care within the UK. It appears they may have different disease processes. Obviously we are aware of the fact that there is a higher incidence of kidney failure and diabetes within those communities but research was done five or six years ago—and I could give you the details—which said there is less likelihood of them going to ICU. Because of that, one can assume that there is less likelihood of them being identified and becoming a potential donor. Whether that equates to the A&E department and if we had a co-ordinator in every ICU we have in the UK is the fact that there are many potential donors in the accident and emergency department and if we had a co-ordinator in every ICU those potential donors would, I believe, be identified.

Q294 Lord Lea of Crondall: We have been talking in this question about family decisions, but I assume that if people find in my wallet a donor card then the family has nothing to do with it. The family cannot just say, “Oh, no, I am not having that” or can they?

Ms Fisher: They can.

Q295 Lord Lea of Crondall: I thought that when I carried a card, that meant that was my decision.

Ms Fisher: No. The present legislation says that if you have recorded a wish pre-mortem, before you have died, that you would like to be considered to be an organ donor, your wishes should be adhered to. It says “should” in the HTA. The donor co-ordinator would come and speak to your family, they would say that your wish was that you wanted to be an organ donor and, in practice, I would say that 97 or 98% of families would agree. But there are occasions when somebody can be registered on the organ donor register and the family can override that wish.

Q296 Baroness Morgan of Huyton: Could we move on to the question of the EU Directive and what it may say about organ quality and safety. What is the balance of benefits of the imposition of high standards of quality and safety against the possible reduction that might occur in the supply of organs. Even before that, in a sense, how relevant do you think the Directive would be in the provision of organs?

Ms Fisher: At the present moment within the UK there are very few organs that are going across borders. UK Transplant would give you the absolute numbers but I would say we are talking of probably 20 a year—so minimal numbers. The reason for that a lot of the time is solely because the clock has started ticking—once the organ is retrieved you only have a certain period of time in which to transport it to another centre. Obviously the most important thing throughout all of this is that we maintain safety of the organ. If we are going to have a Directive then everybody has to work with that Directive to ensure that there is no transmission of disease, parasitic disease, malignancy and all that sort of thing. The danger is that if the legislation is too strict then we will start to lose more marginal donors. By marginal donors I mean people who may have had some disease processes—they may have positive hepatitis; they may have had previous cancers and things like this—and if we start to restrict too much, they, without doubt, will fall by the wayside. As we know, the shortage of donors is not just a UK problem; it is throughout the European community, so I think we need to be very careful. Also, it is important from the other side, as far as the potential recipient goes. Although it will always be the person who implants that organ who takes the final decision over the safety of transplanting that organ, there is always the risk versus benefit. If you have somebody who has less than 24 hours to live, you would take that risk with that organ. I do not believe the Directive will have a major impact in the UK because of the small numbers we are talking about and because we are an island we are never going to change that, are we?

Q297 Chairman: If the UK followed Spanish practice, which seems to have the highest outcome, without any other involvement of the European
Union, might we still achieve what we are trying to get to? What added value would the EU bring?

Ms Fisher: I am not sure. The EU I know have looked at projects of increasing donation within Europe and I think any practice that we can adopt and introduce within the UK that could increase donor numbers and help this problem has to be applauded and welcomed really. As we have all talked about this morning, if the taskforce recommendations are introduced within the UK that will make a tremendous difference to our problem and it should hopefully identify the required number of donors. In the United States they achieved a massive increase in donation rates with legislation. Whether at some point we may need legislation within the UK, I am not sure.

Q298 Chairman: Legislation saying what?

Ms Fisher: Legislation saying that every potential organ donor had to be referred to an organ procurement organisation—in this case, what would be UK Transplant. My personal experience at the moment has been that I can speak to a clinician and say, this gentleman was registered on the organ donor register, he could have been a potential donor, can I just ask why you did not approach his family?” and be told, “We didn’t think he was suitable” or “His family were very upset” and that is as far as it goes. Nobody has to be answerable for that lack of referral. One of my donor families said to me once, “I want my son to be normal, not abnormal. People think of him almost as a freak because he was an organ donor and he helped all these people.” I think the message from that is that organ donation should be normal, standard practice within the UK, within every ICU, and should be recognised as such, and, as Dr Murphy has already said, by informing chief executives and saying to chief executives, “Your Trust is failing at this standard.” Every Trust within the UK has somebody who is on a waiting list of some sort or another, so it is everybody’s business really.

Chairman: Thank you very much indeed. We are very grateful to both of you for giving us that advice. If there is anything else you think we have not covered, please do drop us a note.

Supplementary memorandum by Dr Paul Murphy

1. Provision of ICU facilities in the UK compared with our European neighbours and correlation with organ donation

1.1 It is commonly held, particularly amongst transplant surgeons, that the poor UK performance on organ donation can be attributed to a relative lack of critical care capacity, at least in part. This proposition would seem to imply that lack of ICU beds results in patients who die in the wrong place and in the wrong way, and in so doing lose their potential to donate their organs after death.

1.2 I am not sure that the evidence for this argument is particularly persuasive. Thus, whilst it is true that the UK has fewer critical care beds than many of our European neighbours, there appears to be no correlation between ICU beds (as % of total acute hospital bed capacity) and donation rates, as shown in the table below:

<table>
<thead>
<tr>
<th>Country</th>
<th>ICU Beds / 100 acute beds</th>
<th>donors per million population</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>2.6</td>
<td>12.8</td>
</tr>
<tr>
<td>Austria</td>
<td>2.8</td>
<td>24.8</td>
</tr>
<tr>
<td>France</td>
<td>3.0</td>
<td>22.2</td>
</tr>
<tr>
<td>Spain</td>
<td>3.2</td>
<td>35.1</td>
</tr>
<tr>
<td>Germany</td>
<td>3.3</td>
<td>14.8</td>
</tr>
<tr>
<td>Holland</td>
<td>3.5</td>
<td>14.6</td>
</tr>
<tr>
<td>Belgium</td>
<td>3.7</td>
<td>23.8</td>
</tr>
<tr>
<td>Denmark</td>
<td>4.1</td>
<td>11.9</td>
</tr>
</tbody>
</table>

1.3 Thus whilst Austria, France and Spain all identify many more donors with only a modest increase in ICU beds, Denmark has many more beds but performs even worse than the UK in the identification of deceased donors.

1.4 In addition, the Potential Donor Audit indicates that there is a large cohort of patients who die on ICU—literally hundreds each year—who could have been donors had brainstem death tests been performed or donation systematically considered.
1.5 This is not to say that there will not be occasions when patients lose their potential to donate because a decision is made not to admit to ICU on the grounds that it would be futile to do so, and therefore contrary to the best interests of the patient. The clearest example I know of is the circumstance of a patient with a catastrophic brain haemorrhage in an Emergency Department—it can be clear even at this early stage that admission to ICU would offer no prospect for recovery, and I suspect that even though to admit to ICU would at the very least preserve the potential to donate, increasingly this does not happen—rather, patients die in the Emergency Department or in a ward side room, and are thereby denied their opportunity to donate. I stress that such management is driven more by beliefs around best interests and futility that an absolute shortage of critical care facilities.

2. The Potential Donor Audit (PDA)

2.1 From the outset we need to understand the limitations of the PDA—it is a retrospective and incomplete audit conducted by donor transplant co-ordinators (agents who perhaps have an interest in the outcome of the audit). Nevertheless, it offers a powerful insight into deceased donation in the UK.

2.2 The committee is obviously aware of the headline findings of the PDA, perhaps the most contentious of which is the suggestion that there may be in excess of 500 patients each year who were likely to have been brainstem dead, but who were not tested and who were thereby effectively denied the potential to donate. I have recently conducted a subanalysis of this group of patients to try to understand why brainstem death tests were not performed, finding the following:

<table>
<thead>
<tr>
<th>Reason for not testing</th>
<th>% incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>cardiovascular instability</td>
<td>30</td>
</tr>
<tr>
<td>unknown</td>
<td>28</td>
</tr>
<tr>
<td>residual neurological function (ie not brain dead)</td>
<td>15</td>
</tr>
<tr>
<td>family refusal (for donation)</td>
<td>11</td>
</tr>
<tr>
<td>inability to perform brainstem death tests</td>
<td>8</td>
</tr>
<tr>
<td>medical contra-indications to donation</td>
<td>6</td>
</tr>
<tr>
<td>others</td>
<td>2</td>
</tr>
</tbody>
</table>

2.3 Cardiovascular instability is common in brainstem death, but is usually easily correctable, implying that some clinicians are reluctant to take such measures (because they recognise that this will not prevent the patient’s death) even though the potential to donate will be lost.

2.4 In my opinion this is a large cohort of patients in whom, were management to be different, a substantial number of additional heart beating donors could be identified.

2.5 There is another group of patients in whom donation is not considered even though brainstem death has been confirmed. There are approximately 200 such patients annually. My analysis indicates that, when known, reasons for not pursuing the option of donation include (apparent) medical contra-indication, prior knowledge that the family will refuse to give consent, and obstruction by the Coronial service or CID.

2.6 Non heart beating organ donation (NHBOD) should be considered separately—it is a form of donation that is under development and is currently only supported by a minority of intensive care units—perhaps as few as 20% of the total nationwide (as suggested by recent data from the Potential Donor Audit where NHBOD was considered in only 632 deaths from a total of 1,835 suitable cases). The committee should recognise that many ICUs are actively resistant to the introduction of NHBOD—certainly in the absence of a binding and authoritative statement on the ethico-legal probity of the process.

2.7 NHBOD refers to the retrieval of organs from patients who suffer a cardiac death following the withdrawal of treatment that has been judged to be futile, and necessarily requires the potential to donate to be considered before death has occurred. Current ethico-legal objections to NHBOD include:

2.7.1 The potential for conflict of interest between decision making over futility and the potential to subsequently donate, and the personal liability that clinicians might thereby be exposed to.

2.7.2 The potential unlawfulness of delaying the withdrawal of treatments that have been adjudged futile in order to allow time for a surgical retrieval team to assemble on the donor hospital site, since such a delay is seen to be in the interests of a third party (ie an organ recipient) rather than the dying patient.

2.7.3 The current lack of a robust definition of cardiac death in the UK.
2.8 I would advise the Committee that NHBOD is work in progress, and that although the numbers of non heart beating donors in the UK is increasing, the big gains are to be found in systematically applying best practice to the identification and management of brainstem dead donors. It is perhaps of interest to note that NHBOD from ICU is practically non existent in Spain, and elsewhere in the world is a form of donation introduced because of poorly performing heart beating programs.

3. **What do ICU staff perceive as the main obstacles to donation?**

3.1 Many UK ICUs will have only one to two deceased donors per year, whereas units such as mine might see as many as 20. As a result, I am not sure whether there is any single one answer that captures the views of a profession whose exposure to and focus on deceased donation varies some much—indeed, many ICU will not register it as a problem at all, because it is not viewed as core business of the unit at all. In contrast, others feel profoundly irritated that they are perceived in failing to identify sufficient donors (an necessary element of which is, of course, the death of their patients), and there is a healthy degree of suspicion of the transplantation agenda in general and UK Transplant in particular.

3.2 For those who take a more balanced overview, I suspect that the following views might appear:

   3.2.1 High relative refusal rate.

   3.2.2 On-going ethico-legal obstacles that focus on the degree to which “best interests” justifies the alteration of the way in which a patient dies in order to pursue donation after death.

   3.2.3 Lack of resource to treat the living, never mind the dead—the management of a potential organ donor is labour intensive, particularly of a consultant’s time, and almost always extends well beyond the end of the working day.

3.3 It is not at all clear who ICU staff will react to a system of presumed consent for organ donation. Neither the Intensive Care Society, nor the Royal College of Anaesthetists have a formulated view, and although the BMA are heavily supportive of it, the Royal College of Nursing (who represent thousands of ICU nurses) are heavily critical, describing it as “no consent at all”.

3.3.1 At an individual level there will be a spectrum of opinion, underpinned I suspect by a belief that presumed consent is a pragmatic attempt to increase donation rates rather than a principled approach to more closely approximate the desires of individual to donate (or not) with the eventual outcome. I suspect that the majority of professional reactions to the introduction of presumed consent will be negative.

3.3.2 The evidence that presumed consent in its proposed form (ie a soft opt-out) will increase donation rates is at best equivocal. In this system, families retain the right to veto (although this will very much depend upon the approach of both the requestor and potential donor family). In particular, I do not expect a soft opt out to have any beneficial effect upon donation rates from ethnic minority groups, not least because it is the tension between the authority of caring clinicians versus that of the patient’s family that is so central to the difficulty that BMEs face in interacting with the donation agenda.

3.3.3 Whilst I am aware of the support being given to presumed consent from groups that are either neutral (such as the BMA) or those that represent the interests of transplantation (be them professional such as the British Transplantation Society, or patient-focused such as the National Kidney Federation), I would humbly suggest that presumed consent is a pragmatic construct that offers at best a very limited and partial solution to a problem that is rather more reaching. Thus:

   — if consent rates in the UK rose from their current level of 60% to those achieved in Spain (85%), the donation rates in the UK would only rise to 18 donors per million population (compared to 35 donors pmp in Spain).

   — Spain had a system of presumed consent for some years before any increase in donation rates. The success of the Spanish model is down to systematic performance management of donor identification.

   — the USA has achieved an impressive increase in donor numbers at the same time as rejecting any legislative move towards presumed consent.

   — Northern Italy has successfully adopted the Spanish model of donor identification and organ procurement in all respects but one—namely, presumed consent. Nevertheless, the overnight increases in donor numbers have been truly breath-taking.
4. To what extent have you benefited from activity at the EU level?

4.1 Whilst I recognise the broader responsibilities of the EU towards issues such as the illegal trafficking of organs and measures to ensure the safety of organs, my principal works lies in the identification and procurement of organs. In this regard, it seems to me that the role of the EU lies in the nurturing, identifying and sharing of best practice. I think that it is also the case that the different legislative frameworks that underpin organ donation in various member states represent a significant obstacle to any uniformity in donor identification, and in any event, all my instincts tell me that donation in the UK is a very personal, local thing, a matter of local pride.

4.2 I work on donor identification / organ procurement side of things, and in any event as an island nation with low rates of organ sharing between the UK and mainland Europe have little experience of the operational benefits of organ sharing, organ safety initiatives etc.

4.3 In terms donor identification and organ procurement by far the greatest benefit to the UK has been the examples set elsewhere in Europe, and the demonstrations that deceased donation rates can be increased in a sustainable fashion. The lessons to be learnt have come, of course, principally from Spain, and indeed the Organ Donation Task Force was honoured to received evidence and advice from Dr Rafael Matesanz, the architect of the Spanish model. It is fair to say that the experiences from Spain have heavily influenced the report of the Organ Donation Task Force and the recommendations therein.

5. What are the reasons for the low donation rates amongst ethnic minority groups?

5.1 As outlined in my written evidence, my perception is that failure to engage minority ethnic groups in organ donation is but a single aspect of how clinical staff struggle to interact with the families of critical ill patients from these groups. A specific point of tension is generated over disputes over authority when a patient becomes mentally incompetent, this tension becoming maximal when issues over futility, the withdrawal of care or the significance of brain death become relevant. Very often then, perhaps almost inevitably, organ donation is discussed against a background of an unsatisfactory pre-existing relationship with the family of the potential donor, and very often a lack of respect, understanding and trust. It is clear to me that the national endorsements by all the relevant faith groups of organ donation after death have had little influence on how individual families respond to such requests, and there is anecdotal evidence that local faith leaders do not necessarily support or implement the policies of their national councils.

5.2 There is some evidence that patients from BME groups are not treated in the same way as other potential organ donors—my analysis of the PDA suggests that ethnic minority patients are slightly less likely to have brainstem death tests performed, less likely to have donation considered if they are brainstem dead, and less likely to have the option of donation discussed with their next of kin. This I think reflects the unease that many ICU staff have when working with families from BME groups, and perhaps is also an indication that ICU staff do not have as good an understanding of how different cultures and groups view death and manage its immediate aftermath.

5.3 I have no magic solution for this problem—indeed, I think that this is the most difficult problem facing organ procurement in the UK. I do however believe that the solution to the problem has to be generated, if only in part, from within those groups—until this time it will remain as one of my colleagues puts it “white man’s medicine”. It may be that in some areas of particularly high density of BME populations we should consider how well the ethnic distribution of our clinical staff reflects that of the local population. On a broader setting, we should be doing everything that we can to engage the support of high profile and influential BME individuals (politicians, sports people, celebrities etc) to champion the cause of donation. I also believe that there is a role to play from transplant recipients from BME groups to champion the cause locally.

6. How will the recommendations of the Organ donation Taskforce ameliorate some of these issues?

6.1 At its very heart, the report of the ODTF seeks to consolidate the principles of the Human Tissue Act and the Mental Capacity Act, by recognizing the right of patients to donate their organs after their death if that is their wish and by empowering hospital staff to pursue that option on behalf of their incompetent patient whenever it is clinically possible. In this way, we believe that donation after death should become a routine consideration in the event of any death.
6.2 I think that it is important to recognise that the Task Force report is not recommending anything that is radically new. Fundamentally, the recommendation of the ODTF is that “best practice” regarding donor identification and organ procurement should become “standard practice”—everywhere and all the time. To achieve this goal we need to:

— engage Trusts through better data collection and performance management—currently Trust senior managers have no idea what is going on in terms of organ donation in their hospitals,
— engage clinicians through the appointment of “Donor Champions” and the commissioning of better education and training for them, and
— improve the interaction between ICUs and donor transplant co-ordinators by increasing the number of DTCs and emphasising their role as a member of the critical care team—specializing in bereavement issues—rather than being seen as external agents of organ procurement.

6.3 The Task Force has identified a number of potential obstacles that threaten the success of these recommendations:

— it is absolutely vital that we resolve the outstanding / apparent ethico-legal obstacles to donation;
— we have defined very clearly for clinical staff the circumstances in which we expect potential donors should be referred to the local retrieval service, making it clear that is they who should make the judgement over suitability for donation rather than the ICU team;
— we are moving towards payment by results for critical care medicine, and if this is the case then we should ensure that Trusts are adequately reimbursed for the expenses related to the identification of potential organ donors; and
— it will be apparent that by their very nature, the deaths of some potential donors will be subject to some form of Coronial enquiry, and sometimes even criminal investigation. Although it does not happen that often, it is particularly distressing for both ICU and the family of a potential donor for a Coroner or a police officer to veto organ retrieval. In the United States there is now a zero tolerance towards refusal for donation from the medical examiner, and I think that there is a pressing need for the Department of Justice to review the role of the Coroner in Organ donation here.

6.4 Engagement with the general public is clearly vital, and the Task Force has recommended that:

— we both personally and publicly recognise organ donors in some form of national memorial; and
— we urgently explore the most effective means of increasing public awareness of organ donation and the gift of life, particularly in the BME population.

29 February 2008

COMPREHENSIVE POTENTIAL DONOR IDENTIFICATION

Confidence that all potential deceased donors are being identified everywhere and all the times is central to all successful organ procurement programs. It is equally important that the identification of potential donors occurs early enough for this to furnish the best opportunity for a good donation (ie a donation that is directed by patient autonomy, that is accepted by the family, that is congruent with a nationally endorsed ethico-legal framework and that offers the maximum number of organs in the best possible condition) to take place. Experience from the UK, but also particularly from countries that have already made substantial improvements to their deceased donation rates, suggests that earlier and closer liaison with the teams that currently provide the interface between donation and transplantation can considerably improve deceased donation rates, particularly in circumstances where the attending clinicians might have limited experience in and exposure to patients who might wish to donate after their death.

The two models of deceased donation that are most widely presented as examples of best practice are those that have been developed in Spain and the United States. Both rely heavily upon comprehensive identification of all potential donors, although in somewhat different ways. Thus, whilst the American model is based mandatory referral of patients with catastrophic neurological injury based upon a set of agreed clinical parameters (eg GCS ≤ 5) to a local Organ Procurement Agency, the Spanish approach is to embed into hospitals with a high donation potential teams of co-ordinators who are continually monitoring the donation potential of patients on ICU. Despite these differences, the consequences of identifying a patient who has a high likelihood of death from a neurological condition are rather similar, in that it results in the introduction another influence on the management of the dying patient, viz. a team that is there to support the patient and his/her family in the event that death occurs to achieve the best possible death, that includes donation should this be appropriate.
The current UK donation rate is 12.9 deceased donors per million population per year compared with 22.6 in the United States and 33.8 in Spain. Even were the UK conversion rate 100% (it is currently approximately 45%), the apparent maximum achievable rate of donation in the UK would still fall someway short of those repeatedly reported in Spain. The inevitable conclusion is that whilst there might be significant differences in how potential donations are managed once they have been identified (particularly family consent rates—barely 60% in the UK compared with 85% in Spain), there seems to be fewer identified potential donors in the UK to start with. Whilst it seems likely that this can be explained in part by differences in how patients with unsurvivable brain injury are managed—for instance, withdrawal of ventilatory support is very uncommon in Spain—it would be irresponsible to fail to consider whether significant numbers of potential donors are being missed in the UK.

The Potential Donor Audit (PDA) offers some insight into the current effectiveness of donor identification in the UK, although it is recognised that any conclusions that are reached are tempered by the inevitably limited quality of the data that is sometimes available for those completing this retrospective analysis of patients who die in ICUs in the UK. There are three principle stages within the database structure in which missed potential donors might reside:

— Patients in whom brainstem death was a likely diagnosis, but tests were not performed.
— Patients with confirmed brainstem death, donation was not considered.
— Patients with confirmed brainstem death, donation was considered but the family not approached.

Initial perusal of the data from these three groups suggests that the reasons for not pursuing a clinical course that would maintain the possibility of donation could be grouped under the headings of:

— contra-indications to donation;
— family-related issues, including problems with identifying next of kin;
— cardiovascular instability, be it related to the primary cause of death or that frequently associated with brainstem death;
— problems with the performance of brainstem death tests, including residual neurology;
— actual or anticipated objections from law enforcement agencies, the coroner or the procurator fiscal; and
— not known, ie despite a thorough examination of the available material and follow up with the clinical staff involved, no clear explanation for failure to follow a clinical path that preserved the possibility of donation after death could be defined.

Brainstem death a likely diagnosis, but tests not performed

The PDA indicates that around 650 patients fall into this category each year, the commonest causes of death being neurological catastrophes, trauma and primary cardiac problems (usually cardiac arrest). The most frequent reason for not performing brainstem death tests was cardiovascular instability, both for the
increasing the supply of donor organs within the European Union: evidence

Brainstem death a likely diagnosis, patients not tested (all patients)

<table>
<thead>
<tr>
<th>Reason</th>
<th>% Total</th>
</tr>
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<tbody>
<tr>
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</tr>
<tr>
<td>Coroner</td>
<td>0.7</td>
</tr>
<tr>
<td>Contra-indication to donation (including age)</td>
<td>6.1</td>
</tr>
<tr>
<td>Problems with testing</td>
<td>8.4</td>
</tr>
<tr>
<td>Family-related</td>
<td>11</td>
</tr>
<tr>
<td>Residual neurological function</td>
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</tr>
<tr>
<td>Unknown</td>
<td>28.1</td>
</tr>
<tr>
<td>Cardiovascular instability</td>
<td>30.4</td>
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</tbody>
</table>

Brainstem death a likely diagnosis, patients not tested (all patients)

group as a whole and also for the subgroup of patients dying from a primary neurological catastrophe (the most common of which was spontaneous intracranial haemorrhage). However, inability to identify why tests were not performed was almost equally as common, while it was also clear that some clinicians would not perform brainstem death tests if they thought that donation would not take place, be it because of known family wishes, a perceived medical contra-indication to donation or (less commonly) the possibility of objection from the police or coronial services. Technical problems in performing brainstem death tests were more common in patients dying from trauma, this being largely attributable to issues surrounding residual sedation. 15% of patients had documented evidence of residual neurological activity that was incompatible with a diagnosis of brainstem death.
Diagnosed brainstem death, donation not considered

On around 140 occasions each year brainstem death is confirmed but donation is not considered, the commonest reason appearing to be a belief that it was medically contra-indicated. (It is not clear from the data how often these decisions were made without any discussion with the donor transplant co-ordinators and the surgical retrieval teams). It was frequently impossible to identify any plausible reason why donation had not been considered, although once again, pre-existing knowledge of a likely objection from the family seemed to influence decision making, as did an anticipated objection from the police or coronial service.

Diagnosed brainstem death, donation considered but family not approached

This is a small group of patients, amounting to around 70 cases each year. Prominent reasons for not approaching the family include medical contra-indications to donation and anticipated problems with the police or coroner / procurator fiscal, and again prior knowledge of a family’s wish not to pursue donation also featured strongly.

Potential for expansion of the deceased donor pool

This analysis has attempted to enquire as to why the apparent donation potential of patients dying on ICU has been lost by examining existing PDA at three key stages of the deceased donation pathway, viz:

— when brainstem death was considered likely but not diagnosed,
— when brainstem death was diagnosed but donation not considered, or
increasing the supply of donor organs within the European Union: evidence

when brainstem death was diagnosed and donation considered but the family not approached for their consent.

Common to all three groups, and particularly the first two, was sufficient uncertainty in the data to require a return of “unknown”, indicating the current limitations of the data and areas where the PDA (or the mode of data collection for it) might be revised. Although the first group of patients (i.e. those with a likely

<table>
<thead>
<tr>
<th>Unknown reasons for loss of donation potential;</th>
<th>n</th>
<th>Refusal rate (%)</th>
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</thead>
<tbody>
<tr>
<td>? BSD, not tested</td>
<td>650</td>
<td>28.1</td>
</tr>
<tr>
<td>BSD, not considered</td>
<td>140</td>
<td>37.2</td>
</tr>
<tr>
<td>BSD, considered, family not approached</td>
<td>75</td>
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<tr>
<td>BSD, family approached, consent refused</td>
<td>2,467</td>
<td>n/a</td>
</tr>
</tbody>
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diagnosis of brainstem death who were never tested) is quantitatively the largest (at approximately 650 patients per year), the other two smaller groups have the advantage of brainstem death actually having been diagnosed. An accurate figure for the true incidence of diagnosable brainstem death in the first group remains elusive, although it seems unlikely that it is much more than half. Nevertheless, it is also true to say that within all of these three groups there were brainstem dead patients who could have gone on to donate had the actions and decisions of those involved in their care (including clinical staff, family members and members of the police and coronial services) been different. It is similarly beyond doubt that a significant number of those who were not brainstem dead could have been given the option of donation after cardiac death. Furthermore, where a reason for a patient’s donation potential being lost could be identified, the key issues that do emerge are family refusal, cardiovascular instability, medical contra-indications to donation and the on-going conflicts between the interests of the deceased donor and the necessary legal enquiries that need in some circumstances.

Family refusal is a major obstacle to donation after death in the UK. Although the published PDA data indicates a family refusal rate of 40%, this figure relates only to the stage at which brainstem death has been diagnosed and a formal request made. This analysis suggests the true impact of family objection to donation is somewhat higher, with a figure closer to 45% emerging if the “occult” refusals from these three earlier stages are taken into account.

Both the Spanish and American donation initiatives have invested heavily in approaching potential donor families in a timely, consistent and professional fashion. There is clear evidence from both these programs and elsewhere that an early approach that is made by a trained interviewer, with a re-approach should the initial request be turned down, is more likely to help a donor family to accept donation than the approach currently used in the UK. A recommendation that all patients in whom brainstem death tests are to be performed should be referred to the donor transplant coordinators regardless of whether the donor family have already expressed an objection to donation is likely to be problematic for some intensivists, although will be necessary if the intention is to only accept a refusal once a formal approach has been made by a designated and trained requestor.

Cardiovascular instability is a common reported reason for failing to perform brainstem death tests, and even where brainstem death has been diagnosed will jeopardise the viability of potentially procurable organs. Whilst sometimes it is a reflection of primary cardiac pathology or catastrophic trauma, there are also occasions where it appears to be the cardiovascular collapse associated with brainstem death and the autonomic storm that accompanies it. Whilst
increasing the supply of donor organs within the European Union: evidence

Cardiovascular instability as a cause of loss of donation potential:

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<tr>
<th>Group</th>
<th>n</th>
<th>Refusal rate (%)</th>
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</thead>
<tbody>
<tr>
<td>? BSD, not tested</td>
<td>650</td>
<td>30.4</td>
</tr>
<tr>
<td>BSD, not considered</td>
<td>140</td>
<td>1.4</td>
</tr>
<tr>
<td>BSD, considered, family not approached</td>
<td>75</td>
<td>1.1</td>
</tr>
<tr>
<td>BSD, family approached, consent refused</td>
<td>2,467</td>
<td>n/a</td>
</tr>
</tbody>
</table>

occasionally this can be very difficult to treat, it is usually easily reversed with a combination of invasive monitoring, inotropic support, fluid therapy and PEEP. Nevertheless, it seems possible that some intensivists regard such interventions as ethically or legally unacceptable in the setting of a patient with catastrophic brain injury whose death seems inevitable.

Medical contra-indication to donation is identified as a reason not to perform brainstem death tests, not to consider donation and not to approach a family. It

Medical contra-indication as a cause of loss of donation potential:

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<td>n/a</td>
</tr>
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</table>

is not clear how often these decisions are made independently by the ICU team rather than after discussion with the donor transplant co-ordinators—for instance, intravenous drug addiction was frequently cited as a contra-indication. Since there are few absolute contra-indications to donation after death, and more and more marginal donors are being considered, it would seem prudent to recommend that all potential donors should be discussed with the donor co-ordinators, regardless of age, life-style and co-morbidities.

Although relatively minor in absolute terms, real or potential objections to donation from the police, the coroner or the procurator fiscal are frustrating in as much as they appear to be a completely unnecessary obstacle to donation and frequently emerge in the setting of a family who are completely committed to donation. Understandably, these objections feature most prominently as a reason why a family might not be approached, although very often may only emerge after consent for donation has been obtained.

Conclusions

By its very nature, the potential donor audit can only give an indirect insight into the identification and management of potential deceased donors on UK ICUs. It is however reasonable to conclude that there is a variation in the end of life management of patients with severe brain injury, and that this limits the number of potential donors who are thereby identified. To extend what might be considered best practice into standard practice will require a closer and earlier collaboration between ICU staff and those who in some circumstances will have greater expertise in the identification and management of potential donors and their families, a collaboration that is driven on the one hand by performance management and proper funding, and the other hand by significant and sustained education and training for those involved in the care of potential deceased donors. This collaboration will be based primarily upon a closer operational working relationship between donor co-ordinators and ICU staff, but underwritten by a triggered referral system that is able to ensure that notification is made early enough to allow real changes in practice to be achieved. Specific areas that might benefit from a more timely and collaborative approach would include:

— the management of the cardiovascular instability of brainstem death,
increasing the supply of donor organs within the European Union: evidence

— guidance with brainstem death testing in difficult circumstances,
— the identification of marginal donors who might otherwise be overlooked, and
— a more supportive yet rigorous approach to seeking consent from a patient’s family.
— Real time collection of PDA data to improve data quality and eradicate “unknowns”.

Whilst early discussions with the coronial service etc may reduce the number of legal objections to donation, any significant resolution of these continuing and frustrating problems with the police and the coronial service will require a different approach.

July 2007
Chairman: Good morning, Dr Matesanz. We are very grateful indeed to you for coming all this way. I need to apologise that the Committee, many of whom were really looking forward to your visit and to meeting with you, were actually unable to be here this morning because we have a debate on women’s issues in the House today and it runs into this, and it is one of our major starred debates. But people did ask me to say that they were very grateful to you for coming, as a whole; so thank you very much indeed. I have to do the housekeeping; it is very boring but I have to say a number of things to you, apart from saying welcome and we hope you had a good journey. We have to tell you that the session is open to the public but, as you can see, we have masses of public! Do not be deterred by that, however, because it will be recorded and can be used for future broadcasting or webcasting. As you know, a verbatim transcript is taken of the evidence. This is put on the public record in printed form and on the Parliamentary website, so it will be there on the website. A few days after the session the office will send you a copy and we would like you to check that, if you would, for accuracy, and to tell us if there are any corrections. We do turn this around rather rapidly so I apologise for asking you to do it as rapidly as you possibly can. If at the end you think that we have not covered anything or if when you get away you think that there are other things we should know, please let us have any supplementary evidence. You are an extraordinarily important witness to us and we want to know anything you think that we should know, apart from the things that we have managed to gather. This room, although it looks as if we have amplification, is not good. If you could project your voice rather as I have. We also need you to start, again for the record, to state your name and official title, and then when you have done that I will go on to where we are going to take the questions.

Dr Matesanz: Thank you, my Lord Chairman. My name is Rafael Matesanz; I am a medical nephrologist; I am the Director of the Spanish National Transplant Organisation, which is the official agency in Spain in charge of donations and transplantations of organs, tissues and cells.

Chairman: Thank you very much indeed. You have seen the questions and you know that the Committee might ask you others apart from those that you have had in advance. If you wish to you could make an introductory statement, but you may think that the introductory questions cover quite a lot of the issues. But it is over to you; if you want to begin by making a statement to the Committee?

Dr Matesanz: A short introduction, just to explain that we started in Spain with what has been called the “Spanish Model” in 1989. We started because the situation in the Spain was not really satisfactory—the organ donation was 14 donors per million population and there has been a decrease in organ donation during the recent years, during the late 1980s because of a medical strike. So we started this model, we created the Spanish National Transplant Organisation, the ONT, and it started with a model which in fact is a management system for organ donation. We can discuss during the next few minutes how it is managed but practically I can say that the ONT was the first agency in Europe which was entirely dependent of the Ministry of Health—because until then all of the organisations in Europe—I mean France-Transplant or Eurotransplant—were non-governmental organisations—which is a not for profit organisation, which was mainly in charge of sharing organs. But what we did is to put the essential efforts of the Spanish government in organ donation because we realised that if we have no donors, if we have no organs there is nothing to share. So we put all our efforts in this point and we established, let us say, an official system with national coordination—I mean the ONT—, a regional coordination, because you know that at this moment Spain is a very decentralised country—, and then the hospital coordinator, which is quite different from the hospital coordinator from other European countries. So I can say that the main figure of the system is the hospital coordinator, which is a medical doctor that makes a big difference with what is happening in Central Europe, the UK and in the USA and in many other countries. We looked for, let us say, a clinical champion, a medical doctor with clinical authority inside the hospital, just to look for the potential donor and just to have an
exchange of ideas and an interface with people in the intensive care units or with transplant teams or with many other actors that are involved in organ donation and transplantation. These doctors are working part-time and that also makes a big difference with other coordinators who are working full-time; and we decided it this way because we think that this job is very complicated and it is very difficult to have the same person for many years approaching the families, and after the family has lost the father, the mother or the children, approaching the families is really a very disappointing job. So we realised that after two, three or several years this professional became “burned out” and you had to change this professional. Otherwise what is happening in many countries can happen: that the person who many years ago was the solution has become the problem. So this is the main point of the Spanish Model—because there are some other points that we can discuss later—this is the cornerstone of the Spanish Model.

**Q301 Chairman:** That is very helpful and you have described how a typical hospital might be. If I can take you into evidence that we heard in our last session, where we had a coordinator and a doctor talking to us about how it worked. It was clear that not only the coordinator and the champion were important, but the people who were prepared to identify within their units were important, otherwise nothing happened. How have you managed to make that work in Spain?

**Dr Matesanz:** Since the very beginning of this system we dedicated a great effort to the training of medical professionals and also of the nurses. You should realise that we started only in 1991 and every year we train about 300 or 400 people in all aspects of organ donation—potential donor identification, maintenance of the donor, how to approach the family, how to distribute the organs.

**Q302 Chairman:** So this is multi-disciplinary.

**Dr Matesanz:** Yes, really multi-disciplinary, and we dedicated a great deal of effort and most of the budget of the ONT is to medical training and to train nurses and all kind of professionals. We started in the 1990s and at this moment all our coordination network is formed by 200 doctors and 150 nurses. So you should realise that we have trained no less than 4,000 or 5,000 people. This means that we have a lot of people who are really helping the whole process in the whole of the hospitals. It is not just the coordinator; there are all the intensivists who are working in the intensive care units, who are being trained in the whole process. For instance, tomorrow I have a training course in Madrid with 40 new doctors who will work in the intensive care unit during the future, and we train every year more than 100 people—all the young doctors who will be the intensivists in the future receive special training from the ONT about what is brain dead and how to approach the family. What I mean is that it is not just the coordinators but it is the coordinators and practically the whole hospital because, as you said, organ donation, transplantation, but specifically organ donation is a very new disciplinary work. So we have a lot of people who are really helping and collaborating with the project.

**Q303 Lord Kirkwood of Kirkhope:** Can I ask you a very important question about that? Is anybody trainable and are these numbers of people volunteers? Is everyone required to undertake this kind of training or do you solicit people who are really interested in doing the work?

**Dr Matesanz:** It is totally voluntary but, as you know, at this moment in Spain we really have, after all this work, the ONT as an institution with a great prestige in the medical class, among the medical, among the nurses. So every year we get the promotion of many courses, the specific courses; for instance, every year we make three courses for young intensivists, three general courses for coordinators in which courses we train new coordinators but also coordinators, for example from Latin America or from Italy or from any other countries, and specific courses for brain dead, and we make the announcement to the whole network of coordinators, to our people, and there are some people who say, “I am interested; I am interested” But it is not mandatory because we think that it is better to have the cooperation of the whole people on the voluntary basis. What is important from this scheme is that we can very easily change the coordinators. When a coordinator becomes burned out after two, three, four years or sometimes more, as we have a lot of people who have received the basic training it is really very easy to change the coordinator, because these people are working part-time as coordinators and their basic job is intensive care doctors; more of them, about 80% are in intensive care—there are some nephrologists but more of them are intensivists. So these people are working as a coordinator for a period but then have the basic job of intensivist and they can move into their other job without any problems, and it makes a big difference what is happening in other countries because if you have a person whose only job is to be a coordinator, if you take them away from the job you really do not know what to do with him or her.

**Chairman:** This also enhances their career prospects generally.
Q304 Baroness Neuberger: It is really interesting to hear you say that it is voluntary and obviously then they can go back to being intensivists, or whatever. Is the system in Spain the same as it is here—because I think it is becoming EU-wide—that young doctors get a choice of various options that they might choose to do as specialists—various forms of specialist training. Is this one of the options and is it something that you are not compelled to do it but it is very much expected and it is, if you like, a fashionable thing to do?

Dr Matesanz: The decision for anybody to be a coordinator belongs to the director of the hospital because this is a functional network, which starts with the ONT, which belongs to the Ministry of Health; then the regional coordinator, which belongs to the regional health service, which has the full function for health assistants; then the hospital. The decision to nominate a person or another person belongs to the director of the hospital that on many occasions asks the ONT if this profile of this person is adequate or not. But they ask me or they ask the ONT because they are convinced that I am going to give good advice—not because they have to, because they are 100% autonomous. So what is happening in many regions is that the regional coordinator is discussing with the directors of the hospital who are the more adequate persons because they are in contact with all the coordinators. What is very important is that there is a functional link between the hospital, the regional and the national coordination. For instance, all the decisions about the transplant policy in Spain are taken by the regional councils in which they meet a national coordinator—that is myself—and the 17 regional coordinators. So you realise that this makes a big difference with what is happening with our country because in other countries you know that the real power belongs to the surgeons or the clinicians, and in Spain it is not like this. What we used to say is that the national coordinator and regional coordinator should be some kind of interface between the political or the administrative level, which sometimes are more or less the same, and the professional level—the real work, which are the hospitals. So the key for the system is to have this interface.

Q305 Chairman: So this gives you compliance and consistency across the system and the capacity to share good practice right across; that is what that gives you.

Dr Matesanz: Sure.

Q306 Chairman: The model has obviously been commended to us from every quarter. If you were to improve it in any way in your system, what would you be looking for?

Dr Matesanz: Three months ago in Madrid we celebrated a general conference in which clinicians, surgeons and coordinators were involved. The point is that we have at this moment 34, 35 donors per million but in fact in Spain there are 17 regions and there are seven regions which have over 40 donors per million. The highest during the last year was a very small region, which is La Rioja. La Rioja is very characteristic because of the wines! It is very curious, and very interesting the case of La Rioja; there are some 300,000 people—so very small, and it has no neurosurgery. For a hospital the key point for having or not having donors is to have neurosurgery because in the hospital with neurosurgery, cranial trauma or people with cerebral bleeding and so on are concentrated, so the possibility to have brain dead is much higher in a hospital with neurosurgery than a hospital without neurosurgery. So in La Rioja there was not neurosurgery and for years there was one donor per year, two donors per year, which means three donors per million, seven donors per million and nothing more for many years. The explanation was that there is no neurosurgery so the possibility to have donors is very small. But four years ago there was a change of coordinator. The person who was the coordinator before was an urologist and he did practically nothing at all. But there was a new coordinator who was a very young intensivist, who was right there, and in the first year four donors, seven donors and this year 23 donors—23 donors means 72 donors per million, without neurosurgery. And we detected five more donors in neurological, which were transferred to the neighbouring regions. So in La Rioja during the last year the organ donor rate could reach 94 per million. So that means that we have not reached the top—the epidemiology of brain death is much greater than we thought before if we have enough ICU beds—and that is very important because the key point is to have enough beds in the intensive care unit with mechanical ventilation (otherwise there is competition between the person who is very ill and the potential donor). So what we are trying to do now is what we call the “Plan 40”. I mean, all the regions should reach the 40 donors per million, and in doing this we are trying to develop some new action; specifically we are convinced that we are not detecting 100% of potential donors, and the example of La Rioja is very, very clear. We are trying to develop more the non-heart beating donor’s programme, which in Spain means only 5% of the donors, which is very, very low. We have to develop reaching more of the nation, and that is important; we have to reach more fluently to immigrants who come from Northern Africa and Asia because we have real problems—

Q307 Chairman: Yes, we want to come on to all of that if we can.
Dr Matesanz: We have no problems with Europeans, we have no problems with Latin Americans, but we have real problems with people from Africa, but that is another point. Especially we have to reduce the family refusal rate, which is very low at 15%, but we have to reduce it a little bit. The aim is, the project is that the 17 regions should reach at least 40 donors per million. It is not easy but in fact it is a process of benchmarking; we try to identify the bench, the better practice in the specific region and try to transfer to the other regions. It is very curious because when we started with this process there was a very interesting experience in Madrid, in Catalonia and even in the country of Basque, but now the highest region, the high donation rate is not in any of these regions. In fact the situation changes all the time.

Q308 Baroness Morgan of Huyton: You have touched on the edge of the question I wanted to ask, but maybe you can give us a bit more detail. How do you handle the differences between the possibility of donation from non-heart beating donors and brain stem dead donors?

Dr Matesanz: That is an interesting question because in Spain non-heart beating donation is concentrated in three programmes—two in Madrid and one in Barcelona. But non-heart beating donation does not mean the same as in the UK because, as you know, there are four types of non-heart beating donors according to the Maastricht classification. In Spain we use types 1 and 2, while the UK, Holland and other European countries use type 3.

Q309 Baroness Morgan of Huyton: Could you explain that?

Dr Matesanz: That makes a real difference, but there are different situations.

Q310 Chairman: Tell us that again because I do not think we have quite caught the point.

Dr Matesanz: Types 1 and 2 from the Maastricht classification means dead on arrival—a person who arrives at the hospital and has a cardiac death and on the very rapid action of the coordinator they do everything. Or unsuccessful resuscitation; unsuccessful resuscitation means a cardiac arrest in the street, so the emergency service tries to make resuscitation and after one hour or so of trying resuscitation and there is no possibility to recover there is a strict protocol for sending this patient to a specific hospital where there is such a kind of programme. Then we have a very short time to contact the family, to contact the judge, which in Spain is necessary, and to do everything and then if everything is positive we procure the kidneys, the lungs—we have a specific programme for lungs—and on some occasions also the liver. That is what is happening in Spain, but Spain, as far as I know, is the only country in Europe with such a programme because they are very, very complicated. They are very complicated because you need a team for 24 hours with a surgeon, a coordinator, a lot of people, on which you should concentrate the efforts for the specific programme. In Madrid we have one hospital in the north, which has about 45 to 50 donors a year, which are really very much, and another in the south; and in Barcelona there is one group of perhaps 20 or 30 per year and nothing more. Because to have a programme like this you need a big city with at least one million people. We are trying to develop such a kind of programme in Valencia, Bilbao, Seville, which are also big cities. But what you are doing in the UK and what is done in Holland and also in the States is what is called non-heart beating type 3. Type 3 means those patients who are in a no hope situation; so they are very close to being declared dead but they are not brain dead because there is still some function in the brain stem, and in this situation you take out the mechanical ventilation and you wait for some minutes for the person to be declared dead and you can take out the organs. So that is a different situation. In Spain this is not illegal but when we discuss to do or not to do such a thing we prefer not to do because that is complicated. For instance, if you look at the New York Times about a week ago there was a very complicated case about one of these non-heart beating donors in California and there has been a big discussion about it. We can do it but it is complicated.

Chairman: We are absolutely fascinated by this and I am going to come back to the other part of my question because time is moving on. I am going to ask Lord Lea to come in.

Q311 Lord Lea of Crondall: I am hugely better educated by what you have said in the last 15 minutes and thank you very much for that. I am very glad to see that you have the yellow batch of documents. I am coming on to question five but can I associate that with Annex A, which is our attempt to I hope accurately summarise what the two major areas of EU proposals actually are—there are three actually, as the third one is fighting organ trafficking. But if we take the directive on quality and safety, that is one, and the framework; and the second one is the action plan for strengthened cooperation. Can you first of all just tell us, is that programme one that you support; you think there are good things about it or bad things about it, some things which are a waste of space because they are bureaucratic? Could you comment and then perhaps answer the question five as specifically as you find
it useful to do so? But looking at Annex A, more generally what do you think about these proposals? Dr Matesanz: Thank you very much for the question, which is very interesting. When I was reading that question I started to think about it because the question is very well done—to what extent have you benefited from the activity at EU level in the past around organ donation? I have to say that it is not specifically the European Union which has supported organ donation in a more effective way, but the Council of Europe. I have to say that there has been an institution, the Transplant Committee of the Council of Europe, which was started in 1988, so it is an old institution, and I had the honour to be the President of this Committee for seven years; and there was also someone from the UK who was President also (Dr. Peter Doyle). Before the European Union was involved in organ donation or in tissue and cell donation that was the only official institution, let us say, who coordinated—it was not a mandatory institution because the only thing that we could do for years was just recommendation, but in fact all the EU action had been based on the recommendations which were agreed by all the countries at the Council of Europe level. I have to say that in Spain we learn a lot from other countries in the Council of Europe because we share very good experiences; we define what to do and what not to do—and probably it is the most important not what to do than what to do in organ donation. So we learned a lot in fact in the new situation when the European Union became involved with organ donation, so our philosophy as being responsible for the Spanish programme or organ donation has been that you will learn a lot in the field of transplantation in the field of donation from other countries and it is probably our duty at that time to share our experiences, specifically with the new emerging countries of the European Union. You ask me what are the benefits for the UK from this directive and I would say that probably not many, but I would say just the same for France, for Germany, for the biggest western countries. But we should realise that at the moment the Union is formed by 27 countries with many, many differences. We have 34, 35 donors but there are some countries with less than one donor per million. The situation in Greece is that there are five or six per million, but Cyprus, Malta, Romania or Bulgaria it is practically nothing. So I think that what the European Union can support to the Union is probably some specific recommendation. For instance, one which is very important is that you should put in place in every country an official organ donation and transplantation organisation. This is very important because there are many countries which have nothing at all, and at that time for any aspect in this field where you want to find a solution, even for trafficking, even for ethical, for quality or for possibility of the organs you need to contact country to country; you cannot have a contact from hospital to hospital or to call to the surgeon because “he is a very good friend of mine” or something like this. So in my opinion in respect of quality and safety it will not mean any significant change for the UK, for Spain, for France, for Germany at all because we have now very high standards.

Q312 Lord Lea of Crondall: Could I just say that that body you are now talking about, you would like it obligatory, mandatory to have a national body of the type that you have described. Is that different from the body that is referred to in Annex A in the first bullet point: “The directive would establish a basic quality and safety framework, including: the establishment of a national oversight authority or authorities responsible for implementing the requirements of the directive.” Is that another body or is it the same body that you are talking about? Dr Matesanz: I think that is the same body because you need an official authority—you can say official body, official organisation or whatever—on every country that should be responsible for these quality and safety requirements for organ donation. The main reluctance from many people, from many professionals for this directive is to have a very bureaucratic and very closed practice which can be contrary to the useful practice, but I do not think it is the case, at least as far as I know, that we have been discussing in Brussels with the experts of other countries. It is, let us say, a very light directive with very basic requirements; in fact, I do not think it can be higher than we are using now in western countries.

Q313 Chairman: Dr Matesanz, can I just ask you, you have made an important distinction between the Council of Europe and the EU—
Dr Matesanz: No, I am talking about the EU now.

Q314 Chairman: Yes, I know but you earlier made that important distinction about the influence and where the influence came in terms of the development. Could you just tease out for us, so that we are clear, what it is in each of those bits of the organisation that is pressing forward the transplant issues? Dr Matesanz: The Council of Europe Transplant Committee was formed in 1988 when in fact there was nothing in the European Union—the European Union became involved in this field—

Q315 Chairman: So they responded to the Transplant Committee.
Dr Matesanz: ... in transplantation. They became involved in 2002 and the European Union started with tissue and cells with the present directive on tissue and cells. So the Council of Europe in fact was involved with not just the countries belonging to the Union but all the European countries—even Russia, Norway, Switzerland, and the countries which do not belong to the European Union. So the Council of Europe has made a lot of recommendations; they are not mandatory, the only mandatory document was the Bioethics Committee of the Convention of Oviedo, and nothing more. But with respect to transplantation it was just recommendations. So, the Council of Europe has been replaced by the European Union in this field with the exception of non EU countries. Of course the action of the European Union should be mandatory with a directive or something. So what we are discussing now is if it is really necessary for the organs, such a kind of directive or not. What the European Comission has said is we are trying to do an action plan, which I think nobody is against because an action plan means a kind of cooperation between the different countries in order to improve organ donation. So we can discuss how this action plan should be developed, but I have never heard anything against the action plan. But the point is the directive, the directive of quality and safety and there are two main positions. We did one directive for tissue and cells and everybody agreed it was necessary because of traceability, because of assurance of quality and safety and because it is more or less the same in the United States with FDA—no discussion about tissue and cells. But the point is that it is really necessary that there is a directive for organs?. So there are some points that I stressed before. I do not think that such a kind of directive makes a big difference for western stronger countries. I think what makes a real difference is with what is happening with eastern, with emerging countries, with countries where in fact there is practically nothing at the moment in organ donation and transplantation; but the European citizen can go from country to country in fact and they should receive at least the same basic level of quality in this directive.

Chairman: I am going to come back to Lord Lea to pursue organ sharing a little but I am going to ask Lord Kirkwood if there are other issues on the quality question, and as we have gone into it, Lord Kirkwood, would you like to pursue this now?

Q317 Lord Kirkwood of Kirkhope: And you could not do that just with voluntary cooperation and best practice like the Council of Europe in earlier times? Dr Matesanz: Yes, I think that has been a very good way to work for years, but I do not think that at this moment this is possible because the EU is becoming very big. I remember the first meeting I went to at the Council of Europe was in Paris in 1989 and we were six countries—UK, Germany, France, Spain, Italy—Europe was very, very small; but at this time it is not so small and we have real problems—real problems—with the emerging countries where we do not really know what is happening in many fields, and I am afraid that the field of transplantation is one of these.

Chairman: Thank you very much, that is very helpful. Lord Lea, do you want to pursue the question of organ sharing between Members?

Q318 Lord Lea of Crondall: If there is anything that have not had the chance to say, because we keep interrupting you, in the area of questions five, six and seven, now is your chance. As I understand it you are agreeing substantially with the EU programme but—

Dr Matesanz: More or less; not all but I agree with most of it.

Q319 Lord Lea of Crondall: You are disagreeing with things that would go beyond it?

Dr Matesanz: Yes.

Q320 Lord Lea of Crondall: Is there anything else that you would like to say on this outstanding question? We are talking about question six.
Dr Matesanz: Question six: “what are your views about the potential advantages and disadvantages of an EU-wide unified single organ sharing scheme?” I think that there is no place for a unified single organ sharing scheme—no place at all. No place at all because I think that the only possibility to share organs is for small countries that are very close countries, and for specific organs, for a specific situation. For instance, for a small country for certain urgent patients it is very difficult to find an adequate donor if you do not have a large pool of patients. For instance, it would be impossible for Ireland to find adequate donors outside of Great Britain. For instance, Portugal and Spain have established an agreement for super urgent livers, but just for super urgent livers and nothing more. The European sharing organisation, which is basically Eurotransplant, was formed many years ago because they were very close countries with very good communication and so they can share some of the organs, but for a country with 45 million people, like Spain, the exchange of organs with other countries is less than 1% of the organs. We have no need—the only organs that are really shared at this moment in Europe are organs which cannot be transplanted in our own country. For instance, every time that we have an organ that we cannot transplant: a very small heart of a just born baby or an intestine, or a group AB, we offer it to other countries—we offer to France, to the UK, to Italy, to closer countries. But there is no sense, for instance, to generalise a scheme for exchanging livers because if I sent a liver to Stockholm and then from Stockholm to Rome and from Rome to London it takes a lot of money and a lot of time and so on; so, no.

Chairman: You are saying to us that there are opportunities to exchange in rare circumstances but this is done better by professional contact?

Dr Matesanz: Not professional but organisational contact. No, no, it is strictly forbidden exchanging organs from hospital to hospital, but: hospital of country A → organisation of country A → organisation of country B → hospital of country B.

Baroness Morgan of Huyton: Can I ask a supplemental question on that? One of the issues that have come up in previous sessions we have had has been a belief that it is easier to encourage people to agree to donation the closer to home it is. In terms of what you are saying, you are obviously saying that it is more efficient and it is better value for money and donor organs can usually be used in your own country anyway so why would you go further afield, but do you think that people also are more willing to donate relatives’ organs if it is closer to home as well?

Dr Matesanz: I have told you before that when we started with this system, Madrid and Catalonia—Madrid is six million, Catalonia is seven million, so they are big regions with a lot of people—we were at the highest, but not now. When you professionalise the system you realise with respect to organ donation that “big is not beautiful”—much more efficient are the smaller organisations. So you would need—I would not say a big organisation but a middle sized organisation for sharing organs; but small for the procurement because you can control them much better. The regions with the highest organ donation rate in Spain are the smaller regions. For instance, in the north of Spain is Asturias, we had million; Cantabria, half a million; the country of Basque we had two million; Rioja, half a million. So the smallest regions are those who reach the highest organ donation rate. It is very difficult to control what is happening in every hospital in a very big organisation. And for sharing organs the philosophy 30 years ago was the bigger the pool the easier to find a good match. That was the philosophy for Eurotransplant, which was true 30 years ago but it is not true now because the drugs have been changed very much. So that is the reason that you can do a renal transplantation between two people without any genetic relationship, but that was not possible 30 years ago but is possible now. So the need to find a good match does not exist now or is very relative. So for a country like the UK you do not need anything at all from outside, and the same for Spain and the same for Germany and the same for France. Of course if you want to have an exchange that is okay, but only on a voluntary basis and only for a specific patient, for an intestine or for very small children who need a heart where it is very difficult to find an adequate donor in the country.

Chairman: Dr Matesanz, we have to move on but just before we move on what system do you think should be in place for those specific rare cases?

Dr Matesanz: I think it is very simple and not very different from what it is now in place. The organ sharing organisation and organ donation organisation in my opinion should be the same, in contact by mail or fax or whatever, with other European organisations, and whenever there is a special need or special offer there is no problem to send it to the organisation. That is the way in which we are working now.

Chairman: Thank you very much. We will move on to a different topic with Lady Neuberger.
Baroness Neuberger: Dr Matesanz, I should have declared an interest before—I have a brother in law who is quite well known in the transplant field, James Neuberger. For the record we have to say that here. You may have noticed that the Chief Medical Officer here in the UK, Sir Liam Donaldson, has been recommending that we move to a very different system of consent and that it goes to an “opt-out” system. We have heard very different evidence actually, largely in this inquiry, but the Chief Medical Officer has come out with that and there has been a certain amount of political support for that. So we are really interested in knowing from you what public attitudes are to donation in Spain. You have said a little bit about that from Rioja, which has been very interesting, about the smallness and the localness, but could you tell us whether the attitudes have changed recently and, if there has been this enormous change—which by the success of your programme it sounds as if there may be—how do you explain the change in attitude?

Dr Matesanz: That is a very important question because it is so important whenever you are trying to do something in any country or in any region it is as important what to do as what not to do, as I said before. I will tell you something very interesting, but first of all I have to say that the different laws that are in Europe or in other countries of the world mean nothing in respect of organ donation—nothing. It is true that you need a law but you need a law in which you define what is brain death, how to distribute the organs—all these things—how to approach the family, who should give the consent, who should give the legal consent in accidents, and so on. Theoretically there are two kinds of law—the presumed consent and the expressed consent (opting out and opting in). At the end, as far as I know, in all the European countries—that may not be the case in very far away countries like Singapore or something like this—in Europe and in America and Australia, which is more or less with the same culture, with the same view of life, there is no country in which the family is not consulted, not approached before. So that means that at the end there is the problem of the property for the family, for the Catholics, for the Protestants, and all the European cultures. I do not know of any country in which the family is not consulted. In Spain we have a law, which is from 1979, (so we have almost 30 years with the same law, and being in Spain with the same law for 30 years it means that it is a very good law!) So it is a presumed consent law and when we started I was working at the hospital as a nephrologist and in Spain, as in other countries, the nephrologists were the first who asked the family for the kidneys—not for the other organs but for the kidneys to transplant our patients. I remember that during the first years of application of the law we tried to apply such a card, “You are a donor if you do not state to the contrary during your life”. But in fact in Spain whenever there is a non-medical death, let us say an accident or anything like this, you should go to the judge, ask permission of the judge and the judge is the person who gives the authorisation. And the judge started to ask the nephrologists for the written permission of the family because they established that it was the only way to know what the feeling was of the person who was dead five minutes before death; so, at the end it is the family who is saying. So opting-in, opting-out in my opinion means nothing. It is true that whenever there is a country in which this problem of donation starts to be discussed the first thing is that there is somebody who wants to change the law—it has been happening all the time; it has been happening in France, happening in Argentina, happening in Brazil, happening in Singapore and in Belgium. At the end what is really happening is that during the first years of changing the law the number of organ donors started to rise, but probably not because of the change in the law but because of the expression which is very opportune, very good, which is “moving the water”. Talking about donation and everybody started doing things, but after that . . . That is what is happening in Brazil, in Argentina, in Singapore and practically in all these countries at the end the families always consulted. You have some figures here in this document, which are very interesting and it is the Euro barometer. The Euro barometer is very interesting. I do not trust such a kind of general polls, but it is true that the countries with the highest disposition of the population to donate organs are the lowest in real donation. Malta and Sweden and countries like that where the real organ donation rate is very low. In the UK it is always higher than Spain, as you realise here—Spain is very low. Another thing that is very important, we have a very good poll which put the same question to the population at the beginning of this story in the early 1990s—1992 and 1993—and in 1999, 2000 and 2006, and we asked the same question to the Spanish population, without any explanation, “Would you be willing to donate the organ?—Yes-No-Do not know.” At the beginning there was 58%, in 1999 57% and in 2006 58%—the same. During this period we went from 500 donors to 1,500 donors. And, most important, in Latin American countries the family refusal rate—which is more or less the index, which is very valuable but it is very difficult to obtain because not all countries take the family approach of the family interviews and so the recording of family refusal is not easy—is higher than 60 and 70%. But we have now in Spain a Latin colony which is very, very high—for instance, there
are more than 600,000 from Ecuador and more than half a million from Colombia, and the family refusal rate of Latin Americans in Spain is just the same as the Spanish population. Even more the British; the highest colony in Spain of non-Spanish not born in Spain are British, living in the Mediterranean, in the Balearic Islands, in the Canary Islands and so on.

Q325 Lord Lea of Crondall: I am sorry, the highest doing what?

Dr Matesanz: The highest colony, the highest group.

Lord Lea of Crondall: Yes, but did you say that you knew that the British were higher or lower than others in saying no.

Q326 Baroness Neuberger: Dr Matesanz has not said yet.

Dr Matesanz: In the UK your family refusal rate now is about 40%, but in Spain we have the data for 2005 and 2006 and we know that there were more than 100 to 120 British who came to the state of brain dead and it is very curious because all say yes—all the British who were asked in Spain finally say yes. So the family refusal rate of British in Spain is zero. What is important in this situation is that you cannot change the mentality of the whole country; that is impossible—you need many, many years, many, many actions and so on. You should concentrate the thoughts of what is happening specifically at the moment when a person becomes brain dead in the intensive care unit, and you should have a very good trained professional who is trained in a very professional way. What is happening with non-Spanish is that we have specific translators—of course to English but also to German, to Swedish, to Arabic, to Chinese or whatever disposition of the coordinators, so we approve them.

Q327 Chairman: So it is organisation and leadership.

Dr Matesanz: Organisation is 100%.

Q328 Baroness Neuberger: And leadership.

Dr Matesanz: Yes.

Chairman: We are going to have to move on to the time and you have once or twice alluded to different ethnic groups and Lord Eames is going to ask questions in this area.

Q329 Lord Eames: I, absolutely like the rest of my colleagues, am fascinated by your presentation, and I know that you have touched a good deal on this question of immigration and the various percentages making up the Spanish figure. Is there anything else that you could say to us in relation to any differential between supply and demand with ethnic minorities and so on? You mentioned North Africa specifically earlier on in answer to my colleague, but is there anything you could share with us because immigration is 4.1 million or something like that; and over here it is obviously a major thing as we look at the EU. What else could you say to us about the variation within the ethnic minority groups?

Dr Matesanz: Immigration in Spain is a phenomenon which is quite different to what is happening in the UK, France or Germany because we have very, very strong immigration but very recent immigration. We had no immigration 30 or 40 years ago—we were emigrants—but now we have received during the last, let us say, ten years a lot of immigrants and at this moment it means about 10% of the Spanish population are people who were not born in Spain. So the greatest colonies are European, west—not specifically immigrants but British, German, Swedish who came to live in the Mediterranean; and eastern—Romanian, Bulgarian, Polish who came to work; Latin America, of course; and then Africa, Northern Africa, Islamic countries, and sub-Saharan countries. Then there is a much smaller proportion from Asia. The Asiatic immigration in Spain is Chinese but not very many. So the situation is Europeans, eastern and western are donating at the same level as the Spanish—at the same level. We realised about this new situation about three or four years ago, and the first thing that we did is to summarise how many percentage of donors were not born in Spain. At that time the percentage of donors in Spain not born in Spain is just 9%, so more or less the same as the weight of this population. But this does not mean that everybody donates at the same level because I have told you no problem with Europeans; no problem with Latin Americans but real problems with people who come from Africa specifically for religion—the Islamic religion is the main problem. We have donors from the Islamic religion and what we have done is two things: we provide the coordinators with all kinds of items in the different language and we contacted the kind of social workers who work at a local level in Spain from the different ethnicities, in the groups, and whenever there is a potential donor from China, from Romania or from Northern Africa we call these people and try to approach the family in this way. That is not very different from what I know that they are doing now in the United States with the minorities because they realised this problem with the minorities many, many years ago. We have started now to have donors from the Islamic religion; but Chinese is very, very complicated but it is a very small problem in Spain, so it is not really a problem. Our greatest source of immigrants is Northern Africa and Latin America.

Q330 Lord Eames: Are there any specific lessons— or is it too soon to say it, given the figures you have mentioned—you have learned about the approach to some of some of these ethnic groups?
Dr Matesanz: Yes. For me what is more important that the results that we are getting now in Spain are much better than what is happening with these ethnic groups in their own countries. So we have not changed the mentality of these people but there are probably two things: they are receiving good healthcare, which is probably not the case in the country of origin—in Latin America and so on. Then the fact that we are approaching them in their own language and trying to conserve with their own attitudes and their own way to understand life, and I think this is very positive. Then it is the same thing in other European countries but it is not the same in the country of origin, that they had the same opportunity to receive organs as the Spanish because the opportunity for any people who comes to Spain to live in Spain, whatever your region is you have the opportunity to receive organs the same. So our philosophy is that everybody should donate because everybody can receive.

Chairman: Do you have any evidence that says that it is not necessarily the cultural group but the socioeconomic position of some of those groups; that it is the poor who may not give consent?

Dr Matesanz: We have not seen many differences from the socioeconomic different groups in Spain. In fact with the immigrants there is really little difference. It is true that when you are doing polls it is much easier to receive a positive answer from the higher socioeconomic group, but at the end real donors is what makes a difference. It is very important that when we started with the system in the southern region of Spain, Andalucia, the organ donor rate was very low—it was eight, nine per million and nothing more. The explanation—and “explanation” in brackets—was because of the Catholic religion that this was failing in Andalucia. Now Andalucia is 34 per million. For instance, one of the places that I have worked besides Spain has been in Italy. I worked for three years in Tuscany, in Florence, and in Tuscany the organ donation rate was nine or ten. We established a system which was very similar to the Spanish and now they have 42 per million. But in Italy in the northern regions the results are fairly good at this moment—it is not only Tuscany—they have practically taken the Spanish system with the national regional hospital system, with medical doctors and so on, and are very, very close—in the northern part of Italy in Veneto, Emilia Romagna, Tuscany and so on. But in Italy there is a real difference with the south because, for instance, in the south, in Sicilia the organ donation rate is five, six in Catania in the region of Calabria and so on. So the question is: what is the real difference between Italy and Spain because they are such close countries with such a close culture? In my opinion in Spain there is not a real difference in healthcare between Madrid, Seville, Bilbao, Barcelona and so on. There were 30 years ago but not now. But in Italy it is not the case; Italy is very different from the south to the north, so that makes a difference in the number of ICU beds, in how the hospitals manage. In fact one of the things I learned in Italy is that there are thousands of patients coming from the south to the north; in Spain there was something like this during the 60s or 70s but not now; there is nobody now who comes from Andalucia to Madrid or to Barcelona—nobody. So that makes a real difference in order to understand what is happening why the organ donor rate can increase in some places and why in others it is very difficult. For instance, the organisation in Uruguay, Uruguay was a country with five or six donors ten years ago, so we took people from Uruguay, we train them, we send them there and at this moment there are 26 donors per million. In Argentina, which is a very important country with 40 million people, we totally changed the system at the beginning of this century—it was a very centralised system, which was more or less like the French one, and we changed it to a very decentralised system with coordinators. So Argentina went from six to 12 donors per million.

Chairman: Do you have any evidence that says that it is not necessarily the cultural group but the socioeconomic position of some of those groups; that it is the poor who may not give consent?

Dr Matesanz: We have not seen many differences from the socioeconomic different groups in Spain. In fact with the immigrants there is really little difference. It is true that when you are doing polls it is much easier to receive a positive answer from the higher socioeconomic group, but at the end real donors is what makes a difference. It is very important that when we started with the system in the southern region of Spain, Andalucia, the organ donor rate was very low—it was eight, nine per million and nothing more. The explanation—and “explanation” in brackets—was because of the Catholic religion that this was failing in Andalucia. Now Andalucia is 34 per million. For instance, one of the places that I have worked besides Spain has been in Italy. I worked for three years in Tuscany, in Florence, and in Tuscany the organ donation rate was nine or ten. We established a system which was very similar to the Spanish and now they have 42 per million. But in Italy in the northern regions the results are fairly good at this moment—it is not only Tuscany—they have practically taken the Spanish system with the national regional hospital system, with medical doctors and so on, and are very, very close—in the northern part of Italy in Veneto, Emilia Romagna, Tuscany and so on. But in Italy there is a real difference with the south because, for instance, in the south, in Sicilia the organ donation rate is five, six in Catania in the region of Calabria and so on. So the question is: what is the real difference between Italy and Spain because they are such close countries with such a close culture? In my opinion in Spain there is not a real difference in healthcare between Madrid, Seville, Bilbao, Barcelona and so on. There were 30 years ago but not now. But in Italy it is not the case; Italy is very different from the south to the north, so that makes a difference in the number of ICU beds, in how the hospitals manage. In fact one of the things I learned in Italy is that there are thousands of patients coming from the south to the north; in Spain there was something like this during the 60s or 70s but not now; there is nobody now who comes from Andalucia to Madrid or to Barcelona—nobody. So that makes a real difference in order to understand what is happening why the organ donor rate can increase in some places and why in others it is very difficult. For instance, the organisation in Uruguay, Uruguay was a country with five or six donors ten years ago, so we took people from Uruguay, we train them, we send them there and at this moment there are 26 donors per million. In Argentina, which is a very important country with 40 million people, we totally changed the system at the beginning of this century—it was a very centralised system, which was more or less like the French one, and we changed it to a very decentralised system with coordinators. So Argentina went from six to 12 donors per million.
INCREASING THE SUPPLY OF DONOR ORGS WITHIN THE EUROPEAN UNION: EVIDENCE

6 March 2008

Dr Rafael Matesanz

Q333 Lord Lea of Crondall: You do not have the gap that we have 1000 deaths unnecessarily.

Dr Matesanz: Not at all. For giving visibility to a project donor cards can be good. For instance, in a country you are doing something, or at a European level there is the proposal to do some kind of European donor card, and I say I do not think it is useful but it can give visibility to the project, but you should realise you will spend a lot of money.

Q334 Chairman: Really what you are saying, Dr Matesanz, is that you should invest the money in the hospital system and in the skills and the training and the process.

Dr Matesanz: Sure.

Q335 Chairman: That there is nothing wrong with having a donor card.

Dr Matesanz: There is nothing wrong.

Q336 Chairman: It may raise attitudes but it will not actually help unless it is linked to a very clear system because you may have a donor card in your pocket—

Dr Matesanz: Yes, I have!

Q337 Chairman: . . . but if you get into a hospital that does not have the process to process it—that is what you are saying—then it is pointless having those systems anyway. We have run over our time and I did want you to say one thing briefly, if you could, because I realise I am going to be holding up my Committee over their time otherwise. You have seen the Department of Health’s Organ Donation Taskforce document, I am sure. Just very briefly, if those things in that report were implemented in the UK do you think that it would make a significant difference to our proportion of donations for the population?

Dr Matesanz: I had the opportunity to present the Spanish experience to this taskforce last year, and to have discussions with the members of the group, and I had the opportunity to read the report, which I think is a very good report. So in my opinion from the theoretical point of view the application of those principles should be very, very positive for organ donation in the UK. The problem is probably how to develop all of these points because if you read to do this and this and this there is nothing wrong, but the point is how to have really any influence on the hospital because to put in more coordinators, to have a central organisation in charge of these coordinators and to train these coordinators, all these things are very positive measures, so I fully agree with this plan, but the problem, I know from our experience in Spain and other countries, is that the implementation of such a plan is not easy.

Q338 Chairman: It is the influence in the hospitals which counts?

Dr Matesanz: The general implementation at the national level is complicated. Especially you have a problem in the UK; there is a problem in Holland, in Germany and in many countries with very strong systems in place, which however does not exist when you arrive in a Latin American country and try to implement the model in the Spanish way. The main problem with greatest European countries is that they are resistant to change.

Q339 Chairman: Inertia of change, which we all face.

Dr Matesanz: You have a very old and strong system in place, which is very difficult to modify. That explains why many European countries have not been able to develop a system like the Spanish one and why in Italy they developed because in Italy when we started with this the situation it was really a very big disaster—they had not more than five per million.

Q340 Chairman: So the accession countries may have more opportunity in that they do not have set health services that are resistant to change.

Dr Matesanz: You have your own system which has been effective for many years, which is very strong and which is, because of being so strong, so difficult to modify.

Q341 Chairman: I think you have made one of your most important points at the very end in terms of the UK and you have helped us a lot in terms of looking at some of the European issues and whether or not the EU will help or not. We are going to have to finish there because our time has run out but we are immensely grateful to you.

Dr Matesanz: It has been an honour for me.

Chairman: It has been absolutely fascinating and we hope that we are adequately able to reflect what you have said when we come to make our report; so safe journey back and our gratitude.
Supplementary memorandum by Dr Rafael Matesanz

After coming back to Madrid, I was thinking about the possibility to add something to the inquiry, as you suggested. Here is a paper1 which I think can help to summarize many of the question posed during the session held in Westminster. With respect to the central point: Why a EU directive? I would like to add something to what was expressed last Thursday.

In my opinion, the point for countries like UK, Spain, France, Germany and some other should be instead: EU directive: why not? Provided the Commission has assured a “soft” directive with basic requirements about the quality and safety of organ transplantations, none of these western EU countries which in fact are the leaders in this field and are already working with high standards (surely much higher than those which probably will be required for a common agreement) should be reluctant to this initiative (at least I cannot see any future danger in this sense). This is not the case however for many emerging countries in the EU which are in fact very far from these standards and which would benefit a lot from this initiative, and furthermore from the Action Plan which will go together. Yesterday we had a meeting in Madrid about the DOPKI project (with very significant contributions from UK) and I guess that this “European Process” is and will be very positive for organ donation and transplantation in the whole Union.

Everybody agrees that a common organ EU sharing system has no sense, out of very specific cases, but the establishment of very basic organisational rules which assure for all the EU citizens an access to these therapies and minimum common standards can be very helpful and contribute to save many lives. I would remark the especial importance that for all the recently (and not so recently) admitted countries have all these projects and how negative would be not to continue. The differences registered in this field both from a qualitative and quantitative point of view (from 35 to < 1 donors) are really not acceptable in a common political space like the EU because they mean differences in the possibilities of access of our citizens. I guess it is in our hands try to find a solution.

Hope these reflections can help the Committee in its important job.

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1 Matesanz R and Dominguez-Gil B. Strategies to optimize deceased organ donation, Transplantation Reviews 21 (2007) 177–188
THURSDAY 13 MARCH 2008

Memorandum by the Human Tissue Authority

INTRODUCTION

1. The Human Tissue Authority (HTA) welcomes the opportunity to contribute to the Select Committee on the European Union’s Inquiry into the EU Commission’s Communication on organ donation and transplantation: policy actions at EU level.

2. The HTA’s evidence covers topics raised within the Commission’s Communication and other relevant issues which relate to the work and remit of the organisation.

3. We would of course be happy to provide further oral or written evidence to the Inquiry.

THE HUMAN TISSUE AUTHORITY

4. The Human Tissue Authority was established in April 2005 to implement the Human Tissue Act 2004. The Authority's remit covers the removal, storage, use and disposal of human bodies, organs and tissue for a number of purposes including transplantation. The Act and the Authority’s remit apply to England, Wales and Northern Ireland.

5. The Authority regulates the donation by living people of solid organs, bone marrow and stem cells. It is responsible for approving all organ transplants from living donors; and this latter role is also extended to Scotland.

6. The Authority is also one of two UK Competent Authorities for the implementation of the European Tissues and Cells Directive.

CONSENT

7. Underpinning the provisions of the Human Tissue Act 2004 is the need to obtain appropriate consent for the removal, storage, use and disposal of human tissue, organs or cells for transplantation—and for other purposes specified in the Act. Consent is therefore a mandatory first step in removing, storing and using human tissue for transplantation. The Human Tissue Authority has taken the view that the giving of consent is a positive act; that the absence of refusal is not evidence of consent; and that consent should where appropriate be generic and enduring. We have stated this in our published statutory guidance.

8. The Human Tissue Act 2004 specifies whose consent is needed, but is generally silent on defining what form appropriate consent should take, or how it should be sought or recorded. The Human Tissue Authority is charged through its remit to consider these ethical and practical matters, and has published guidance on them in its code of practice on consent. The HTA has also issued a code of practice on the donation of organs for transplantation, which provides guidance on the donation process and sets the standards practitioners are expected to meet.

LIVING DONORS

9. The Human Tissue Authority replaced and extended the role of the erstwhile Unrelated Live Transplant Regulatory Authority (ULTRA). Before the Authority was established, organ donations from living people could only be made to genetic relatives and to people with a close personal relationship. The Human Tissue Act 2004 has now widened the scope of living donation to include altruistic and paired cases (covered in more detail below).
10. Under the provisions of the Act, which came into force on 1 September 2006, the Human Tissue Authority is responsible for approving all organ transplants from living donors. All donors and recipients have to be individually assessed by a local independent assessor, who is trained and accredited by the Authority to act on behalf of the donor. The independent assessor ensures that the donor and recipient have an appropriate relationship; that the donor fully understands the risks which donation involves; that s/he is not under any pressure to donate; and that consent has been given freely and voluntarily. The independent assessor then submits an on-line report making a recommendation on approval to the HTA.

11. The HTA will make a decision on each individual transplant case based on the report provided by the independent assessor, subject to the requirements of the Human Tissue Act 2004 and the Authority’s guidance. Most HTA decisions are made by a dedicated transplant approvals team. Decisions on complex cases including altruistic and paired donations are made by a panel of Authority members. The average turn-round time for approval by the HTA for straightforward genetically or emotionally related living donor cases is two working days.

12. Since the Act came into force in September 2006, we have approved almost 900 living donor transplants, mainly involving kidneys.

13. We note the EU Commission’s Communication states that “exploring the promotion of altruistic donations from volunteer living donors, on the basis of appropriate safeguards for the donors and the prevention of trafficking, could be important in expanding the organ pool.” The HTA has already introduced systems to enable more flexibility in who can donate to whom, by allowing both non-directed altruistic donation and paired donation. Non-directed altruistic donation involves a donation by a person who does not have a relationship with the recipient. In such cases a psychiatric assessment of the donor is required. Paired donation is where a related donor and recipient whose blood groups or tissue types are mismatched (or incompatible) are paired with another donor and recipient in the same situation.

14. These new means of finding suitable organ donors are expected to increase transplant numbers. Two altruistic and two paired donations have already taken place since the Act came into force. Altruistic donations are probably never likely to be numerous, but enthusiasm on the part of the transplant community and the wide national publicity that accompanied the first paired donation suggests that the number of paired donations is likely to increase substantially, perhaps to as many as fifty per year.

**Organ Donation from the Deceased**

15. The Human Tissue Act 2004 makes it lawful for organ donation from a deceased person to take place provided that consent was given by the person prior to their death. In the absence of the known wishes of the deceased, consent may be obtained from the person nominated by the deceased person to act on his or her behalf or, if there is no-one so nominated, from a person in a qualifying relationship—such as a spouse, partner or other relative or friend.

16. Under the Act the wishes of the deceased person are paramount and take precedence over the views of the family.

17. The Human Tissue Authority’s code of practice on donation of organs for transplantation advises that if the family or those close to the deceased person object to the donation, even though the deceased person (or his/her nominated representative) has explicitly consented, clinicians should seek to discuss the matter sensitively with them. The family should be encouraged to accept the deceased person’s wishes and it should be made clear that they do not have the legal right to veto or overrule the wishes of the deceased person.

18. Currently all deceased organ donation in the UK is non-directed: organs are allocated according to clinical need rather than according to any specific wishes of the donor communicated while they were alive or of their family. In the past year the Authority has been made aware of a number of cases which might merit consideration as exceptions to that general rule. We are examining these with other members of the transplant community at the moment.

**“Presumed Consent”**

19. As we have explained, the underpinning principle of the Human Tissue Act 2004 is that consent must be obtained to use human organs and tissue for transplantation, whether from the living or after death. The option of presumed consent was debated extensively during the passage of the Act through Parliament. It was decided then that the opt-in system should remain.
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increasing the supply of donor organs within the European Union: evidence

20. Any move to a system of presumed consent within the UK would thus require a change in the law. There would need to be extensive consultation and debate before that happened. The Human Tissue Authority would favour as much transparency as possible in shaping and conducting that debate.

21. Provisions for appropriate consent have only recently been established through the Act, and the Authority would see an argument for giving the current legislation more time to take effect before considering whether to change the nature of what constitutes appropriate consent for deceased donation of organs for transplantation.

22. Furthermore, the HTA would want to be reassured about the impact that a system of presumed consent for organ transplantation would have on the current provisions in the Human Tissue Act 2004 for fully informed consent for other purposes, such as body donation for medical science or removal of tissue at autopsies.

ETHICAL ISSUES RELATING TO ORGAN DONATION

23. A number of ethical principles inform the Human Tissue Act 2004 and its provisions for organ donation and transplantation: these include the need for consent and for freedom from coercion, for equity and justice in assessing individual need, and for respect to be accorded to bonds of kinship in directing donations.

24. These principles have been central to our development of both the HTA codes of practice and the systems for regulating living and deceased donation.

ILLEGAL TRAFFICKING

25. We share the view of the European Commission Communication that organ trafficking is an issue of serious political and ethical concern.

26. The Human Tissue Act 2004 makes it an offence to give or receive a reward for the supply or offer of human material for transplantation. The offences relating to the prohibition of commercial dealings in human material came into force on 20 October 2005.

27. The Act does not however prevent import or export of organs for transplants. Numbers are small but there is a regular exchange of organs between European countries that meet similar quality and safety standards to ours. The UK Transplant wing of the NHS Blood and Transplant Authority facilitates this on the occasions that it occurs.

EUROPEAN ACTION IN THE FIELD

28. The European Commission Communication examines the scope for a European directive setting standards for the quality and safety for organs.

29. The Authority has experience of implementing a European directive. We are one of the two Competent Authorities for the implementation of the EU Tissues and Cells Directive in the UK: that Directive is intended to create a common framework for ensuring consistent standards across the EU community.

30. This has required the HTA to set up and regulate two systems of licensing, one under the Human Tissue Act 2004 and another under the regulations which transposed the European Directive into UK law.

31. Implementing this dual approach has created significant challenges for the Authority in keeping the resulting regulatory burden within the confines of Better Regulation expectations.

32. From our experience of implementing the European Tissue and Cells Directive, we would strongly suggest that any directive for the quality and safety of organ donation should be flexible and practicable in approach: one way to encourage this would be to involve stake-holders directly from the beginning in the drafting of the proposals to ensure that unintended consequences are minimised. We believe that this involvement should be in addition to consulting stake-holders after the work is done. We would also suggest that any directive should endorse the principle of subsidiarity among member states: for example, different legislative models for consent should be allowed to co-exist; and any wider system should be organised in such a way to enable these different models to work as intended.
CONCLUSION

33. The Human Tissue Authority’s role under the Human Tissue Act 2004 in regulating living and deceased donation for transplantation has given it experience and insights into a number of the issues under consideration by the Inquiry.

34. In implementing the provisions of the Act, the Authority has had the opportunity to consider the practical and ethical aspects of both living and deceased donation.

35. And our experiences of implementing the European Directive on tissues and cells points to the benefits of a flexible and practical approach to developing any European directive on organ donation.

36. The Authority would be happy to provide the Committee with further evidence on any of these points.

30 October 2007

Memorandum by Dr Muireann Quigley and Professor Margaret Brazier

Please accept this submission on the Inquiry into the EU Commission’s Communication on organ donation and transplantation: policy actions at EU level. This is being submitted on behalf of core participants in the ESRC-sponsored Seminar Series: Transplantation and Organ Deficit in the UK: Pragmatic Solutions to Ethical Controversy.

This submission has been prepared by Dr Muireann Quigley and Professor Margaret Brazier, CSEP, School of Law, University of Manchester. It draws on discussions to date between core participants, as well as findings, from the seminar series. For further information concerning core participants in the seminar series, please refer to the website created for the series:

Members of the Centre for Social Ethics and Policy (CSEP), School of Law, University of Manchester, were awarded funding by the Economic and Social Research Council (ESRC) to conduct a five part seminar series examining key issues relating to organ shortage in the United Kingdom (UK). The series runs from November 2006 until March 2008. The core participants come from a range of backgrounds, including bioethicists, lawyers, health care professionals and patient advocates. Details of the seminar series can be found at:

This group recently made a submission to the Organ Donation Taskforce (copy available on request). This submission draws on discussions and findings from the seminar series to date and responds on the following issues:

1. General comments
2. Harmonisation of systems
3. Presumed consent
4. European donor card
5. Living organ donation
6. Organ trafficking

GENERAL COMMENTS

1. We regard it as immensely important that national governments unequivocally endorse the importance of transplant medicine and that the Department of Health should be expressly subject to a duty to seek to promote an adequate supply of organs for transplant as is provided for in the Human Tissue (Scotland) Act 2006. We appreciate that there is no easy, “quick-fix” solution to the problem of the chronic shortage of organs available for transplantation in the UK and Europe. Finding solutions to address such shortage is imperative, however, given current waiting lists and the likelihood that they will increase in the future. One of the key aims of the seminar series is to identify a pragmatic way to address organ shortage which is principled in approach, but shifts the focus away from the longstanding ethical, religious and cultural controversy over organ donation, which has inhibited productive debate and resolution of differences. Priority should be accorded to measures that can be effected swiftly and without significant changes to national laws (See comments below on presumed consent).

2. The collection of robust empirical evidence is key in informing policy-making and regulation, therefore, the Commission should set aside money to conduct much needed research into (i) the social, psychological, institutional and economic aspects of organ donation, (ii) evaluation of the empirical data on annual organ donation rates for individual European countries and/or for individual transplantation units with a view to
increasing any disparities in practice and the reasons for such disparities, and (iii) an assessment of the existence and extent of organ trafficking.

3. Organ and tissue donation require the participation of society for their full development and depend on public support. This support is fragile because organ donation is an emotive issue and deceased donation depends to a large extent on public trust in the professionals making decisions about the life or death of a critically injured relative. We believe that transparency is vital to improving and maintaining public faith in the organ donation system, especially amongst minority groups. At present, there is a lack of accessibility to and knowledge of the allocation rules, which should be simplified and conveyed much more overtly to the public. Likewise, clear rules relating to the definition of death and the procedures and tests used to determine death. This information would help to allay concerns about fairness and would emphasise the consistency of practices in this sphere.

HARMONISATION OF SYSTEM

4. We favour the third level option: active coordination through the Open Method of Coordination (OMC), backed up by a legal instrument such as a framework Directive on quality and safety standards with regard to organ donation and transplantation.

5. A European dimension could potentially assist in effecting increased donation and distribution of organs and tissues for transplantation. This may be achieved in the sphere of living as well as deceased donors, as kidney “exchange” and “pool” schemes become established. The critical mass necessary for such programmes to work optimally lends itself to an EU wide scheme for kidneys, provided transport and organ deterioration issues are addressed.

6. The adoption of a framework Directive on organ donation and transplantation would follow the legislative model previously adopted in both the Blood Directive (2002/98/EC) and Tissues and Cells Directives (EUTD—2004/23/EC). These Directives set minimum standards of quality and safety pursuant to the narrow legal competence granted under Article 152(4)(a) EC. This minimum harmonisation approach has proved particularly useful in ensuring that Member States (MS) have appropriate standards in place.

7. Given that donors can donate both organs and tissues, there is a need to ensure uniformity in standard-setting between both the Tissues/Cells Directive and any proposed Directive on Organ Donation/Transplantation (see p. 43, Impact Assessment).

PRESUMED CONSENT

8. Any attempt to focus exclusively on the need for presumed consent regimes as providing the answer to organ shortage fails to address the fact that this is a complex issue which requires a multi-pronged approach. In our view, a multi-pronged approach at EU level requires at a minimum a focus on (1) donor education; and (2) ensuring appropriate institutional and staffing arrangements are in place for the promotion of organ donation/transplantation. A presumed consent regime is only going to work well if (1) and (2) are in place, as the preference for professional staff is still to ask for families’ agreement where deceased donation is involved.

9. Proponents of presumed consent often cite Spain as incontrovertible evidence that it is presumed consent which results in better rates of organ donation. Spain has the highest rate of deceased donor transplantation in the world, 33.8 pmp, but we do not consider their presumed consent legislation to be the key to their success.

10. In Spain deceased donation rates did not start to rise for 10 years after the change in the law. It was the introduction of an organisation to coordinate all aspects of donation activity, the Organización Nacional de Trasplantes, which made the difference. Donation activity is coordinated at national, regional, and local levels, with highly trained and qualified physicians taking on the role of transplant co-ordinators and being responsible for, inter alia, donor detection and approaches to families. Hospitals which provide donors receive suitable re-imbursement, recognising donation as part of a hospital’s core role. In practice, Spanish transplant co-ordinators always consult relatives and never take organs against the objections of the family. Accordingly the UK could adopt most of the model implemented in Spain without introducing presumed consent.

11. As the Spanish Model indicates, whatever legal rules regarding organ donation may be in place, Europe and national governments need to commit significant financial resources to the process of organ procurement. If an effective system is in place this is likely to achieve an increase in donation rates more swiftly than a mere change in the law which might take up to five years to come into force.

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12. We think EU “best practice” guidance on consent requirements with regard to organ donation/transplantation would be useful, however, we would be against any legally-mandated requirements in this regard being included in the Directive. In any case, there is likely to be too much political opposition to any attempt at setting “one size fits all” consent requirements across the EU.

**European Donor Card**

13. The evidence does not suggest the benefit of an EU donor card as effort is required to obtain/retain/maintain a donor card (Please see related abstract in Appendix 1). Some people who carry donor cards do not know what is involved in the donation process (Sque et al 2006). Organ registries may be more effective as they require less “work”.

**Living Organ Donation**

14. We are in favour of the promotion of donation from living donors where possible, although there needs to be greater public awareness and/or evidence of favourable outcomes through this method of donation. Greater transparency (through national standard setting) is needed in relation to determining criteria for living organ donation.

15. While criteria are in place for living organ donation (see Human Tissue Authority Code of Practice No. 2), there may be practical obstacles placed in the way of living organ donors (particularly if they are non-related altruistic donors). Such obstacles include loss of earnings while the donor is in hospital and during their recovery from the operation, pejorative views of professional staff, and the overriding fear that this type of donor is seeking “financial reward”.

16. We support the reimbursement to living donors of costs incurred and losses attributable to the transplant donation process. Policy makers must give careful thought and due consideration to the possible ways in which costs incurred and losses attributable may arise in this context. Donors should be assured of free and adequate medical and psychological follow-up for the rest of their lives under their national health care systems.

17. There needs to be greater clarity about which organisation is responsible and/or willing to pay for reimbursement of expenses. It is our view that such reimbursement should be the responsibility of the health services and any system set up to provide such reimbursement should have appropriate safeguards in place that effectively exclude the possibility of exploitation of donors or profit to intermediaries.

18. The commitment to voluntary, unrewarded “altruistic” donation is stated in almost mantra-like fashion in EU policy-making and regulation in relation to human body parts/substances. It is stated to be an “ethical issue” (see Impact Assessment, page 24) that is explicitly and/or implicitly linked into “quality and safety”. Our view (whether or not individual participants are opposed to payments) is that this has not been substantiated on the available evidence. We would like to see policy-makers being more open to giving at least some consideration to the promotion of alternative methods of organ donation (preferably through state-controlled or state-sponsored initiatives both in the regulatory domain and outside of it).

**Organ Trafficking**

19. An illegal market in human body parts for transplantation exists. There is evidence that this illegal market results in the exploitation of (often) vulnerable persons and allows intermediaries to profit financially. Collective action across the EU could help stop exploitation of (often vulnerable) individuals from organ trafficking.

20. This said, however, it is not clear from the evidence presented to date by either the European Parliament or the Council of Europe that it is a significant problem in the EU context. Their published reports seem to rely largely on anecdotal evidence and we would want to see more robust evidence/empirical research on the issue.

21. If there is a particular concern that organ trafficking is becoming a significant issue, all MS should agree to the adoption of legislation setting out criminal penalties for trafficking.

**References**


*5 October 2007*
INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE

APPENDIX 1

PROMOTING THE ORGAN DONOR CARD—AN EXPERIMENTAL STUDY
(Paper at the International Society of Critical Health Psychology (ISCHP) Symposium on Organ Donation and Transplantation, Boston, USA, 18–21 July, 2007).

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ABSTRACT:
Empathy arousal is regarded as essential for altruistic behaviour. However, using empathic cues to stimulate organ donation commitment might be two folded. Becoming a potential post mortem donor means accepting one’s own mortality. Therefore, being confronted with the distress of organ donation patients might stimulate mortality salience. Referring to the Terror Management Theory mortality salience activates fears of death and dying. Thus, mortality salience is likely to heighten the salience of fears negatively connected to organ donation, such as premature declaration of death. The present research tested the role of empathic cues in stimulating organ donation commitment. We compared an empathic cue message to messages providing their audience with fear reducing information. In the experiment 320 persons participated who had not signed an organ donor card before. Results revealed that the empathic cue message led to significantly higher anti-donation attitudes and lower intentions to sign an organ donor card compared to messages including fear reducing information. Furthermore, reading the empathic cue message resulted in significantly less frequent organ donor card request. The results implicate that trust in the medical system is more important than stimulating empathy to promote the organ donor card.

Examination of Witnesses

Witnesses: Lord Patel, a Member of the House, Chairman, National Patient Safety Agency, and Dr Janet Wisely, Director, National Research Ethics Service, NPSA, examined.

Q342 Chairman: We welcome our guests, Lord Patel and Dr Wisely. Welcome. We are very pleased that you have been able to come and help us with our inquiry. So far we have quite a wealth of evidence but there are some details which we hope you will be able to help us with today. Before we start I have to go through a sort of housekeeping list. The first thing for you to know is that we are going to be televised today. We are looking forward to hearing from you because we do think this is a particularly important inquiry. Just to remind you, we are not looking at organ donation per se; our responsibility is to look at the way the Commission is thinking about it but to remember that we have to have some understanding of the baseline. That is why it is very important that we understand the nature of the work that you undertake as we move forward into our inquiry. We have Professor Bobbie Farsides with us, who is our specialist adviser, who will be helping us when we put the report together. We are open to the public today. As you can see, we have vast arrays of people at the back there. The material will be televised live and on the parliamentary website and may be shown later on TV parliamentary channels. As you know, a verbatim transcript will be taken of your evidence and this will be put on the public record. A few days after this session your office will be sent a copy of the transcript and we would be grateful if you could
check it for accuracy speedily and return it. The turnaround, as Lord Patel will know well, in this place is very speedy. You can submit supplementary evidence after the session if you think we have not understood or you wish to amplify or clarify any points that we have not be able to do today. This room is not easy acoustically. You can hear that I am speaking as if I am in a public place. We would be really grateful if you could do that because we do want to hear what you have to say. When you do start, could you start by stating for the record your name and official title. You may or may not wish to make a short opening statement, and then we will go into the questions, of which you have a list, although you know Members may ask alternative questions. I am sorry that is so long and boring but it is important that we have the ground rules to start with. Your areas are ones that we have not really had a chance to look at in great detail, the National Patient Safety Agency and the National Research Ethics Service. We know that the first encourages greater transparency and accountability and the second works with colleagues in the UK to maintain the wider system of ethical review. Could you begin either by making a statement if you wish to or go straight into the question, describing the work, which I think probably is part of the statement, of the NPSA and NRES which relates to issues associated with organ donation and transplantation, and what are the specific ethical issues that have been addressed in this field. Lord Patel, maybe you would begin.

Lord Patel: Lord Chairman, thank you very much. It is a pleasure to address such distinguished company. I think we might just go to the questions that you have because it will cover any statement that we might want to make. Dr Wisely is going to take the first question you have, particularly in relation to what the National Research Ethics Service is all about and what it is for.

Dr Wisely: I am Janet Wisely and I am the Director of the National Research Ethics Service. It is a division within the National Patient Safety Agency. As you describe, the National Research Ethics Service is responsible for the Research Ethics Committees in England and works with colleagues in Scotland, Wales and Northern Ireland to maintain a UK-wide system for the ethical review of research applications. The last four years have seen a period of significant change for the National Research Ethics Service with the introduction of procedures to improve the efficiency and effectiveness of the service provided to protect actual and potential research participants. The National Research Ethics Service provides operational support, funding, guidance, training and quality assurance programmes for the ethics committees essentially to ensure they are fit for purpose, but the ethics committees themselves make independent ethical decisions on the research applications. We have an administrative database but it is possible through that, although it is not designed as a research base database itself, to estimate from keyword searches that we have received a relatively small number of research applications relating to organ donation and transplantation, I estimate around 200 in the four years from April 2004, which is less than 1% of the number of applications that we have reviewed in this period. Of these, 90% of the studies have been approved by the research ethics committees but with 65% of those first receiving a provisional opinion and the ethics committee requesting changes before they could give their approval. The majority of the studies identified were looking at clinical outcomes around organ donation and transplantation, with a smaller number looking at attitudes, risk perception and longer term quality of life factors. In terms of the ethical issues raised, they are, as you may expect, predominantly around the issues of informed consent. We encourage the ethics committees themselves to rely on the licensing process for the assurance regarding quality and safety, and any of the studies that will be reviewed by the ethics committee will have a licence in place for the transplantation and organ donation itself. Therefore, the ethics committees can focus on the additional ethical issues, which will be around consent, including future use; the burden on the individuals; support for the individuals; confidentiality; and fundamentally to ensure that research participants fully understand what will happen at each part of the research study, if they agree to take part in it. Consequently, many of the issues raised by the ethics committees relate to the participant information. I thought it may be helpful for the Committee to hear some actual feedback from some of these research applications that have been ethically reviewed by the committees. The first is from a study that received a favourable opinion after a provisional opinion had been put in place and the ethics committees requested some changes. The committee wanted to be reassured that patients had consented for the future use of their blood samples for the studies, and requested a copy of the clinical consent form used when patients give blood samples for the transplant programme, and also asked for any background to the clinical consenting process as we were concerned that some of this may be verbal. A second study, which received an unfavourable opinion for a number of reasons, but including: the patient documentation did not provide sufficient information for the patient and should explicitly detail what will happen to the patient; it should detail all the extra hospital visits, the number of blood tests, side-effects and any potential risks. Finally, a third study that also received an unfavourable opinion for a number of reasons, including: any data of patients being used...
outside of the NHS, for example, on a home computer, must be anonymised and the key to participants held separately by the chief investigator; and a second point, the researcher should disclose to all participants that she is a transplant recipient. This raised questions for the committee on whether the researcher may have a conflict of interest. I would like to draw to the attention of the committee that, whilst these quotes are from correspondence from professionals and others, so that every time there is a transplant donation or recipient, that checklist is generic to many of the research applications that would be coming through the ethics committee system.

Q343 Chairman: Lord Patel, do you want to make any additions?
Lord Patel: No.

Q344 Chairman: Can I just ask a supplementary question before we move on? One of the issues that we have heard time and time again from witnesses to the Committee is how you make clinical diagnosis on the safety and quality of organs, and I just wondered, if you are having so little research in that area, how that comparator information is gathered.
Lord Patel: I am not familiar with transplantation and how they make this judgement about the safety of donation of organs. We may be going into the second question to a degree but if I might take it as such, the two bullet points in annex A which the Directive wishes to establish, which relate to a common set of quality and safety standards, and also means of ensuring traceability and reporting of serious adverse events, and your second question particularly related to what views we might have in the NPSA on the potential value of the EU Directive relating to quality and safety I think is an important question. That is where the supplementary that you ask spills over. Let me give you some examples first of all, and you must take this with a little bit of latitude because the numbers I am going to give you might well be an overestimate, because the way safety incidents are reported and the way we then access the data using the software can produce an overestimate, depending on the people who reported the incidents and how many times they might have used the term “transplant”, “safety”, “incident”, et cetera. After that proviso, nonetheless, from October 2006 to September 2007 we had 800 patient safety incidents reported in relation to transplant or donation, which is a significant number, you might say, but remember what I said; there might be an overestimate. Nevertheless, what is important when you break it down is that they fall into treatment procedures, consent issues, and medication issues. One particular example that I would like to tell you about is how an error in putting data on a computer resulted in the wrong kidney being transplanted to a patient, which then had to be removed. That is a serious example of safety, but I use it to highlight that one important recommendation that you can make that covers both these bullet points is a safety-style checklist in both donation and receipt of transplant organs that could be used EU-wide and could be developed by professionals and others, so that every time there is a transplant donation or recipient, that checklist is gone through. The second one would be relates to an EU-wide reporting system of incidents in all transplant patients. It is not rocket science to do that but, if it were an EU-wide reporting system of incidents—and I do not use the word “errors”: these are patient safety incidents, from which comes much learning, and if there were an EU-wide reporting system and a way of analysing, there could be a central data collection point. If it so happens it might be the NPSA, we would be delighted because we already have the infrastructure required to do that, but that would be an important area, an important recommendation that would make patient care in transplantations much safer and reduce the errors of the kind that I have just highlighted. That is a real case. Fortunately, it is a one-off. There was a lot of learning from it. It identified the causes and the systems failure. Most of these are systems failures.
Chairman: This is Lord Lea’s question and he will want to pursue this issue.

Q345 Lord Lea of Crondall: I have no ownership of the question but it is very interesting that you should come to annex A, and if I can slightly rephrase the question, are there some bullet points which you think are particularly good ones and some that you think are perhaps not necessary?
Lord Patel: I only focus on those bullet points that relate to quality and safety.

Q346 Lord Lea of Crondall: I am talking about the bullet points under that EU Directive on quality and safety.
Lord Patel: Yes, that is what I am talking about.

Q347 Lord Lea of Crondall: I know that is what you are talking about. You think the whole lot are useful, all of those, 1, 2, 3, 4, 5?
Lord Patel: Yes, I think they are, but I was particularly focusing on the ones that relate to quality and safety standards and means of ensuring traceability and reporting of serious adverse events. That is the one I referred to and I think they are important.

Q348 Lord Lea of Crondall: Do the others not follow from that? Obviously, the first one is a logical consequence of the second and the third.
Lord Patel: Correct.

Q349 Lord Lea of Crondall: How do you see the others fitting together with those two that you attach importance to?
Lord Patel: The ones for the establishment of inspection structures and control measures: in any transplant you will have some kind of control measures. Inspection is about whether it is a soft-touch inspectorate or a hard-line inspectorate that is required. I have focused on the importance of safety for patients and I think having one format EU-wide that registers all the data, that reports on incidents and that there is learning from would be a very good idea.

Q350 Baroness Young of Hornsey: Just on a point of information, are there other organisations across the EU with a similar function to yours? Do you think there would be any kind of value in looking at an EU-wide organisation with responsibility for these issues?
Lord Patel: I think for transplant purposes particularly it would be valuable to have an EU-wide safety check procedure for all transplant surgeons, whoever they are.

Q351 Baroness Young of Hornsey: With a body to oversee that?
Lord Patel: Yes. The analogy I am using is rather like an aircraft check system. There are plans to introduce such a check system in surgery generally, but it particularly applies to transplants and I have highlighted the example. If there were a check system, that incident might not have occurred. Such incidents, if they occur once because there is a system failure, they will occur again unless you stop it.

Q352 Chairman: We have heard time and time again that it is the systems that count.
Lord Patel: Correct.
Chairman: I would just ask the Committee if there are any other questions they would ask of our two witnesses before they leave us?

Q353 Lord Trefgarne: A question that I guess I should have put to all the witnesses, or at least to some of them, and to which I do not know the answer: I am clear that during the course of my lifetime my body is my own and therefore I can decide what happens to it but after the end of my life, who owns my body?
Lord Patel: Shall I ask the noble Lord Eames? Maybe he does not want to get involved! It is a good question to ask. If you have already consented that parts of your body can be used or if you have a law that says consent is generically agreed to, i.e. the discussions which are going on just now: if I do not carry a card that says my organs must not be used, there is presumed consent that my organs can be used, but it is implied. But the body belongs to you if you have made a decision as to what should happen to it after your death. If not, maybe your next of kin can decide.

Lord Trefgarne: I gather this question is challenging undertakers, to be honest, if the next of kin do not agree on whether a body should be cremated or not, for example.

Q354 Lord Eames: Leaving theology aside, there is an extremely difficult legal area over this whole field. The question of leaving something to your kith and kin does create certain obligations, but if you die and do not leave any stipulation whatsoever, there is a sense, some of the commentators believe, that in fact you belong to nobody; your body belongs to nobody. That is the legal side of it but I do not want to take it on.
Lord Patel: I was going to concentrate on safety. Fortunately, I am not yet asked to look after the safety of dead bodies.

Baroness Neuberger: You should be grateful.

Q355 Chairman: We have spent a lot of time discussing opt-in and opt-out and the point of death and the involvement of relatives, and we are very grateful to you for actually giving us another dimension, particularly focusing on the EU point, because that is where we are going to have to look. It has been, I think, very interesting to hear you talk about the safety issues, and in particular the gathering of information and research, because I think that is somewhere where we have had a bit of a gap in terms of the gathering of information.

Lord Patel: I think a strong recommendation that relates to an EU-wide reporting system of incidents, an EU-wide safety check of transplant recipients particularly, and an EU-wide protocol would go a long way to making transplantation safer.

Q356 Chairman: There is a distinction in what you call an “incident” between those that are to do with consent and those that are to do with clinical or medical outcomes.
Lord Patel: Yes, correct.

Q357 Chairman: We need to be clear that that is another issue in terms of the way we look at it. Lord Patel: The bullet point says it is about quality and safety of transplantation.
Chairman: That is extremely helpful. Thank you very much for your time. I know how busy you are, Lord Patel.
Examination of Witnesses

Witness: Mr Peter Lemmey, Director of Policy, Human Tissue Authority, examined.

Mr Lemmey: I am Peter Lemmey and I am the Policy Director of the Human Tissue Authority.

Baroness Neuberger: Before I ask my question I need to declare an interest, which is that my brother-in-law is deeply involved in transplant policy and practice at Queen Elizabeth in Birmingham, James Neuberger. Mr Lemmey, really it is a multiple question I have to ask you. The first bit of it is asking you to explain how the 2004 Human Tissue Act impacts on organ donation in England and Wales and how the Scottish Act differs from it, if it does, and whether it leads to different practices. If you could start with that, I have a bit more to say.

Mr Lemmey: Let me start with the impact of the 2004 Act. The first point to make is that the Human Tissue Act covers both donation from living people and donation from the dead. The Act sets out provisions to ensure that appropriate consent is obtained for donation for transplantation, and indeed other activities involving organs and tissue and human bodies. The Act set up the Human Tissue Authority, which came into being in 2005 with a role to issue guidance and advice to Ministers, to practitioners and to the public—and in some cases to license and inspect, but those provisions do not apply to transplantation or donation for transplants. The Authority also implements the European Tissue and Cells Directive, and I think we may get on to that in a bit more detail in a minute. The Act outlaws trafficking in organs and commercial dealings. It also covers Northern Ireland as well as England and Wales. The impact of the Act is rather different as between donation of organs from the deceased and from the living. For donations in death the Human Tissue Act regulates through its requirements on consent. The Authority regulates through the Act’s requirements on consent and on the guidance and the codes of practice that the Authority issues. They are approved by Parliament, they are statutory documents, and they set out good practice. We also work with stakeholders in the field, particularly with partner organisations like, for example, UK Transplant. For live donations, donations from the living, the situation is different. Each individual case of a donation for transplantation—we are talking about live transplants—has to be approved by the Human Tissue Authority according to the Human Tissue Act and also according to the secondary legislation, the regulations that came afterwards. Those require that the consent be properly informed, and that it is clear, and that the risks have been explained to both the donor of the organ—the donor of a kidney perhaps—and the recipient, and that it is clear as far as we can be that there has been no coercion of the donor and that there has been no payment. That process of regulating donation for live transplantation is particularly focused by the Act on the need for the Authority to consider the interests of the donor in the transplant. The process works like this. The Authority accredits independent assessors in each of the hospitals where there is a transplant unit. There are about 110 assessors, several to each unit, and they are almost entirely senior medical staff, consultants, but, crucially, not working in the area of transplantation. At an appropriate point in the working up of a transplant those independent assessors will interview both the donor and the recipient of the organ, and the donor and recipient together, to ensure that the issues that I mentioned earlier about consent, risk and coercion, and indeed payment, are explored. The independent assessor will then send a report electronically to the Human Tissue Authority, and we then check that the provisions of the Act have been complied with and deal with any unstraightforward points that the assessor may have raised. In that way, we check through local assessment and then centrally that the provisions of the Act in each case have been met. As far as we can see, the whole process works smoothly. It has been running since 2006. There is generally a two-day turn-round in approvals from the Human Tissue Authority.

Baroness Neuberger: Presumably you can do it more quickly if necessary?

Mr Lemmey: Indeed.

Baroness Neuberger: And have done sometimes.

Mr Lemmey: Yes indeed, and also for unstraightforward cases, where the local assessor has picked up some particularly complex issue, or in novel cases—and I think the Committee have already heard about the way in which the Human Tissue Act has brought in altruistic donation and also the paired donation between two couples. Those are approved by a panel of Authority members. For altruistic donations, since the Act came into force we have approved eight cases altogether. For paired, there have been two sets of pairs approved. We think there will never be enormous numbers of altruistic donations to add to the total number of transplants but we do think that there is a lot of scope, particularly working with our colleagues in UK Transplant, to expand the number of paired donations, perhaps up to about 50 a year. Last year, in 2006–07, the Authority approved 690 recommendations for live organ donation and in the current year, 2007–08, we think by the end of March we should have approved between 1,000 and 1,010.
There is, of course, a slight discrepancy between the number of approvals and the number of operations. In a few cases perhaps, donor or recipient may for medical reasons not be able to proceed with the transplantation. There is also a six-month period after the Human Tissue Authority has approved a particular transplant in which it can take place, so some transplants may take place slightly after the counting period.

Q362 Baroness Neuberger: I just want to pursue the other bit of the question. You have given us the basis, the core principles, on which the work is based when it is live donors. What we have not had from you are the core principles underlying the Human Tissue Authority rather more generally, and we do actually want you to try and link some of that, if you can, with the Commission’s own Communication.

Mr Lemmey: Certainly. Just a quick word about Scotland?

Baroness Neuberger: Yes, and Scotland. You mentioned Northern Ireland, so, particularly given Lord Eames’ presence here, we ought to take that on board to.

Q363 Lord Trefgarne: Could I ask also one factual point? You have recited at length how many approvals there have been. How many refusals have there been?

Mr Lemmey: There have been, I think, two cases in which the Authority has not approved. It is a very small number, and the reason for that is that the training and accreditation process for the independent assessors, the people working locally to assess the cases in the hospitals with transplant units, involves quite a lot of work with the Authority in working on the provisions of the Act. There is also a fair amount of telephone discussion between us in the Authority and assessors during the assessment process. All that serves to ensure that in almost all cases the independent assessor is able to ensure that cases do not come to the Authority if there are any doubts. Those doubts will be shared with the staff of the transplant unit and, of course, the donor coordinators who run much of the process locally, as you know.

Q364 Chairman: Can I pursue that, before you move on to the second part of the question. Would there be any way of knowing when cases are almost turned down informally at the earliest stage? If the assessors are making the assessment, and having a discussion, there must be a point when they decide not to bring the case forward. Would there be any picture of that at all?

Mr Lemmey: I think it certainly happens in the way I described. I will perhaps give two examples of where this might happen, and again, as I say, the independent assessor, while making an independent assessment, is part of the process in the hospital involving the transplant team and the donor coordinators. So far as consent is concerned, there have been occasions, I think, when a family has presented and it may be that the father, who may be a pater familias figure, has got kidney disease and needs a transplant. There are a number of children, and perhaps the youngest child, who is perhaps a rather quiet young man, is the one who apparently is going to be the donor, and the issues there about consent are clearly quite interesting. It is not just an issue for the independent assessor but, of course, particularly the donor coordinators will have been working to see whether there is in fact a possibility of taking this case forward under the Human Tissue Act, and it may be that at an early stage the donor coordinator will decide that the consent issues are not clear and the transplant team will not proceed.

Q365 Baroness Gale: Before I put my question, I need to declare an interest in that I am a patron of Kidney Wales Foundation. You talk about paired donations. We have had very few in this country so far, and we all know about them because there was lots of publicity about it. I wondered, would it work if you had paired couples from, say, Spain and Britain? Would you see that as being extended across Europe?

How would you then determine giving permission or authority with people in different countries?

Mr Lemmey: There are very few organs either imported or exported for transplantation. I think I am right in saying the figures for last year, for 2007, both in and out, barely got into double figures. Even in this country paired donations, paired transplants, are very difficult to arrange, partly because of the time. It would, I suppose, be possible in theory if you are carrying out a paired donation to have both pairs in the same hospital, in the same transplant unit but, for all sorts of reasons, that is not possible at the moment. Indeed, paired donations that have taken place, as I think you know, have involved places as far apart as Cambridge and Edinburgh and have involved the use of an aeroplane. The timing of that is crucial. Also we are finding that the set-up work, even within a single UK system overseen by UK Transplant is very complex. I think we are some way away from either an organisational synergy that would allow that to happen, but also there is always going to be a problem about the time taken to swap the organs between one unit and another.

Q366 Chairman: Can we come back to the Scotland question?

Mr Lemmey: Very quickly: in practice, live organ donation in Scotland operates under the same system as it does in England, Wales and Northern Ireland, and consistency of approach across the UK has been
the watchword, and the Human Tissue Authority acts on the Scottish Government’s behalf in cases of organ donation in Scotland. Having said that, Scotland has its own Act, the Human Tissue (Scotland) Act 2006, and there are one or two detail differences. For example, the concept of consent in the Human Tissue Act 2004 is known as “authorisation” in Scotland. The provisions as regards children are slightly different because in Scotland people over 16 are regarded as adult and it is over 18 in this country. There are a number of other small differences which I can provide information to the Committee about.

Q367 Baroness Neuberger: The link-up to the Commission’s Communication. Do you feel—I think we need this for the record as this is particularly our area of concern—that the principles that underpin what you do in the Human Tissue Act, and, indeed, what there is in the Scottish Act, link well with the Commission’s Communication? Do you feel that the same principles underpin both?

Mr Lemmey: Can I start to answer that by setting out what I think the principles are?

Q368 Baroness Neuberger: Yes, that would be very helpful.

Mr Lemmey: I think there are two sets of principles which underpin the regulation of live donation and also by which the Human Tissue Authority steers. The first of these I think are the ethical principles set out in the 2004 Act, and they are about ideas of a degree of individual autonomy, the primacy of consent in the process, the importance of consent being properly informed, people giving consent properly informed, and the importance of there being, certainly in terms of organ transplantation, no trafficking and no coercion. There is a second set of principles which I think shape the regulatory activities of the Human Tissue Authority, and those are ones derived from the work of the erstwhile Better Regulation Commission, the Better Regulation Executive. Those are about accountability, proportionality, being targeted and transparent, and the Better Regulation principles are actually written into the Human Tissue Act as something that the Human Tissue Authority needs to bear in mind. I think there are those ethical principles and Better Regulation as well. There is actually I think a third, perhaps not a principle, but it is an important, again, guide to the Authority. We are sponsored and partly funded by the Department of Health and the Authority supports the Secretary of State for Health’s objectives on maximising transplantation rates, to the extent it can without compromising its remit to regulate the process. With those sets of principles in mind, we look at the proposals in the Commission’s Communication really from two immediate standpoints. One is that it should allow subsidiarity, so far as it can, to allow individual Member States to support their own ethical principles and, secondly, that any regulation, any proposal, any EU action, should be able to be implemented in this country in terms of Better Regulation. Shall I go on?

Q369 Baroness Neuberger: If you have a specific point, yes, although we are running short of time. Have you any particular areas where you think there is a conflict?

Mr Lemmey: The Communication has three themes. The first one is quality and safety. Despite what the Committee has already heard, I do not think that is a major problem in this country. Standards of quality and safety are derived from both statutory and professional bodies, and there are mechanisms in this country, the NPSA being one, for tackling those. I think it is also correct to say that standards in this country are seen as being pretty robust in other parts of Europe. So it is not immediately obvious that European action—

Q370 Chairman: May I just make a precise point that has come to us on a number of occasions? We have had a number of witnesses who have been concerned that an EU Directive might make it difficult to be flexible in relation to certain organs where people are dying—we know that—because there is a shortage of organs, and that there may be such a high standard that a number of organs that might be usable, putting it very simply, would be rejected if we had a Commission Directive that was too tight. That is what Lady Neuberger is trying to see whether or not you think that a Directive needs to be flexible enough to ensure that what is commonly called, I suppose, “gold plating” does not happen.

Mr Lemmey: I think flexibility is very important. One of the lessons that the Human Tissue Authority has learned from implementing the previous Directive, the Tissue and Cells Directive, is that too much detail in Directives can sometimes be a hazard. I think good European legislation works well, and the Tissue and Cells Directive in many ways does work well, but it is a very detailed document and detail tends to ossify over time, and it is difficult to adapt and be flexible if the transposed regulations from EU Directives are too detailed and prescriptive.

Baroness Neuberger: That is what we wanted. Thank you very much indeed.

Q371 Baroness Gale: We have been told that there is a conflict of interests between the Human Tissue Act and the Coroners Act which leads to a lack of clarity about the way in which the medical treatment of potential organ donors—particularly non-heart beating donors—should be determined so as to
reconcile any conflict between the coroner’s forensic interests and the objective of retrieving organs of good quality. Does the HTA recognise this problem and, if so, how would you like to see clarification being provided?

Mr Lemmey: We do recognise this as a problem. It is not a very widespread problem at the moment but it may be that, if it is further addressed, it may enable a greater number of transplants to take place. Cases coming in through accident and emergency, through casualty, dead or dying, are in many cases potentially coroner’s cases but also may potentially be transplant donors. So far as possible donation for transplantation of organs is concerned, the transplant unit, the hospital, will need to check on the consent status, and that can take a little time. Part 3 of the Human Tissue Act 2004 allows what are called “minimum steps” for preservation for transplantation to take place while that consent is sought, while the donor register status is sought or contact is made with the relatives, with the family. Those minimum steps could include a process called cold perfusion, which is passing cooling preserving fluid through the body to keep the organs cool until the question of consent can be resolved. This only happens in a limited number of hospitals. I think currently actually it is only at Newcastle, although there have been programmes run elsewhere. It is quite resource-intensive but, at the same time, while that process might go on the coroners will be concerned that their criminal justice investigations, for example, blood tests or toxicology tests, might be impeded or jeopardised if that process takes place, although certainly, if it is done in a planned way, there are ways in which both the cooling process can take place and the forensic examination can also take place. Until the 2004 Act the lawfulness or not of these immediate steps was not clear, but the Act goes out of its way to explain that those processes are lawful and, interestingly, the provisions of the Act that cover minimum steps and cold perfusion are actually in Part 3 of the Act, which is the part of the Act which does not contain the exemption for coroners’ purposes. The Human Tissue Authority interprets this as recognising the importance and validity both of the coroners and criminal justice interest on the one hand and the transplantation team and the potential for donation on the other. Where cold perfusion has taken place across the country, there have been different arrangements. I think, locally with coroners and with hospitals. As I say, I think now in fact only one programme is running. There needs to be a practical way to balance both those interests. What the Human Tissue Authority has done is, we are in the process at the moment of writing a generic protocol to enable hospitals and coroners on this issue to work through the issues and come to an agreement which allows both sets of interests to be recognised and to be worked through. Writing a protocol is one thing; getting it enacted is another. This is where the Human Tissue Authority feels it is so important that the recommendations of the Department of Health task force on organ donation, the Organs for Transplants report, are enacted. I think recommendation 14 of that report covers this area and what that holds out the hope of is some centrally driven work both by the Department of Health and the Ministry of Justice on ensuring that these sort of agreements and protocols can be taken forward, and we might then see this minimum steps cold perfusion programme being adopted a little more widely, and that again would add to the number of transplants, we would hope.

Chairman: That is really helpful.

Q372 Baroness Neuberger: Obviously, from what you have said, in fact it has not been an easy process if you are down to one centre doing it. In that remaining one centre, is it handled through intensive care or is it also through A&E?

Mr Lemmey: I think it is through both but I do not know the detail. What I do know though is that they are resource-intensive programmes because, of course, it is difficult to predict when cases are going to actually appear.

Chairman: If you have any thoughts that might clarify that, maybe you would let us know.

Q373 Lord Eames: In a sense, what I want to draw attention to has been touched on in various aspects in some of the evidence you have given this morning. It is to do with the experience of the Authority in operating the Tissues and Cells Directive within the UK. In addition to what you have said about the experience of the Authority in these various Directives, could you say something more to us about the relevance you have seen, the problems you have come across when we have to have a Directive such as this on a very sensitive issue operated within the UK culture, legal system, and so on. Could you tell us something about that?

Q374 Chairman: Have you anything to add to what you have already said?

Mr Lemmey: Yes, certainly. I have explained that the Human Tissue Authority is one of the Competent authorities. I have explained that we are now regulating 200 or more establishments that deal with tissues and cells. We are talking here about stem cells, heart valves, corneas, skin, and so on. I have also said a little bit about what we thought was in some parts an over-detailed aspect of the Directive. Another aspect of implementing the Tissues and Cells Directive has been that a dual licensing system has had to be set up. It may have been helpful during the development of the Directive if there had been a
greater attempt perhaps to map the proposals on to the individual legislation of Member States. The Human Tissue Authority has to operate two licensing systems: one under the Human Tissue Act and one under the Tissue and Cells Directive covering similar areas involving human tissue, and indeed, some establishments have to have a licence under both systems, under both regimes. It really is, I think, stretching the boundaries of the Better Regulation to suggest that is an optimal position. That is really an issue, I think, about the way in which European legislation and legislation in Member States is looked at.

Q375 Lord Eames: Before you leave that, could I just ask this? Are you in fact saying that there was perhaps a lack of pre-consultation, of wedding what was going to come in the Directive with what was happening in individual Member States, that is, before the Directive arrived on the scene? Mr Lemmey: I think that is broadly right. Before the Tissue and Cells Directive was ratified something called an RIA, a regulatory impact assessment, was carried out to try and judge the impact but that was, I think, at the start of the process. It took about two years, from Spring 2004 to Spring 2006, to complete the Directive and its two detailed technical annexes and during that time, of course, the proposals it contained had changed. I think there is an argument for perhaps revisiting those impact assessments at least annually during these long drawn-out developments of European legislation.

Q376 Lord Lea of Crondall: So there was not so much a lack of consultation as a fine-tuning of the consultation according to the iterative process going on at that time? Mr Lemmey: That is right, and indeed, the Commission is now having to fine-tune the Directive because, as I say, of the way in which life has gone on since then.

Chairman: We are going to have to move on. If there are other areas in this, would you write to us about it, because that would be really helpful?

Q377 Baroness Perry of Southwark: Mr Lemmey, I think you have probably answered quite a lot of my question. You know that the British Transplant Society said to us that they thought the Directive should cover just the issue of minimum standards relating to organ retrieval, including the training of staff. What we would like to hear from you is what areas that are not currently mentioned in the Commission’s document you think the Directive should cover?

Mr Lemmey: I am not sure whether this is so much issues to be covered by the Directive as a Commission action plan or indeed Commission action more generally. The Committee has already heard today of the possibility of greater sharing of information, particularly about incidents that have happened in transplantation. I think the Human Tissue Authority would particularly pick out the importance of sharing information about the organisation and management of organ transplant systems in other countries. All Member States would have something to learn from each other there. I think also there are questions about access to transplant services which it would be helpful to exchange information about. I think those are two of the areas in which we would see benefits from greater European action.

Q378 Baroness Young of Hornsey: I have a couple of questions around presumed consent. What would a move to presumed consent in the context of organ donation entail in terms of changing the Human Tissue Act? Secondly, how would such a change in the law affect the HTA’s general working principles and the way it organises its work? Thirdly, what, if any, significant problems do you think could arise in implementing an Act which allows for presumed consent?

Mr Lemmey: There is a lot here. I think at minimum the Human Tissue Act 2004 would need a change to Part 1 of the Act, because the appropriate consent provisions for deceased organ donation provisions would need to change, and also there would have to be a change in Part 2 of the Act to change the remit of the Human Tissue Authority in that area. Having said that, I think in reality it may be that Ministers might prefer a much more radical legislative change, in the form perhaps of a Transplantation Bill, but it is not for the Human Tissue Authority to make that choice. I think it is important that I state that the Human Tissue Authority has not come to any decision about presumed consent, although it has debated the issue and it has identified in its meetings some of the questions which it thinks it is important to address. Also, I think the Authority has noted that if presumed consent were brought in for deceased organ donation, it would actually also have to pick up some other activities, investigative and clinical, that are part of the transplant process as well and that should perhaps be borne in mind. The Authority supports a balanced and evidence-based approach to policy-making and, through the Chair of the Authority, we are already involved in the work of the reconstituted Department of Health task force that is looking into presumed consent. That is gathering and assessing evidence, as you know, about the impact of presumed consent on the transplantation programme. Should the evidence point to presumed consent being a major trigger for improved donation rates, I think the authority would certainly hear that strongly in mind in any advice it wanted to give to Ministers about that. Clearly, if the law changed, the
Authority would implement and regulate under the new arrangements. Having said that, the Authority has highlighted a couple of points at this stage. One is an ethical issue really, and it is about informed consent. The current provisions in the Act require there to be informed individual consent and, if that notion of information as the context in which consent is given is to continue under presumed consent, a soft opt-out arrangement, there are clearly important issues about how a population of 60 million people can be properly informed. That is certainly an area which the Human Tissue Authority would hope the task force would address.

Q379 Chairman: We heard from the Spanish senior coordinator last week that all of this does not matter if the organisation is quite clearly set out, that donor cards might be quite useful, information will be helpful, but unless the structures are there in the hospitals where there are coordinators who can work with families on the ground, the numbers will not go up. What would your view be about that?
Mr Lemmey: I think that is the sort of area that some further evidence on which will both be helpful to the Human Tissue Authority and I think it is actually issues like that which point towards the answer on this particular debate. To go back to your question, there is a second issue that the Authority has particularly identified, and that is about the integrity of the Human Tissue Act across all its other uses and activities affecting human tissue like research, like post-mortems, like anatomical dissection by medical undergraduates, and even public displays of bodies. Currently the notion of informed consent, the requirement for informed consent, applies to all those activities as well and the Authority is, I think, concerned that if one of the activities within its remit, which is organ donation in death, if presumed consent is brought in for that, then the informed consent provisions, explicit consent provisions, across those other activities should not be jeopardised.

Q380 Chairman: Is that why you think that there would be a useful exchange of information across Europe? We have already learned from a number of other countries about the value of exchanging information. It underpins some of the issues you have just been describing. You mentioned the need for that exchange of information, and then you have described some of the issues. How could they be shared across Europe and taken forward?
Mr Lemmey: I think it is particularly in the area that you mentioned earlier about the management of organisation of transplant services within hospitals: but there is also another aspect which the Authority would see as important, and again, has been raised in the initial work of the task force, and that is attempting to make organ donation, organ transplantation, a more everyday process, something which comes to mind for professionals and staff working in hospitals as not being a particularly unusual or exceptional process but being one that is almost an everyday activity, the way in which I think in other countries there may have been progress in that area, and again, if that sort of information can be shared, its sharing will then help the implementation of those task force recommendations, which we think are a very important step in improving the numbers of transplants in this country.

Q381 Lord Trefgarne: You have said that your Authority do not at this moment have a position on whether or not we should move to presumed consent but, if Ministers were minded to move in that direction, they would presumably ask the Authority for advice and you would have to form a view at that point.
Mr Lemmey: I think that is right, and perhaps even if we were not asked, we nonetheless would provide it.

Q382 Lord Trefgarne: Would that then become public? Advice to Ministers is generally not public.
Mr Lemmey: I think that would depend. I certainly cannot say that it would definitely become public.
Lord Trefgarne: It might leak!
Chairman: Can we say thank you very much indeed. There is never enough time to get all the details but, as we said earlier, if there are things you think we have not had in enough detail on the questions we have asked you, we would be very grateful if you could just follow up in writing. We have found your answers extremely helpful and detailed, and one or two leads that have been very important to us. Thank you very much for joining us.

Supplementary memorandum by the Human Tissue Authority

First—Q372 at the foot of page 21—the Chairman invited you to send any further thoughts on how cold perfusion is handled in those hospitals (possibly just one hospital) that use it.

Baroness Neuberger had asked me whether the process of cold perfusion of a body to keep organs cool while the consent position was checked—the classic area of tension between Cororers and transplant teams—generally took place in intensive care units or in accident & emergency departments.
I am informed by colleagues in the field that cold perfusion would normally take place in accident &
emergency—where someone has been brought in dead or has died after a fruitless attempt to resuscitate.

As I mentioned in my evidence, the process of cold perfusion is lawful under the Human Tissue Act 2004 but
currently only takes place at one hospital; the need to agree an approach with the Coroner is one reason why
it does not obtain elsewhere.

Second, Q376—on page 23—the Chairman asked if you would write about the issues that had arisen with the
implementation of the Tissue and Cells Directive which had led to the need for it to be “fine-tuned”.

The Chairman's request goes back to the point I had earlier made about the degree of detail contained within
the Tissues and Cells Directive. The Directive was very specific about processes and materials to which it
applied, or not; and is now having to be amended to pick up initial omissions, for example donor lymphocyte
infusions.

A point we would make here is that, because of the degree of detailed prescription contained in that Directive,
we were unable to enact it through existing UK legislation—the Human Tissue Act 2004—but, had we been
able to do so, we would have had the flexibility which that Act provides (through Directions, for example) to
adapt and to fine-tune the provisions in the light of experience in implementing them.

Several Members were puzzled both last week after the session with Lord Patel and after the session this week
with the GMC about the issue (which I did not mark up in the suggested questions list) as to the legal position
relating to the ownership of a deceased person’s body. The response that Jane O’Brien of the GMC gave was
helpful—but I wonder whether it would be possible to send me a short written account of how the HTA sees
the position.

I’m not sure that we can add much to the evidence of other witnesses. The Human Tissue Act 2004’s provisions
on consent for activities including organ donation are framed in a way which does not involve the issue of
ownership; and have been implemented successfully on that basis.

It has not therefore been necessary for the Human Tissue Authority to provide guidance on the topic.

Our view (I imagine widely shared) is that, as there is no statute, the position is as established in common law.
Halsbury’s Laws of England states that “It is said that the law recognises no property in a dead body . . . .”
We have also noted that in Dobson and another v Tyneside Health Authority and another [1996]4 All ER 474
(case law) it says “in the present state of the English authorities there is no property in a corpse (see Williams

2 April 2008

Supplementary evidence by Professor Margaret Brazier, Centre for Ethics and Social Policy,
University of Manchester

LEGISLATION RELATING TO ORGAN DONATION

Q. What lessons have you learned from your work with the Retained Organs Commission which are of direct relevance
for consideration of the legislation and which you feel should be in place to regulate organ donation?

The evidence that we received from families and the many hundreds of relatives whom we met demonstrated
very graphically to me that reverence for the bodies of the dead and the freedom to ensure that a dead loved
one was treated with respect was of great importance to many people. They saw such reverence as the last
service that they could undertake for that person—an exercise in love. How that service should be rendered
varied. While there are a number of people for whom burial or cremation entire is of supreme importance
many families would have donated organs for transplant and indeed donated organs for research or education
had they been asked. It was treating their relatives as mere objects that inflamed such anger and provoked
such grief.

I think it is important too to avoid stereotyping. Religious observance was a major factor in a number of cases.
And beliefs about the body are of immense significance to many families but it is not simply families from
certain faith or ethnic groups who have deep seated objections to tampering with the body. It was not only
organ retention from children that provoked such distress. And that distress was absolutely genuine and not
part of a media frenzy or driven by a desire for compensation.
So I think we must not forget those lessons and how important it is for families to be part of decisions about what happens after death. Any death where transplantation is an option is likely to be traumatic and deciding what becomes of the remains of the loved person is a crucial factor in how a family comes to terms with the death.

I worry that changing the law again now might result in a level of distrust that even if any change was said to be solely relevant to removal of organs for transplant there would be suspicions that all the undertakings made organ removal.

Q. What is your view of the need for an EU directive covering organ quality and safety? What pitfalls do you think should be avoided in framing such a Directive, and what areas, if any, do you think it should cover beyond those envisaged so far by the Commission?

It at first sight sensible and logical to act at EU level in relation to quality and safety. There is an obvious model in the Blood and Tissue directive. As EU citizens become more mobile across the EU and if we are to have more pooling of organs there is a need to be reassured that wherever you receive treatment the process is as safe as it can be. I suspect that agreeing and enforcing such standards may not be easy I think it is important to remain within the safety and quality brief and be cautious about attempting to impose greater uniformity under the cloak of quality eg a common consent regime And I think we must ask whether the time is yet right for a Directive even one limited to quality and safety.

As the Commission states in the Communication, the “main challenge” that needs to be addressed at both national and EU levels is the shortage of organs available for transplantation.

The Commission has identified a number of areas which it will focus in the short to medium term in this policy area which are (1) improving quality and safety; (2) increasing organ availability; and (3) making transplantation systems more efficient and accessible. In terms of an action plan for addressing these issues, the Commission will promote greater cooperation between Member States through the use of the Open Method of Coordination which will include the reporting and exchange of information on best practices, as well as the setting of benchmarks based on qualitative and quantitative indicators.

It is clear from the Commission’s research (as set out in the Impact Assessment accompanying the Communication) that there is significant variability amongst Member States across a range of issues involved in the organ transplantation process. It is also clear that some Member States have systems in place that result in significantly higher rates of (cadaveric) organ donation (eg, Spain). So, we welcome any structured process through which best practice in the organ transplantation process can be developed and disseminated on a uniform basis throughout the EU.

In the Communication, the Commission is clearly aware that any action it takes in this field including the development of a legislative proposal for a framework Directive needs to take account of the “main challenge” of organ shortage. It acknowledges that this challenge significantly alters the risk-benefit ratio, and that any Directive setting out standards of quality and safety would need to take this into account. The problem that the Commission faces is that the terms of its formal legal competence to act in this field including the development of a legislative proposal for a framework Directive needs to take account of the “main challenge” of organ shortage OR will it divert attention and resources unnecessarily from this issue?

Nobody would deny that quality and safety are important factors in organ donation and transplantation, but they are just two factors among many that need to be addressed in the field. Indeed, in some of the newer accession States, setting standards in relation to quality and safety may be particularly useful as they develop systems for organ donation and procurement. For most Member States, however, the main challenge in the short to medium term is how to address organ shortage.
It is clear from the success enjoyed in Spain that how organ donation and procurement is organised at an institutional level has been crucial. The Council of Europe has published a consensus document on how this organisational model can be adapted and implemented at national level and this clearly needs to be the focus in the short to medium term. To ensure appropriate organisation in organ donation and procurement requires time, effort and significant financial and personnel resources. While countries such as the UK may draw on the experience of the Spanish model, there is a need to evaluate how best that can be adapted in the national context and particularly in the context of the organisation of the national health system.

The danger in adopting a Directive at this point which has as its focus standard setting in quality and safety in organ donation and transplantation runs the risk of creating additional layers of (unnecessary) bureaucracy, particularly as a Directive is likely to mandate the implementation of standards with respect to authorising establishments to engage in organ donation and procurement, setting up inspection and control measures, and setting standards in relation to the storage, preservation and transport of organs. While implementing such standards may be useful in the long term, it is likely to divert valuable (and in many Member States scarce) personnel and financial resources away from a necessary focus on organ shortage in the short to medium term.

In short, we consider that any move towards the publication of a legislative proposal for a Directive would be premature in the short to medium term. The focus instead should be on strengthening cooperation through OMC along the lines noted above. The adoption of a Directive should be viewed as an option for the long term.

Perhaps it would be best if EU institutions gave consideration to expanding the treaty competence to act in relation to organ donation and transplantation so as to allow the issue of organ shortage to be addressed more directly as the main focus in any regulatory initiative that may be brought forward in the field.

**WIDER ROLE OF THE EU IN RELATION TO ORGAN DONATION**

Q. In your discussions, as a medical lawyer, with academic and clinical colleagues from around Europe, what have you identified as successful European collaboration in relation to organ donation, and where do you feel the Commission could or should encourage further work?

What we have heard suggests that around Europe there is a wealth of evidence about what works and what does not. The EU is best placed to conduct the research that will allow the preparation of guidance on best practice including on how consent regimes may work and how they are received in MS. It is obvious that there is much to be learned from Spain but we need to understand more about how far the Spanish model is exportable to MS with different health service organisation, different population make up, and perhaps a different perspective on ethical debates. Specifically a mechanism needs to be put in place to bring together and analyse the results of research already available on what works and what does not. Additionally more research may be needed to try and identify these factors within the varying donation systems across the EU.

Greater understanding of why we see such different patterns of donation within the EU is also important. We need to identify the limits of harmonisation. In some MS geography means that there will always be a greater emphasis on living donors. Cultures differ and imposition of EU “Rules” can sometimes be counterproductive.

Support for the promotion of donation and education would be good. Let people learn about Spain and get Spanish donor families to share their experiences. However, we would guard against a one size fits all approach to education in this area. The differing practice and culture of donation amongst the member states may necessitate differing approaches. A mechanism by which member states can draw on research in this area would be useful.

A recent European collaboration is the ELPAT platform which aims to establish continuity in European communication on “Ethical, Legal and Psychosocial aspects of Organ Transplantation”. ELPAT functions as an independent entity within the European Society for Organ Transplantation (ESOT). This or a similar EU-led organisation would serve as an effective mechanism for both the collection and analysis of relevant research that is already available, and for conducting further research (funded by either the EU or individual member states).
INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE

HUMAN TRAFFICKING IN RELATION TO ORGAN DONATION

Q. To your knowledge, how significant a problem is human trafficking in relation to organ donation? To what extent do you judge that the legal structures already in place to deal with this issue are adequate? Please could you expand on what you had in mind in your written evidence to us about the potential for the introduction of EU legislation which sets out criminal penalties for trafficking.

Our concern is just that such robust empirical evidence is not to our knowledge available. We have heard many anecdotes some of them very disturbing. We recognise that often the problem lies outside the EU with recipients travelling to countries where donors may be at risk and/or be exploited and where recipients own health care may be sub optimal. But a common approach within the EU would be valuable first step to limiting trafficking. However I suspect that laws will have only a marginal effect while desperate people judge that they will not be bale to have timely access to organs within the legal and ethical framework of their own EU state. The best answer to trafficking is to make it unnecessary.

It is clear that the issue of organ trafficking was identified as an issue of concern during the Greek and Italian Presidencies in 2003. This has been followed through by a request for Europol to provide a report on the extent of the problem in the EU context. At this stage, no further data has been forthcoming from the Commission on the issue so it is difficult to know the extent of the problem and therefore how to address it in a systematic way in terms of policy or regulatory processes at either national or EU levels. It is interesting to note that the Commission in its Communication acknowledges organ trafficking as an issue which it will monitor in terms of any developments (see p.8), and a survey has been commissioned to ascertain what legislation exists at Member State level in the area, as well as to identify problems and solutions (see IA, p. 8). The Commission makes clear in the Communication, however, that further work in the area is not seen as a priority in its proposed action plan.

We also need to be clear whether if EU states retain a ban on markets in organs whether certain kinds of incentive/reward are nonetheless permissible such as meeting funeral expenses (a recent report on this has been carried out in the Netherlands—van Dijk, G, Hilhorst, M.T., Financial Incentives for Organ Donation: An Investigation of the Ethical Issues, available via www.ceg.nl or www.rvz.net).

ORGAN DONATION TASKFORCE PROPOSAL TO SET UP A UK-WIDE DONATION ETHICS GROUP

Q. What do you see as the most difficult ethical issues surrounding organ donation and transplantation? What advantages do envisage there would be in establishing an independent UK-wide Donation Ethics Group? To what extent do you think there could be benefits in extending the discussion of such ethical issues across other EU Member States?

I suspect that the difficult ethical issues are little different from 20 years ago, should payments be allowed for any kinds of donation, should explicit consent to cadaver donation be required. I do think an effective forum to debate these issues would be useful but care needs to be taken not to duplicate work done elsewhere and in particular to work out here the HTA would sit in such a framework. Given the benefit of an EU approach to how we organise transplantation yes I think an EU dimension to the ethical review of such issues is valuable and offers an opportunity to exchange experiences of different consent regimes and how the ethical debate has developed in MS. My worry would be practical how could an EU wide group function efficiently and not be a mere expensive talking shop.

To answer the first part of the question our experience has been that the focus on grand ethical debates has diverted attention from what can practically be done. What laws say or how states vies ethical issues seems much less important than good systems to co-ordinate transplantation. Our group has very different views in many of the grand ethical questions. What we agree on is that there are so many practical questions that could be addressed without any change in legislation that would improve current donation rates.

Identifying donors and asking for consent and asking well is so important that how to seek consent must be a priority for future work.

March 2008
EXECUTIVE SUMMARY

The BMA has been concerned for many years about the shortage of organs available for donation and has been actively working with other organisations to find ways to address the problem. We welcome any initiatives that are likely to improve organ donation rates in the UK, and in particular, seeing what lessons we can learn from other countries within Europe.

The BMA believes that the most effective way of addressing this issue is a shift to presumed consent, combined with continued organisational change and financial investment. Over the last seven years we have seen increasing support for presumed consent and we believe that it is time to move to this option, following public debate.

The BMA supports increased communication and sharing of examples of good practice within Europe but is concerned that any European approach to the problem should bring clear benefits to the UK and not simply add an additional layer of bureaucracy which could, in fact, hinder progress.

SHORTAGE OF ORGANS AVAILABLE FOR TRANSPLANTATION

1. Surveys show that around 90% of the UK population are willing to donate organs after their death, yet only 23% have signed up to the NHS Organ Donor Register. For those whose wishes are not known, a nominated individual or family member is asked to give consent on their behalf but the Potential Donor Audit, co-ordinated by UK Transplant, shows that the relative refusal rate currently sits at around 40%. This means that many organs that could be used for donation are lost because individuals never got around to making their views known—either by signing up to the ODR or discussing their wishes with their relatives. This is the fundamental problem that needs to be addressed and, we believe, where attention needs to be focussed.

Public campaigns

2. There is an important role for public campaigns and the BMA has supported and initiated many campaigns to improve awareness of organ donation generally and specifically to encourage people to make their wishes about donation known. We have co-ordinated public campaigns and run campaigns within our own membership. One of the most successful campaigns run by UK Transplant was the “vote for life” scheme where people could register on the ODR at the same time as completing their electoral registration forms. Between 1999 and 2004, this campaign was taken up by a number of councils resulting in responses from more than 719,000 people. This campaign was stopped however when the Electoral Commission issued a Circular informing electoral registration staff that the scheme risked contravening regulation 94(3) of the Representation of the People (England and Wales) Regulations, since the material had no connection with electoral issues. Similar advice was provided in Scotland. The BMA recommends amending the relevant statutory instruments so that this very successful campaign can continue.

2 UK Transplant. Transplants saves lives. www.uktransplant.org.uk
The role of relatives

3. The BMA welcomes the changes introduced in the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 clarifying that where an individual has given prior consent to donation, there is no legal right of veto by the relatives. The Human Tissue Authority’s code of practice and, we understand, training of transplant co-ordinators, now focuses on the importance of strongly encouraging relatives to respect the wishes of the deceased person. The legislation is, however, permissive and does not require donation to proceed, so there are exceptional cases where donation would not proceed despite consent having been obtained from the potential donor. The BMA believes, from a practical perspective, that this is correct since insisting on donation against the very strong and sustained views of the relatives risks causing more, and lasting, damage to the organ donor programme. The duty of care owed by health professionals to recently bereaved relatives also requires a flexible and humane approach in exceptional cases where donation is likely to cause additional severe distress. The more individuals are encouraged to discuss their wishes with their relatives, however, the less likely such disagreements are to occur.

Presumed consent

4. Whilst supporting all of these attempts to increase the number of donors available, the BMA strongly believes that the change that is likely to have the most impact on donor numbers is a shift to a system of presumed consent with safeguards. The Chief Medical Officer for England has also recently supported a shift to presumed consent in order to address “the current supply and demand crisis” and we are delighted that the Government has asked the Organ Donation Task Force to investigate this option. This is the way such a scheme would work:

— in advance of the change there would be extensive and high profile publicity advising people of how to opt out if they do not wish to be donors;
— mechanisms must be in place to ensure all sections of the public are informed and can register an objection easily and quickly;
— after the system has come into effect, when a person dies in a situation that makes donation a possibility, the opt-out register must be checked;
— if the individual had not opted out, the relatives would be informed of this and asked if they are aware of any objection to donation by the individual that had not been registered;
— if the relatives are not aware of any objection, they would be informed that the intention would be to proceed with donation; and
— donation would proceed unless it became evident that to do so would cause severe distress to those close to the deceased patient.

5. The main reasons underpinning the BMA’s support for this change are:

— the vast majority of people are willing to donate their organs for transplantation purposes, but less than a quarter of the population are on the NHS Organ Donor Register;
— given that the majority of people would be willing to donate, presuming consent rather than presuming objection is more likely to achieve the aim of respecting the wishes of the deceased person;
— unlike the current system, there would be a clear mechanism for protecting the wishes of those who do not want to become a donor;
— while relatives would still be consulted, they would be relieved of the burden of making the decision in the absence of any indication of the deceased person’s wishes;
— a shift to presumed consent would prompt more discussion within families about organ donation; and
— with such a shift, organ donation becomes the default position—this represents a more positive view of organ donation, which is to be encouraged.

6. Despite the difficulties of obtaining meaningful data about the success of presumed consent in other countries, there is growing evidence that presumed consent has a positive effect on donation rates. In 2006, a detailed regression analysis was published comparing 22 countries over 10 years taking account of determinants that might affect donation rates including gross domestic product per capita, health expenditure, religious beliefs, legislative system, and number of deaths from road traffic accidents and cerebrovascular

diseases. It concluded that “When other determinants of donation rates are accounted for, presumed consent countries have roughly 25–30% higher donation rates than informed consent countries.” Another study, published in 2003 concluded that presumed consent was one of four variables considered that was a significant predictor of cadaveric organ donation rates. The authors stated that evidence from their study clearly suggest that the practice of presumed consent legislation has a “significant effect” on the number of cadaveric donors per million population.

7. The BMA agrees with those who say that it is crucial that there is public support for a change to presumed consent but we firmly believe that there is growing support for such a shift. There have been a number of public opinion surveys on this topic over the last five years, which show up to 60% support for such a change. This is 60% before there has been any concerted effort to educate and inform the public about the way such a system would work and to facilitate an informed public debate on the matter. The BMA does not believe it is acceptable to use lack of public support as a reason to reject presumed consent without at least making a clear effort to determine what the public’s opinion is on this matter. We believe that now is the time for an informed public debate about moving to this option.

European organ donor card

8. We have been able to find very little information in the European Commission’s reports about the benefits of a European organ donor card, or how such a card would work. Donor cards can be helpful in promoting debate within families but they are less effective than the ODR in terms of advising health care staff of the donor’s wishes at the time of an illness or accident.

9. It is not clear whether the intention of a European organ donor card is that organs would be routinely shared throughout Europe, rather than throughout the UK as at present, but this seems unlikely because of the short period of time available between retrieval and transplantation of the organ. We would also be concerned that routine sharing across Europe may make people less, rather than more, inclined to sign up for donation. If this is not the intention of such a card, it is unclear why the European Commission is considering putting in place a system to facilitate the transmission of “full donor records” within Europe which, in itself, raises issues about confidentiality.

10. The idea may be that if an individual is in another European country and is taken ill or has an accident whilst carrying a European donor card, that card would be sufficient evidence of consent to permit donation in that country. This would require harmonisation of the legal framework throughout Europe which is likely to be difficult. In the UK most people sign up to the ODR rather than carrying a card. Although some people may wish to carry a European card, in addition to being on the register, the numbers may be small and it is questionable how much of an impact such a scheme would have on the donation rates in specific countries.

11. We have concerns about the idea of a European organ donor card, but we do not feel that sufficient information has been provided to make an informed judgement on this issue. We would need to see good evidence of benefit arising from such an initiative before we could support it.

EXTENDING DONORS

12. The BMA strongly supports the increased use of living organ donors and non-heartbeating donors with the safeguards that are currently in place in the UK. We are pleased that the new system for approval of living organ donation in the UK appears to be working well and that, with the implementation of the new legislation new safeguards have been put in place to ensure that potential donors are not subject to coercion.

13. We also support the use of “expanded donors” (increased donor age, donors with a history of malignancy, congenital or inherited disorders etc) subject to a careful assessment of the benefits and risks in each individual case.

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7 In May 2005, a representative sample of 2,067 people over 16 years of age was interviewed on behalf of the BBC and 6/10 respondents supported a shift to presumed consent.
Organisation of Organ Transplantation Systems

14. It is clear from those countries that have successfully increased their donation rates, most notably Spain, that this has been achieved through financial investment in the donation service, including the recruitment of additional staff. In Spain, for example, over a decade the number of transplant coordinator teams increased from 25 to 139.9 If the UK is serious about improving donation rates, financial investment in the service is an important factor.

15. Spain also has a system of presumed consent, although in practice relatives are still consulted before donation proceeds. As discussed above, the BMA believes that presumed consent would significantly increase donation rates in the UK and would provide a more positive ethos around donation, which would eventually be seen as the norm rather than the exception.

EU Directive on the Safety and Quality of Organs

16. Whilst safety is an important issue, we believe that the main problem that needs to be addressed in the UK is the shortage of donors. The EU Tissues and Cells Directive has created considerable additional work, with the need for inspections every two years by a “competent authority” and we are concerned that money would be diverted away from transplantation and patient care towards meeting regulatory requirements for inspections and additional bureaucracy, without any clear benefits. There are existing procedures in place to ensure the safety and quality of organs and this does not appear to be a major problem in the UK.

17. Unless clear benefits to the UK can be demonstrated from a European Directive on organs, we would have serious concerns about this option.

Illegal Organ Trafficking

18. The BMA supports moves to stop illegal organ trafficking and the UK has enacted legislation with this aim. Other countries that have not taken this action may wish to adopt a similar approach. It is not clear how a European approach to this problem would work but the BMA would be willing to consider any proposals aimed at reducing this practice.

Ethical Issues Relating to Transplantation

19. The current opt-in system of organ donation is usually presented as requiring explicit consent from the donor but in reality this is not the case. While some people have given explicit consent to donation, before their death, the majority have not. In these cases it is the wishes of the relatives that prevail, usually based on their “best guess” of what the deceased person would have wanted. At a time of recent bereavement and in the absence of any prior discussion with the deceased, many relatives, understandably, opt for the default position—which is not to donate and this leads to the high relative refusal rate.

20. Although the current opt-in scheme is often justified as respecting the autonomy of the individual, this is highly questionable. In fact, given that we know the majority of people are willing to donate, a system that presumes consent is more likely to respect the wishes and autonomy of the donor, than the current system which presumes objection.

21. Whilst the autonomy and interests of the donor are important, the needs and interests of those who are waiting for a transplant are often overlooked. Many of these people will die because of the organ shortage. An appropriate balance needs to be sought between the interests of the donors and those of the potential recipients. It is interesting, for example, that the Human Tissue (Scotland) Act 2006 gives priority to transplantation over other uses of the body after death. So, if an individual had given prior consent to the donation of his or her body for research but the relatives were willing to donate the body for transplantation, the relatives’ consent for donation would override the individuals’ own wishes. The rationale for this approach was that transplantation can save lives.

AN EU APPROACH

22. The BMA supports improved co-operation and communication within Europe, particularly in order to identify methods that have been effective in increasing donor numbers in other countries and exchanging examples of good practice. We are concerned, however, that any measures should help and not hinder the current situation in the UK. There is a risk that European activity, such as an EU Directive, may simply add another layer of bureaucracy to existing practice in the UK without bringing added benefit or addressing the main problem, which is the shortage of donors.

8 October 2007

Examination of Witnesses

Witnesses: Dr Vivienne Nathanson, Director of Professional Activities, and Dr Tony Calland, Chairman, Medical Ethics Committee, British Medical Association (BMA), examined.

Q383 Chairman: On behalf of the Committee, welcome. We are extremely grateful to you for coming and spending time talking to us about what we think is an extremely important inquiry. We have had a lot of evidence and we particularly need to have yours to give some balance and a framework. Please could you state your name and, then, if you want to make a short opening statement you may or we can go straight into questions.

Dr Calland: Thank you very much, my Lord Chairman. My name is Dr Tony Calland and I am Chairman of the British Medical Association’s Medical Ethics Committee. I would like to start with a very brief opening statement, if I may. The BMA is very grateful to the Committee for asking us to give evidence today and we welcome the attention that is being given to this issue by the Committee. About 900 people die in the UK every year awaiting a donated organ and obviously there are still many more people on dialysis at that time.

We welcomed the Organ Donation Taskforce first report and the recommendations it made and we welcome the fact that the Government have accepted these. We look forward very much to the second report and we hope this work will increase the pool of potential donors. I think it is important that the European Union works together on this to facilitate the sharing of experience and enhanced co-operation and we do believe that having international safety safeguards are very important.

We think the infrastructure improvements that would be made in the United Kingdom and the EU will lead to better systems and we would hope to see an increase in the number of potential donors not only from the infrastructure improvements that would be made but also from a change to presumed consent. That is really all we need to say as an opening statement.

Q384 Chairman: Many of those things we will want to pursue in more detail through the questions. Can you begin by describing much more the role of the BMA in relation to organ donation and transplant? We are interested in knowing what information you have about the extent to which the BMA view is supported by your members in England, as well as in Scotland and in Wales—and, were Lord Eames here he would be saying in Northern Ireland too. Dr Calland: Absolutely. The British Medical Association has an annual conference which is attended by between 400 and 500 representatives of the profession representing the different craft committees in the different regions of the United Kingdom, including the Celtic nations. We debate the motions put to conference and if those motions are passed it forms the basis of policy for the British Medical Association. Since 1999 we have had a policy of wishing to move to a system of presumed consent, to improve the rate of organ donation—so we have been quite long in this business, as it were—and we have been pushing at regular intervals, certainly in the last few years, to bring about a change and a recognition of the problem. Wearing one of my other hats—I am Chairman of the Welsh Council of the BMA—I can certainly confirm that in Wales we have been working with Kidney Wales to raise the profile of the problem in Wales and I know colleagues in Scotland and in Northern Ireland have been doing the same as well. I can say with some confidence that the position of the BMA that we are going to explain today is supported by our membership or at least a majority of our membership and it is also supported by other nations apart from England.

Q385 Chairman: Could you go on to say what exchanges you have with the European Union and other countries? Following up on what you have just said, we have been interested that Spain, although they have presumed consent, do not see it as central to their activity and their success. I wondered if you had had discussions across and whether that had affected your thinking in any way.

Dr Nathanson: Perhaps I could take that question. I am Dr Vivienne Nathanson. I am Director of Professional Activities at the BMA, although I am more usually described as Head of Science and Ethics. One of the sets of relationships that the BMA has is that we are members of a series of European medical associations. There is a European
increasing the supply of donor organs within the European Union: evidence

20 March 2008

Dr Vivienne Nathanson and Dr Tony Calland

GP groups; a European hospital consultants group; a European junior doctors group; and a European medical association, the CPME. We happen to hold the Presidency of that at the moment. Dr Calland’s predecessor, as Chair of Ethics, is President of the European doctors. Organ transplantation has been on their agenda at different times but one of the things we find is that doctors are very aware that the first thing you have to do to increase the number of donations is to get the infrastructure right, and that that is arguably the most important thing and it is extremely complex. It is one of the reasons why we welcome the taskforce report so much because it really does deal with all of those issues. It challenges many of the ways in which we are currently organised and almost says, “If we had a completely clean sheet, where would we start?” which we think is very positive. That is very much the way doctors across Europe are looking at this. There is not complete consensus on presumed consent. There are some people who do not like it; there are others who say, “Let’s get the infrastructure right first and then look at it.” In many ways, that is exactly where we are. We are very much in favour of presumed consent but we also recognise that it can only work if you have the infrastructure right. It is a terrible waste of time to increase the number of people who say yes if you then cannot benefit anybody by taking those organs and using them in the proper way. That is much the same in Europe. Interestingly, it is also very much on the agenda of the World Medical Association. That includes doctors from 85 nations at the moment, including Canada and the USA, much of EU Europe and many other countries: Africa, South America and so on. Again, exactly the same debate goes on: How do we get the best infrastructure? What is the best infrastructure? How do we maximise the yeses to benefit from all of those? How do we persuade people to say yes? Many countries are looking at presumed consent and saying, “What is the percentage extra that this will offer?” The debate always starts in exactly the same place, that doctors in every country see people dying on their organ donor waiting list—not something we expected when these were set up—and say, “We really have to do something about this. We have to find the best ways to help.” Not all countries have the opportunity of cutting health costs by increasing their numbers of renal transplants, as we do, because in a non-nationalised health service it is not necessarily a benefit to the state in that way, but for us there is that double-positive. You have heard of the positive whammy but this is the double positive: it saves money as well as being the humane and appropriate treatment.

Q386 Lord Lea of Crondall: I thought it was a very useful clarification on this balancing act between presumed consent and the infrastructure, but can I just go back to the Chairman’s question about how salient Europe, in some sense—the EU and all the rest of it—is in the BMA’s work. Twenty years ago, I was doing the TUC stuff on Europe, amongst other things, and I introduced the BMA to one or two people in Brussels. At that time there was hardly any Brussels dimension: I think there was some mutual recognition of qualifications or something. Anyhow, where does Brussels fit in generally to the work of the BMA? Is it normally benchmarking, best practice, or how far do you see the Directive route, which more or less is a mandatory requirement?

Dr Nathanson: We have recognised for a long time the importance of Europe. For many years we bought time from professional advocates in Europe. We decided some 12 years ago that that was not good enough and we now have our own office in Brussels, a permanent office, permanently staffed, because we think it is so important to be part of the process, because Directives can increase patient safety or decrease it or produce bureaucracy that stops you going for the highest possible denominator and move you to the lowest. We are very committed to working in Europe to make sure that European legislation, Directives, et cetera, that have a medical, health, public health or clinical focus of any sort are looked at, so that we can maximise the benefits to patients. That is the way we work on it. Every now and then you see a Directive which makes you recoil in horror simply because it seems to be completely contrary to the way we organise medicine but, generally speaking, we find them useful bits of legislation that we can work with, and say, “How can we use this as an opportunity to improve patient care, patient safety, the working conditions of doctors?”—particularly things like the European Working Time Directive, how that impinges on patient safety—so we are very committed to Europe. We think there are opportunities. The danger is that you could end up with so much bureaucracy that you hamstring the doctors’ ability to say, “In this patient’s case a non-standard answer is the only proper answer.”

Q387 Lord Lea of Crondall: Forgive me, but perhaps I could clarify something you have said. You wear two hats in fact. You are wearing an industrial relations hat on behalf of doctors in their contracts and the Working Time Directive—junior hospital doctors and all that—and yet, wearing your professional hat, you could be concerned that you cannot go on for 24 hours in a transplant. That dilemma is one you have to address.

Dr Nathanson: Absolutely. That is one of the dichotomies for the BMA because we are a voluntary professional association, which is one side of the BMA, and we are a trade union, but very
often those things come together because what you want to do is to make sure that the system works. For example, with the taskforce making the point that some of the transplant co-ordinators are working 24 hours, that cannot be good for them, it cannot be good for the donor and the donor’s family, and it cannot be good for the recipients. There needs, as the taskforce says, to be a splitting of that role: more people to give the best possible care, in that broadest concept, to all the people involved.

**Chairman:** You have mentioned health and I am going to move on to the Lord Trefgarne who is going to ask you about the safety and quality of organs.

Q388 **Lord Trefgarne:** We hear that there is talk of a Directive on the Safety and Quality of Organs—another EU Directive. I think the BMA have expressed some concerns about that and I would like to hear about those, please.

**Dr Nathanson:** I think the concern comes about from worry about the building up a bureaucracy which may have very little benefit to patients in the UK. We are starting from the fact, looking at what happens in the UK, that the system has faults in terms of it is not adequately resourced but there is no problem that we have seen in terms of quality, patient safety issues. We want to spend money, resources, time, new people, efforts in making sure that we reinforce the UK system so that we are better able to use more organs, in the hope that we will also find other ways of using that same system to produce more donors. There is no evidence that we have seen of poor quality. We recognise that if you had, for example, a Europe-wide transplant authority that allocated organs as they came in, the UK could potentially be a net recipient at the moment. We are very unlikely to be a major exporter because we are one of the poorest at recruiting donors. Nevertheless, we still think it is better to work within the country to make sure of patient safety, and then to share those patient safety measures European-wide so that we all move things up. Again it comes back to the question: If we think we have it right—and we do—in terms of quality, would we gain from this or would we instead run the risk of being bureaucratically tied and unable to move things and to develop? We have a significant note of caution about producing a new European body.

Q389 **Lord Trefgarne:** You do not see any prospect of increasing the availability of organs by having access to a European supply which we rather do not at the moment?

**Dr Nathanson:** I think we would be likely to be an importer of organs simply because we are one of the lowest recruiters—which is a good thing—but there is a second issue which is that we do need to ask the questions whether for all our populations in all the countries in Europe a European-wide donor register would increase or decrease national donation levels. We rely on altruism, we rely on a feeling of neighbourliness, and I do not know that that would be increased by being European-wide. My feeling is that people want to benefit people in their communities, the people they know, and they may not feel as altruistically for a pan-European thing, even though we would be net beneficiaries to start with.

Q390 **Chairman:** We have heard from other evidence that local brings best results, except when there are specialist organs or particularly difficult matches. I declare an interest now as a trustee of a charity that deals with children with hypoplastic left heart syndrome who are all going to need transplants later on. We have to make these declarations at the point when we are going to ask this sort of question. Can you see that there might be, if you like, a two-tier system in terms of complexity in Europe? I know Spain has given hearts to children.

**Dr Nathanson:** There already is, of course, a system which allows exchange, so that the matches that are done are: “Where are the local donors?” Local is very local and UK-wide, in that sense. We export about 20 organs a year, as I understand it, from the UK to elsewhere in Europe under this system and we receive some back. That is particularly important for organs which are not necessarily more specialised but more rarely available. Most people who die are not children, thankfully. It is important for organs where there is always going to be a very limited pool to have the widest possible availability but then again we also know that, for heart survival, short distances, short timescales may be important as well, so it is always a balance. More interesting would be whether a European system would offer any help to us with our very serious problem in recruiting donors from our black and minority ethnic community or with the right tissue types for those people who already have an over-representation of many of the diseases that lead to a need for transplantation in adults. We are not good at recruiting from that group and we certainly need to learn how to do that better because, even with presumed consent, we do not want a very high percentage dropping out from within the one community which can only benefit from donation within that community.

**Chairman:** That sort of action plan Lord Wade is going to pursue.
Q391 Lord Wade of Chorlton: My question was to build up on what you have just said, but to understand clearly what added value you see out of the proposals for an EU-led Action Plan.

Dr Nathanson: The truth of this is that we see very little benefit from having a European centre of bureaucracy around this. We do think the learning opportunities are very important and the exchange of information, the sharing of research, particularly research about: How do you affect public opinion? How do you reach the hard-to-reach groups? There are different hard-to-reach groups in all of our countries but we all have them. Which are the groups that do not donate? Why do they not donate? What is it that makes a difference? That sharing of experience beyond just the publishing of academic articles is extremely important. The publishing of academic articles, of course, will continue to have a place and we have been very interested by a study that said in many countries in Europe the percentage of the population who are Catholic had a very positive impact on donation rates. That is something we need to learn. This is a community that has been persuaded this is a good thing to do, so how do we learn that with other communities? Those kinds of exchanges of experience will help. It also means that different countries will try different legislative guidance systems and we can see what happens. We can measure what happens and then see whether this is something that will be worth other countries importing.

Q392 Lord Wade of Chorlton: You seem to be suggesting that the solution for how you can build up more organs available in the UK is really our problem; that we might learn better ways of doing it but, at the end of the day, it is us who has to do it. Is that right?

Dr Nathanson: I think that is absolutely right.

Q393 Lord Wade of Chorlton: And that this particular Action Plan in itself is not going to help that; it is going to be each individual country to use its knowledge that it might derive from it.

Dr Nathanson: Indeed. The best thing that Europe can do is to encourage countries to help them make the legislation simple and effective where legislation is needed.

Q394 Lord Wade of Chorlton: You mentioned earlier that we appear to be low down on the scale. Could you give me some indication of what the various rates of organ donations are and how we compare with other countries?

Dr Nathanson: The highest rate is Spain, which is at around 35 donors per million population. The lowest is Greece, which is around seven. We are near the bottom, at around 12, 13, 14 per million—so Spain and other countries have two or three times the level. There is quite a steep curve coming down, but many countries in Europe hit between 15 and 25 and we should certainly be doing that. If we did that, we would be almost doubling potentially. That would make a very significant difference if we have the infrastructure to then benefit from people’s gift.

Q395 Baroness Perry of Southwark: I would like to get clear in my mind what the EU Action Plan would do in practical terms. Would it give funding for conferences which would bring people together?

I am really conscious that doctors and academics of all kinds do find ways of talking to each other and meeting together and sharing their experience and I am sure this happens in the transplant field. What more would an EU Action Plan do? Would it just be money?

Dr Nathanson: It does not necessarily need to be money. I think national governments can do that themselves. It is about encouraging a multidisciplinary exchange of expertise and information. It is about making sure that there is a good exchange of best practice; that everybody in different countries learns from what other people are doing. It is also about stimulating, perhaps, multinational research, multinational research that is not at the very clinical end—not about whether particular anti-rejection therapy works or not, because that is already there, that is already funded and that tends to work multinational—but more around the social determinants of donation, the experience of donor families, the experience of recipients and so on, because that is the area in which it is most difficult to learn.

Q396 Baroness Perry of Southwark: Yes, I do understand that but you are using words like “stimulating” and I am just not understanding what this mechanism is. What is the EU going to do that will make these things happen in a way that they are not happening now?

Dr Nathanson: It can bring people together, perhaps in conferences, perhaps just in steering groups. For example, the Organ Taskforce in the UK has suggested that there needs to be a standing committee looking at transplantation, at the ethics and law and so on. I think that would be a good thing to have Europe-wide. How do we make sure, not that it is flexible but that it gives people advice on how best to frame the law and public policy, because I think these are extraordinarily difficult areas. People can struggle with finding the best ways to frame the law, that allows good practice and stops bad practice without becoming such a bureaucratic burden that you have to turn your health system on its head. It is that encouragement
We were broadly satisfied with what it Dr Calland: is going to say more about that. Are there other feel that it could have gone further, and Lord Lea January. Clearly, on the presumed consent area you Health Organ Donation Taskforce came up with in really a question of what your view is of the Standards Committee. Having declared those interests, you have answered part of this but it is really a question of what your view is of the recommendations that the UK Department of Health Organ Donation Taskforce came up with in January. Clearly, on the presumed consent area you feel that it could have gone further, and Lord Lea is going to say more about that. Are there other areas where you think it could have gone further? Were you satisfied broadly with what it said? Dr Calland: We were broadly satisfied with what it did say and we are very supportive of that. We think there is quite a lot of evidence to show that infrastructure is a key part of this. I suspect that we have not reached the pinnacle of where we could have got to in this country in terms of infrastructure, a substantial investment in the infrastructure. By that I mean transplant co-ordinators, having enough resources into transplant teams, having people in A&E departments well enough aware of when a potential donor may be a potential donor—because I think quite a lot of people are lost to the system at that point. We are very supportive of that and hope that those changes take place. Certainly in Spain the evidence has shown, whether you look at presumed consent or not in Spain, that because of their infrastructure they have significantly improved the situation. Yes, we are very supportive of it. The bit we felt was missing, which may be coming later, was about presumed consent. Would you like me to expand about presumed consent? Lord Lea of Crondall: You have seen the sort of question we were going to come up with. We are at the stage in the inquiry where we have run into a little bit of a contradiction of evidence almost, and maybe it is a failure to get, as it were, apples to compare with apples. On the one hand, some people say, “There is a missing ingredient and the key missing ingredient is the infrastructure,” almost as if, therefore, the queue of people who die because there are not enough donors is a sort of red herring. That is a bit counterintuitive, so how would you make this balance? I do not know how many witnesses there were, but certainly one from Spain, whose evidence impressed us, did more or less say that the infrastructure question was a lot more important than the availability of volunteers—and yet a lot of us have been left feeling very confused about that.

Q397 Baroness Neuberger: I need to declare an interest before I start. First, I have a brother-in-law who is deeply involved in these issues, James Neuberger, and, also, I am a former member both of the BMA’s Ethics Committee and of the GMC’s Standards Committee. Having declared those interests, you have answered part of this but it is really a question of what your view is of the recommendations that the UK Department of Health Organ Donation Taskforce came up with in January. Clearly, on the presumed consent area you feel that it could have gone further, and Lord Lea is going to say more about that. Are there other areas where you think it could have gone further? Were you satisfied broadly with what it said? Dr Calland: We were broadly satisfied with what it did say and we are very supportive of that. We think there is quite a lot of evidence to show that infrastructure is a key part of this. I suspect that we have not reached the pinnacle of where we could have got to in this country in terms of infrastructure, a substantial investment in the infrastructure. By that I mean transplant co-ordinators, having enough resources into transplant teams, having people in A&E departments well enough aware of when a potential donor may be a potential donor—because I think quite a lot of people are lost to the system at that point. We are very supportive of that and hope that those changes take place. Certainly in Spain the evidence has shown, whether you look at presumed consent or not in Spain, that because of their infrastructure they have significantly improved the situation. Yes, we are very supportive of it. The bit we felt was missing, which may be coming later, was about presumed consent. Would you like me to expand about presumed consent? Lord Lea of Crondall: You have seen the sort of question we were going to come up with. We are at the stage in the inquiry where we have run into a little bit of a contradiction of evidence almost, and maybe it is a failure to get, as it were, apples to compare with apples. On the one hand, some people say, “There is a missing ingredient and the key missing ingredient is the infrastructure,” almost as if, therefore, the queue of people who die because there are not enough donors is a sort of red herring. That is a bit counterintuitive, so how would you make this balance? I do not know how many witnesses there were, but certainly one from Spain, whose evidence impressed us, did more or less say that the infrastructure question was a lot more important than the availability of volunteers—and yet a lot of us have been left feeling very confused about that.

Q398 Chairman: Infrastructure versus presumed consent.

Dr Calland: I do not think there should be a contest of infrastructure versus presumed consent because I think they are all part of a jigsaw. As I said, there is plenty of evidence to show that infrastructure is a part of it but there is also evidence to show that presumed consent is a part of it. I would like to make it quite clear where the BMA is on presumed consent because it is a difficult and confusing issue. In simple terms we are supportive of what might be called “soft presumed consent”1, but before we would support that we would need there to be a very clear publicity campaign so that the understanding of what is meant by presumed consent is much better understood by the general public. We would probably not want to see, although I am not sure how you avoid it, the kind of debate we had a couple of months ago, when the Chief Medical Officer and the Prime Minister made comments about presumed consent. That, in my view, was unhelpful.

Q399 Chairman: The “body snatchers” suggestion Dr Calland: It drove the Daily Mail and various other people into explaining to people that all of a sudden they were going to be owned by the Government and their organs would be “untimely ripped” from them. That is not what we want from this. We want for people to understand that there is a change to the default position, in a way that anybody who wanted to opt out would have many different ways to do it easily, so that they could do it. We want for the publicity to generate the conversations across dinner tables throughout the land, so that people have some idea of what their family members’ feelings would be. There is lots of evidence to show that one of the difficulties that relatives have with coming to terms with the death of their loved one they then have to be asked, “Do you mind if we have some of their organs?” It is a very difficult question to ask at an even more difficult time. If we had a system whereby the public understood about presumed consent and understood that the implication would be that if they did not know and the deceased had not opted out then it would be assumed that they would consent to that. It is just moving that difficulty of the decision a little bit more. It is making it a little bit more easy for the relatives and making them a little less likely to refuse. That is the position that we want to get to with presumed consent, so that donation is looked upon as the usual thing to do.

1 Soft presumed consent would mean that when someone dies in circumstances which make donation possible, the register is checked to see whether they had opted out of donation. If they had not opted out, relatives would be asked if they know of any unregistered objection to donation. In the absence of any objection, donation would proceed unless to do so would cause severe distress to relatives.
rather than the unusual thing to do. I do not think we believe it is the magic bullet for a minute; but it is a piece of the jigsaw which, if properly implemented, would hold all the other bits together. I do not personally believe that it would dramatically improve the rate of donation in itself but I think, as I have said, that being part of the jigsaw it would improve the rates, and there is no point in improving the rates through presumed consent if you do not have an infrastructure in place to support the numbers if they suddenly come rushing through. You only have to look at Spain’s figures: in 1989 they had a waiting list of 5,000; in 2004 they had a waiting list of 4,000. That, in your own evidence in the yellow papers here, is the only country which has made a significant reduction over that period of time. Britain has got worse in that time.

Q400 Lord Trefgarne: We know there is an acute shortage of organs available in this country. You say that 900 people a year sadly die through lack of a suitable organ. We are asked to believe that infrastructure is not the issue in this case. Can we be sure that organs are not lost through the lack of a surgeon to remove the organ or the lack of a theatre in which he could do it?
Dr Calland: I do not think we can.

Q401 Lord Trefgarne: Is that significant?
Dr Nathanson: I think the lack of infrastructure is almost certainly a major contributing factor at the moment.

Q402 Lord Trefgarne: We have been told that before.
Dr Nathanson: The most worrying is that we certainly could not benefit as significantly as we should from an increased number of donors if we do not increase the infrastructure. I am not using the word “improve” because that would suggest poor quality. It is not about quality; it is about numbers. It is about resources. It is about operating theatres; intensive care units: the numbers of transplant co-ordinators, the people to ask the question and people then to go through all the systems—and it is a very complex process—of making sure that this person is right for donation, that the family is comfortable, that the recipients are lined up, that the transport arrangements are in place, that the operating theatre time in all the other places is available.

Q403 Lord Trefgarne: And the simple shortage of donors is only part of the problem.

Dr Nathanson: We know there is an acute shortage of organs available in this country. You say that 900 people a year sadly die through lack of a suitable organ. We are asked to believe that infrastructure is not the issue in this case. Can we be sure that organs are not lost through the lack of a surgeon to remove the organ or the lack of a theatre in which he could do it?
Dr Calland: I do not think we can.

Q404 Lord Trefgarne: And at the moment it could not.
Dr Nathanson: It is pretty borderline. It could not—certainly not a significant increase.

Q405 Lord Trefgarne: Could it cope with another 900?
Dr Nathanson: I doubt it.
Dr Calland: Probably not.
Dr Nathanson: Most transplant co-ordinators say that they are currently working absolutely at the edge of the limits of the constraints that they are under.

Q406 Lord Trefgarne: With more than enough donors but just not enough—
Dr Nathanson: No, even with 900 extra donors we would still probably have an increasing level of donor waiting lists. One of the things that is interesting about the donor waiting list is that people come off it because they are treated, people come off it because they become too ill—

Q407 Lord Trefgarne: This is the recipient waiting list.
Dr Nathanson: This is the recipient waiting list. People come off that because they are too ill to be treated now or because they die or because they are treated. But there is good evidence that people are not put on the list: when their condition is such that the doctors feel the chance of any donor being found or of organisationally getting them treated puts them relatively low in the list, in the hierarchy which has to be there, and therefore it is not worth currently putting them on the list.

Q408 Chairman: Dr Nathanson, I am sorry to interrupt you, but we want to get to the core of some of this. Dr Matesanz who came to see us from Spain, the person who has really driven the co-ordination, suggested to us not to spend a whole lot of money on donor cards, advertising and all of that, but to concentrate the funding on the infrastructure until that was properly in place. If you were advising the Committee and we were looking at this European piece of advice we have had, if you like, what would your view be of that European bit of advice?
Dr Nathanson: Number one, spend the money on getting the infrastructure right so that you can benefit from more donors. Once you have got your infrastructure in place then you move to presumed consent. Let us say that the UK could pass a law...
this month on presumed consent, it would take three or four years to get that in place because we would want this long period of getting people to understand and giving real opportunities to opt out. I think you go ahead with the debate upon the potential for the legislation as you get the infrastructure in place and as you put your infrastructure in place to deal with a significant increase in the numbers of donors and therefore of recipients.

Q409 Chairman: We needed to have that on the record. That is what we are looking for.

Dr Calland: Perhaps I might add that I think there is also an education issue in terms of staff working in A&E departments or medical assessment units or whatever. Their primary aim is to deal with the patient and get everything moving through the system, and I think opportunities are missed in the heat of a busy running, overheating A&E department, where people will perhaps die and potential donors are lost because people have not had the time or have not thought about it or whatever. That is no criticism of them and their professionalism. It is just one of the things, that this is another additional think to think about.

Lord Lea of Crondall: There is one element which will have to be addressed in our report—and you did touch on it in a way which I found a bit surprising—which is the need for more publicity. You mentioned the Prime Minister’s statement as being perhaps unhelpful. I do not normally rush to support the Prime Minister, although I am a member of the Labour Party, but I would ask you this question: Is it not the case that what he did succeed in doing is exactly what you demanded, that at dinner parties people started to discuss this? I do not go to a lot of dinner parties, but I can tell you that everybody was. Is that not a fair comment?

Chairman: I think the point is made. We do have to change over, otherwise we will not hear from our second set of witnesses.

Q410 Lord Lea of Crondall: Could you just give a brief answer to that?

Dr Calland: I do not think it was the Prime Minister’s fault. I think it was the Daily Mail and radio stations, where it just disappeared into hyperbole.

Chairman: Could I say thank you very much indeed. I just would just like to say one more sentence to you, the other thing our Spanish doctor said to us when we asked him what was stopping things happening in this country. He thought for a minute and he said, “Well, you have a very old, established Health Service.” It may be that people like you have a chance to make change happen, but he was saying to us that there is inertia in our system because people do not like change. I just say that as a piece of evidence we had because I think people in your position are helpful in trying to help those changes come about. Thank you very much indeed for coming. We are very grateful.

Examination of Witnesses

Witnesses: Dr John Jenkins, Chairman, Standards Committee, and Ms Jane O’Brien, Assistant Director, Standards, General Medical Council (GMC), examined.

Q411 Chairman: Welcome to you. Would you like to make a short introductory statement before we begin?

Dr Jenkins: Thank you, my Lord Chairman, and thank you to the Committee for affording us the opportunity to join you in your deliberations today. My name is Dr John Jenkins. I am Chairman of the Standards and Ethics Committee at the General Medical Council and in my day job I am a consultant paediatrician—as you probably gathered, in Northern Ireland. Really all I wanted to say by way of opening comment was to refer you to annex C of the yellow papers in which we have set out the role of the GMC. It is particularly important that in relation to specialist areas such as the one you are considering we need to point out the very broad remit of the GMC in relation to what we describe as our four interlocking functions: keeping an up-to-date register of qualified doctors; fostering good medical practice—which is the bit in which we are particularly involved; equally, promoting high standards of medical education right across the spectrum of medical education; and, finally—possibly the one which gets most publicity but which in our view is perhaps not the most important aspect—dealing firmly and fairly with doctors whose fitness to practice is in question. It is in the context of our remit as a whole within the overall functioning of the General Medical Council that we wish to give evidence today.

Q412 Chairman: Having set out that context, I am not going to read out the whole question I have but simply say: in that context, what is the GMC’s position in relation to fostering good practice in relation to organ donation and transplantation?

Dr Jenkins: We go back to the Medical Act and from that we derive our authority to issue guidance to the medical profession on issues relating to standards and ethics. It is in that broader context that we would wish to give guidance to the
profession which would be relevant to those working in this specialist area. Our general guidance is set out in our booklet *Good Medical Practice* which we reissued in 2006. We can certainly make copies available and it is also available on the website. That sets out the ethical framework for all doctors practising right across the very broad spectrum of medical practice and, while it will not relate to specific specialist areas, such as the one we are discussing today, it does deal with topics like the requirement for doctors to listen to patients and respect their views, for doctors to respect patients’ dignity, to provide treatment within a context of consent or other valid authority, to act within the law, for doctors to keep up-to-date, to work within their competence and, indeed, to work effectively with other healthcare professionals in teams. All of those are relevant to the issue of transplantation although they do not deal with it specifically, but it is that ethical context which the GMC sets and within which each specialist area of medical practice has to interpret that guidance and then to act ethically.

**Q413 Chairman:** What thinking has there been in the GMC about the balance between working with families and the careful work that has to be done at the point of asking for organs, and the worry about the queue, if you like—the people who are waiting for organs—and how you balance those two issues?

**Dr Jenkins:** We have recently been considering the issue of consent particularly. We are just finalising our guidance on consent at the moment, so that type of issue has been one that we have considered, although not in the specific but in the more general sense. The concept which we have been trying to develop in recent years at the GMC is one of partnership. Doctors and patients and, indeed, the public need to develop partnerships to which they each bring different strengths, different knowledge, different concerns relating to any individual question, and a question relating to the availability of organs for transplant is one where we would see this having to develop. In effect, if a doctor has been working with a family in an intensive care setting or whatever setting and has developed a relationship with them, so that there is a common understanding of how the family are addressing the particular issue, it is much easier then for a decision to be made which is relevant to that particular setting and which is agreeable within that particular family setting. In developing our consent guidance, we have not specifically addressed the issue that is before us today. In particular, we have not specifically addressed the issue of presumed consent because, at the moment, that is not something which is within the legislative framework and so is not something which our remit would give us the authority to advise doctors. But we have looked at it in the broader context of how families, doctors and, indeed, patients can work together to reach agreed decisions.

**Chairman:** Clearly there are other issues when people do not have a relationship because they have been knocked down in the road. That is one of the partnerships we know there is a problem about, and Lady Perry is going to follow this up.

**Q414 Baroness Perry of Southwark:** We have been told there is a conflict between the Human Tissue Act and the Coroners Act and that this leads to a lack of clarity about the way in which potential organ donors should receive medical treatment. That seems to be particularly the case with non-heart-beating donors. How should this be determined so as to reconcile the conflict between the donors’ best interests and retrieving organs of good quality? Does the GMC recognise this problem? How would you like to see clarification?

**Ms O’Brien:** I am Jane O’Brien. I am Assistant Director in the Standards and Fitness to Practise Directorate. We do know about this issue. I think it arises where there has been a sudden or violent death which needs to be reported to a coroner. At that point, the coroner is responsible for what happens to the body and, clearly, in some cases, where a serious crime is suspected, a murder or whatever, there would be a post-mortem, which may have police evidential value, where it may never be sensible or appropriate to try to use the organs for donation purposes. There are a number of cases where it is not nearly so clear cut and there is no particular reason why the donation should not go ahead. As we understand it, the main problem is the variation across the country in the view that coroners take. There is nothing in the law which precludes them from immediately releasing the body for donation, but it is, if you like, a question of personal caution in the way they would interpret their responsibilities. Some unified government advice would be probably the solution to try to get consistency and not to have very cautious coroners preventing donations which other coroners would be perfectly happy to go ahead with. There is a slightly separate problem, I might say, which has been raised with us which is with the Mental Capacity Act, which occurs where a person who is not brain-stem dead but who has had major neurological trauma will be assessed to see whether they should receive treatment, whether they are going to get any benefit from continuing treatment, usually in an intensive care unit. Clearly a decision has to be made in these difficult cases as to whether there is any benefit to patients in providing that treatment. That decision has to be made completely in that patient’s interests. If there is no overall
benefit to the patient, no prospect of recovery and their treatment is simply prolonging the process of dying, then the normal procedure would be to stop the treatment and the patient would die fairly quickly after that. The difficulty there is that if you want to have a hope of using this difficult infrastructure to use the organs from that person, then you need some time, usually a matter of hours, to organise the transplant teams to undertake the necessary tests, to get things in place, and so, in the past, normally that treatment would continue during those two/four/six hours. It is very unclear that that is lawful under the Mental Capacity Act. You have to take a decision in the patient’s best interests and best interests is defined. The criteria you use are defined in the Act and elaborated in the Code of Practice which supports the Act. However, while this Code goes quite a long way in encouraging a kind of substituted judgment test of saying, “What is it that the patient would have wanted in these circumstances? We will do that as being in their best interests?” it does not quite go all the way in doing that. It pulls back at the end, particularly in the Code of Practice, where it says, “You can do things which benefit others but they must be in the patient’s best interests”. At this point, you have decided absolutely that it is not in the patient’s interests to continue with treatment. Nonetheless you are going to do so, so you are saying this is really in the interests of the recipient. Can you make that square with the Act? I think it is possible. There are ways of reading it in which it is perfectly reasonable to do so, to say, “Because it is clearly what the patient wanted” or “Because they have lived a life in which their values have been x and y which would lead us to believe that,” but it is not clear.

Q415 Baroness Perry of Southwark: Has there ever been a test case?
Ms O’Brien: No. I think that does lead doctors to interpret it differently and some to be very cautious about doing something which they see to be unlawful. Again, we would see clarification through the Code of Practice as being really helpful in this area, to remove that question of doubt one way or the other. It may be that government would wish to say, “No, best interests cannot simply serve somebody else’s interests at that point in life.” Fine, but at least it would resolve the conflict.

Q416 Lord Lea of Crondall: Are you a doctor?
Ms O’Brien: No.

Q417 Lord Lea of Crondall: You sound to know a lot about it.

Ms O’Brien: That is a very good act!

Q418 Chairman: The job of this Committee is really to look at the European Union dimension. Lord Wade is going to do that but presumably that very good exposition will have been made to the taskforce whose job it is to clarify some of those issues.

Ms O’Brien: That is right, yes.

Lord Wade of Chorlton: Perhaps I could ask another question first. You seem to be an expert on these sort of things. What is the legal status of a body?

Q419 Lord Trefgarne: I asked this question last week and got no answer.
Ms O’Brien: The body is in the possession of somebody—usually the hospital, the Trust —once the patient has died and it will then be released to the family. That will not be the case where there is a need to report the death to the coroner, where the coroner has responsibility for the body until cremation or burial.

Q420 Lord Trefgarne: The coroner does not own the body though, does he?
Ms O’Brien: He does not own the body. I do not think anybody owns the body.

Lord Trefgarne: Somebody must do.

Chairman: Perhaps that is why you cannot get an answer to your question.

Q421 Lord Wade of Chorlton: This seems to me very, very unclear. We talk about what can happen to a body afterwards but where ultimately would the decision lie? Who legally has the right to make a decision about a dead body?

Ms O’Brien: I think a number of possible people. As I say, when a death is reported to the coroner, the coroner has the responsibility while the body is in his or her care. When a person dies in hospital, responsibility will rest with the Trust, as I understand it, to decide on the disposal of the body or the removal of the body until—

Q422 Lord Wade of Chorlton: The Trust has legal responsibility. Does the Trust then decide whether its organs are used or not and overrule anybody else’s view?

Ms O’Brien: No, because I think that is covered by the Human Tissues Act, as to who decides. That is clearly set out in the Act, I think, about who is consulted where there is not a clear indication from the deceased about what they would want to happen. I do not think there is a single answer to that question: it is quite a patchwork of what happens to the body. Who decides whether the body is cremated or buried will usually be the family.
**Lord Trefgarne:** You can leave your body to somebody.

**Chairman:** I can see your fascination with this question increasing but I will have to move you on.

**Q423 Lord Wade of Chorlton:** My Lord Chairman is keeping me to order. I apologise for that. What exchanges of information have you, the GMC, had on issues relating to organ donation with professional colleagues in the other EU Member States. Can you tell us about their views on organ donation issues which are being held most widely by similar bodies. Do you discuss these issues with your colleagues throughout Europe?

**Dr Jenkins:** The GMC has activity and interest in what is going on in Europe. We have been involved with a number of organisations which have those interests at heart, both other healthcare professionals within the UK who reach out to Europe and also within Europe itself. But the primary areas of interest and activity in recent years have been more in relation to the registration of doctors (for example, doctors who qualify in one country and want to work in another country) and how those registration particulars can be most easily transferred between jurisdictions to facilitate the free movement of professionals in relation to EU requirements, and, secondly, in relation to fitness to practise, so that doctors who are in trouble with one country, if you like, cannot just move across a border and practice somewhere else because the other country would not be aware. Those have been the two major areas of our activity in Europe. We are only beginning to develop some interests in standards and ethics with our colleagues in Europe and we are currently in the process of picking that up but not to the extent which we have had any discussions with colleagues in relation to transplantation.

**Q424 Lord Wade of Chorlton:** Do you have any views on the added value that these proposals for the Action Plan could have on the availability of organs and the system throughout Europe?

**Dr Jenkins:** The GMC as a body does not have a view, no.

**Q425 Chairman:** You talked about having a code. Would it be helpful to talk to colleagues across Europe about how they are looking at the ethical issues in relation to organ donation? Would that be informing for doctors generally or would you see that as the responsibility of your colleagues in the BMA?

**Dr Jenkins:** We would be interested in beginning conversations but at a much higher, more global level in relation to the generality of standards and ethics. We would not foresee any time in the immediate future where we would be able to get into the degree of detail in relation to an individual specialist area of practice. That, I suppose, is one of the areas where we see our role as different from that of our colleagues in the BMA. Where that is entirely appropriate, different specialist associations within the BMA have those contacts and develop those contacts.

**Q426 Lord Lea of Crondall:** You are saying that the GMC does not really comment on public policy issues in a certain sense—but obviously you are giving evidence to us this morning. Vis-à-vis Brussels, would there be some sort of line of demarcation between you and a body like the BMA, to do with you having to give views about the proper implementation of legislation but you are not an inputting body into the formation of legislation?

**Dr Jenkins:** My understanding—and I am probably not the best person in the GMC to answer that specific question—from the point of view of standards and ethics, which is my primary responsibility, and as a council member, is that our activities in Europe have not extended to trying to work with the development of legislation, although we do keep in touch. For example, if we became aware that a piece of proposed legislation in our view would have an adverse impact on the relationship between doctors and patients in the partnership that I have described, then we would certainly make representations through official channels as to our concerns in relation to that.

**Q427 Lord Lea of Crondall:** But you are not on a body in Europe in the same sense as the BMA are on a body in Europe, or are you?

**Dr Jenkins:** I will ask Jane if she can specifically answer that.

**Ms O'Brien:** I think we are not on that. We are a member of two different organisations. One is called Health Professionals Crossing Borders which is groupings of, basically, the regulators rather than the professional associations of bodies. We are a groping of broadly similar organisations to the GMC, although health is regulated and managed in different ways across Europe, so there are often not direct parallels. That is a group which is looking particularly at the impact on doctors and patients of increased mobility around Europe and those are quite specific issues. We also belong to a group which represents health organisations within the UK and is represented in Europe, but, again, it is the health regulators, so we are very much looking at it from the point of view of our four functions, which are keeping a proper register and protecting patient safety in that way. Rightly or wrongly, up
until now the question of ethical professional standards that we deal with has not been a high profile area in those contexts. We have been thinking about how we would perhaps change that and try to develop those discussions and exchanges. As John was saying, we do not stand a chance and do not try to be specialists across the vast range of medical practice. We are trying to set high-level standards using a framework within which doctors can comfortably work and develop more specialty-specific standards based on their much greater knowledge of the problems on the ground and the real issues which face doctors in these specialties, where we do not think we can do such a good job. There is no point in trying to replicate good work that is being done elsewhere. It is probably not helpful to us either in our other functions, particularly in our fitness to practise procedures, where we do not want to create a great list of rules and standards, so that doctors must do this, in the circumstances and for the reasons that Dr Nathanson was saying before. Chairman: Thank you very much indeed. We have that picture and that is very helpful. Thank you both for coming and giving us your time. It has been extremely helpful.

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**Supplementary memorandum by the General Medical Council**

Thank you for your e-mail in which you seek further clarification of the question asked by Lord Wade about the legal status and ownership of bodies.

As this is a question of law, it is not appropriate for the GMC to respond formally on this point. You asked whether, if this were the case, we could direct you to a source for such information. The questions relating to ownership and rights over a body are dealt with both in common and statute law. The Human Tissue Act, and other legislation, deals with what may be done by a person in lawful possession of a body. I am sure that the Human Tissue Authority will be able to explain that issue more fully.

The common law addresses the question whether there is property in a body. The Sub-Committee may find the judgment of the Court of Appeal in the case of *Anthony-Noel Kelly, Niel Lindsay, R v. [1998] EWCA Crim 1578* (14 May 1998) helpful as a starting point. The case considers the “no property” in a corpse rule and the circumstances in which this rule may not apply. In the course of their judgment the Appeal Court said:

> We return to the first question, that is to say whether or not a corpse or part of a corpse is property. We accept that, however questionable the historical origins of the principle, it has now been the common law for 150 years at least that neither a corpse, nor parts of a corpse, are in themselves and without more capable of being property protected by rights (see, for example, Earl J, delivering the judgment of a powerful Court of Crown Cases Reserved in the *R v Sharp* 1857 Dears & Bell 160, at page 163, where he said:

> “Our law recognises no property in a corpse, and the protection of the grave at common law as contradistinguished from ecclesiastic protection to consecrated ground depends on this form of indictment.”

He was there referring to an indictment which charged not theft of a corpse but removal of a corpse from a grave.

If that principle is now to be changed, in our view, it must be by Parliament, because it has been express or implicit in all the subsequent authorities and writings to which we have been referred that a corpse or part of it cannot be stolen.

We recommend, however, that the Committee obtains formal legal advice on this issue, as the GMC is not able to provide any analysis of this case or of any subsequent judgments on the same issue.

*4 April 2008*
THURSDAY 27 MARCH 2008

Examination of Witnesses

Witnesses: Dr Adamos Adamou, a Member of the European Parliament, Rapporteur to European Parliament Committee and Ms Anna Pavlou, Parliamentary Adviser and Assistant to Dr Adamou, examined.

Q428 
**Chairman:** Good morning and welcome. Dr Adamou, we are absolutely delighted that you have come to talk with us and immensely grateful that you and Ms Pavlou have taken the trouble to join us. We think this is an incredibly important inquiry. We have heard from a large number of witnesses and we have been able to read your report. Before I start I have to do some housekeeping points. I always feel slightly silly about this but we just have to make sure that you know all of this. The first is to tell you that the session is open to the public. Also a webcast will be made of the session and that will go on the web as well as there being an audio submission. This will go wider even though there are not masses of public here now. As you know, a verbatim transcript will be taken which will be put on the public record and in a printed form on the parliamentary website. A few days after you receive that—we do need it back in a few days—could you make sure it is accurate and return it to us. We do have rather swift turn round times here. If you do not think we have covered everything in this session you can send supplementary evidence in afterwards, but we ware already very impressed by where you are in relation to where we are and what we have received, so thank you for that. This room is not good acoustically. Although we are fairly intimate you can see I am public speaking and that is because the sound goes up and the acoustic equipment is not brilliant. What you have to say is so important that we want to be able to hear you. When you start can we ask you to state your name for the record because we have to have you tell us that you are who you are. If you want to make a short opening statement please do so; if you prefer to move into questions just let me know. I am sorry about all that, but now we can begin properly.

Dr Adamou: My name is Adamos Adamou. I am a physician by profession; I am a member of the European Parliament. My speciality is medical oncology, dealing with cancer. I am a member of the Environment, Public Health and Food Safety Committee of the European Parliament. I do not want to make any statement but I would just like to mention that my report was voted yesterday afternoon unanimously by the Committee. The report you have in front of you is not the final one; it is the one we voted yesterday which now has some changes and will be voted in the Plenary Session in Strasbourg next month. We will send it to you for your Committee here.

Q429 
**Chairman:** Do you think you could tell us a little about how the European Parliament came to be interested in this particular issue? How would you describe the MEPs’ reaction to your work generally, apart from your Committee?

Dr Adamou: The issue of organ donation and transplantation is primarily a medical one. The three main themes covered by the Commission’s Communication and taken on board by my report are organ safety, organ availability and trafficking; they are in a sense life and death issues. The particularity of organ donation lies with the fact that it encompasses a wide range of social issues as well; that may be even more pertinent. I knew from the start that the issue would draw a lot of attention. The public hearing we organised with DG internal policies was very successful. The majority of stakeholders were present—patient groups, NGOs, representatives from the Commission and the Council of Europe—from the biotechnology industry. Since I was appointed Rapporteur I have also bilaterally met with most of the above mentioned interested parties, heard their concerns and included many of their comments in the report. I have also had meetings with the Federation of German Hospitals, with the umbrella association of European hospitals, with the Commission health attache’s from various Member States and many more. It is thus obvious that the topic has attracted a lot of attention. An additional factor that demonstrates that the topic has attracted a lot of political intention within the European Parliament is the fact that I received nearly 160 amendments and the report is not even a legislative one. Another important factor that contributes to the increased political attention given to this report across the European Parliament is that most of my colleagues or, at least, members of my
Committee, know that the directive will also publish on the quality and safety aspects of organ donation. As you know, health issues predominantly remain within the confidence of the Member States. There is another directive in preparation as you probably know and this is cross-border healthcare, which for me is one of the most important things of the mandate of this parliament now, 2004–09. I think that your Committee in the future might want to deal with this; it is a very important issue.

Q430 Chairman: You said there were many amendments. Could you tell us what kind of reaction you are getting? What kind of things are people talking about?

Dr Adamou: Referring to the over-reactions of the Committee to the Commission Report. I should, first of all, stress the general satisfaction with the time the communication was issued since it follows a series of initiatives between 2003 and 2007. Overall Meps work out the communication and acknowledge the positive direction in which it is moving. More precisely, there has been a consensus on the need for a pan-European initiative on organ donation and transplantation, although there is disagreement within the Committee on what form this should take. Most MEPs argue for coordination, for exchange of best practices, for reinforcement of best practices without any harmonising measures which deprive Member States of their autonomy to decide and put in place their own rules. Only some were in favour of harmonising measures which involved measures like a European donor card or a common organisational structure. Nonetheless most Meps seem to acknowledge the need for increased interstate cooperation in their attempt to deal with the issue of organ shortage and in order to accommodate the needs of travellers and people who reside away from their home country. The general provision of the Commission’s Communication was also thought to be in line with a general consensus of the need to increase public awareness among the European people. I have to say here that since my report was voted yesterday we have to sit down again and see how the report looks now after these 159 amendments. I managed with my office and with the help of the shadow rapporteurs to make 12 compromise amendments, but they include all the 159 ones. The pan-European initiative of organ donation was not voted; they voted for coordination, for exchange of best practices, for public awareness and also for the donor card as being complementary to what the Member States have now.

Q431 Lord Trefgarne: May I take it from what you have been saying that you see a European directive as to organ quality and safety as an entirely good thing and one that is to be supported and encouraged?

Dr Adamou: The Commission is proposing a combination of two mechanisms, a directive on organ quality and safety and an EU action plan to coordinate the activities of the Member States. A future directive on the issue would be based on Article 152 of the Treaty which enables the European Parliament and the Council, after a proposal by the Commission, to adopt harmonising health measures by setting high standards of quality and safety of human organs. Patients across the EU can be confident they will benefit from a directive setting broad quality and safety requirements for organs. To start with, actions for quality and safety could have an effect in increasing organ availability. Common safety standards could potentially give additional expertise to doctors and scientists, fill gaps that might exist in certain Member States; urgent, difficult and special situations and precisions involving, for instance, expanded donors could be dealt with more efficiently if guidelines exist. Member States would be able to promote cross-border organ donations where geographical limitations permit it. On the other hand now such a directive raises potential questions of implementation. How will Member States implement such a directive? Will it create an excessive administrative and economic burden on the health systems of Member States? Should Member States fear that a directive setting safety and quality standards for organs will diminish their current and in some cases already high levels of protection? These are some questions we should pose ourselves and consider as potential drawbacks but not disadvantages of such a directive. Of course these are the questions we have not yet seen because Parliament has to co-decide on this, on the safety and quality of organs. We do not know how the report is going to look, how the directive is going to look. I do not have any information on it but when they have prepared the draft we are going to discuss it with them and we have to agree so the directive can be a directive which is different from a regulation. A directive is indeed different. It leaves an open window to the Member States to choose how they want to implement it; a regulation is a regulation; you cannot do anything.

Q432 Lord Trefgarne: I conclude from what you are saying that standards among different Member States are not all good, or at least not as good as the best in all Member States, and that therefore there is a need for such a directive to bring the less good standards up to the better ones.

Dr Adamou: I could not say with certainty whether some Member States need such a directive more than others. Unfortunately neither do I have studies on the topic, nor am I aware of the existence of such studies. In any case, I think it is a bit unfair to pinpoint certain
Member States and blame their health systems but praise others.

**Q433 Lord Trefgarne:** That is a very diplomatic answer. I am not in the business of slating one country or the other, but it stands to reason, does it not, that standards are not necessarily the same across the whole of the 27 Member States and to bring them all up to the best standard would be a good thing.

**Dr Adamou:** Yes, I agree.

**Chairman:** We do not think we are doing that well in this country. We are not at a very good level and we do not feel complacent here. Lord Kirkwood?

**Q434 Lord Kirkwood of Kirkhope:** May I ask you to clarify the process for us? Your evidence is very welcome and it is very timely; your Committee has just been completing its work. Did I understand you to say that there were 159 amendments tabled but that you managed to reconcile these down to a dozen, twelve that you were comfortable with? Would it therefore be safe to assume that the 12 amendments are all amendments with which you are comfortable?

**Dr Adamou:** Yes. We worked very hard on these. There was a paragraph and on this same paragraph there were ten amendments. When discussing with my colleagues and the shadow rapporteurs of the other political groups we found common ways. Sometimes we noticed they were only linguistic amendments, a difference in what they want to express.

**Q435 Lord Kirkwood of Kirkhope:** So you are still comfortable with the general direction of travel. Nothing has changed that causes you concern?

**Dr Adamou:** No.

**Q436 Lord Kirkwood of Kirkhope:** We will see the final fruits of the plenary session after the Strasbourg Plenary has taken place.

**Dr Adamou:** Yes.

**Q437 Lord Kirkwood of Kirkhope:** Could you tell me whether you believe that the Commission will then take real note and take proper concern and pay attention to the work of that Committee? To what extent do you think the Commission will accept Parliament’s view as expressed in the Strasbourg Plenary?

**Dr Adamou:** You know very well that the Commission—and only the Commission—is the initiator of any legislative proposal. I would like to make a personal comment here. I am an elected member of the European Parliament by European people; do I have the right to be the legislator? So the Commission decides and is the initiator of any legislative proposal. The Parliament, as co-legislator, can of course influence the procedure together with the Council once the proposal is issued by the Commission, in other words not during the drafting stage. One could argue that in theory the Commission might not at all take into account the Parliament’s suggestions and concerns, but I want to be fair on this. I should say that in the field of public health they do to a great extent take into account our suggestions. It is also to their best benefit to issue a directive that has the approval of the elected representatives of the European people. The Commission is aware of the many implementation problems that occur with the Tissue and Cell Directive and in my opinion they do not want that to happen again with a potential directive on quality and safety aspects. Moreover, it seems that the Commission is trying really hard to gather as much information on the topic as possible in order to achieve the widest possible consensus. It issued a consultation document, a communication and is organising regular national expert meetings on organ donation and transplantation at EU level. I am quite positive and I believe that the Commission will take into account our suggestions, not only concerning a possible administrative burden but on all -relevant issues.

**Q438 Lord Kirkwood of Kirkhope:** That is quite an optimistic answer. You are optimistic that you committee’s views will prevail.

**Dr Adamou:** I am optimistic that they are going to accept our opinion because at the end of the day it is the opinion of the European people.

**Q439 Lord Kirkwood of Kirkhope:** We have identified a vein of concern about what we call in the United Kingdom “gold plating”, overdoing the bureaucracy and having heavy layers of extra work and practical difficulties. Can you give us any assurances that your Committee is alive to the dangers of stifling best practice and good work by over zealous administrative conditions and burdens?

**Dr Adamou:** This is a problem not just for the UK but for all the Member States. They are afraid of this burden if we adopt measures that are going to change their current practice. There are countries today which have very good organisational systems and if we change that we might help some countries which have low or medium standards, but what about the others that already have high standards? How are we going to do this? Are they going to diminish their standards to come to a common level? I do not think this is the issue here; we are trying to help, we do not want to add bureaucracy for the Member States. This is very clear and it is made very clear to the Commission that the Member States will not accept such a burden.
**27 March 2008**

Dr Adamos Adamou and Ms Anna Pavlou

**Q440 Lord Kirkwood of Kirkhope:** Will your report reflect that?

*Dr Adamou:* Yes, it already voted on this issue yesterday.

*Chairman:* It may well be reflected and reinforced by another report, as you can hear.

**Q441 Lord Lea of Crondall:** You have no particular problems with the process, given the nature of the European treaties, between the Parliament and the Commission; you are doing your job and your procedure. When it comes to action plans for cooperation with Member States, can you just say how you relate as a Parliament to Member States during the development stage of the directive. Under co-decision you are feeding in Parliament views to the Commission and yet there is a very critical co-decision you are feeding in Parliament views to the Commission as far as we have understood from the meetings and the negotiations we have had so far.

*Chairman:* That is very clear. We have been looking for an answer like that; that is very helpful.

**Q443 Lord Eames:** I want to raise a practical issue with you and that is the question of the difficulties of transportation across Europe. Why should there be more transportation problems within the European states than bringing a donation from the north of Britain to the south of Britain? It is a practical issue and I wonder how you react to that.

*Dr Adamou:* As you very well know organs are vulnerable. It is not only their flight time from one country to the other. It starts from the time the surgeon has removed the kidney or heart or liver or lungs, which are then taken to be prepared in certain boxes. There is then travel from the hospital to the airport, from the airport to the other airport and so on. There is a time limit. It does not make any sense to transport one organ from Cyprus to London or to Sweden. What are we looking for is for neighbouring countries to cooperate. We know this very well because we have examples like Eurotransplant or Scandiatransplant where countries have built up an alliance among them. They exchange best practices and they exchange organs. If you say from London to Scotland then this is very practical. And I want to mention something else. How many organs will be needed to be transported to another country a big country like the UK or France or Germany? In my country we only transplant kidneys so all the other organs—liver, lungs, et cetera—travel to neighbouring countries: Israel, Greece, Austria and sometimes Turkey. There is cooperation between the Turkish Cypriots and the Greek Cypriots; this is not an issue with political problems. We exchange organs with them. I want to say here that in Cyprus we have the biggest bone marrow donor trust in the world. One in three Cypriots are members of this, and this includes the Turkish Cypriot people. We give bone marrow to Turkish Cypriot people; they give to the Greek Cypriots. When we come to health and humanitarian issues we are together. Cyprus is number one in Europe in living donors and this is because of the very tight family ties. The mother gives to the son; the sister to the brother and even our new president has been transplanted with a kidney from his sister nine years ago. This is not a secret; it is published.
Q444 Lord Eames: You mentioned local countries agreeing, therefore cutting the journey time of the whole process. What happens if a particular organ is required and it is at the extremities of the European Community? Are we talking about real live difficulties in that case or do you foresee that as purely exceptional?

Dr Adamou: Distance is a problem. The organs are vulnerable. There are other scientific and clinical issues which are not dealt with in the report; it does not deal with clinical aspects or interfere with scientific decisions. However, as a doctor let me explain to you that organs are very vulnerable. Not only this, it is the recipient as well, who is not able sometimes to receive an organ despite the recipient being identical, because there are other comorbidities on the recipient like other organ failures or systems that even if we transplanted here we might have a high percentage of rejection. Distance plays a major role. We need to be accurate on this and be on time. That is why in my country when we remove the organs you see police everywhere: it is as if the prime minister is moving.

Q445 Lord Wade of Chorlton: Following on from that very interesting answer, do you believe that if cross-border movement of donors’ organs were to develop as a result of these proposals that there are any particular issues that either the donor countries or the EU particularly ought to set up to make it easier and to make it more likely to happen?

Dr Adamou: As I explained just before, organ donation between Member States has many disadvantages. On the one hand there are the long distances that exist between Member States and on the other the vulnerability of the organs. It is far more likely for countries that have common borders to exchange organs and to be even more precise it is far more likely for cross-border regions to exchange organs. Evidence exists that countries will firstly accommodate their own needs and then provide their so-called surplus of organs to another country. As I said to Lord Eames, the UK is a big country therefore, how many organs will not have a recipient? I do not think that happens, but in my country we have this; we take only the kidneys and all the others we transfer to neighbouring countries. I think there are more efficient ways to promote cross-border organ donation to increase the pool of organs. If we look at the Spanish model in giving incentives to Member States to have within the majority of hospitals in-house transplant coordinators. The establishment of an efficient system to identify persons that could become organ donors after their death, once all mandatory consent requirements of Member States have been met, is a key element in fighting organ shortage. The process of organ suitability evaluation is multi-faceted. Focus on the definition of acceptance and acceptable risk, of transmission of infectious disease, the establishment of practical steps of the risk evaluation process, considering in a single case the transmittable disease, the specific conditions of the recipient with respect to the transmittability of disease, are means for the prevention and treatment of the disease. Another important option in expanding the donor pool is to consider the promotion of tourist donation from living donors. That is what is happening in my country. Another is to use another term for expanded donors, allowing transplants from an HIV positive person to another HIV positive person. This includes the term expanded donor. Doctors are concerned with the increased likelihood of rejection of the organs and here comes the issue of biotechnology or the advances in biotechnology we have today, so we eliminate the rejection process. Let me move ahead and tell you that maybe in the next decade we will not be discussing organ donation; we will be able to create an organ from our own cells. From just a skin cell, if we drive it correctly, we will create the organ we need. This research in biotechnology is going on now and of course, as you know, research in medicine takes some time to produce a result. When I mentioned this at a meeting with the NGOs in Brussels they looked at me as if I was talking about science fiction. I told them that this was not science fiction; it is something that is coming. Maybe in the next ten to 20 years there will be no need to do organ donor cards or all of these things we are doing now.

Chairman: Meanwhile we are ploughing on with what we can do now and one of the issues is this next one about the European donor card. Lady Gale is going to follow up this issue.

Q446 Baroness Gale: Before I put my question I ought to declare an interest in that I am a patron of the Kidney Wales Foundation. My question is about donor cards which you have already touched upon. How effective do you think that the introduction of an EU donor card would be in increasing the willingness of EU citizens to identify themselves as a potential donor after their death? In which Member States might such a card be likely to have a beneficial effect?

Dr Adamou: The vast majority of the Council, including the UK if I am not mistaken, oppose the introduction of an EU donor card. Many Member States argue that such a donor card might create an administrative burden for those Member States that do not already have it. The creation of an EU organ donor card will not per se increase the number of donors. In many Member States where they have introduced the donor card it is legally possible that family members of a brain-dead patient who is a donor card holder refuse to donate the organs. So that makes one wonder what is the need of donor
Lord Lea of Crondall: Is there a danger of two or three different issues being confused here? It may be just me who is confusing them, but I would like to ask you to comment if you would. First of all, there is the question of hospitals around Europe recognising anybody’s donor card from a national donor card. Secondly, you then go onto the question of the wishes of the donor card holder being overridden by the family. I find that a bit strange, but can you say that that is what you are saying, that these donor cards do not mean what they seem to say, that they can be overridden by the family? Thirdly, on the so-called shortage of organs it is by definition not a shortage of organs but a shortage of technical capacity if the organs are available but it is not an issue of technical capacity if the organs are not available. You certainly need donor cards as well as the technical capacity. Have I understood those three separate issues?

Ms Pavlou: The Commission is actually proposing an EU donor card in its Communication as far as we understand from discussions we had with them. You have the Parliament where most members seem not to be in favour of an EU donor card, although we voted for it as being complementary to existing national systems. The other half of your question was whether an EU national donor card would be more suitable. From the evidence we have gathered we think it would be more suited in smaller countries and in smaller regions than on a pan-European level, but we do not really have evidence on that because we are mostly using the evidence we have taken from the Commission and from national expert meetings. For the time being, the Commission is pushing for an EU donor card whereas we would be more in favour of having it complementary to existing national practices. Mr Adamou mentioned that with a donor card the numbers will not raise per se. This is what we gathered from information from Spain but, as you know, they have one of the best systems in the world. They told us that although it helps people identify themselves as donors it does not per se raise the numbers of potential donors. It is in Spain where they have very big problems with the family overriding the wishes of donors. Even people who work, let us say, for the transplant organisations and they want to be donors themselves when they die, their families sometimes do refuse to give the organ. That is why we want to promote donations so that you will raise awareness and people will discuss it within their families so we will not have such problems. Then you mentioned technical capacity and shortage of organs. Potentially there is going to be technical capacity if you have enough organs to donate, but for the time being in Europe there is more a problem of shortage of organs than the capacity. In Spain they have so many organs and they have managed to accommodate the organs they have because they have what they call the ONT which is a national transplantation organisation, and then they tried to accommodate the organs and to diffuse them across the country. I do not think we will have the technical capacity to accommodate a large number of organs.
the civil liberties and legal affairs committees. Furthermore, some of my colleagues came up with the idea of having a legal representative that would be entrusted with the task of carrying out the wish of a person to become a donor after his death. This legal representative would be able to contravene family members in case they decided not to donate the organs of their deceased relative. This was amendment 73 and it was rejected. It was a detail we learned yesterday. The principle of presumed consent implies that a person is automatically a donor unless he states otherwise. This in theory would be a very good system and would probably drastically increase organ donation rates. However, as you know, due to the principle of subsidiarity health issues and also issues that are intrinsic to the legal system of the Member States do not fall within the competences of the EU. We should let Member States decide on their own which systems would work better, whether this be an opt-in or opt-out system, or one of presumed consent. What the EU can do is provide Member States with information of which works better and achieves optimal results. As with ethical issues I am of the opinion that certain issues should be dealt with at Member States level.

Q450 Baroness Gale: So from what you are saying you do not see any likelihood of a European directive on this and it would not work anyway, and it would have to be decided in each nation state.
Dr Adamou: Yes, issues of ethics are usually left to the Member States. If you bring it up with the Parliament there are a lot of disagreements so there was the concept of advanced therapies to make the amendments so we leave the ethical issues to the Member States to decide. Otherwise the rapporteur was strongly against this but we managed in three major political groups to agree and so we passed this legislation, first reading, and it was a great success.

Q451 Baroness Neuberger: I need to declare an interest because I have a brother-in-law, James Neuberger, who is deeply involved in organ transplantation, particularly livers. Dr Adamou, before I ask my question I want to ask you about a discrepancy that some of us have picked up in the question of shortage of organs and organ trafficking. If you look in the draft report it says that there are 40,000 people waiting for kidney transplants in Western Europe, but if you look in the Commission Communication: Policy Actions at EU level it says simply that there are 40,000 people waiting for transplants in Europe. We do not know which figure is the correct one. I would be interested in that before I move onto the question about trafficking.

Dr Adamou: It is more than 40,000.

Q452 Baroness Neuberger: In general, across Europe.
Dr Adamou: More. More than 50,000. These people are on the waiting list and every day ten of them die. It is more than 50,000; it is 53,000 or 56,000; something like that.
Ms Pavlou: Currently there is no data on Eastern Europe but out of political correctness we wanted to do the whole of Europe. There seems not to be a lot of data on the new Member States.

Q453 Chairman: Would it be fair to say that we really do not know? We have some ideas of waiting lists but not a lot of idea of how many people would be on waiting lists and indeed would receive an organ in a perfect world. Your answer is saying that we do not know but it is a lot more than 40,000.
Dr Adamou: We do not have the numbers; we presume that there are more. We are talking about 40,000 people without Eastern Europe.

Q454 Baroness Neuberger: Can I just pick up one little bit about what we were just discussing? In one it says “kidney transplants” and in the other it just says “transplants” so presumably, although it is a relatively small number for liver and heart and so on there is a further discrepancy.
Dr Adamou: I think the 40,000 refers to all the transplants, not only kidney.

Q455 Baroness Neuberger: In the draft report it says kidneys. I just wanted to pick that up.
Dr Adamou: The vast majority of transplant patients are for kidneys.

Q456 Baroness Neuberger: Moving on to question ten, how serious a problem do you think organ trafficking and transplant tourism are across the EU? What measures, beyond what is already in place, do you think are necessary at either EU level and Member State level to combat what is going on?
Dr Adamou: Of course the issue of trafficking is important. However, the Committee, according to the rules of procedure, does not have the competence to extensively deal with issues of trafficking. That is why the Committee of Civil Liberties as well as the Committee of Legal Affairs, were charged with the task of producing subpoenas to my report. Many of their suggestions, including those related to trafficking, were incorporated in the text of the report and were voted on yesterday. To get back to your question, despite what I mentioned, I should stress that on the face of available data of the trafficking of human organs and evidence of rapidly developing commercialism in transplant tourism, it is pertinent not to underestimate organ trafficking as a secondary
area of concern. Scientific studies have shown that organ trafficking is caused by poverty, homelessness, the desire to work and make a living, corruption, criminals, globalisation of the economy and exploitation of human beings. On many occasions people in the east become the spare parts inventory for the sick of the west. Although the problems of people in the east become the spare parts inventory exploitation of human beings. On many occasions criminals, globalisation of the economy and the desire to work and make a living, corruption, Union more than they concern Member States, a link between organ shortage and organ trafficking has been established. Therefore, the best way to fight organ trafficking is by increasing organ availability through appropriate action at both Member States and EU level and to subsequently fight and block the import of organs from outside the EU. In order to do this a mechanism of traceability should be put in place so as to prevent these organs entering the European Union. During the discussion with the Committee one colleague mentioned that he asked Europol if it knows that there is any organ trafficking in the European Union and the answer was no. Of course it is no, but European citizens are going to developing, poor countries and they pay and they receive an organ. After we finished the session one of my colleagues discussed face to face and said, “Why not? If I am sick, I need a kidney I will pay to take it because it is my living, I will live with this”. If the other person gives it to you altruistically like what happened two days ago in Cyprus, a Canadian lady came to Cyprus because she found a 29 year old resident in Australia on the internet and their kidneys are identical. Because the lady needed a kidney they both came to Cyprus, the boy gave the kidney to the lady without any financial interest in this; it was an altruistic action. However, nobody should ignore that transplant tourism exists in Europe. I will give you another example I have. Insurance companies in neighbouring to Cyprus countries pay you for this. If you find a donor in a third country or a developing country you go and receive a kidney and they pay the expenses. This is incredible. They are saying, “Okay, you are transplanted, where have you been? You’ve been in India.” Everybody remembers the publication in the newspaper some months ago about finding European citizens in a clinic in India where they were receiving kidneys for 10,000 dollar a kidney. When they discovered this the doctor who was going to be arrested disappeared. So trafficking exists, maybe not within the European Union but it happens to European citizens who go to third countries to receive an organ.

Ms Pavlou: Can I comment on something you said before? On page four of the impact assessment in the fourth paragraph, they mention the fact about Western Europe. It is not mentioned in the Communication that the data comes from Western European countries.

Baroness Neuberger: Thank you for that clarification.

Q457 Baroness Young of Hornsey: On a number of occasions we have talked about information and evidence and so on and obviously it is absolutely key to understanding the issues we are trying to address. Can you say something about your Committee’s view about the need for better quality information, particularly around different communities and the extent to which they are willing to donate organs, looking at perhaps demographic and socio-economic factors that influence people’s organ donation rates?

Dr Adamou: Our Committee dealt with this issue extensively. It was a part of the compromise amendments which we unanimously adopted in our vote yesterday. We understand that there are important differences in respect to the source of organs, deceased or living donors, within the EU. There are large differences between Member States in their success in increasing their donor pool; there are large discrepancies when it comes to quality and safety of organs. There are also different organisational approaches to organ donation and transplantation. We consider that the discrepancies can be partly explained by a combination of economic, structural, administrative, ethical, religious, historical, social and legal factors. The critical factor seems to be how the whole process leading to donation and transplantation is organised. That is why better quality information is needed. If we want to increase the rates of organ donation we should try to explain these large differences and discrepancies that exist. Our Committee underlines the importance of increasing public awareness across Europe on organ donation and transplantation since it can facilitate the identification of organ donors and thus increase organ availability. The Commission’s role on the issue should be strengthened. They should try to take a more active role in collecting such data and information. I am in favour of promoting and funding cross-border research designed to improve this information and to make its results widely accessible. That is why now in the Commission we stress that the establishment of a well-structured operational system and the promotion of successful models between Member States and, where appropriate, at an international level, are of the utmost importance. The Commission acknowledged that the different organisational systems are the results of culture and ethnic differences but should further promote the collection of such information.

Q458 Baroness Young of Hornsey: One of the issues that we have come up against in this country is that people from some communities within this country have lower organ donation rates than others. One of the questions we have been asking some of our witnesses is the extent to which there is any knowledge and research that exists about whether, within other nation states, there are these
discrepancies between communities within those countries.

**Dr Adamou:** Let me refer to other examples. I am an oncologist and I am deeply involved in the screening tests of cancer—breast cancer, colon cancer, cervical cancer—and I was part of a team that initiated this screening programme in my country. We succeeded by going down directly to the people, even in the schools, to talk to them about their health. We gave health lessons. There are organisations in the UK, the NGOs, that are interested in public awareness so that should be the target. You have studies in the UK that show you where you are weak on this, so you have to go down to that level and explain to the people. They are not scientists; they are not aware of many things. They are aware of things only when they get sick from a certain disease, either needing an organ or having a type of cancer, and then some of them become very strong advocates in your effort to promote the system. That is what I did in my country and we have been successful in this, especially the mammogram screening test for women. We took mobile units of mammogram equipment and we went to the villages, we gathered them together, we talked to them and the next day they came to have a mammogram. This is the power of communication. You go there you educate them and then you see that your numbers are raised.

**Q459 Baroness Young of Hornsey:** I think it would be interesting and useful to share practice on those kinds of issues. Could you say what measures you think should be taken at EU level and at Member State level to promote and fund cross-border research which is designed to improve the kind of information that is available and to make the results widely accessible?

**Dr Adamou:** I think I have answered this.

**Q460 Baroness Young of Hornsey:** You mean what you were saying in answer to my last question covers that. Is that what you are saying?

**Dr Adamou:** Yes.

**Q461 Chairman:** Some of our witnesses have suggested that the EU would be well placed because it has a wider pool of people of different groupings to undertake socio-demographic and cultural research to show why and how you do what you have been describing and what it is that helps to get to these groups. Do you think the EU could contribute to that research or do you think people should just get on and get to their communities?

**Dr Adamou:** You can coordinate the effort. That is the only thing you can do, coordinate and give guidelines. Otherwise you cannot interfere with the Member States; the Member States should understand what to do. The Commission and the Council and everybody, let us say screening for cancer—I am taking cancer because I have a great expertise in this—everybody knows that screening saves lives. The Commission is just giving recommendations; it cannot force the Member States to implement a programme. They can say these programme save lives if they are implemented, the same as with public awareness, just give guidelines and information to Member States and ask them to implement and to come together.

**Q462 Baroness Young of Hornsey:** It is a slightly different question. If I could give you an example of what I mean, let us say that in this country, for argument’s sake, that members of the Greek Cypriot community in North London are not giving organs at the same rate as neighbouring and other communities and yet maybe we would find out that in Cyprus there is this big willingness to give organs. What we are suggesting is that it would be very useful for us to know what the differences are across the different Member States within different communities as to what really is the barrier preventing some people giving their organs.

**Dr Adamou:** Different cultures, different religions, different deep roots where they come from. You mentioned the Cypriot community but Cyprus would have a problem with dead donors; we are the last on the list, but we are the first for the living donors. This is the culture but it is not happening in other Member States. Can we take this practice and try to implement another one? No, we cannot do this. The only thing we can do is to raise public awareness to find common guidelines based on different things, not cultural, not religious, because people are suffering commonly from these diseases. Of course, we have to respect the religions and the cultures for other Member States but when we come to health and to measures that you will take to eliminate the disease or deaths coming from this disease, then I think everybody must be united. That is why this is the work of the Commission, to coordinate the Member States even if they have a different culture or a different religion.

**Q463 Baroness Young of Hornsey:** Obviously the coordination is absolutely important, but I think what has been suggested in the past by other witnesses is that we do not actually have enough information and evidence about what the differences are and what is driving that. Could the EU make a contribution by funding some key research in this area?

**Ms Pavlou:** That is what Mr Adamou said. You could help us collect all this information and make extensive research within the Member States to see first of all what discrepancies exist within the Member States, within which communities, which
communities have lower levels, which communities have higher levels. Coming back to the point you said about the Greek Cypriot community in North London not wanting to donate to the other communities, this happens quite often. Many people say that they do not want their organ to go to X, Y or Z but by raising awareness and giving information we are trying to promote equality and equity. The organ will go to the person who needs it, not to a person who needs it less but fits the idea of the donor. Obviously this is very hard to balance in some cases.

**Q464 Chairman:** I am sorry but we have run out of time, in fact we have run over because we are so interested in what you have been saying. Just for the record to clarify that last point, it seems to me that you are saying that there is some role for the EU in terms of exchanging information and coordination. Certainly we have felt that we have learned already a lot from other countries in this hearing. You are saying that when it comes to interference in relation to the delivery of the services that the EU does not have a role. Do I have the distinction clear?

**Ms Pavlou:** Yes. It cannot interfere within the decisions of the Member States unfortunately. It can try to coordinate, it can try to set minimum levels but it will not come to the UK and tell you that you have to do something about your communities that do not want to donate. It is up to the UK to try to raise awareness and raise the levels.

**Q465 Chairman:** We are immensely grateful. We do think we are travelling along the same road. I was just trying to work out where our report would come in relation to your report. Although we are reporting obviously to our Government we do send copies to the Commission and you might well find that what we are supporting will be very helpful. We have certainly found your evidence extremely helpful and we wish you a safe journey home.

**Dr Adamou:** Thank you very much. I want to state here that as soon as we are back in Brussels and the report is ready after the voting yesterday, we will send you a copy and of course, in April we will send you the copy of the Plenary Session so that you will have the final results of what the European Parliament thinks about this. Thank you very much for accepting me here; it was a great pleasure.
THURSDAY 3 APRIL 2008

Examination of Witnesses

Witnesses: Ann Keen, a Member of the House of Commons, Parliamentary Under-Secretary, Ms Triona Norman, Transplantation Policy Lead, and Mr Peter Jones, Human Tissue Policy Lead, Department of Health (DH), and Mrs Elisabeth Buggins, Chair, Organ Donation Taskforce, examined.

Q466 Chairman: Good morning, Minister and colleagues. We are delighted you could come. We know how busy everyone’s schedule is that this time, but we also feel that the work we have been doing is important in relation to many of the things in which you are all involved at this time. They have come together in an interesting way and we have found it interesting. We have also had some useful evidence from the Department and from the Taskforce and from other colleagues which, again, has been helpful. Today is a time for us to draw threads together and to flesh out and for you to tell us anything you think we should know at this point, so if they are not contained in the questions, just make sure we know what we should know at this moment in time because we will be trying to pull the whole of this complex inquiry together into some sort of form and order. Perhaps you would start by stating for the record your name and official title, because we have to have it from you. Then, if you want to make a short opening statement that would be useful, or we could go straight ahead with the questions.

Ann Keen: Thank you. I am Ann Keen, Parliamentary Under-Secretary of State for Health Services. I have a short statement which might help—it would help me anyway to bring me into the situation. I have been a minister since the beginning of July last year and the Minister responsible for organ donation and transplants. Of course the whole area of my job is of particular interest because I am a former nurse (for over 25 years) and I have been in situations where relatives have been asked if they would donate and I have been in situations where I have cared for people who have required transplants. To be part of this inquiry here with you today is a great privilege. I have learned masses by looking at the evidence and in many different ways, but I feel a particular privilege to have been on the service side and directly sitting with you today, and I really welcome what you are doing. It is so, so important. I know you are eager to start and that we have a short period of time, so I will not go on any further but I felt I needed to state that. To have Elisabeth Buggins with us today, who is doing such great work with the Taskforce, is very important as well. Prior to coming into the room, one of the members of the public was pleased to be able to see me and to say he had had a heart and lung transplant and we are going to meet afterwards. I feel it is a very, very special hour and that I am going to learn some more at the end of it by meeting a very good man who obviously is doing good work outside of this Place.

Q467 Chairman: You know that our particular focus is the position in Europe. In order to understand what added value or not Europe might bring to this area, we have had to get some grasp, and that is why we have found it so useful to have the Taskforce Report. We have heard about some of the baselines and the difficulties in the UK because we had to understand that in order to get into the European dimension, but that added bit is what we are really about in terms of our scrutiny. We have heard about standards in a number of countries. Particularly I wanted to begin by asking for your view on the need for a European Directive relating to the safety and quality of organs for transplant; that being, if you like, the area of the EU, although we have heard from some witnesses of their worries that they may stray into other areas. I think those are concerns. To what extent do you agree with the evidence we have heard that this would be of value only as a means of raising standards in some of the newer EU Member States? Really we want to ask you: do you think it would be valuable to this country?

Ann Keen: Thank you. I would suspect that all Member States would agree that there is a need for a common high quality standard in organ donation. More safe, high-quality donor organs available for transplant across Europe will benefit all Member States. Clinicians, from my understanding, need the assurance that organs received from other countries are retrieved appropriately, in line with agreed consent provisions, and that appropriate procedures are followed to optimise graft survival. All countries could have the potential to benefit in some respects. We would learn. It would be a good way of
improving the system. I do not know, my Lord Chairman, if you would allow Elizabeth to add to that. Is that all right with the Committee?

Q468 Chairman: Yes.
Mrs Buggins: I am Elisabeth Buggins, Chair of the Organ Donation Taskforce. I am also Chair of the Strategic Health Authority in the West Midlands and a non-executive director of the Blood and Transplant Authority, which is really what brought me into organ donation work. There are three things in relation to which I think we may be able to benefit from some European collaboration. One is about learning, as the Minister has said; the second is about the traceability of organs in the rare cases currently where organs are transplanted across country boundaries; and the third is that the quality of retrieval elsewhere is sufficiently high for clinicians to be able to have confidence in implanting those organs into their own patients.

Chairman: We may come back to some of that, but I want to come on to Lord Wade, who is going to follow up some of the potential problems with an EU Directive and will also go on to talk with you about the action plan. Other members might want to follow up on some of the detail of that.

Q469 Lord Wade of Chorlton: Some people have suggested that the Directive could cause problems within the UK. What is the scope of the proposal that would affect the development of a Directive on organ safety and quality? What elements would you resist being included in such a Directive because of the damage they could cause to existing UK arrangements. What can you tell us about the views of other EU Member States about the proposal for a Directive?

Ann Keen: I think it is important that we say straight away that UK transplant clinicians already work to high quality standards in organ procurement and transplantation. It is almost a gold-plated service. What problems could we have if we were to work to a real Directive? I think clinicians must ultimately make that judgment for themselves and not necessarily follow the Directive. That is the evidence I have had from clinicians, that they want still to be able to make their own judgments. They may wish any Directive to recognize that the risk-benefit for donated organs is different for organ transplantation than, say, for tissue and cell transplantation. Clinicians worry that a Directive will introduce additional regulation and that that might put people off, for want of a better way of saying it; that if it got too regulated, how would a particular area of expertise follow such a strict regulation and it could have the potential to put off organisations, particular hospitals/Trusts which would have to follow such strict guidance, because the framework of support would not be in place for them to achieve that. That is the general feeling in relation to the first part of your question.

Q470 Lord Wade of Chorlton: That supports other evidence we have received, that if the Directive is too specific it might end up restricting some of the work that we already do. You are saying the same thing.

Ann Keen: But, again, an action plan is very different.

Q471 Lord Wade of Chorlton: I am coming on to a question about the action plan, which, as you say, might take us to a different area. What is your view of the Commission’s idea that it is necessary for the EU to develop an action plan relating to organ donation and transplantation? What benefits do you think that the UK and other Member States will be able to gain from this that would not have been available anyway through the existing exchange of information between medical professionals across national boundaries? What is the action plan going to add, in your view, to what is happening now?

Ann Keen: I believe that we can learn from each other. In most walks of life, we can learn from looking and listening to other people. In particular in this area I think there is the potential for this to improve the quality and safety. Common definitions to help evaluate transplant results and monitor outcomes: there is bound to be so much learning and so much benefit that could come from that. Promote the best organisation of donation and transplant services: looking at best practice and promoting what is also something that I believe we are very keen to follow and to do. Training of professionals: that is very important. I know myself how I was put in positions of asking relatives without appropriate training—but this was some years ago. Nevertheless, it is like being given the opportunity to do your job well when you have had the help and advice as to how to do that, when you work in a culture where you know everyone has had a standard training of how to approach what, of course, is a very difficult area at a time when people are at their most vulnerable, when families are at their most vulnerable. You need to have, I think, a standard training, because it is a community. The professionals in this community do need a lot of support. I think that would help us do that too.

Q472 Lord Wade of Chorlton: How do you see the UK in relation to other countries in the respect of quality of care in these areas? Do you see that an action plan that did these things would add value to the UK? Or is the UK going to be the one that is going to pass information to others?

Ann Keen: I think it is both. I think we would learn, but we could also benefit other countries with how we manage ourselves as well—because we do have a very...
Chairman: Could I ask two supplementaries on that, because they link into questions we have had before. I have to declare an interest. I am a trustee of Little Hearts Matter, which deals with children with hypoplastic left heart syndrome and similar heart conditions and they will at some point find themselves in competition for heart transplants with the general population. With so many people dying on the waiting lists, one of the bits of evidence we have heard is about how the assessment on quality is made and whether it has to be perfect or good enough. Some of the early evidence we had was that people were concerned that if their clinical judgment was to be interfered with then some of organs that might be good enough and save someone’s life might be rejected because of some of the marginal quality issues. I know that is a clinical judgment and I think the clinicians want to be very much assured they could make that judgment. From what you have just said, it sounds as though the Government take that view as well.

Ann Keen: Most definitely. We would support that.

Chairman: It is the gold-plating question.

Ann Keen: In what is already a high quality service, would it reduce transplant rates? I think at all times clinicians have to be free to make that decision.

Mrs Buggins: The waiting list, as you know, my Lord Chairman, is far too high and one of the objectives of the Taskforce was to reduce numbers on the waiting list, make more organs available for transplant, but the clinician knows the patient and the degree of risk that the patient is prepared to take, which could never be known at a European level. The quality of that relationship between the clinician and the patient is very, very important in making that risk assessment.

Chairman: The other question—and I do not know whether your colleagues might like to come in—is that we have heard that the Directive on human tissue did make life very difficult for people in that field. Would there be learning from that area?

Ms Norman: I am Triona Norman, the Transplantation Policy Lead in the Department of Health. There is learning that we can learn from the implementation of the Tissue and Cells Directive. You have taken evidence from Mr Lemmey, who is here from the Human Tissue Authority, who I think has gone through that with you. An Organ Directive is quite different from a Tissues and Cell Directive, for the reasons that the Minister has laid out. The risk:benefit ratio is completely different with an organ transplant than it would be for a tissue transplant where there is much longer to undertake a series of tests to look at the viability of that particular piece of tissue.

Chairman: That is really helpful. We just wanted a government view on some of those crucial issues.

Lord Wade of Chorlton: I do get the impression—and I want you to confirm this—that you do feel it would be right for us to express concerns that the Directive must not come to the level of interfering with what the clinician or the person on the ground would want to do.

Ann Keen: That would be correct.

Lord Wade of Chorlton: That would be your view.

Ann Keen: Yes.

Baroness Perry of Southwark: Turning to a different topic now about trafficking of organs, we were told by Dr Adamou that his view was that organ trafficking was not a particular issue within the EU. My question is: what is the UK government doing to fight organ trafficking across the world? To what extent do you think this is an EU-related problem and in what way could the Commission’s involvement help to prevent that practice? My second question is: what can the EU and/or Member States do to stop the “organ tourism”; that is EU citizens going abroad to buy organs in third world countries?

Ann Keen: First of all, may I make it very clear that the Government’s position on organ trafficking is that the Human Tissue Act of 2004 prohibits commercial dealings in human material for transplantation; to give or receive a reward; to seek to find a person willing to supply; and to take part in the management or control of a body or persons, corporate or incorporate, is not acceptable to us at all. We are very aware of transplant tourism. Some people from the UK do go abroad for transplants from a live donor. On the figures I have here, there are 15 to 30 cases each year that we know of in the UK. It might be legitimate if it is a friend or a relative, of course, but it is not a major problem in EU states. However Member States always have to remain very, very vigilant on this. Action has been taken against an individual who contravened that Act, so we have acted on that Act. That was new information for me to have which was good to share with you today.

Chairman: Could we move on to Lady Gale.

Baroness Gale: Good morning, Minister. Before I put my question to you, I wish to declare an interest, in that I am a patron of Kidney Wales Foundation. My question deals with the European donor card. How important is the existing organ donor card in the UK and what suggestions do you
have, if any, for changing it? To what extent could the Commission’s idea of a European donor card be helpful? Could there be a place in the UK for community-based donor cards along the lines of the card developed in the USA for use by the Orthodox Jewish community?

**Ann Keen:** First of all, the debate is happening now with the Taskforce in relation to how important the card is. To explain it in my own words: if I have—as I have—a card, does that mean that I would be willing to have my organs donated in another European country? I had never had that debate until knowing I was coming to sit in front of your Committee. When I had that debate in my own mind, I personally decided I would not mind. I personally would not mind that. However, that debate is still to be had and I know Elisabeth with the Taskforce is looking at that. Until we have completed that those are my personal views, but I do not believe we have taken this debate to within the country and it is obviously something we have to have. Elisabeth at some stage may want to say that. It is consent, is it not? That is the difference. It is complicated and it is about the consent. If you put yourself on the register you are more willing to have had that consent. Families will still of course be asked. This is what makes it all so very complex, because the relatives will still be asked regardless of my individual or of our community’s individual consent. I am not completely clear what you mean by a community-based card. I am not sure how to answer that, to be very honest with you. I am not clear on what you mean.

**Chairman:** The European Union have made a suggestion that there might be a European donor card and we have had very mixed responses about it. Dr Adamou in Spain said, “Forget donor cards altogether—just get on with your reorganisation.”

**Baroness Gale:** There does seem to be some evidence that if somebody is willing to make a donation of an organ then if it was Community rather than locally based they would think, “Oh, I’m giving it to the whole of Europe,” type of thing.

**Mrs Buggins:** I think you have heard from Professor Gurch Randhawa already and his advice to the Taskforce was really quite clear about this, that we need to see donation of organs very much in the context of how an individual views donation otherwise. I give to those things which with which I identify for some reason, and it may be a cause or it may be a location that will prompt my giving. You have also heard from Rafael Matesanz from Spain, and the donation rates in the smaller regions there are far, far higher than in the larger regions. I think that suggests that the smaller the scale the more people will be encouraged to donate. I guess the majority of people across Europe if they were asked, “Who are you?” would not say, “I’m a European.” They would say, “I’m a Londoner” or “I’m a Midlander or a British person” in my own case.
case-by-case basis by local imams, for example, means that the delay in seeking that advice mitigates against donation. There is a whole sequence of things that need to be taken into account.

Chairman: That seems a good point to bring in Lady Young.

Q483 Baroness Young of Hornsey: Thank you. I am glad you have said you would foresee real dangers of going down that route for a particular community because I think that is a really bad road to be going down—although we will come on to targeted awareness and other issues in a later question. How satisfactory do you think the Commission’s current ideas for research into socio-economic and cultural factors are in influencing organ donation? We have heard from a number of witnesses that there are lots of areas where people do not really know what is going on across the EU. What do you think our Government’s action should be in order to support this work most effectively? Finally, if funding for research does not emerge at an EU level, what plans does the Government have for addressing that situation?

Ann Keen: There is already very helpful research being funded in Europe to inform the socio-economic and cultural factors influencing organ donation, such as Alliance-O and DOPKI.

Ms Norman: You probably already have information on that but if you need further information I can certainly supply it after the meeting.

Q484 Chairman: Thank you.

Ann Keen: We undertake research in the UK to support organ donation and transplantation. The results of such research can be made available, of course, across Europe. Elisabeth might want to comment on the recommendation of the Taskforce.

Mrs Buggins: We made two particular recommendations for research. One was about promoting the gift of life in the black and minority ethnic community, in particular, and we heard some fairly compelling evidence that the range of communication around particular diseases where they are prevalent in those communities often has not included reference to the value of donation. But we need to understand how to communicate those messages better and to encourage people from those communities and all communities, indeed, to donate in greater numbers. There are a lot of questions to which we do not have answers at the moment. That is a key area. The other area which I think is interesting is identifying personal and public recognition of donation where desired. It is anecdotal but I heard from a number of different people from different backgrounds about their different preferences, and we have recognition in this country. In Glasgow, for example, there is a love seat in the Kelvingrove Art Gallery, and every family that donates an organ is given a silver leaf that may be implanted into that seat as a sort of recognition if they wish. There is a memorial in Wales. Some people would like a letter from the CMO to acknowledge the value of their gift to society; others would like a much more public recognition. In some south Asian communities, for example, if money is donated from here back overseas, when they visit their home town they are feted on arrival if their donation is significant. That seems to encourage donation in those communities. In some British communities that would be anathema. We probably need to differentiate the recognition in some way but we do not understand enough about that to know what is the right thing to do currently. Probably of most interest to me—it is alluded to in the Taskforce Report but not made as a specific recommendation—is understanding better what would make clinical and emergency clinicians and those dealing with end of life more comfortable with referral for donation. For me, that is a really key issue.

Q485 Baroness Young of Hornsey: You used the very interesting example of Glasgow and there are other examples you have used. Are you aware of research that has gone on around Europe that also highlights different ways of valuing the gift, as it were, that had an impact?

Mrs Buggins: I am not.

Q486 Baroness Young of Hornsey: That is the kind of thing that it would be quite useful to know about. We are wondering what it is that we can get from across the EU.

Ann Keen: It has been 60 years and we are looking to see, in the celebration of the National Health Service, how we could promote giving. We talk of giving in so many ways. In a very moving incident, two sisters were being looked at clinically to see which sister could donate to their sister who needed a kidney. The eldest sister so much wanted it to be her because she had not had children and therefore she felt she was still giving life in some way. There are some moving stories of live donors in particular. I visited Hammersmith Hospital recently with Professor Taube where I met a daughter who had given a kidney to her mum, her brother who had given to his sister. Everybody I met. It was unbelievable. It was so significant to the family. I wanted to tell people, when I came out, what I had just seen. I think we are still very ignorant on this line of what changes have been made and what giving really does mean.

Q487 Baroness Young of Hornsey: Perhaps I could push you quickly on that question of what our Government should do in order to support the research more effectively across Europe.
Ms Norman: This is something we can look at within the action plan. One of the strands of the action plan is to look at increasing organ availability, looking at the guidelines for living donors, for raising public awareness. That is still at an embryonic stage but, as part of that work, we can see what funding is needed to support research that could come out of that. If indeed funding is available, I would imagine that it would be possible to look at that area and to take up that point which you make as part of the action plan.

Q488 Chairman: Europe spends a lot of money on a lot of things. We are thinking this might be a useful thing for them to spend money on that might enhance work that is going across Europe in all countries on this area. It might be a recommendation that might be helpful.

Ms Norman: Yes.

Q489 Chairman: Could I move on to the Taskforce and implementing. During our evidence taking, of course, your report came out. It has been described as a first class document by a number of witnesses who valued the content. However, it sticks in my memory that, when listening to Dr Rafael Matesanz from Spain, we asked him about our Taskforce and whether what they were doing in Spain could be implemented here so that our numbers could come up to that of the Spanish level. He sat for a moment and thought about it, and said, “You have a very old established Health Service” or words to that effect. I think the point was that change might be quite difficult to achieve. The next question is about what firm commitment the Government is making both in funding the recommendations of your report during 2008–09, 2009–10, and 2010–11, and how that commitment of the professional and other staff in the NHS can be secured so that there are changes in attitudes and methods of working which we need to implement the report. I think you alluded to this a little earlier in what you said. What barriers do you envisage will need to be overcome in order to ensure the successful implementation of the report?

Mrs Buggins: First of all, I would like to say that I am absolutely delighted with the enthusiasm with which this report has been received. I think that is a tribute to all the people who helped us, of which there were many. I am also delighted that the Government has funded it in full. The Minister would like to tell you about some of the implementation arrangements that are being made within the Department. You are right, of course, that implementation is what matters, because it is making the organs available for transplants that will be the key success criterion. If I could turn to the Minister for a moment to say about the implementation arrangements within the Department and then perhaps I could elaborate on how we think that will work out in the service, in this wonderful 60-year old institution.

Ann Keen: We are not biased!

Q490 Chairman: We are not saying that was our opinion.

Ann Keen: I am really pleased to say that to come to your Committee today is a pleasure in itself, but to come to your Committee today with an announcement that has gone out on the wires, as they say, today, that we have appointed Mr Chris Rudge to join the Department of Health on secondment from the NHS Blood and Transplant as the National Clinical Director for Transplant, is very exciting. It is hot off the press into your Committee today. He will be accountable to Sir Bruce Keogh for the delivery of the recommendations, and the whole Department, in particular my colleagues here today, are so pleased and excited. We have been waiting to be able to tell you this today and to get to a part where we could say this. We all wanted to say it and I got the chance to say it and I got the chance to say it because I am the Minister. It is back over to Elisabeth to elaborate on the plans.

Q491 Chairman: We can share your excitement.

Ann Keen: I can calm down now.

Mrs Buggins: Both of those appointments are very important to the implementation of the report: Sir Bruce Keogh as medical director heads up the clinical community within the NHS and also has a very strong relationship with Sir Liam Donaldson who is the Chief Medical Officer in whose department responsibility for transplant sits, and Chris Rudge, as you know, has huge expertise in this area and will be able to impact the NHS on a day-to-day practical level, particularly within the clinical community. It is not just the clinicians though who need to understand the importance of transplants and particularly the importance of donation; it is also the management community. The management community have not really been sighted on the value of transplantation in sufficient numbers to date and one of the things that Chris and Sir Bruce will need to oversee is the collection of data and the dissemination of data in a way that is meaningful to individual chief executives and medical directors within the NHS. Once we get that comparative data and they can understand how well or not they are doing in terms of translating potential donors into actual donors, we will really begin to see the acceleration of donation in this country.

Chairman: That takes us very much into targeting and the question Lord Trefgarne wanted to ask.

Q492 Lord Trefgarne: The Taskforce Report calls for a dramatic increase in the donor rate, which is of course supported by everybody. If that increase can be achieved or something like it, will that be sufficient...
or will there still be a huge waiting list for organs? Secondly, along the route to achieve that increase it is not just a question of finding more donors or persuading more donors; it is a question, as we have heard in evidence, of being able to retrieve the organs at the critical moment and often there are not enough surgeons or theatres or whatever is needed for that purpose. Can you reassure us in relation to either of those things: first of all, the residual waiting list if a significant increase can be achieved and, secondly, the infrastructure that goes with an increased number of donors?

**Ann Keen:** I think we have to be very careful not to raise expectations and to take small steps at this moment. The Taskforce is a very aware—there is the health ministers are talking about it—that we may be raising expectations that the increase will happen very quickly and we do not believe that it will be as dramatic as that. Of course, we are learning lessons, as we said at the beginning, on how to implement this in relation to our standards and our quality and our professional training—and, as you have said: Is there always a team there? I know how difficult that is, but we have huge awareness raising to make. We are looking in many interesting ways at how we can develop that, but if it is said in five years we have increased our donor rate by 50%, then clearly we would look for further improvement on the waiting list.

**Mrs Buggins:** The waiting list is currently rising: 6.2% over the last 12 months, and is likely to carry on rising. It is also true that patients are not put on the waiting list if clinicians do not feel there is a realistic possibility of them receiving an organ. As the supply goes up, the demand also may rise, and so there is a worry in saying that waiting lists will reduce even though the numbers of transplants have increased quite dramatically. We need to see how that unfolds over time.

**Q493 Lord Trefgarne:** The real waiting list is probably twice the length of the published one, is it not?

**Mrs Buggins:** We do not collect the data, so we do not really know and it would be a guess.

**Q494 Baroness Gale:** The report on the Taskforce was a UK report. In order to increase the numbers of donations, you are working on a UK basis. What links or consultations do you have with the devolved nations? I am thinking of Wales in particular. Do you talk to the Welsh ministers and do you talk to the Welsh charities? Their concern is that there voice might not be heard on a UK basis and it is important for all parts of the UK to be involved in this.

**Ann Keen:** Yes, we are. I know that Elisabeth is visiting countries and I intend to visit the ministers and the ministers visit me too. We have had a dialogue already.

**Mrs Buggins:** I am visiting the Scottish Minister on Tuesday next week and I have offered to talk to all of them. I am going to Northern Ireland shortly too and I have written to the Welsh Minister. While there have not been members of the first Taskforce work from the devolved administrations—because it was set up as an English Taskforce—people did attend and were welcome and fully took part in the debate as part of developing the first Taskforce report. Each of the countries has signed the report and accepted it and its recommendations. In terms of the next piece of work that we are now doing, on presumed consent, we are involving explicitly people from each of the devolved administrations in the expert work that is going on, and looking for full membership of the Taskforce from people from the devolved administrations.

**Chairman:** Lady Young is going to pursue the issue about ethnic groups and organ donations.

**Q495 Baroness Young of Hornsey:** We have already discussed this to some extent, but I have a question to do with this high prevalence of kidney failure induced by diabetes type 2. Is that caused by a genetic predisposition or is it about lifestyle and diet? Going on to what we have on the sheet: what plans does the Government have to reduce the need for transplants in the first place? What preventative work can be done amongst those communities? What plans does it have to help bring about an increase in a relatively low organ donation rate? Again, you have already alluded to some of those ideas.

**Ann Keen:** First of all, this week, on Tuesday, we launched our cardiovascular screening programme. I attended events for people aged between 40 and 74, and of course young people will need the advice and help too. We are screening for diabetes and all of the areas that would create concern. For prevention and take-up on the education side, much investment is being made. The nursing workforce—the practice nurses and primary healthcare teams—is very involved in how we will manage this and we are talking to GPs about how we will manage this, but the whole scheduled programme for screening to prevent is already under way. A huge investment has gone into that and a huge commitment. The Prime Minister launched this on Tuesday morning. With the communities that are more likely to have a problem, there are more educative ways of getting into those communities to assist, from school nurses right the way through the spectrum to the older age group as well, who are slightly more reluctant to talk about their health, so we need to do much more work there.
Q496 Baroness Young of Hornsey: There are those kinds of preventative and educational issues but I am also wondering about lifestyle and diet. Is that an issue or is it just something that happens? That is what I cannot quite understand.

Ann Keen: On Tuesday in Tooting I witnessed people coming in who were given advice on smoking—as always; diet; there was screening for cholesterol; blood pressure checks. Aortic aneurism for men, in particular, would be checked, and weight. They were then given advice and special help—not a lecture. Lectures do not work on anyone, do they? It is really serious, supportive health education from school right the way through the age groups, and in the most imaginative ways that you can get into some of the more difficult communities. The retail trade is offering to help greatly. Asda do a lot of work in offering checks in their supermarkets. The labelling of food of course has made a difference, and getting a consensus on that would be helpful. All of the preventative measures that we can look at we are doing.

Mrs Buggins: One of the interesting things we are doing in the West Midlands, which I think harks back a little bit to how you engage people in these discussions, is training people from deprived communities to become health trainers. You are taking people from a particular community, giving them some understanding about lifestyle and its impact on disease and genetic predisposition, and then they are going back into their own community and helping people to change their health behaviours. That is remarkable on a number of fronts: the impact that it is having in those communities, as well as what it is doing for that individual in terms of getting them into a new career and new aspirations and understanding about the control they have over their own health and wellbeing. That is a perfect vehicle for having conversations about donation too. That local focus and rooting it in communities means that it is their conversation, they can own it in a way that perhaps health professionals telling them what they should or should not do does not have quite the same impact.

Q497 Baroness Young of Hornsey: You mentioned both genetic predisposition and lifestyle. Is it a combination of both that accounts for this prevalence in those communities?

Mrs Buggins: I am clearly not a clinician.

Q498 Baroness Young of Hornsey: No, I understand that.

Ann Keen: But that is my understanding.

Chairman: What is interesting is the move from clinical health services to holistic health services. That, we think, is something to do with why some groups do not engage. They do not engage with the clinical but will engage with the holistic.

Q499 Lord Wade of Chorlton: May I make a point on this, my Lord Chairman? I am an insulin dependent diabetic. I started off as a type 2 diabetic and I was put on pills. We are all put on pills when we start and it is when you are on the pills that everybody gets the problems. As soon as you are on insulin, you become a different person. Suddenly you can cope with it and all these problems disappear. The number of people in a similar position to me who agree entirely with what I have just said is quite amazing, and, yet, as soon as the person is first diagnosed with diabetes they put them on pills and say, “Do this and do that” and slowly that is when your sugar levels go very high and that is when the damage is done to your kidneys, your eyes and all these other things that go wrong with you. I can never understand why the medical profession do not get people on insulin a lot, lot sooner. As soon as they do that, you are a different person. There is some advice.

Ann Keen: And duly noted.

Chairman: We would like to move on to a lot of difference of opinion we have heard and that is about presumed consent and Lady Neuberger is going to pursue this area.

Q500 Baroness Neuberger: Minister, I have to declare an interest which has always struck me as a rather odd one: my brother-in-law is involved in transplantation, particularly kidneys and livers, and I would really prefer you to know that. My Lord Chairman has already said that we have heard very different evidence from people about this question of presumed consent, and at the moment public expectation seems to have been raised, particularly by some very prominent individuals and organisations, that moving to a system of presumed consent would increase organ donation rates. You have already said that we have to have that debate—you have already touched on some of this—but the specific questions to which we want to get answers from you are about the extent to which you think that presumed consent might raise alarm amongst some groups, because they really might be fearful that their organs are going to be taken and that might reduce willing consent, willing donation. Also, were we to go to this, how could a legal basis be introduced and would this require a new Act? I realise that those two specific issues are in a much broader debate that you have already highlighted.

Ann Keen: It is so very complex. All the people I have heard who support presumed consent—of which I am one—is because there is a keen desire for transplantation to take place. That is the only platform from which people are seen to come. How those rates and how that is influenced is what the
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Taskforce is looking at. I am not privy to how that Taskforce is developing at the moment because they are yet to report back to us. Of course everybody knows Elisabeth is chairing that. I do not want to say that I do not want to say any more but it is very difficult to say any more because of that situation. The media, as always, is either very helpful or not. In the debate that is taking place—which you have had, of course, here already with hybrid embryo research—everybody then becomes very emotional and misguided in many instances as to what is taking place. People will remember serious incidents, like Alder Hey. If they do not remember, somebody will come up and remind them as to what has happened there and panic people. That is why the work the Taskforce is doing is so, so important, and responsible people telling the truth as to what will happen. There have been people who, to be honest, have not been honest as to what will happen. The more that we can get patients as advocates of how important this is the better, recognising and very much valuing the fact that the families’ wishes at the end will still be taken fully into account.—and that nobody could sign up to the fact that that would not happen. As I still feel a health professional myself, there is no way that that could ever happen. Therefore, we do need to bring in all of the experts but also all the lay people as well to talk about how they feel in the best way we can do this, and your report will help considerably and people like yourselves will help us considerably to do this important work.

Mrs Buggins: Shall I describe the approach we are taking?

Q501 Baroness Neuberger: I think that would be useful. Obviously you will look at all the evidence we have, but the European experts we have talked to have not really thought it would make a huge amount of difference. They say do it or not, but they have not thought that that is really what made the difference. You have touched on that with the Spanish circumstances.

Mrs Buggins: Certainly Spain had presumed consent for ten years—back in 1979 to 1989, I believe—and it made no difference to their organ donation rate. That is interesting, but that then set the context for all the other changes they brought about in 1989, so we are looking at those two things in tandem really and wondering what difference it would make in the UK context. The approach we have taken, because it is so complex, is to set up six expert working groups looking at the practical, clinical, legal, ethical, cultural and communication aspects of different consent regimes, to try to understand what the evidence currently would tell us about whether presumed consent would be a better option for the UK or not. I would like to say that we have been put under no pressure to come up with a particular answer, so this is an honest inquiry, and we are committed to producing the report, based on the evidence that is currently available to us, in the summer this year and also in that report to highlight further questions to which we feel we need answers if we cannot come to a definitive view at that point. Again we are indebted to a huge number—I have a list here—of experts who are on those six working groups and some fascinating debate is underway. They are due to report back to the Taskforce by the end of May, so that we may then formulate our report in the summer. I am not really in a position to say what the conclusion is going to be at the moment but we are addressing it very seriously and thoroughly and it is a fascinating debate.

Q502 Baroness Neuberger: I presume there would be some kind of changed needed for the Human Tissue Act if you go down that path but at the moment you are not going to discuss that. Is that right?

Mr Jones: I am Peter Jones, Branch Head of the Human Tissue Branch at the Department of Health. We look after the Human Tissue Act legislation. I am also providing secretariat help to Elisabeth and the Taskforce work on presumed consent. The extent to which the law would need to be changed depends on how far we go—which is an obvious statement. The way the law works at the moment is that where there was a decision made by the deceased person one way or the other when they were alive, that endures beyond death and has legal force. If that is not the case, the Human Tissue Act requires you to get consent from either someone nominated by the person when they were alive to make those sorts of decisions for them or to go to someone in what is called a qualifying relationship, which is usually family member—it is ranked from spouse down to a friend of longstanding. Anything that involved, in the absence of any decision one way or the other by the deceased, making a presumption or an assumption, in those circumstances would need a change in the primary legislation. To what extent we would need change would depend on the Taskforce’s findings.

Baroness Neuberger: Thank you very much indeed. Could I just say that it is great about Chris Rudge.

Q503 Lord Kirkwood of Kirkhope: Minister, thank you for your appearance and your evidence. As someone who has come new to this whole subject, you only need to have been listening to our hearings for ten minutes to understand that we are really dealing with public ignorance. My own view has been completely transformed just by listening to what is being done. Also I think we would acknowledge that the Government have done a lot and that is well recognised. Public awareness is part of the problem. I would like to put it to you that it is, and get an
assurance that the Government does understand the importance of trying not to manipulate but to achieve informed consent in the best way that we can. I would like an assurance about that. I would like to know what other initiatives or projects the Government may have in mind, bearing in mind I have a very clear recollection of the mid 1990s, when AIDS became a problem, that the TV promotional campaigns were very effective and, indeed, some of the smoking campaigns more recently have been very effective. If Parliament does believe in making progress in this area—and I believe the evidence is that they do—can you really do that without putting some effort and money inevitably into some of these publicity campaigns that could get the informed public into a situation where they can make decisions for themselves? Do you have a budget within the EU Comprehensive Spending Review to help you do that? The Taskforce, fully funded as it is, as Elisabeth Buggins was right to point out—and that is welcome—does not have an element for public awareness raising in terms of publicity that I am aware of.

Ann Keen: This is a very important question. Yes, we are funding the Taskforce for more public awareness. That will take place.

Q504 Lord Kirkwood of Kirkhope: Is that known?

Ann Keen: Yes.

Mrs Buggins: £4.5 million over the next two years.

Ann Keen: National Health Service Blood and Transplant and bodies like that—and I think our welcome appointment today will make a huge difference—and newspaper campaigns have been supportive. Last Saturday’s Sun was very helpful. I think the soaps are a good way in. Sport in particular. We work very closely now with the Football Foundation in the Department of Health. Rugby want to come in. All of the sports people can help us. When we were talking this morning, Elisabeth came up with the idea that we should make a film. It would be a very powerful film. I do not want to steal her idea, but I think it would be. Having seen the Diving Bell and the Butterfly in the last few weeks and seen how powerful that media is, this would cross all languages and cultures, and there is so much now that we are ready to do and so many people ready to do it. I met Graham Bruchete outside and he is going to give me more examples of his work when the Committee is ended. He has received a heart and lung transplant and is going around schools, and getting into schools is so important. The Health Service, as we have said in previous answers, needs education. Professions do. There is such a powerful media out there: Casualty, Holby City, all of those, are powerful programmes for getting messages across. But funding needs to be there too.

Q505 Lord Kirkwood of Kirkhope: That is a helpful reassurance. The other point that struck me, which I was completely ignorant about, is that even when people are on the Organ Donor Register family members can resist. That is a trickier problem, I guess, from a public awareness point of view. Just to get people to sign up is perhaps simpler than trying to get across to families that people have made a choice and it is something that really ought to be respected. That is an important part of the public awareness campaign as well I hope.

Mrs Buggins: What you have just said is so important. One of the things that was really interesting, looking at the data around the donation in this country, is that being on the Organ Donor Register does not necessarily mean that you donate, as you say, because family members are so important. But, also, the way the NHS operates at the time of that person’s death has a big impact which is something that the Taskforce Report sought to address. It is also interesting that people who are on the register do not donate necessarily in proportion to the population. Perhaps I can explain that a bit more clearly. People who are on the Organ Donor Register tend to be people who are in the higher socio-economic groups; I understand that the people who donate tend to be in the lower socio-economic groups. Again we need research. We do not understand why. There does seem to be some suggestion that the degree of confidence that people have in their professional carers at the time of death leads to their willingness or not to donate. We do need to understand a great deal more about why people donate and why they do not donate but a publicity campaign is overdue.

Chairman: It illustrates the need for research again.

We are immensely grateful to you for coming to talk to us—some of you, yet again. Minister we are very grateful that you have given us the time. I suppose we have discovered just how immensely complex a problem this is but I think the one message we have taken is that, whatever else you do, if you do not have the system in place to take the organ, and transplant it at the time when someone is prepared to give it, then whatever else you spend your money on will be lost. I suppose that is the core message that has come across to us and of course it was a central message in the Taskforce report. I suppose we would be saying to you that we have to look at the EU proposals but as far as the UK is concerned, the top priority will be to put your system in place. This is what we have been told both by the people we have heard from across Europe and from UK witnesses. We recognise how distressing it is that so many people sit on waiting lists for organ transplants and that relatives lose their family members. We are very aware of how important all this is. We will do our best with all the evidence we have received and we wish you well in trying to make it all work for the UK. Thank you very much indeed.
Written Evidence

Inquiry into the EU Commission’s Communication on organ donation and transplantation:

policy actions at EU level

CALL FOR EVIDENCE

EU Sub-Committee G (Social Policy and Consumer Affairs) is conducting an Inquiry into the issues raised by the European Commission’s Communication “Organ donation and transplantation: policy actions at EU level”, which was published on 31 May 2007. The relevant Commission document COM(2007) 275 final is accessible on the Commission website at:


An associated Impact Assessment which gives greater detail relating to the subject has also been prepared by the Commission and is available at:


The Commission Communication is intended to stimulate discussion of the issues that arise increasingly now that organ transplantation has come to be a successful form of treatment for medical conditions involving the failure of the kidney, liver, lung and heart. In the case of kidney failure, transplantation is now the most cost-effective treatment available (the alternative being daily kidney dialysis); while for failure of the liver, lung and heart, it is the only treatment available.

The Commission cites Article 152(4)(a) of the EC Treaty as the basis for its action in this field. They assert that this Article enables the European Parliament and Council to adopt harmonised health measures on the basis of the co decision procedure set out in Article 251 EC, by setting high standards of quality and safety of human organs.

Particular issues raised in the Commission’s Communication on which we invite responses are the following:

— EU-wide shortage of organs available for transplantation;
— organisation of organ donor and transplantation systems;
— raising public awareness of organ donation;
— use of organ donor cards, including the idea of a European organ donor card;
— use of volunteer living donors;
— ensuring the quality and safety of cross-border organ donation within the EU;
— ethical issues relating to organ donation and transplantation;
— health and social welfare benefits of organ transplantation;
— medical risks of organ transplantation; and
— illegal trafficking in organs.

We also invite responses on the following issues of relevance to the Commission document:

— questions which may arise in relation to organ donation and transplantation from a faith-based point of view;
— questions which may arise in relation to organ donation and transplantation from the point of view of population sub-groups within the UK;
— the “presumed consent” approach for identifying organ donors (under which a willingness to donate organs becomes the default position and people wishing to opt out from this need to make this known); and
— the arrangements for taking into account the views of relatives about removing organs for transplantation from a deceased donor (both under the present system of “opting in” or under the “presumed consent” system for identifying donors).

In addition, we seek views on the need for an EU role in this field—the Commission’s argument is that it is needed for three main reasons:
INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE

— To promote cooperation between Member States in order to share expertise and to expand the size of the potential donor pool in each Member State.
— To provide a cross-border framework for the organisation of organ donation and transplantation, with harmonised rules that would provide EU citizens with higher standards for organ safety and quality than can be assured by the national legislations of Member States acting separately.
— To enable more effective action across the EU to fight illegal organ trafficking.

We also would welcome views on any other aspect of the Commission’s Communication and Impact Assessment.

Memorandum by Nicholas Blyth

I’ve witnessed with increasing dismay—albeit from a layman’s distance—the current debate concerning organ transplantation and “presumed consent”.

I have a number of observations to make and they concern what seem to me to be three points—both major and (largely) overlooked.

The first is quite simple. Most of the articles I have read—including (indeed, notably) one by Veronica English (see bma.org.uk or venglish@bma.org.uk: “Is presumed consent the answer to organ shortage? Yes”)—were driven by one single consideration and directed towards one single objective (and these were one and the same): the assumed desirability—above (and, indeed, to the exclusion of) most other ends—of an increase in the number of organs available for transplantation. In many cases there has been little or no serious attempt even to begin to address the ethical issues involved. The assumption—and Ms English’s article is both facile and massively assumptive—arises from a failure or neglect of serious thought and of moral logic (in fact, sometimes of any proper logic at all). That the transplantation of a vital organ can prolong life is, of course, undeniable. Her next “step”, however, (though in reality it’s more of a clumsy lunge) reaches the conclusion that organ transplantation on as large a scale as possible is, ipso facto, desirable; and that any case against it is inconceivable; in fact, unthinkable; which is possibly the reason why people like Ms English don’t trouble to think about it at all, but are contented simply by the demonstration that in countries where “presumed consent” is practised, the organ “harvest” is far greater than in the UK. (It amazes and distresses me that Ms English is the BMA’s Deputy Head of Medical Ethics should occupy this—when she appears not to know what an ethical issue actually is!)

The fact remains (and will continue to remain until it is properly addressed) that there are ethical issues to be confronted.

I would not dream of trying to introduce a debate on whether it is morally right for a person to be given the heart, lung or liver of another (deceased) person. That is beyond the realm of discussion and I suspect that instinct, natural squeamishness and religion are three, at least, of the motivational forces that might determine how people align themselves concerning this matter. There are, however, areas in which debate can and must take place, and with your patience I shall try to identify them.

1. There must be a serious attempt to agree on a definition of “death”. I am indebted to articles by a number of medical practitioners on this subject—especially one by Dr D W Evans of Queens College Cambridge, formerly a physician at Papworth Hospital—in which the confusion over current definitions is identified and high-lighted. It would be impertinent of me to rehearse arguments already delivered by experts, but my point is a simple one: people who are being solicited as prospective donors (and soliciting becomes a considerable pressure when the “presumed consent” factor is introduced) are entitled to a detailed and unmistakably clear explanation of exactly what is to be understood by “death” insofar as it relates to these circumstances. In other words, when I am invited to carry a donor card stating that I give my permission for any (or all) of my bodily organs to be used for transplantation on my “death”, I must know, beyond all doubt and ambiguity, precisely what definition of “death” is being used and under what conditions my body—supposed lifeless—will be operated on for the removal of my organs. Unless people know the full facts, it is impossible for them to make a responsible and informed decision about the matter. I have a suspicion—not, I admit, susceptible of proof—that the confusion that exists and that has been so lucidly expounded in Dr Evans’s article is more than accidental. The writings I have seen—by Veronica English and the many others of her “persuasion”—are so eager to gloss over the detail with breezy, casual assumptions, specious arguments and sloppy logic that I become uneasy. One of the easiest (and most time-dishonoured) methods of control involves keeping people in the dark or confusing them with a deceptive twilight. Where water-tight definitions and lucid explication are provided, people are obliged (or at least able) to see things as they are and to make responsible decisions. In the current case, the opposite is true and I suspect a large measure of disingenuousness.
2. Once the definition of death is concluded and agreed upon (by those who decide these things) steps must be taken to ensure that the information is available in a comprehensible form to everyone. Nor must those who provide this information hold back from clarifying exactly the circumstances under which a person declared dead will be operated upon to have his or her organs removed. Anything less is an insult to people's intelligent and a totally unjustifiable violation of their rights.

3. There must be an end, once and for all, to the “presumed consent” monstrosity. It’s a logical nonsense in itself, of course: designed (along with the various strategies of obfuscation) as a means of exerting pressure on people. When it comes to something as important as the donation of organs, people must opt in not out! And this must be the case, even if it means that the number of organs available for transplantation diminishes! The numbers card must never be played when ethical issues are at stake. The medical profession—also, sadly, the BMA—are disgracing themselves in this matter.

For further discussion of Ms English’s article and point of view, I attach my own article—available also as a “rapid response” to that article on the BMA web site—in case any of your committee feels it would be worthwhile to read it; also this submission.

October 2007

Annex A

PRESUMPTUOUS CONTENT

I was interested in the articles I read relating to presumed consent” and submit a layman’s point of view.

Regarding Veronica English’s contribution, I was arrested immediately (and angered) by the sheer lack—absence, almost—of either intellectual rigour or logical thought. From the very start, I was alarmed by a kind of facile assumptiveness—implicit in phrases such as “it seems likely that”, “we all have the same aim”, “changing the default position”, “assuming… unless there is evidence to the contrary”, “analyses seem to indicate” et al. They set the tone for the whole piece. Add to those the ones that spell danger because they conceal (albeit under a thin disguise) some sinister sub-texts and there’s a cause for grave concern. I always worry when something is presented as being “easier for all concerned” (as though convenience were the main—even the sole—criterion). It alerts me immediately to the probability that something is being slipped in and that an attempt is being made to disarm or anaesthetise my critical faculties!

Looking at the essay more closely, I found roughly what the cursory reading had led me to expect: the ethical issue is simply not dealt with at all! The entire “argument” (to call it that) is based on convenience and on the assumption that any system which increases the number of donations requires, ipso facto, no further justification. Countries where the donation rates are highest are thus presented as “evidence” that a “presumed consent” policy is ‘better’.

I found the first major assumption of the piece both baffling and disgraceful: that bodies had been buried or cremated “intact” (rather than used for organ transplantation) “not because people objected to donating their organs but simply because they never got around to making their wishes known!” That anyone should present such an obviously self-serving proposition on the basis, merely, that it “seemed likely” was, I thought, staggering.

The rest of the piece is riddled with logical falsehoods and ineptitude. The idea that because some people may “support organ donation” as a principle they will necessarily be willing to give pre-emptive consent to the use of their own organs—and that without being made fully aware of the conditions under which this will happen (and understanding/accepting those conditions)—is preposterous.

I’ve no doubt, of course, that the idea that an assumption that people want to donate unless there is evidence to the contrary will cause an increase in availability. That’s obvious. But—as in the whole of Ms English’s thesis—this makes not the slightest attempt to confront (even to touch on) the moral issues. Mostly, throughout her entire essay, moral considerations are simply ignored. As far as she’s concerned, increased availability = success = justification; which even a naive moral philosopher like myself can see to be nonsense. It’s back to the old end-justifies-the-means debate.

And when she questions the validity of “current law” because it “assumes, when people die, that they are in the minority who do not wish to donate”, she is on equally thin ice; in fact, on no ice at all. Dead in the water! Of course the law assumes that! It “assumes” that unless I make it clear before my death that when I die I wish to “donate” something that belongs to me to a specific cause or for a specific purpose, then I do not so wish. Otherwise, all kinds of “assumptions” could be made about how I might want to dispose of my possessions (including my own body): eg, that I wanted (in the absence of any clear indication to the contrary) to donate
my body to medical research or that I wished the proceeds of my estate to be donated to the Battersea Dogs' Home!

Once we start “assuming” what people want, we’re already part way down a very slippery slope. It soon becomes an assumption of authority to decide what people ought to want. As if that were not enough, the people “who do not wish to donate” are implicitly derogated as a “minority”. (I’ve noticed before that when people want to foist otherwise untenable notions on others, they often use the “minority” idea as an argument.

It’s typical, I’ve found, of such people to assume that the majority is always right; which is something no intelligent and honest person would ever claim!

I’m amazed, too (though perhaps not), that the basis itself for establishing that people who do not wish to donate are a minority is so ill-defined. “Surveys show . . . !” It’s one of those corny old expressions—like “research on both sides of the Atlantic has established . . .” or “A highly-placed Government source assures me that . . .” (In this case, that the only reference to any actual survey is distinctly anonymous and general: a “UK Transplant Survey”. If such a survey existed, I would be very interested to see and analyse the questions on which its conclusions were based. I would anticipate much of the kind of box-ticking that manoeuvres respondents into false positions by cutting off their options (probably without anaesthetic).)

As regards her claim—and apparent surprise at the fact—that “although 90% of the population supports donation, only 23% have registered their wish to donate”, one can only register surprise oneself that Ms English is surprised. The questions to be asked are, surely, (a) if this is so, why is it so? and (b) why have people like Ms English not asked (and found the answer to) this obvious question? The obvious answers, it seems to me, are: (a) that a general support for the idea of organ “harvesting” is very different from a willingness to give permission for one’s own organs to be used; (b) that without far more—and far more precise—information concerning how and under what circumstances one’s organs might be removed and re-distributed and one’s death defined, one would, of course, be reluctant to make any commitment whatsoever.

And one has only to consider the “efforts” (eg strategies) “to improve transplantation rates over the last decade” to see even more clearly where Ms English is coming from. For “publicity” read “propaganda”, for “education” (with its facile and patronising implications—that if only we can explain to these simpletons (the 90%) just how silly and selfish their point of view is, they will fall in line and thank us for it—) read, effectively, “coercion”. For “simplifying the process” read “falsifying the reality” through carefully contrived box-ticking questionnaires that manipulate the respondents into compromising positions by offering limiting alternatives which discourage both freedom of thought and accuracy of response.

Nor would I have a jot of confidence in “extensive publicity advising people how to opt out”. We’ve most of us, at some time or other, been supplied with “opt-out” information, or been offered opportunities to “register objections”. Those of us who’ve attempted these complicated and often (I suspect deliberately) baffling procedures would, in most cases, I think, be very sceptical; if for no other reasons than that the people offering the opportunity don’t want you to opt out!

Paragraph 5 seems to me to be the most offensive of all. The idea that the relative of a dead or dying “target” person who has not opted out should be asked if they know of any “unregistered objection” is bizarre—and, in a sense, wicked. The terminally sick or deceased person not having opted out (confusion, mental fatigue, the near-to-death physical condition itself, not even having considered the matter, etc), the relatives, if they fail to declare knowledge of an unregistered objection, “are informed of the intention to proceed!” The only reservation allows the possibility of the process causing the relatives “severe distress”. Well—we’ve all seen how expressions like that have helped to open the flood gates to literally millions of abortions whose justification depended on “severe mental distress” being caused to the “mother” and have created a climate in which mass-murder presents itself as social concern.

Ms English goes blithely on to show—though the phrases describing her frames of reference (“careful analyses seem to indicate”) ring immediate alarm bells—that in countries where the policy of “presumed consent” has been implemented there have been “higher donation rates”. This is one of the few assumptions she makes that I would not be disposed to doubt. It’s the one thing about which I’m sure she’s right. But in spouting these statistics she is only coming up with the answer that most people would expect. She has still not even begin to address the moral issue that would concern most people; and clearly doesn’t see that there is one. Firstly, she implies that the government argues lack of support for “presumed consent” without any serious attempt to test this assertion (where, I wonder, does that idea come from?), then claims—with the arrogant assumptiveness that one has now come to expect of the whole piece—that “We all have the same aim: to improve donation rates.” That, I think, caps everything! Any other criterion is irrelevant. People who do not agree are committed to a “strategy that has failed” but which they “doggedly pursue”. It’s all pretty insulting—and one of the most facile pieces I think I’ve read. The lack of logic, even, coupled with the over-confident, hectoring tone is itself an insult. Whatever one’s moral instincts concerning this issue, one would have to be no more than a half-intelligent person to feel disquieted by it. The “strategy” that she condemns can be judged
a failure only if you agree with its fundamental premise: that to “improve donation rates” is the sole criterion of success.

The bullet points with which she concludes are an appropriate summary of her method and of the sloppiness of her thought.

Gordon Skilling’s article accepts, almost without demur Ms. English’s whole thesis, while throwing a casual sop to conscience by accepting that “The issue is complex” (Wow!) “having spiritual and religious facets”, but sees the only way forward (ie to the achievement of the stated aims) as devising “strategies to address public perception” (ie, to show dissidents that they’re wrong). Well—one would hardly expect a balanced argument from someone who maintains “there is no convincing ethical argument against presumed consent” and accepts English and Somerville’s claim that “most major religions positively encourage donation”. What he understands by a “religion”, I’m not clear. All the “inspired” documents that form the bases of the world’s major religions came into being, obviously, centuries before the idea of organ transplantation was even seriously imaginable. I don’t think he—or Veronica English—have any real intention to grapple with the ethical or religious issues.

He asserts blandly: “The bottom line is that a system of presumed consent would save many more lives each year”. If that’s the case, then there’s no point in any argument at all; except to say “No! It simply isn’t. That is not the ‘bottom line’”. As for his ideas about the infringement of personal autonomy—they seem to me to be intellectually puerile. “If we breach the autonomy of those who do not wish to donate by presuming consent”, he writes, “then so too do we breach the autonomy of those who wish to donate but whose organs are not used.” I could hardly believe I read that. Is he really saying that a person who has donated organs but whose organs are either unsuitable or surplus to requirements has had his “autonomy” breached? Would he use the same “logic” in support of the use of all organs offered—including diseased ones—for fear of breaching someone’s “autonomy?” (See Gwendoline Harlow’s comment about former cancer patients, who are “not permitted to donate blood, never mind organs!”) It doesn’t surprise me, therefore, that he should come up with “To give more moral weight to a decision not to donate than to a decision to donate is illogical.” What a muddle! The point has to do not with donating or not donating but with donating freely, on the one hand, or being pressured into donating on the other, or having one right to decide whether or not to donate unfairly influenced or actually abrogated. And that the notion of infringement of autonomy can be proved to be “already accepted in our society” by comparing the legal requirement to wear safety belts in cars with “presumed consent” is, frankly, risible!

Not surprisingly, I liked Michael Potts’s article and the contributions by Graham Kyle (not, I hope, merely because I agree with their ethical premises ) and—in a slightly modified form—Barry Groves’s provocative and feisty comment on human “cannibalism”.

Also, the contribution by Dr David W Evans had, I found, a strength and a depth of focus that the others did not. I particularly appreciated (a) its undistracted concentration on the central issue, (b) its closely reasoned logic, (c) its calm non-rhetorical delivery, (d) its precision of statement. Yes—“The fundamental ethical issue . . . is that of truth and its telling.” I believe, too, (as argues earlier) that he is absolutely right in his judgement concerning the attitude that “may well explain the difference in numbers of those declaring support for organ transplantation in the general, impersonal, sense and those prepared to register as “opt-in” potential donors . . .”

Memorandum by Mr S R Bramhall MD FRCS Consultant Hepatobiliary and Transplant Surgeon

**BACKGROUND**

The number of cadaveric donors in the UK has remained at approximately 12 per million per calendar year for a number of years now and this is despite medical attempts to increase donor numbers by taking on more and more what are termed marginal donors (older donors, donors with diseases that would traditionally not have been considered for donation and increase in non-heart beating organ donation). What this means is that the number of cadaveric heart beating donors, which are the main stem of organ replacement, has declined dramatically in the last 20 years from more than 800 to just around 600 per year. Over this time period the waiting list for renal replacement has increased dramatically and now in excess of 6,000 patients are awaiting renal transplantation. The liver surgeons have controlled their waiting list by applying arbitrary guidelines for the inclusion of patients on the waiting list. The nationally agreed guideline is that patients should have a 50% chance of five year survival before they are listed for liver replacement. This is of course completely arbitrary and many patients who fall out with this criteria would gain significantly from liver replacement. For instance the five year survival following the cancer surgery for GI organs ranges from 25–50% depending on the organ involved. What this has meant is that referring gastroenterologists control the number of patients that are referred to liver transplant centres and act as primary gatekeepers and then liver transplant physicians also control the number of patients going on the waiting list according to the national guidelines. Despite this
control the number of patients waiting for liver transplant has dramatically increased over the last two years and consequently the death on the waiting list for liver transplantation now runs in the order of 15% and is rising. I have little doubt that similar controls are placed on patients waiting for cardiothoracic organ replacement and that deaths on the cardiothoracic organ waiting list are also rising.

The national donation rate in the United Kingdom is now one of the lowest in the developed world. Donation rates in the US run at 24 donors per million population, in Spain it is 35 per million population, in Northern Italy it is 25 per million population, in Austria it is 24 and Belgium 23 per million population. The UK donation rate mirrors that of Croatia, Slovakia and Greece. Despite this, there is very good evidence that the types of patient being admitted to the Intensive Care Unit in all of these countries is very similar and therefore the potential for organ donation across all of these countries is similar. It has often been quoted that the mixed ethnicity of the UK is part of the reason for the relatively high family refusal rates, although the ethnic mix in many of the countries quoted above is different from the UK there is absolutely no reason to suspect that donation rates similar to theirs could not be achieved.

FINANCIAL COST

There are enormous financial costs to keeping patients with end stage organ disease alive. The cost for renal dialysis and the cost benefit of renal replacement therapy is well recognised and easy to compute. However, this is not the case for patients with end stage liver disease. In Birmingham our current waiting list is 75 patients. At any one time 10% of these patients will be inpatients either here at the University Hospital Birmingham NHS Trust or in their local referring hospital. The average stay for these patients is approximately seven days and this computes to 2,500 bed days per year which costs the NHS approximately £750,000 per year: in addition 1% of our waiting list population will be inpatients on Intensive Care Unit which approximates to 12 patients per year each of them an inpatient for a minimum of seven days. The cost of this is an additional £100,000 per year and therefore if this was extrapolated throughout the UK the cost of keeping patients in hospital who are currently on waiting lists for liver replacement is in excess of £3,000,000 per year. It is impossible to get accurate figures but the cost of keeping patients alive with end stage liver disease who fall out with the current guidelines for liver replacement will be at least 10 times this. I have little doubt that similar figures would apply for cardiothoracic organ replacement. In addition those countries that do not have legally recognised brain stem death have developed living related liver replacement and this has been taken on in some countries because of a shortage of donor organs. UHB NHS Foundation Trust has recently submitted a bid to the DoH for funding of living related liver transplantation. This has involved a detailed financial evaluation and an overall cost to UHB of assessing and providing organs from a living related donor will come in at £23,000 per donor. It is interesting to note that in the US five years ago living related liver transplantation was performed in approximately 400 patients per year, over the last five years since the donation rate in the US has increased from 12 per million to 24 per million the number of patients undergoing living related liver transplants has now reduced to under 200 per year. In addition living related liver transplantation is barely practised at all in Spain which has the highest donor rates anywhere in the world.

MODELS OF ORGAN PROCUREMENT

In the United States transplantation is overseen by the Organ Procurement and Transplantation Network (OPTN) which is a government funded body contracted to the United Network for Organ Sharing (UNOS) and operates under a federal mandate and in line with a number of federal laws related to organ transplantation. The OPTN monitors and regulates transplant activity and oversees the activity of 58 Organ Procurement Organisations (OPO) within 11 regions. The OPO is a not for profit organisation which charges recipient hospitals for services obtaining organs. All of the above is backed up by legislation and hospitals have a legal obligation to perform death tests where brain stem death is suspected and report all deaths and potential donors to the OPO. This is regularly audited by the OPO staff and hospitals are penalised if they do not meet the requirements. In addition each hospital is financially remunerated for the costs to that organisation for the donation process.

The Spanish system uses medically qualified transplant coordinators in every hospital with an ITU and these doctors are proactive in identifying potential donors and discussing them with clinicians to optimise donor identification and organ retrieval. Since the inception of this system in Spain donation rates have rocketed, pressure on the waiting lists have relieved and organ donation is the highest in the world.

In the late 1990’s organ donation in Italy was at an all time low with many patients seeking organ replacement outside Italy; however, a legal framework for transplantation was introduced into the Northern Italian Procurement Organisation in the late 1990’s, they introduced the Spanish model and donation rates in
Northern Italy have increased from approximately eight per million to numbers approaching that of the Spanish donation rates.

In the UK organ donation is entirely a voluntary process and is highly dependent on the interests and motivation of the clinicians working on the Intensive Care Units. It is well recognised anecdotally that many patients who are suspected of being brain stem dead never have the tests performed and it has also been recognised anecdotally that many patients confirmed as being brain stem dead are not referred. It is entirely dependent on the level of interest of the clinician and in addition religious and cultural differences also influence referral. There is a constant battle within Intensive Care Units for ITU beds, there is no doubt that the donation process will delay discharge from an Intensive Care Unit by several hours, there is also conflict in providing operating theatre space for the donation process to carry on and hospitals do not receive any remuneration for the process of organ donation. It is usually perceived that organ donation is a favour to the transplant unit rather than an aspect of good patient care and in addition the option of donation may actually help bereaved families.

**Potential Donor Audit**

UK Transplant has been performing a potential donor audit and the 30 month data from this audit has recently been published by UK Transplant. All deaths on an Intensive Care Unit have been audited by transplant coordinators and over this 30 month period this has led to an audit of 57,972 deaths. The data is fascinating and demonstrates three areas where there is very significant leakage of potential donors.

1. **Performing brain stem death tests**

   The audit demonstrated that over the 30 month period 5,072 patients died with brain stem death being a likely diagnosis. This amounts to 2,028 patients per year. Of these patients brain stem death tests were only performed in 3,519 (1,408 patients per year), therefore brain stem death tests were not performed in approximately 620 patients per year. The data also shows that when brain stem death tests were performed brain stem death was confirmed in almost 97% of cases. There is therefore more than 600 patients per year who could be potential donors were brain stem death tests performed and this is a very difficult group of patients to access. Clinicians will produce a variety of excuses as to why brain stem death tests were not performed and it is very difficult under these circumstances to argue.

2. **Brain stem death tests performed not referred**

   The audit also reveals that of the 3,400 patients in whom brain stem death was diagnosed (1,360 per year) 99% of them were medically suitable for organ donation but 514 of these patients (205 per year) were not considered for organ donation with no approach to the family being made or no consideration of solid organ donation. It is possible to influence this group of patients because the diagnosis of brain stem death has been made but again ensuring these patients are referred for organ donation is paramount.

3. **Family refusal rate**

   Over the course of the 30 month period 1,158 families refused organ donation when approached (463 per year) giving a family refusal rate of approximately 40%. There is no doubt that family refusal rate can be influenced in a number of ways, this has been ably demonstrated in the US, Spain and small areas within the UK. Family refusal rates are improved when collaborative requesting is carried out (requesting by a trained transplant coordinator in conjunction with ITU staff). The family refusal rate is also dramatically reduced in families where the potential donor is on the organ donor register.

**Summary**

The 30 month data from the PDA has demonstrated that over this period 1,536 solid organ heart beating donors donated organs (614 per year), however, the total scope for donation was 2,228 which means that 1,288 patients per year who were potentially suitable for organ donation did not come to fruition. If even half of this excess were turned into donors then the UK would have no waiting list for renal replacement in 10 years, death on the waiting list for liver replacement would be eliminated and many more patients who are subsequently offered liver replacement could be considered. If even 50% of the 1,288 potential donors per year that are currently lost through leakage in the system were converted into donors then the organ donor rates
Increasing the supply of donor organs within the European Union: evidence

in the UK would mirror that of the US and would become close to the rates achieved in Northern Italy and Spain. This adds further weight to the argument that there is the potential in the UK for significantly increasing organ donation with an appropriate approach.

Current Initiatives

UK Transplant has recently merged with the Blood Transfusion Service to become part of NHS BT. The strategy for solid organ donation is currently being considered by UKT and if successful will certainly help to address some of the issues of family refusal rates and possibly address some of the potential untapped source for organ donors where brain stem death tests are performed and referral is not made. The strategy for UK Transplant over the next three years should be to centrally employ coordinators. Currently coordinators are employed by the host NHS Trust, there is little management of these individuals and certainly no performance management simply because the local trusts have no experience of organ donation. In addition many of the coordinators around the country still perform dual organ donor and organ recipient roles which are clearly unacceptable in the current climate and centralised employment will address many of these issues. In addition extra funding is being sought by UK Transplant as part of its strategy to place in-house coordinators in all of the larger ITUs throughout the country (80% of organ donors come from 20% of UK ITUs); this is similar to the Spanish model although the in-house coordinators from the UK will be from a nurse background rather than a medical background. The 2003 10 year transplant plan whilst clearly failing at the moment aims to have 16,000,000 people on the organ donor register by the end of the plan and this is well ahead of schedule with more than 13,000,000 people on the ODR currently. Provided that the strategy put in place by UK Transplant is fully funded the family refusal rates in the UK should start to come down and potentially the patients in whom brain stem death is confirmed but who are not referred will also slowly start to be influenced.

Remaining Problem

The most significant remaining problem therefore is in the patients in whom brain stem death tests are not performed currently. The number of potential patients per year that fall into this group is equivalent to the number of actual heart beating donors. This clinical practice is clearly bad medical practice and needs to be addressed. It is good medical practice to perform brain stem death tests in patients in whom brain stem death is performed for a number of reasons but not least that if brain stem death is confirmed then continued management on an Intensive Care Unit is futile; in addition it is good medical practice to ensure that where brain stem death tests are performed and confirmed that the families of the deceased are offered the option of organ donation at a time of great sadness. These two problems have been addressed in the US by legislation, it is a requirement for clinicians to perform brain stem death tests were brain stem death is suspected and in addition where brain stem death is confirmed to the requirement for such patient to be referred to the OPO. Such a system in the UK, even with current family refusal rates, would lead to a further 495 solid organ donors per year and an extra 1,240 solid organ transplants per year.

16 July 2007

Memorandum by the British Humanist Association

1. The British Humanist Association (BHA) welcomes the opportunity to submit evidence to the inquiry into organ donation and transplantation.

2. The BHA is the principal organisation representing the interests of the large and growing population of ethically concerned but non-religious people living in the UK. It exists to support and represent people who seek to live good and responsible lives without religious or superstitious beliefs. It is committed to human rights and democracy, and has a long history of active engagement in work for an open and inclusive society. The BHA’s policies are informed by its members, who include eminent authorities in many fields, and by other specialists and experts who share humanist values and concerns.

Our Position

3. Humanists generally support scientists and researchers in their quest for knowledge, and support scientific and medical advances for the improvement of our health. Most of us would not object to our body parts and organs being donated and used for good ends. We believe that better public education about organ donation and transplantation is essential, and that policy actions at both state and European levels are needed in order to increase the number of organ transplants and so save lives.
4. We are also very concerned that the low number and availability of organs donated across Europe is contributing to unnecessary deaths for want of transplants and to an increased trafficking in organs, and in human beings for the purpose of removal of organs, from outside of Europe and that this will create serious ethical issues and is contributing to systematic human rights violations of some of the most vulnerable people from across the world.

5. This response is from a humanist perspective and covers in particular issues arising from that view, the health and social welfare benefits and ethical issues of organ transplantation, the use of living donors and, especially, the “presumed consent” approach and the arrangements for taking into account the views of relatives. We wholly oppose general policy being made on the basis of religious dogma or superstition—though we recognise that provision must be made to accommodate the personal wishes of individuals based on such considerations—and we support policy-making based on evidence, rational decision-making and that which seeks to maximise the well-being of individuals and so society more generally.

6. With any change to the approaches for organ donation for transplantation, there must be appropriate safeguards in place to protect the wishes of the deceased individual, and the health of both living donors and those needing an organ transplantation.

**Presumed Consent**

7. Humanists are concerned with the maximisation of well-being of individuals for the social good and benefit of society as a whole. Humanists believe in individual rights and freedoms—but believe that individual responsibility, social cooperation and mutual respect are just as important. In terms of organ donation and transplantation, most humanists would consider that we have a moral responsibility to allow our organs to be used for transplantation, if that will improve the quality of life for others and contribute to the well-being of the human family.

8. The BHA holds that the current system where individuals must “opt in” to have their organs removed for donation after their death has contributed to the present shortage of organs and so to many preventable deaths every year. We fully support the replacement of the opting in approach to one of “presumed consent”, whereby individuals must actively opt out should they not wish their organs to be used for donation after their death.

9. The presumed consent approach would better match the fact that the majority of the population support organ donation for transplantation, would be likely to vastly increase the number and availability of organs suitable for transplantation, would decrease the trafficking in organs and human beings, would increase awareness of organ donation more generally and would better assist individuals and families to make decisions about organ donation.

10. Under the present system, unless someone has actively opted in, it is usually left to relatives to consent to donation of the deceased’s organs. There is a range of reasons why relatives may not wish the individual’s organs to be donated—historical, cultural, social, religious and so on—but these may actually have been in direct conflict with the views of the individual. Under a system of presumed consent, supported by good public information, education and awareness of that system, if an individual has particularly strong objections to organ donation after death, then she is able make her feelings clear and opt out, while she is alive. Moreover, the presumed consent system seems better able to protect the wishes of someone who had not opted-out, even if the relatives themselves have strong views against organ transplantation, because the individual should have been given good enough information to make an informed choice when she was alive and the presumed consent should usually be taken as paramount.

11. This is not to say that relatives’ views should never be taken into account. We would support the British Medical Association’s “soft” system of “presumed consent”, whereby organ donation (for those over the age of 16) is the default position, but where relatives would not be asked to consent to donation (as in the present system), but would be told that the individual had not opted out and would be asked if they are aware of any unregistered objection⁵. We believe that this would help decrease the number of objections from relatives.

**Living Volunteers**

12. The BHA would support a policy move to promote the altruistic donation of organs, such as kidneys, from living donors. As with any change to the organ donation after death system, this would need to be accompanied by raising public awareness through comprehensive education and information. If someone wishes to be a living volunteer donor, that must be an individual choice. She must have enough information to make a rational choice for herself about the risks of such a procedure to her well-being and life compared

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with the benefits to the well-being and health of the person needing that organ. We wholly endorse the present ban on a sale of organs.

January 2008

Memorandum by the British Kidney Patient Association

1. EU-wide Shortage of Organs Available for Transplantation

There is no one magic solution to the EU-wide, or indeed worldwide, shortage of organs available for transplantation. Some methods in some countries for procuring organs for transplantation seem to be more successful than others but even in the most successful countries, still organs for transplantation are in short supply and patients are dying on waiting lists. A major barrier to organ transplantation is the relatively high refusal rate amongst deceased patients’ relatives to give permission to organ donation, even when in many cases it has been shown that it was the wish of the deceased patient to be an organ donor. Certainly a system of presumed consent, which operates throughout most of Western Europe, would be a step in the right direction and would undoubtedly yield many more organs for transplantation in the UK than under the present system. However, education and publicity should go hand in hand with any shift to a system of presumed consent.

2. Organisation of Organ Donor and Transplantation Systems

We are fortunate in the UK to have a highly organised centralised organ donor and transplant system in UK Transplant. UK Transplant has recently devised a new system for the allocation of kidneys throughout the country. Having one centralised system such as this means that no kidney patient is subjected to a ‘postcode lottery’ whereby they stand a greater chance of receiving an organ by virtue of living in one county as opposed to another.

3. Raising Public Awareness of Organ Donation

It is essential that we raise public awareness of organ donation. In the absence at the present time of a “presumed consent” approach for identifying organ donors, all steps should be taken to educate the general public, so that as many people as possible register as organ donors under the present system. Additional government funding for such a campaign should be made available since a kidney transplant is the most cost effective form of treatment for a person with end stage renal failure. Such an advertising campaign should encompass all the media and positive images showing the result of a successful organ transplant (eg a patient restored to good health) would also play an important part.

4. Use of Organ Donor Cards, Including the Idea of a European Organ Donor Card

The continued use of the organ donor card is to be encouraged but we are not certain about the benefit of introducing a European organ donor card. Whilst a small number of inter-country organ transplants will inevitably continue to take place in unusual or urgent cases, nevertheless a European organ donor card with its implied suggestion that one’s organs are likely to be used for transplantation overseas, could have the opposite effect on organ donation to that desired. The UK press, always keen to pander to the perceived fears of their readers, would no doubt be more than happy to print such headlines as “Now they (i.e. Europe) want our organs too!” which could seriously damage our ultimate shared goal of persuading as many people as possible to become organ donors.

5. Use of Volunteer Living Donors

Whilst our organisation is not in favour of living donors, we appreciate that no change in policy, even to our preferred option of “presumed consent” will entirely bridge the gap. We believe that everything possible should be done to increase the supply of cadaver organs for transplantation. However, living donation should be considered as the final course of action when, after a period of time, no cadaver kidney has become available.

Organ transplants between totally unrelated people should in our view be actively discouraged, since it would be difficult to prove that no financial incentive had been sought or offered.
6. **Ensuring the Quality and Safety of Cross-border Organ Donation within the EU**

In the rare but important instances when cross-border organ donation takes place within the EU, it is incredibly important that donor and recipient units adhere to the same very stringent conditions relating to all the safety issues.

7. **Ethical Issues Relating to Organ Donation and Transplantation**

Clearly it is only ethical to remove the organs of a deceased patient where consent has been given, either by the deceased patient or their next-of-kin. In the case of a system of presumed consent, consent is deemed to have been given by the fact that they had not “opted out”. Therefore the all-important issue of consent has not been compromised.

8. **Health and Social Welfare Benefits of Organ Transplantation**

There are obvious, considerable health benefits to organ transplantation. The recipient’s quality of life is restored. The benefits to wider society are also considerable. The organ recipient will be able to fully engage with his or her community once more and will hopefully be able to take up employment. There are benefits to their immediate family as well, since the implications of the condition of renal failure impinge on all family members, restricting their lifestyle, employment, leisure activities, etc. Also, it should not be forgotten that a considerable number of fit and healthy babies have been born to mothers post-transplant; babies that would not otherwise have been born at all.

9. **Medical Risks of Organ Transplantation**

The medical risks of organ transplantation to both donor and recipient are low, especially when compared to the risk to the recipient of remaining on dialysis. Risks to the donor are also extremely low. It is essential for the reputation of transplantation that all Member States adopt the same high standards of good practice. Information relating to outcomes and methodology should be readily available for sharing with other Member States.

10. **Illegal Trafficking in Organs**

It is imperative that any instances of illegal trafficking are dealt with very severely and that the penalty acts as a deterrent to others. Any perceived problem in this respect will undoubtedly serve to undermine the transplant programme by causing a loss of confidence amongst the general public. Measures to improve the organ donor situation will hopefully lessen the incidence of illegal trafficking. EU wide measures to deal with this problem should be implemented.

11. **Questions which may Arise in Relation to Organ Donation and Transplantation from a Faith-based Point of View**

We are not aware of any faith-based barriers to organ donation. There may be misconceptions amongst the public that certain faiths preclude organ donation and it is very important that such misconceptions are addressed. Education is the key, and an EU wide policy for addressing such concerns should be developed.

12. **Questions which may Arise in Relation to Organ Donation and Transplantation from the Point of View of Population Sub-groups within the UK**

It is important that the views of all sub-groups of the population are sought and that specific concerns are addressed.
13. **The “Presumed Consent” Approach for Identifying Organ Donors**

Our organisation firmly believes in this approach for identifying organ donors and this view now has the backing of the BMA and the Government’s Chief Medical Officer, Sir Liam Donaldson. There is no doubt whatsoever that such a system would produce many more cadaveric organs for transplantation. We see no reason why this system would not work extremely well, providing an “opting out” register was easily available and readily accessible. This would also be a step in the direction of harmonising the UK with most other EU countries, since the majority of other Member States already operate a system of “presumed consent”.

14. **The Arrangements for Taking into Account the View of Relatives about Receiving Organs for Transplantation from a Deceased Donor**

Under the present system of “opting in”, despite a change in the law so that the wishes of the deceased are paramount, still some relatives override their deceased relative’s wish to be an organ donor, and in such cases the transplant team, not wanting to cause further distress at a difficult time, choose not to exercise their legal right to comply with the wishes of the deceased patient. This is unlikely to change under the present system. However, the reluctance on the part of the deceased’s relative could be due, in part, to the fact that they were unaware of their relative’s wish, which is why an advertising campaign, prompting people to discuss their wishes with other family members is very important.

In countries across Europe where “opting out” is the norm, some countries still choose to consult the deceased patient’s relative about the proposed organ donation, whilst others choose not to consult. The British Kidney Patient Association is in favour of the latter. This is because to be asked whether it would be acceptable to remove their deceased relative’s organs causes considerable additional distress to a family a time of great anguish. Presumed consent, as the name implies, means just that. An education programme aimed at the general public would of course be essential so that everyone would be fully aware of the implication of “presumed consent”. An extensive education/publicity programme should also alert the general population to the means by which they can “opt out”.

15. **The Promotion of Cooperation between Member States in Order to Share Expertise and to Expand the Size of the Potential Donor Pool in each Member State**

There is an important role for the EU in sharing expertise and endeavouring to expand the size of the potential donor pool in each Member State. The pooling and sharing of information relating to examples of best practice and good “models” can only be beneficial, especially in those Member States whose organ donor programmes are less successful or less well developed. Information regarding such examples should be disseminated to all Member States. Minimum standards and benchmarks should be set, to which all EU countries should aspire. Harmonising rules would also make it less attractive for patients to travel to other countries within the EU where the chance of receiving an organ transplant is greater.


Again we believe there is an important role for the EU in harmonising rules for organ donation and transplantation that would provide EU citizens with higher standards for organ safety and quality than can be assured by the national legislations of Member States acting separately. It can only be beneficial to all to aspire to the highest standards operated throughout the most successful EU Member States.

17. **Enabling More Effective Action Across the EU to Fight Illegal Organ Trafficking**

A harmonised approach to illegal organ trafficking is essential if the organ traffickers aren’t to simply target one country as opposed to another. We suggest that a hard-line approach, with severe penalties should be replicated across the Member States in an attempt to thwart the perpetrators.

*September 2007*

**Memorandum by College of Health Care Chaplains (CHCC)**

I am pleased to submit comments to the above Inquiry on behalf of the College of Health Care Chaplains. In order to appreciate the context from which these comments come it may be helpful to know that the College is a one thousand member professional association within the Health Sector of Unite the Union. It provides
both representation for individual chaplains and also resources the professional development of chaplaincy across the UK. A small number of CHCC members now also work as Independent Assessors for organ donation. The College advised UK Transplant on the content of its advice leaflet containing different faith perspectives on the issue of transplantation.

1. The College supports the increasing use of organ donation and transplantation from all sections of the community in order to improve and extend the lives of others.

2. Great care is required in order to exclude any donation which does not arise from proper motivation. Chaplains are keen to engage with this work, but in the light of cuts to chaplaincy services across the NHS it is unclear whether practical support can be sustained.

3. We support increased publicity around donation and transplantation which allow all members of the public to make informed choices about their bodies both while alive and after death.

4. We do not support “presumed consent” approaches to donation and transplantation. Donation must be informed and arise from a positive choice. Whatever safeguards may be applied to “presumed consent” there would inevitably be cases where spiritual distress would be caused to relatives and friends of the deceased when their views had not been stated before death. This would be a very strong feeling in some religious communities.

5. Hospital chaplains had significant experience during the lifetime of the Retained Organs Commission of disparities between the views of health professionals and those of relatives. The importance of the body should not be underestimated. It has been the way in which the deceased has been known, and the dignity of the deceased continues to be associated with their physical remains. While not all people feel the same way, chaplains know that the removal of tissue without explicit consent either in life or death can cause major trauma.

6. The College believes that people have the right to be buried or cremated intact unless they have clearly expressed their agreement to organ removal.

5 October 2007

Memorandum by the Cystic Fibrosis Trust

This submission from the Cystic Fibrosis Trust reflects a growing concern on the part of the Cystic Fibrosis community, including those affected by Cystic Fibrosis, the medical teams who look after them and the transplant teams in the UK that the shortage of lungs for transplantation means that many (probably around 50%) of those with end-stage Cystic Fibrosis who would be suitable for a transplant die because lungs are not available. We therefore welcome this opportunity to make a submission to this enquiry.

1. We recognise that there is an EU wide shortage of organs. We also recognise that this is hugely variable, depending not only on the country in which people live, but the part of that country in which they live. We would wish this to be addressed in a constructive and positive manner to improve the opportunity for all of those within the European Union who need new lungs to be able to benefit from this procedure.

2. We recognise that there has been considerable improvement in Spain, and would urge the European community to consider adopting some of the Spanish initiatives to improve the situation.

3. It is extremely important to raise public awareness of organ donation. It may be sensible to remind people that they are far more likely to need an organ than to be in a position to donate one. There could also be a process where people sign up to the principle of transplantation in general, either as a potential recipient or a potential donor, making it clear that this is a two way commitment (ie to be eligible to receive an organ, one must also consent to donate organs).

4. Donor cards are a good idea, but a national register is even better in that people do not always have their donor card on their person at the time of a serious accident.

5. The Cystic Fibrosis Trust has no objection in principle to the use of volunteer living donors, but recognises the complexity of this situation as well as the ethical problems involved. Those with Cystic Fibrosis who need lungs need two lungs, and so two donors are needed for each recipient. It is, therefore, a very rare operation in that theoretically the mortality rate could be 300%, of whom two people were not ill in the first place, so this has to be explored very tentatively.

6. The Cystic Fibrosis Trust would have no problem with cross-border organ donation within the EU, although recognises that as donor lungs have to be used within five hours of being retrieved, there are obviously practical problems.
The fallacy of that initial claim was formally recognized in 1995 but the certification of death for testable) and the prescribed tests lacking the power even to diagnose death of the brain stem as a matter of fact. The medical risks of transplantation are well documented. However, in the case of those with Cystic Fibrosis, for those who need organs there is no viable alternative other than inevitable death.

We see the health and social welfare benefits of organ transplantation as being considerable. Someone with Cystic Fibrosis who will otherwise die shortly may have an extension of many years of good quality life, during which time they may be able to work and make a contribution to society, to their own family, and indeed to fulfil many of their own ambitions. This cannot be underestimated.

The Cystic Fibrosis Trust understands that all major religions have given their approval to transplantation, and ethical issues can usually be addressed in a positive manner. However, we would be very reluctant to condone a policy which insisted that organs should be available from a person who had made their views known before their death. On a more contentious point, we also have grave reservations about taking organs from a brain dead patient if their family is vehemently opposed to this process. We feel it would be counter-productive and would cause considerable ill will, which is likely to harm the transplant programme more than it will help it.

We would of course strongly oppose the illegal trafficking of organs.

On the specific issues which are considered to be of relevance to the commission, whilst the Cystic Fibrosis Trust would like to see a presumed consent approach adopted, as already outlined we would not wish to see this managed in a confrontational manner. For either an individual who does not want their organs to be used, or from a distraught family who even after careful and sensitive counselling are adamantly opposed to allowing the organs of their loved one to be used, we feel it would be counter-productive to proceed.

The Cystic Fibrosis Trust is actively involved in obtaining relevant information and making recommendations for improvement in the area of transplantation in general, and lung transplantation in particular. We will be submitting a paper to the Department of Health shortly. We would be very pleased to forward a copy of this to the enquiry if it would be helpful.

October 2007

Memorandum by David Wainwright Evans, MD, FRCP Emeritus Consultant Cardiologist

1. The procurement of organs for transplantation, as currently practised, is unethical on several counts.

2. To be capable of continuing function in different bodies, organs must be removed from donors’ bodies while they are still alive. So-called “brain stem dead” patients who are designated as organ donors are self-evidently alive. This is obvious to parents who are asked for permission to remove their son’s organs while—mechanical ventilation being continued—he remains in that state. Finding him warm, reactive and respiring, still perfused by his naturally beating heart, they find it difficult to accept that he is regarded as already dead by those preparing to operate upon him—to procure the wanted organs—with no change in his condition apart from drug-induced paralysis to facilitate the surgery. It should occasion no surprise that many parents, faced with that request, refuse their permission—particularly those who have been fully and frankly informed about the possibility of remaining brain function which it is beyond the power of the clinical tests routinely used to detect.

They may refuse their permission despite their son’s name being on the NHS Organ Donor Register in the readily understandable belief that, when he registered, he did not envisage being in that state when used as an organ donor (vide infra.)

3. Many doctors (and philosophers) do not accept that patients who meet the UK “brain stem death” criteria—or the various “brain death” criteria in other countries—are dead. They acknowledge that those patients are, indeed, manifestly alive. In terms of the usual concept of death—the absence of all signs of life—such patients cannot reasonably be diagnosed and certified as dead. Most of the world’s doctors would not, or could not, certify them dead. The more conservative members of the medical profession are not prepared to certify death until there are not only no remaining signs of life but also positive signs of death.1

4. Nevertheless, there are some doctors who continue to be willing to certify those clearly living patients dead as a legally necessary preliminary to removal of their organs for transplantation. They do so on the basis of the simple bedside tests prescribed (in the UK by the Department of Health in its Code of Practice) despite the increasing body of evidence2, 3, 4 that they are inadequate for the purpose. When introduced, over 30 years ago, those tests were claimed to have the power to diagnose death of the brain—it being tacitly assumed that “brain death”, as clinically diagnosed, would be a generally acceptable basis for certifying death while the body remained alive—but that claim was clearly spurious, most of the brain not being tested at all (or, indeed, testable) and the prescribed tests lacking the power even to diagnose death of the brain stem as a matter of fact. The fallacy of that initial claim was formally recognized in 1995 but the certification of death for...
transplant purposes has continued on essentially the same clinical assessment, albeit on a novel conceptual basis which, insofar as it has been debated at all, has not found wide philosophical acceptance.

5. This new concept of human death is comprised of only two elements—the irreversible loss of the capacity to breathe spontaneously and the irreversible loss of the capacity for consciousness. It was claimed—without presentation of evidence in support—that death of the brain stem sufficed to ensure those permanent losses and that the prescribed tests sufficed to establish death of the brain stem. There is, in fact, no sound scientific evidence to support those claims. The prescribed test for irreversible loss of ventilatory function (breathing) is dangerous but not sufficiently stringent, and there is no means of testing for residual capacity for consciousness. Consciousness is not understood. The notion that its arousal depends crucially and exclusively on elements of the brain stem looks increasingly insecure in light of recent neuroscientific observations. Those elements are, in any case, not specifically testable. They can be said to be permanently functionless only by implication, i.e., when it is certain that the whole of the brain stem is truly dead—a state which it is beyond the power of the prescribed tests to establish.

6. The most plausible basis for the continuing certification of “death for transplant purposes” on the diagnostic criteria currently in use is that they are widely believed to suffice for the purpose of forecasting death—the final cessation of blood circulation and respiration (plus the passage of a sufficiently long period of time)—within a few hours or days, despite the continuation of mechanical ventilation and other life-support measures. That is of course, in reality, their use as prognostic guidelines. But their confusion with criteria for the actual diagnosis of death is essential to current organ transplantation practice and is backed by the Department of Health in the Code of Practice which governs those procedures. It may be that the doctors involved come to terms with this inappropriate use on the premise that, although the patients they certify dead on that basis are not de facto dead, it doesn’t matter because they have no chance of recovery. This is the utilitarian view—that they are “dead enough” for transplant purposes and that it is in some distorted sense “unethical” to await de facto death because to do so would render the wanted organs unviable. But it ignores the inescapable fact that, as the donor is not really dead—whatever his status on paper—he is killed by the operation for removal of his organs.

7. In recent years, concerns about this pragmatically useful confusion have been raised worldwide, and there have been calls, e.g., by Truog and Robinson, to face the facts and provide them to potential organ donors without obfuscation. Only then would it be possible to know the true level of public support for transplantation practice and only on that fully and frankly informed basis would consent to the use of one’s body as a source of organs—to be removed while in some clearly defined and frankly described pre-mortal state—be valid. I have welcomed such proposals for full and frank information of the public about such procedures as a long overdue precaution against possible misunderstanding of the offer made by registration as a potential organ donor under the system currently in use.

8. As things are at present, some 14.6 million people have signified their willingness to be used as organ donors after death by adding their names to the NHS Organ Donor Register. The official leaflet promoting such registration describes the register as “a nationwide confidential list of people, held on a central computer database, who are prepared to be organ donors after their death.” The application forms record a request that “after my death” the specified organs “may be used for the treatment of others”. The same crucial wording “after my death”, without explanation or qualification, appears on Donor Cards and on Driving Licence Application Forms.

9. There is, at least, the possibility that some of those signifying their willingness to be used as organ donors by ticking boxes on those forms have a different understanding of the meaning of the term “after my death” from that of the organ procurement team and the two doctors who will certify them “dead” so that the operation can begin, if their offer is ever taken up. It seems to me that the possibility of so serious a misunderstanding must invalidate the offer. It is, therefore, surprising that greater efforts have not been made to clarify that crucial wording so that both parties to the offer have an identical view of its meaning.

10. It is, indeed, rather likely that many or even most people who “sign up” by ticking boxes on the simple forms in use, e.g. on Driving Licence Applications, without actively seeking further information, do so in the belief that they will be dead in the commonly understood sense—pulseless, not breathing, totally unreactive and, perhaps, cooling and stiffening—before surgery to remove their organs will begin. I have heard that belief expressed many times.

11. Others, who have taken the trouble to seek more information about the procurement process, have understood that certain tests of brain function must be done by two specially authorized doctors before surgery can begin. They may say they understand that this is to establish “brain stem death” (still too often referred to as “brain death”), that this means that there can be no further hope of useful recovery whatever may be done, and that this justifies (indeed requires) the withdrawal of life-support measures to allow death to occur. [That was, of course, the stated purpose of the criteria when they were introduced in 1976.] However,
many of these registered potential donors are under the misapprehension that mechanical ventilation will be permanently discontinued, and the consequent cessation of the heartbeat awaited, before they are subjected to organ procurement surgery.

12. Registered donors in the categories described in (10) and (11) above have not understood that they will, in fact, still be very much alive when organ procurement surgery begins and, indeed, during that procedure. They do not realize, because it has not been made clear to them, that mechanical ventilation is continued after the diagnosis of “brain stem death”; and kept going while the wanted organs are removed—which may take several hours. In consequence of that continuing provision of oxygen to the lungs, their hearts will be continuing to beat naturally—maintaining the blood circulation throughout the body, including parts of the brain, which are active to an unknown degree. Their bodies will remain so reactive that muscle-paralysing and anaesthetic drugs will be administered to facilitate the surgery—which nevertheless causes inevitable bleeding and other (cardiovascular) reflex responses. The latter are identical to those which, when seen by anaesthetists during everyday therapeutic surgery, prompt the administration of extra anaesthesia to alleviate the patient’s thereby expressed pain or distress.

13. The registered donors described above have, at the very least, been misled by the unexplained term “after my death”. It might well be argued that they have been actively deceived, given the continuing use of that term without qualification or explanation despite many calls for its clarification over the years. Whatever the interpretation of what might seem that legally interesting aspect, it can be said with confidence that at least some of those who have registered under the impression that they will be truly dead—certainly without heartbeat—before their organs are removed would not have done so if the relevant facts pertaining to their offer had been made clear to them when registering. If there is even one such registration on a false premise, it must be a matter of concern—and there may well be millions in that category. There is a case for contacting all those registered to establish the scale of possibly false registrations.

14. The above refers to organ procurement from patients pronounced “dead” on the so-called “brain stem death” criteria specified in the current Code of Practice. Possibly because of the low provision of transplantable organs from that source, there is now a move towards procurement from donors whose hearts have been allowed to stop for very brief periods, eg two to five minutes, with or without restoration of the heartbeat and circulation thereafter. This is no more than a sinister charade—aimed at persuading people that death is being certified on the age-old criteria (cessation of breathing and circulation) and conveniently ignoring the fact that those criteria demanded the permanent cessation of the blood circulation and a period of waiting thereafter to ensure that irreversible destruction of the body is certainly under way. Verheijde et al[10] have recently exposed the abuse of ethical principles involved in these resource-driven developments.

15. If there is to be a truly ethical basis for the procurement of organs for transplantation, there must first be a fully and frankly informed public discussion and debate about the various options capable of providing organs in a viable state for the purpose. In practice—because procurement from living, healthy donors offends against the fundamental “first, do no harm” principle, and organs taken from unequivocally dead people are no good for transplantation—these are limited to the acquisition of organs from the dying. It may be that, when all the relevant facts have been made clearly and universally known, without obfuscation or concealment, some people will be willing to allow removal of their organs for the sake of others when they are, as certainly as can be known in the current state of medical practice, doomed to die soon. Consent to donation on that fully informed basis would seem to constitute an ethically valid offer if the legal difficulties could be overcome.

16. Until we can be sure that everybody who might be used as an organ donor has fully understood the nature of that procedure, it cannot be presumed that they have consented to such use merely because they have not registered objection. In the present state of public knowledge about transplant procedures, we are clearly very far from being able to make that assumption of universal comprehension and approval.

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Memorandum by Mr John L R Forsythe, Clinical Director and Consultant Surgeon

Many thanks for the invitation to submit evidence regarding the Inquiry into the EU Commission’s Communication on Organ Donation and Transplantation: policy actions at EU level. Please find enclosed written evidence. I have also enclosed a list of my interests but stress that these comments are made on a personal basis although the comments have also been submitted to a number of the different organisations (Scottish Transplant Group, British Transplantation Society, Board of NHSBT).

List of Relevant Interests
Immediate Past-President, British Transplantation Society.
Chairman, Scottish Transplant Group (Advisory Group to Scottish Minister of Health).
Non-executive Board Member, NHS Blood & Transplant.
Specialty Advisor to Chief Medical Officer (Scottish Executive).
Regional Advisor to Royal College of Surgeons of Edinburgh.

Issues raised in the Commission’s Communication

EU-wide shortage of organs available for transplantation

There have been dramatic advances in the field of transplantation over the last 20 years. In patients with terminal heart, liver or lung failure, transplantation offers the only current option for survival and renal transplantation is established as the optimum treatment for irreversible kidney failure. Transplantation is also successful in the long-term, a number of transplant patients have survived well over 25 years and five year survival rates for most organ transplant recipients are over 70%.

The shortage of cadaveric organ donors imposes a severe limit on the number of patients who can benefit from transplantation while there is an ever increasing demand for cadaveric solid organs in most countries.

The situation in Europe is very heterogeneous from very low levels in Eastern European countries to over 30 donors per million population in Spain and some regions in Italy, France and Austria. The reasons for this variability are multiple although it is clear that it cannot be attributed to differences in the public willingness to donate organs but rather to differences in health structure, hospital facilities and especially the organisation of the organ donation system.

It is clear that all European countries share an ever increasing gap between the number of available organs and the number of patients waiting on the transplant list.

Spain

In the early 1990s, under the leadership of Rafael Matesanz, Spain began an original, integrated approach designed to improve cadaveric organ donation. This programme was accomplished by a combination of:

(i) A proactive donor detection programme run by well trained transplant co-ordinators.

(ii) Systematic death audits in hospital.

(iii) Positive public attitudes enhanced by education and publicity through mass media.

(iv) Adequate reimbursement for hospitals for donor expenses.
The result was a massive increase in the donor rate up to 35 donors per million population in 2005. This compares with 2005 rates in other European countries as follows.

UK 12.8, Ireland 17.6, France 22.2, Germany 14.8, Italy 21, Portugal 19 donors pmp (figures from September 2006, Newsletter Transplant, EU document).

At first many explained these figures as a “Spanish phenomenon”; some even commented that the Spanish road traffic accident death rate was very high to explain the comparative difference between their own member state and Spain. Since that time, the programme in Spain has been “transplanted” to the Northern region of Italy with similar increase in the organ donor numbers. The principles of the Spanish system were also used in a region of Australia, again with similar effectiveness.

Rafael Matesanz summarises the recommendations which have been at the centre of the Spanish programme as shown below. It is of note that these recommendations touch on many of the issues on which responses have been invited in relation to the Commission’s Communication. These include:

(i) Organisation of organ donor and transplantation systems.
(ii) Raising public awareness of organ donation.
(iii) Ensuring the quality and safety of cross-border organ donation within the EU.
(iv) Medical risks of organ transplantation.

Recommendations to Meet the Organ Shortage

1. The transplant process is long and complex and cannot be left to chance. Protocols should be developed for each step. A key person should be made responsible in each area/hospital for managing and monitoring the process with the power to determine where efforts and resources should be directed.

2. Published national or regional figures cannot be extrapolated to provide local rates of potential versus effective donors (although marked differences from published rates for potential donors should be considered as suggestive of underdetection). A donor detection gap should be established for each hospital/area and systems for monitoring the rates established.

3. A means should be developed to evaluate the size and characteristics of the potential donor pool to measure and monitor potential donor detection rates. To ensure reliability, data should be collected prospectively and analysed retrospectively as recommended in the “Donor Action Programme”.

4. Proactive donor detection programmes should be instituted in every acute hospital using specially trained professionals (key donation persons) working to agreed protocols and ethical rules.

5. A “key donation person”, independent from transplant teams, should be appointed in every acute hospital, with a clearly defined role and responsibility for establishing, managing and auditing systems for donor identification and identifying potential areas for improvement.

6. Protocols should be developed setting out the criteria for screening potential donors and their organs for the risk of disease transmission of infectious and neoplastic diseases.

7. The incidence of irreversible cardiac arrest, sepsis and other contraindications to organ donation relating to management of potential donors should be monitored and audited to detect and correct any problems identified. Involvement of ICU staff in research and/or educational programmes on donor management should help raise standards.

8. An appropriate legal framework for donation and transplantation is required, which adequately defines:
   — brain death;
   — the type of consent authorisation required for retrieval (see below); and
   — the means of organ retrieval that ensures traceability but maintains confidentiality and bans organ trafficking.

9. Law professionals should be fully aware of the transplant process, and the cooperation of those most closely involved, i.e. judges and coroners, should be sought to reduce legal refusals to a minimum.

10. It is advisable to ascertain the opinion of the public and health professionals about presumed or informed consent for organ donation before considering legal changes that might be potentially detrimental. The key donation person appointed in each centre/area must be aware of all local legal criteria and should be responsible for meeting these requirements. There should be a system for the safe custody of all certificates and test results required by the law.
11. Because both positive and negative messages can affect the public’s willingness to donate organs, there is a need for a professional attitude to communications, which may require support from experts. They should help to minimise the impact of “bad news”, and maximise the communication of “good news” about transplantation to health professionals, the media and the public. Special attention should be paid to both content of the message and the best means of dealing with the most controversial topics. The preparation of specific briefing materials should be considered.

12. The most cost-effective means of increasing the public’s willingness to donate seems to be improving the knowledge of health professionals (not directly involved in transplantation) and the media about transplantation issues. Continuing education should form an essential element of any communication strategy. A transplant “hotline” manned by appropriately trained professionals should be considered.

13. People should be encouraged to speak about organ donation and transplantation and to communicate their wishes to their relatives. As a donor’s wishes will not always be known, staff in a position to make requested for agreement to organ donation to relatives should be properly trained for the purpose. If such requests are well handled the rate of donation refusals can be reduced.

14. Organ retrieval procedures should be well planned to minimise delay and disruption to the donor hospital. Retrieval teams should be led by experienced surgeons trained, where appropriate, in multiorgan retrieval. Organ damage during retrieval should be reported and monitored and further training provided as necessary to minimise damage during retrieval or transportation.

15. An organ sharing/allocation organisation is essential but its roles and responsibilities must be clearly defined, particularly if it is to have a role in organ donation and procurement (see below).

16. Attention should be paid to ensuring that hospitals are properly resourced and, if necessary, reimbursed for maximising organ procurement.

17. In order to optimise organ donation there is need for a supra-hospital transplant organisation, appropriate in size and structure to the local situation with specific responsibilities for the whole process of organ procurement.

18. The most effective organisational approach is one that balances the requirements for effective organ procurement (small, local) with those for organ allocation (large, national/multinational) (see below). The aim should be to optimise organ procurement whilst ensuring the most clinically effective allocation of organs and tissues.

19. Health administrations are responsible for ensuring that there is proper organisational support for organ donation and distribution and should guarantee the fairness, transparency and safety of the whole system.

20. International cooperation on the promotion of organ donation is desirable to help maximise organ donation and equalise access to transplantation between countries. Governments should actively promote such cooperation.

21. Priority should be given to international cooperation that improves standards of training, exchange of experience, and helps guarantee the safety of organs and the ethical standards by which they are retrieved and transplanted.

There is no doubting the success of the Spanish system and the fact that it is possible to translate principles from one national context to another. However there are other issues which play in this area. Within Spain, the population is relatively homogeneous but in large cities where there is more heterogeneity (increased black and ethnic minority groups) the organ donation rate is not as great as the rest of Spain. Therefore cultural differences and inter-faith differences continue to be important (see relevant section below).

**Use of organ donor cards including the idea of a European Organ Donor Card**

The concept of an organ donor card has become very familiar in everyday language and usage. When there has been critical appraisal of its success in raising awareness of organ donation, there has been no definite confirmation of the prime importance of such a card. Rather the use of cards (or registers) act as a focus for public education and awareness and programmes to increase awareness of the organ donor shortage. With recent legislative change in the UK, inclusion on the organ donor register acts as a “living will” and if a European organ donor card is to be used, the ethical dilemma of whether a signature on a card acts as such a form of consent should be considered. Undoubtedly the production of a European organ donor card would serve as a focus for organ donation awareness across the whole of the EU but perhaps the money might be spent on mass media programmes more effectively. If a European card was produced would all European members be asked to sign it? What would be the status of the organ donor card held (and signed) by individuals within each member state?
Ethical issues relating to organ donation and transplantation

It has been said that transplantation is medical ethics in action. Examples include:

— Consent for organ donation:
  Should consent be an “opt-in” or “opt-out” system? Should minors be considered for organ donation purposes in the event of tragic death? What if a child of 15 has clearly stated a wish to donate but their parents do not wish donation to take place? Should registration on an organ donor register act as a living will? What if the relatives say that the potential organ donor changed their mind and forgot to remove their name from the register?

— Organ allocation:
  Should organs go to the most needy (with the least chance of long-term survival) or the slightly fitter patient? How should the time on waiting list affect the organ allocation process? If the organ allocation policy is (unwittingly) allocating less organs to the ethnic minority populations, should this be rectified or is this a natural result of less organs being donated by those populations?

— Living donation:
  Should paired donation be accepted? (Now accepted in the UK but not across all EU states). Should volunteer living donors be accepted without question? If there is a higher risk than usual for a particular donor to give to a relative, at what level of risk should that donor be told that the procedure cannot go ahead?

Clearly it is relatively easy to set principles of ethics such as the right to justice and promotion of fairness, respect of autonomy and beneficence; however strict detailed regulations in this general area would be very difficult to enforce and make future proof.

Use of volunteer living donors

Living donation for the purposes of kidney transplantation has increased markedly across the world in the last few years. 40 to 50% of kidney transplants in Norway and the United States now occur from a live donor. The figures have also increased in the United Kingdom so that many units are performing 30% of total transplants as live donor operations. This has happened for a number of different reasons which could be listed as follows:

(i) Realisation of the severe organ donor shortage with the individual impact which that brings for patients on dialysis waiting for transplantation for a long time.

(ii) Recent figures which have shown a significant survival benefit of transplantation over dialysis and live donor transplant over transplant from a dead donor.

(iii) Laparoscopic surgery (keyhole surgery) as a successful technique for many cases of live donor transplantation enabling a faster recovery for the donor.

(iv) Modern immunosuppression means that more patients can benefit from live donor transplantation; spouse to spouse, partner to partner, friend to friend, paired donation transplants are all now possible when they were not a few years ago.

It would be the view in the UK that this increase in live donation has been very successful and has allowed many patients to escape dialysis. Live donation rates vary quite considerably across the EU and these benefits of live donation could therefore be spread to other European countries.

Altruistic donation (Non-directed donation)

A relatively controversial form of live donor transplantation is altruistic donation (or since all live donation is altruistic this is sometimes called non-directed donation). Here an individual decides to give a kidney into the general pool simply for the purposes of “doing good”. Clearly it is important that any individual who puts their name up for such a procedure is both physically and psychologically robust. This minimises the potential negative effect of any donation. However there are a small number of individuals who have gone through the whole process of medical and psychiatric work-up successfully in a few centres in the world. It is the view in the UK that this procedure should be allowed, provided donor work-up is comprehensive and uniformly satisfactory. It is unlikely that the small number of donors per country will significantly reduce the organ donor shortage but in circumstances where genuine individuals wish to take this course, it is the view in the UK that they should not be prevented.
HEALTH AND SOCIAL WELFARE BENEFITS OF ORGAN TRANSPLANTATION

The Commission’s Communication cites evidence of the benefit of organ transplantation. These include direct health benefits, quality of life improvement and economic benefits.

Direct health benefits

Clearly in those patients where organ failure will lead to death without a transplant, there is an obvious direct health benefit. But in the last few years it has become clear that even when there is an alternative such as dialysis, the direct health benefit of transplantation over dialysis is considerable. Patients not only have a better quality of life but they have a better quantity of life. This has been proven by US and British data (Wolfe et al, Oniscu et al).

Quality of life

Again for those where there is no alternative other than transplantation, quality of life must be better. However those who require transplantation for renal failure also have better quality of life even though the drugs for avoidance of rejection have many side effects. Patients cite return to almost normal activity including return to work with the consequent economic benefits for the society.

Economic

There have been multiple assessments of the economic benefits of transplantation. All these show that transplantation is more expensive than dialysis in the first year after the transplant procedure but thereafter is much less expensive. The economic benefit is addressed in a number of sections of the Commission’s Communication.

ENSURING THE QUALITY AND SAFETY OF CROSS-BORDER ORGAN DONATION WITHIN THE EU AND MEDICAL RISKS OF ORGAN TRANSPLANTATION

The EU has been very successful in harmonising quality standards for blood donation and administration as well as tissue donation and transplantation. It is commonly accepted that this harmonisation has improved the situation across Europe and made the administration of these bio-substances much safer. It is quite natural and logical to extend the same wish for quality assessment into the field of organ transplantation. However the risk/benefit analysis of any particular organ transplant is very different from the same analysis carried out for the recipient of a tissue donation.

Transplants have many benefits, whether live-saving (such as heart or bone marrow transplants) or aimed at improving the quality of life (such as bone grafts). The risk of infection from a particular donor may be an absolute contra indication to accepting a bone donation but a relatively minor contra indication for liver donation where the potential recipient would otherwise die from liver failure. Therefore it is very important that a zeal to harmonise quality standards across the EU does not remove the clinical ability to make a high risk decision for a patient who would otherwise die from organ failure. An example would be the acceptance of a liver from a donor with a higher risk of tumour transmission than average, for a patient who has taken a paracetamol overdose with 24 to 48 hours to live. The important factor here would be that in all cases, where unusual or extra risks of infection are identified, these should be discussed in detail with the person who would receive the organs or their family. At times within the Commission’s Communication, the desire to harmonise quality initiatives seems to be paramount to the desire to improve the organ donor shortage. It is important that the priorities are set correctly.

ILLEGAL TRAFFICKING IN ORGANS

There is little evidence (other than urban myth) of significant involvement in organ trafficking by criminal groups within the UK. However there is a large number of patients, particularly those from Asian origin, who have travelled to other countries in the world to receive organs which have been bought. There is also evidence of patients travelling to China to receive organs from executed prisoners prior to this practice being made illegal by the Chinese authorities. Most UK clinicians have direct experience of patients who ask about travelling to other countries (outside the EU) to receive organs which are retrieved from individuals who have presumably been paid for this donation. Patients are discouraged from doing this because of the illegality and also because of the risk to their health since the quality of donor organ and the risk of transmission of infection
or malignancy is much higher. Nevertheless there is evidence that the practice is continuing and patients return to the UK requesting continued care. In general terms clinicians feel duty-bound to care for these patients even though they have acted against previous medical advice.

There is also anecdotal evidence of illegal organ trafficking particularly at the geographical fringes of the EU. This is illegal and the UK community would support all measures to make any such practice more difficult for any criminal individuals involved.

Situation in the UK

Leading individuals in the UK were pioneers in the field of transplantation and therefore transplant services have a relatively long history compared with other countries in the world. These services are therefore well developed and the results of solid organ transplantation are as good as or better than most in the world.

The organ donor shortage is, however, very severe. The organ donor numbers are lower than most other EU countries.

There is good organisation of transplant services in the UK with a multidisciplinary professional organisation, the British Transplantation Society, which has led the way in the production of guidelines, standards and protocols for many aspects of transplantation (http://www.bts.org.uk/).

United Kingdom Transplant which is now an operating division of NHS Blood and Transplant, has duties to keep records of patients on the waiting list, organ donors, patients in follow-up after transplantation and information about transplant units in the UK. In the last years, UKT has been involved in a number of initiatives to increase the number of transplants performed. Although there has been a very small increase in the total number of transplants carried out in the last year, the difference between the organ donor rate in the UK and that in other European countries, especially Spain, remains a significant gap.

Patient groups within the UK are also relatively powerful and the National Kidney Federation is an example of this. It is a patient charity that led a 2006 transplant summit hosted by the All Party Parliamentary Kidney Group. At this summit it was agreed that the organ donor shortage was very severe and with an aging population and a higher incidence of renal disease, this problem was likely to get worse.

In 2006, with the support of patient groups, transplant professionals and NHSBT, a Donor Task Force was set-up to report directly to the Minister of Health and this group also had representation from all the devolved administrations. The task force is made up of patients, public, media experts, NHSBT staff and transplant professionals. The group has considered evidence from a wide variety of sources including experts in the United States and Spain. Recommendations are in last draft form and are wide ranging. These are to be produced in September 2007. There is a real feeling that these recommendations, if fully enacted, will make a major difference to the organ donor rate within the UK.

Quality and safety

All aspects of organ donation come under close scrutiny, from the assessment prior to donation of a potential donor through to transplant follow-up. There are many important protocols enacted by transplant coordinators and transplant surgeons. Not least is the guidance on the Microbiological Safety of Human Organs, Tissues and Cells produced in August 2000. A re-write of this document is presently in preparation, organised by the Department of Health.

Questions which may arise in relation to organ donation and transplantation from a faith-based point of view

All of the major religions of the world support the concept of organ donation for the purposes of transplantation. Cultural differences remain which are complex and are to do with the physical treatment of the body after death and belief about the spirit of the individual. This means that in countries where the religious leaders have backed organ donation, cultural and social mores have resulted in poor organ donor rates. In the UK there has been much effort to promote organ donation within black and minority ethnic groups. It is clear that this is a long-term programme which requires much education and support from religious leaders, which has been readily given. Nevertheless further work is required.
Presumed Consent

Recently the Chief Medical Officer of England and the British Medical Association have confirmed their support for a system of opting out in the legislation for organ donation. It is clear that there is a level of public support for such an initiative even allowing for the fact that the relevant legislation changed only in 2006 (Human Tissue Act 2006). It is also clear that there are also individuals in the community who disagree with a system of opting out given the reaction in the print media.

The severity of the organ donor shortage allows some people to argue that opting out is required since those countries that have an opt out approach have, in general, a higher rate of organ donation than those with an opt in approach. It is also felt that the discussion with relatives at the time of tragedy, is much easier if one can approach the loved ones of the deceased saying that organ donation is “what usually happens” and so this may ease the decision for the relatives at a difficult time.

Those that oppose opt out are generally pro organ donation but feel that to assume (or presume) any particular action for a donor after their death is fraught with danger particularly in a country which experienced the Alder Hey scandal. It is felt that the potential negative effects of a single case which goes wrong could be wide-ranging. The Human Tissue Act (2006) has enabled transplant co-ordinators to make a much more sensitive approach to relatives and therefore the system acts much more like the soft opt out approach in most European countries. It is of interest that Rafael Matesanz from Spain says that the way our legislation is enacted is exactly the same as the way opt out policy is used in Spain. He does not feel that legislation, in and by itself, will be the answer to organ donor problems. Rather a raft of measures is required to make a difference.

Lastly, the hard opt out approach (where relatives have no say at all over the potential for organ donation) is used in a full way in only one country in the EU (Austria) and this is a country where post mortems have been mandatory for many years.

Particular Issues Raised in the Commission’s Communication

The need for an EU role in this field

The impact document which accompanies the Commission’s Communication describes three levels of options which are available. These are as follows:

(i) Use of existing programmes only.
(ii) Active co-ordination between member states on organ quality, safety and availability.
(iii) Second level plus harmonisation of quality and safety with an initiative on organ trafficking.

After consideration, there is a role for the EU in this area. It is clear that some EU countries have put in place initiatives which are successful for the population of that member state and these best practices could be spread to other countries as long as the national and cultural context is sensitively managed. Examples are as follows.

(i) Deceased donors.

A number of countries, but Spain in particular, have achieved donor rates which are almost double their neighbouring countries and many times more than the least developed EU countries. Those involved in a Spanish programme have translated their ideas to other European countries most successfully. This would indicate that a similar approach would be of considerable benefit across Europe. It is likely that the same level of success will not be achieved because of cultural differences but it is also likely that a substantial increase in organ donor numbers could be brought about.

(ii) Living donation.

There are differing views on living donation across the EU and indeed there are also different legislative programmes in place across different countries. The benefits of living donation are clear and new techniques such as laparoscopic nephrectomy will enhance these programmes further. Again these best practices could be spread from those countries in which high live donor rates exist across to others where dialysis patients, patients with liver failure and even patients with lung failure could benefit from live donor transplantation.

(iii) Quality and safety.

It is important that this third option is seen as lesser in priority to the two above. It may be easier to establish rules in quality and safety and these are important especially because some organs are transported across borders. It should be expected that organ transplantation should be equally safe
across the EU and some harmonisation of quality is required. However just because this is an easier task does not mean that it should take priority over attempts to increase organ availability which would benefit many more European citizens.

The way in which the EU can help

The resources and skills which are available to the EU could allow programmes to be developed which may enhance the process of organ donation and transplantation across Europe. Programmes could include the following:

(i) Public awareness campaigns.
(ii) Mass media campaigns.
(iii) Public education and school education programmes.
(iv) Spreading of best practice by the organisation of focused conferences and meetings between individuals involved in the organisation of donor and transplant services.
(v) Initiation of partnerships between transplant units in different countries.
(vi) Continued funding of research programmes in organ donation and transplant programmes.

References

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23 August 2007

Memorandum by Dr David J Hill MA FRCA

This evidence is submitted from an individual. I am a retired Consultant Anaesthetist from Addenbrooke’s Hospital in Cambridge with more than thirty years experience and concern about the medical, ethical and legal problems associated with organ harvesting.

INTRODUCTION

1. The issues raised in the EU Commission’s Communication to the European Parliament assume that the present techniques of organ harvesting are scientifically and ethically correct and that we merely require a system for obtaining more donor organs.

2. However, the perceived beneficial ends for recipients are only obtained by unacceptable means of obtaining donor organs, which rely on insecure pragmatic ways of determining death for transplant purposes; deception by omission in failing to ensure that donors understand this different meaning of death; and failure to obtain informed consent for organ harvesting.
Diagnosing Death

3. Death, in lay terms, implies the complete absence of life (in the same way that darkness implies the complete absence of light). Death can only be assured by complete cardio-pulmonary failure over a period of time and at normal temperature.

4. Because the major organs, especially heart, lungs and liver, do not survive after death at normal temperatures, it is necessary for these organs to be taken from living bodies. (Kidneys can survive after cardio-pulmonary death for some hours and corneas for much longer. It has become usual practice, though, to take kidneys also from living bodies).

5. It became the practice in the UK in 1979 to determine that patients, who were previously (1976) given a prognosis that they were irrecoverable (but not yet dead and thus might have life support removed and be allowed to die), should, by the same tests, in future have the diagnosis made that they are already dead. It remains the situation that some doctors (myself included) may perform the tests and allow life support to be removed, but not pronounce death until all such life support has been removed (ie for the ventilator to be turned off) for a period of time. This period of time is arbitrary but at least is many minutes.

6. In the UK, after certain pre-conditions, only some tests for brainstem activity need be made at the bedside for death to be declared. In other countries different rules apply (eg the requirement for absent electro-encephalographic activity or absence of cerebral blood flow by arteriography). This has led to the paradox that a patient may be regarded as dead in one country but not in another, and in the UK can be certified dead by one doctor or doctors but not by others. Both cannot be factually correct.

7. This synthetic concept of death (in the UK) allows for a patient who is being artificially ventilated (“on a life support machine”) but has spontaneous heartbeat and circulation, is warm and pink, has functioning physiology (ie heart, lungs, liver, kidney functioning), has residual brain and central nervous system activity, and is responsive to surgery such that paralysing drugs and some form of anaesthesia are required for the surgery—such a patient can be declared dead for transplant purposes. It is inconceivable that such a responsive patient, with so many signs of life, could legitimately or ethically be cremated or buried or be subjected to a post mortem examination. Death for transplant purposes is different from death for all other purposes.

8. As an anaesthetist, I have particular anxiety that whereas most, but not all, anaesthetists would give a full anaesthetic for removal of donor organs, others would not see the necessity for anaesthetising a patient who has been declared dead. Increasingly it appears that non-medically qualified technicians rather than medically qualified anaesthetists deal with the organ donor during the operation. No animal, reactive and with so many signs of life, could legally be subjected to surgery without anaesthesia. There is no requirement for organ donors to be given anaesthesia—they have lost such rights by being declared dead.

Potential Donors’ understanding of Death

9. In various places in the Communication from the Commission to the European Parliament and the Council on “Organ donation and transplantation: policy action at EU level”, reference is made to “deceased” organ donors (Guidance for submitting written evidence, page 3; Introduction, para 6; Action plan on strengthened co-operation between Member States, para 1; 2.1 Transplantation risks, para 2) and “death” of organ donors (3.2.1. Co-operation between Member States—organ availability). Ordinary use of these words and dictionary definitions, imply the complete absence of life. No-where is there any indication that they are here used quite differently.

10. In the UK there is no indication on Donor Cards or the Donor Registry that the phrase “after my death” to which potential donors consent has a different and extra-ordinary meaning from the usual lay understanding of death.

11. There is a reported 40–50% refusal rate by relatives at the bedside of patients on “life support” for whom consent for removal of organs for transplantation is sought. It is likely that that is when relatives observe that the patient, said to be dead, retains many attributes of life, eg respiration, circulation, nutrition, responsiveness and, in some reported cases, maintenance of a pregnancy until delivery is possible.
THE QUESTION OF CONSENT

12. The basis of consent is that full information and explanation is given by an attending doctor and that both patient and doctor sign the consent form in agreement. This applies even to minor procedures.

13. For the Donor Card or Registry, the UK Government encourages “consent” to be obtained by the discredited method of “ticking boxes” on a variety of forms, from Driving Licence applications to company Loyalty Card applications. Others can be picked up in pharmaceutical and other shops. The consent to donate organs is worded “after my death”, but there is no explanation that “death” will be determined by an unfamiliar and unknown means. There is no requirement for explanation or counter-signature from a doctor. If the doctor and potential donor are not ad idem with the nature of death, consent cannot be said to be informed and thus not valid.

14. In the UK the Human Tissue Act (2004) states that the bequest of a body post mortem for research or education must be made by the donor in writing and signed in the presence of at least one witness. Power of Attorney does not permit consent for this purpose. In this respect we give more protection to the undoubtedly dead than to the living bodies of organ donors.

“PRESUMED CONSENT” AND “OPTING OUT”

15. The notion that consent can be presumed to a procedure to which a large majority of the population are unwilling (for whatever reason) to sign up, is outrageous. “Presumed consent” is not consent, involving, as it does, a measure of compulsion. The fate of one’s body should surely be the last bastion for freedom of choice.

16. Consent should always be voluntary, informed and positive. It is equally outrageous that the onus should be to “opt out” rather than to “opt in”. Present consent, as given on organ Donor Cards or Registry, is of doubtful validity (viz para 12); “opting out” would be consent by omission.

17. If either procedure of “presumed consent” or “opting out” were to be adopted, the use of the word “donor” would be as inappropriate as to refer to us as “tax donors”.

THE VIEWS OF RELATIVES

18. Although trust in the medical profession has been severely damaged (by, for example, the Bristol and Alder Hey scandals), we rely on doctors to determine whether we are alive or dead. The diagnosis of death for transplant purposes can be seen as a further deception by relatives at the bedside. Those who altruistically offer themselves for donor organs are in no position to assess the reality of their life or death. Relatives of the “deceased” patient who observe what is in fact taking place should retain the right to have their views taken into account regarding the harvesting of organs.

8 October 2007

Memorandum by Kidney Research (UK)

INTRODUCTION

1. Kidney Research (UK) warmly welcomes the involvement of the European Commission in developing policy in regard to organ donation and transplantation. For those patients with kidney failure for whom transplantation is an appropriate option, it offers on average a doubling of their life expectancy and a similarly significant rise in the quality of their lives compared with remaining on dialysis. However, too few patients have this option because of the lack of organs available for transplantation. We believe that the involvement of the Commission may indeed provide opportunities to increase the number of available organs. Given the interests of Kidney Research (UK), the focus of our comments will be on the potential for the Commission to support research into organ donation and transplantation.

2. Shortage of donors.

DECEASED DONOR TRANSPLANTATION

3. There are many different reasons for the shortage of organs donated for transplantation. However, the differences between countries may be less that those between different groups within any individual country. This means that there are potentially significantly greater insights to be gained by the sharing of information. Research needs to undertaken across national boundaries to address the impact of ethnicity, country of origin,
religion, level of education and socio-economic class on the decision to offer organs for donation. All these
factors have all been shown to affect attitudes to donation. This need for research is underscored by the
(2007)704), that the differences in donation rates are “not easy to understand”.

4. A greater understanding of how each of these impacts on the decision to donate has the potential to inform
public policy responses. Kidney Research (UK) believes that such public policy responses include not just a
re-evaluation of the legislative framework by which transplantation is regulated, but also the way in which
organ donation is treated as a factor in health education. This is an area in which Kidney Research (UK) has
a significant track record of achievement. In our ABLE (“A Better Life”) programme of research we have
studied the impact of renal disease in the ethnic minority communities in the UK, including attitudes to organ
donation. We have been instrumental in developing and studying “peer educators” as a route by which to
disseminate rapidly the outcomes of research we have sponsored with a view to informing the public and
altering misperceptions.

5. Recent research and clinical experience in the UK and abroad has shown that non-heart beating donors
(NHBD) can be an effective additional source of organs for cadaveric renal transplantation. This requires
significant investment in infrastructure and attention to service organisation. However, although NHBD is
very successful, it remains somewhat less successful than heart-beating donor transplantation. Kidney
Research (UK) believes that it is important to invest further in more research in this area to improve organ
preservation techniques and to address the common problem of poor initial function associated with these
grafts.

LIVING DONOR TRANSPLANTATION

6. Living donor transplantation is very successful and is associated with very low level risk to the donor.
However, in this field too there is much still to be understood about the factors that motivate and concern
potential donors. Similarly, the cultural context has a significant bearing on attitudes to altruistic unrelated
organ donation, including “paired” and “pooled” donations and non-directed donation. These need to be the
subject of further research. As above, we believe that the pooled knowledge across different countries of the
EU will be useful in informing public policy and practice.

RECIPIENTS WHO ARE DIFFICULT TO TRANSPLANT

7. An additional benefit of collaboration between EU countries which is discussed in the Impact Assessment,
but is insufficiently emphasised in the Commission’s Communication, is the potential value of organ sharing
between EU countries. We believe this has the maximum potential applicability to help potential recipients
who are difficult to transplant.

8. Some patients represent a significant challenge to the transplant team in that they are more likely to reject
an organ because, for example, their donor is blood group-incompatible or the recipient has been sensitised
to HLA antigens. Other patients are difficult to transplant because of concurrent co-morbidities, because of
sensitivities to immunosuppression or because of anatomical abnormalities. In many of these cases, a
successful transplant is still in the patient’s interest. Hence, there is great potential for improving these people’s
transplantability by undertaking basic and clinical research on how to develop these programmes for higher
risk transplantation. This would be very appropriately organised at an EU-level since there are laboratories
and clinical services with extensive appropriate experience located throughout Europe which could and should
effectively collaborate in order to understand better how to serve these particularly disadvantaged patients.

9. An additional factor derives from the potential for sharing organs to help patients who are difficult to
transplant. Even in a country as large as the UK, UK Transplant has found it difficult to develop the practice
of paired donation. This would be greatly improved if the pool of potential participants could be expanded.

CONSENT ISSUES

10. UK law has recently changed to move the focus of consent directly to the donor him or herself. Different
countries have different approaches to consent. The decision as to which approach should be implemented is
often cultural or historical. However, Kidney Research (UK) believes it would be much better to base the
decision on how to best obtain consent for organ donation on the basis of evidence. We would encourage the
EU to commission research into the factors that render each form of consenting acceptable, the ethical
implications of each and to disseminate information of consent between states to maximise citizen comfort
and satisfaction. This would have a potential knock-on effect for improving organ shortage.
INFRASTRUCTURE

11. Every acute hospital in the EU should be involved in recruitment of deceased organ donors. Indeed, there is potential for encouraging registration as potential donors at the level of primary care. The reality of all health care systems is that all professionals are subject to a number of competing pressures. In order to make the encouragement of organ donation a high priority, ways of incentivising these professionals must be identified. These will vary between environments as disparate, say, as intensive care units and general practice. Kidney Research (UK) believes that there is important health service organisation research to be undertaken across the EU from which member countries can learn from each other. We believe that the supporting of this type of research should be a priority for the EU.

12. There are obvious issues around the conflict of interest between donor and the recipient in pre-donation donor care. However, it is well known that the pre-donation phase has a significant impact on the outcome following transplantation. Kidney Research (UK) would like to encourage the support of research into both the organic and the ethical aspects of optimal pre-donation donor care. Also in this area, the regulatory aspects of undertaking pre-donation and post-brain stem death research need to be made less onerous.

CONCLUSION

13. In this brief submission, we have identified several areas of research which we believe should be considered in the context of the response to the Communication from the Commission to the European Parliament and the Council, “Organ Donation and Transplantation: Policy actions at EU Level” (COM (2007)275 Final). It is clear that this will demand significant extra research funding. Kidney Research (UK) believes that such an investment will be well spent. Not only will there be real benefit in terms of life expectancy and quality of life for the citizens of the EU; numerous health economic studies have demonstrated that the cost to the health care provider of maintaining a person with a transplant is much less that maintaining him on dialysis. Hence, investment in research that leads to an increase in successful transplantation will be cost effective for the EU and we would commend it to the Commission.

1 October 2007

Memorandum by the National Kidney Federation

Please note that the NKF is a charity run by Kidney Patients for Kidney Patients. There are currently just under 40,000 Established Renal Failure (ERF) patients who are our members, and who cannot live without either Dialysis or Transplantation.

As Chief Executive, I am not myself a kidney patient but am employed to speak for kidney patients.

1. There is a shortage of organs in all member states with the possible exception of Spain. The extent of the shortage varies, but is particularly bad in the UK.

2. The organ donor system is run by UKTransplant, however it does not have the resource to make Organ Donation a “Household Word”. Transplantation is organised in 21 centres—who co-operate with UKTransplant. The current Organ Allocation system was developed by UKTransplant to spread the available organs more fairly, however, it cannot generate sufficient organs and therefore “fails”.

3. More resource is required to make the public aware of organ donation—Television and poster adverts are required in the same way as the need for Blood is advertised.

4. Sadly UKTransplant believes that a campaign to “sign up to the organ donor register” is as good as a campaign to “Carry an Organ Donor Card”. It is not as good—it has no visual impact and the public have no sense of belonging to the scheme. It is faceless and hard to promote, although we are sure it is a cheaper system—as both schemes need the register. A European Donor Card may be a good idea, but it depends whether altruistic people will be put off by organs being perceived to be going abroad to be transplanted to other nationalities—whilst this does happen now, it is not so obvious and may not suffer this downside. All Cards should carry the signature of the potential donor and his/her next of kin in order that his wishes are known by other members of the family.

5. In the UK, it is only by using living donors that Kidney Donation has not faced “melt down”. The numbers of cadaveric donors have been steadily falling—many of my patient members are alive today because of Living donation. It has been essential.

6. Each Country needs an Authority like UKTransplant to ensure equity of distribution and quality and safety of organs.
7. Altruistic donation, pooled donation, paired donation, living donation and cadaveric donation with the previous consent of the donor are all ethical. A Trade in organs for financial benefit by any person or business is not ethical. A Trade in organs is a trade in human misery suffered by both donor and recipient and should be stamped out.

8. A Dialysis patient leads a poor quality of life, unable to work and a non-contributor to society. A Transplanted patient usually leads a near normal life and is part of the community. A transplanted patient is a contributor—not a taker.

9. There are medical risks in organ Transplantation, but for the donor these are very small. For the recipient the alternative is usually death either immediate or within a small number of years (Average life span on Dialysis eight years).

10. Illegal Trafficking needs to be halted, however patients should not be made criminals as they do it to save their own lives—or at least try to.

11. Although all religions support organ donation there is a wide perception that some religions are not in favour. More attention needs to be focussed on this mis-understanding.

12. Asian and Afro-Caribbean patients are four times more likely to suffer renal failure than patients from the indigenous white population and yet Asian and Afro-Caribbean populations are far less likely to be organ donors—escalating dramatically this problem.

13. A Change to presumed Consent is desired by the National Kidney Federation, however unless substantial changes are made to the NHS infrastructure to cope with any resulting increase in organs—it will all be wasted.

The UK needs More Transplant Surgeons, more Intensive Care Unit beds, More Transplant Coordinators, more operating theatre time, more of a transplant culture in hospitals and amongst NHS staff. The UK needs to recognise the importance of increasing Transplantation, it needs to double the donation rate and find a way to stop relatives refusing permission for the operation. Above all it needs a national organ retrieval programme—particularly with Non-Heart Beating donors.

14. Relatives need to be aware of a potential donors wishes—they should have had this discussion at the time the donor chose to carry a card. If the card required the relatives signature as well this would ensure this discussion took place. Trained Transplant Coordinators should be brought in earlier and it is they that should talk to the relatives—not doctors and other busy staff who handle this badly. Britain has the worst possible figures in relation to how many relatives refuse—49%.

This organisation applauds the EU for this initiative and fully supports the final three bulleted points signifying why the EU should take a lead in organ donation and transplantation across the member states.

The NKF would also like to draw the following report to the committee’s attention


26 July 2007

Memorandum by the National Specialised Commissioning Team

IMPLICATIONS OF THE EUROPEAN WORKING TIME DIRECTIVE (EWTD) FOR ORGAN TRANSPLANTATION SERVICES

The EU Commission’s Communication makes no mention of the potential impact of the European Working Time Directive (EWTD) on the availability of donor organs and transplantation. Full implementation of EWTD and strict compliance threaten the viability of heart and lung transplant services in England.

EWTD compliance is particularly difficult for heart and lung transplantation because:

— It is a 24-hour a day service requiring two rotas: one for retrieval of donor organs and one for implantation (ie transplanting the organ).

— Transplants usually occur at night because hearts and lungs are the last donor organs to be removed.

— The ischaemic time that can safely elapse before transplantation (ie the time between removing and transplanting the donor organ) is shorter for heart and lung than for kidney and liver.

— Implantation needs a consultant transplant surgeon available at all times and consultants also have a role in training retrieval teams.

— From notification that an organ is available to completion of the transplant takes about 12 hours.
— The availability of suitable donor organs is unpredictable, which limits the potential for planning transplant work to fit in with other commitments.
— All heart and lung transplant surgeons carry out their transplant work in addition to the same general cardiothoracic surgery workload as their non-transplant colleagues.
— Strict compliance with compensatory rest would lead to cancellation of theatre lists for non-transplant work, delays for patients and difficulties meeting targets.

In late 2003, the National Specialist Commissioning Advisory Group (now called the National Commissioning Group), which is the body that commissions the national heart, lung, liver and pancreas transplant services in England, carried out a survey on EWTD compliance at the heart and lung transplant centres in England. The survey report drew the following conclusions:
— Few of the current heart and lung transplant rotas were compliant with the EWTD.
— The supply of potential new recruits (particularly transplant surgeons) was not enough to meet the demands of compliance.
— Even if additional staff could be recruited, there were serious concerns that this would dilute training opportunities and reduce surgery volumes thus impairing maintenance of expertise.
— Strict adherence to the EWTD in transplant surgery would have an opportunity cost for non-transplant cardiothoracic surgery.
— The challenge of EWTD was particularly marked for paediatric heart and lung transplantation.

In 2004, the National Specialist Commissioning Advisory Group (NSCAG) explored the implications of EWTD for heart and lung transplantation further through computer modelling of consultant rotas to show what was required to achieve compliance. The attached Appendix gives examples of this modelling.

The first example shows a compliant implantation rota for nine consultant transplant surgeons. It raises the following questions. Would there be enough daytime transplant-related and other non-transplant work to make full use of the number of surgeons available? Would there be a sufficient volume of surgery for individual surgeons to maintain their skills and experience? Such a rota might be feasible in a centre covering a larger catchment population than that of any of the existing transplant centres, but reducing the number of transplant centres was ruled out by Ministers in 2002.

The second example shows a compliant implantation rota for four consultant transplant surgeons that ensures immediate compensatory rest on the day after carrying out a transplant at night. It shows how many weekdays would have to be taken off to ensure compliance, thus reducing greatly the availability of consultants to fulfil their non-transplant work. Such a rota would only be feasible if surgeons were to do nothing other than transplant work.

In 2004, NSCAG also considered a number of options to address the threat presented by EWTD. It concluded that none of these lay within its power or that of the heart and lung transplant centres, and it decided to keep the situation under review.

Although this fully worked example refers to heart and lung transplantation, similar issues apply in other transplant services such as liver, pancreas and small bowel.

**In summary**, strict compliance with the EWTD is incompatible with a viable transplant service. The EU Commission should acknowledge this and amend the EWTD accordingly to avoid transplantation ceasing to be viable in countries that enforce compliance and the law being broken in countries that do not.

21 September 2007

**APPENDIX**

**A Heart and Lung Transplant Surgeon’s Working Week**

There are no surgeons whose sole work is heart and lung transplantation. Transplant work is over and above a full commitment in general cardiothoracic surgery. Estimates from the Job Planning Report of the Society of Cardiothoracic Surgeons of Great Britain and Ireland (August 2003) and from transplant centres give an indication of the out of hours work of an adult heart and lung transplant surgeon:
— 3.5 to 13.8 hours transplant work per week (depending on number of surgeons in the rota).
— 6.5–10.9 hours non-transplant cardiothoracic work per week (one in six rota).

2 The modelling package was the Doctors’ Rostering System (London and South East Regional Action Team).
INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE

COMPUTER MODELING OF CONSULTANT ROTAS

The tables below give examples of computer modelling of EWTD compliant rotas. These models underestimate the challenge, as they make no allowance for study leave and the professional support activities defined in the new consultant contract. Both rotas ensure immediate compensatory rest on the day after implantation at night. The first example shows a compliant implantation rota for nine consultant surgeons. Such a rota might be feasible in a centre that can sustain enough non-transplant work to make full use of the number of surgeons available. The second example shows a compliant implantation rota for four surgeons. It shows how many weekdays will have to be taken off to ensure compliance, thus reducing greatly the availability of consultants for non-transplant cardiothoracic work. Such a rota might be feasible if surgeons did nothing other than transplant work.

MODELLING FOR EWTD COMPLIANCE: HEART AND LUNG TRANSPLANTATION CONSULTANT’S IMPLANTATION ROTA

USING THE DOCTORS’ ROSTERING SYSTEM (LONDON AND SOUTH EAST REGIONAL ACTION TEAM)

Speciality: Cardio-thoracic Surgery (Transplant) WORK PATTERN: nine consultant surgeons non-resident on-call.

Work Pattern Analysis–Actuals against the Working Time Directive.

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<th>EWTD Analysis</th>
<th>Actual</th>
<th>Target</th>
<th>Comments</th>
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<tr>
<td>11 hrs continuous rest in any 24 hour period</td>
<td>OK</td>
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</table>

WORK PATTERN DETAILS

The tables below represent one permutation for one week’s on-call for nine consultant surgeons. The shaded area represents on-call for implantation and other cardiothoracic work. The assumption is that, when on non-resident call, the surgeon achieves eight hours rest between 5pm and 9am and 12 hours rest per 24 hours at the weekend. The hours worked in the week in this example are less than the target of 48 hours because the modelling compensates for extra on-call in weeks when a colleague is on leave.

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<th>Thu</th>
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<th>Sat</th>
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<td>08:00–18:00</td>
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<td>Mr2</td>
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<td>Zero Hours</td>
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<tr>
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<td>Zero Hours</td>
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COVER PROVIDED BY THE WORK PATTERN

| Hour | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 |
|------|---|---|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Mr 1 |   |   |   |   |   |   |   |   |   |   |   | 1   |   |   |   |   |   |   |   |   |   |   |   |   |
| Mr 3 |   |   |   |   |   |   |   |   |   |   |   | 8   |   |   |   |   |   |   |   |   |   |   |   |   |
Increasing the supply of donor organs within the European Union: Evidence

MODELLING FOR EWTD COMPLIANCE: HEART AND LUNG TRANSPLANTATION

CONSULTANT'S IMPLANTATION ROTA

USING THE DOCTORS' ROSTERING SYSTEM (LONDON AND SOUTH EAST REGIONAL ACTION TEAM)

SPECIALITY: Cardio-thoracic Surgery (Transplant) WORK PATTERN: Four consultant surgeons non-resident on-call

WORK PATTERN ANALYSIS—ACTUALS AGAINST THE WORKING TIME DIRECTIVE

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WORK PATTERN DETAILS

The tables below represent one possibility for one week’s on-call for four consultant surgeons. The shaded area represents on-call for implantation and other cardiothoracic work. The assumption is that, when on non-resident call, the surgeon achieves eight hours rest between 5pm and 9am and 12 hours rest per 24 hours at the weekend. The hours worked in the week in this example are less than the target of 48 hours because the modelling compensates for extra on-call in weeks when a colleague is on leave.

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* No of transplant surgeons available. The modelling assumes that consultants never take leave at the same time. Numbers of doctors available will be less in weeks when one is on leave.
Memorandum by Gordon Nicholas, Patient

I am a patient of some 30 years, on dialysis, and then transplanted, for 12 years now back on dialysis.

1. My experience of waiting on average four years for a transplant is the norm for dialysis patients in the UK, some wait even longer.

2. UK Transplant operates the organ donor system, the current organ allocation was developed to spread organs fairly but is failing as it cannot generate sufficient organs.

3. Better advertising via Television and other outlets to make the public aware of the importance of organ donation.

4. Signing up to the register alone is not the way forward, we need something like the donor card which is visual so that the public have a sense of belonging, a European Donor card is a good idea in my opinion but whether the public will take on the idea of UK organs being used abroad, may be a downside on organ donation.

5. In the UK the living donors for transplants is a great success, but it has distorted the transplant figures as the number of cadaveric donors is falling.

6. UK transplant is needed to ensure equity of distribution and quality and safety of organs.

7. All organ donations in whatever way they are given:- Altruistic, pooled, paired, living, cadaveric donations are all ethical, the trade in organs for financial benefit is not ethical, and should stamped out.

8. When I had my transplant my life was transformed leading as normal life as others, my time on dialysis was/is not a pleasant experience.

9. Transplantation gave me back my life; dialysis gives me eight years to live.

10. Patients should not be made criminals trying to save their own live.

11. All religions support organ donation, but attention is needed to bring this fact to the publics attention.

12. Asian and afro-Caribbean suffer from renal failure more than the indigenous white population, but the former less likely to become organ donors.

13. I believe that a system of presumed consent is the way forward to increase organ donation here in the UK, every member of the public that I have spoken to in all my thirty years of renal failure supports the Opt-out system, but if organs are increased, the medical infrastructures needs to be altered to cater for increase in organ donation or it will be wasted.

14. Organ donor relatives need to be made aware of the donor wishes, there has been a reported drop in organs donated because relatives who are overriding their loved ones wishes.

I fully support the EU for this initiative especially the final three bulleted points signifying why the EU should take the a lead in organ donation and transplantation.

2 August 2007

Memorandum by Sean O’Neill MA and Paul Tighe MA

We are writing to you in response to a call for public submissions on the scope/content of the proposed human tissue legislation. In particular, we wish to address the question of whether an individual who has given no indication of his/her wishes in respect of organ donation whilst alive, and has not nominated a personal representative, should be dealt with on the presumption that he/she would have agreed to the donation of organs after death.

We are of the opinion that the presumption should indeed be that the deceased wishes to donate their organs. The current system is flawed in that the emphasis is on the potential donor to get an organ donor card. We believe that the majority of people would not have a problem with donating organs and those who do object to the procedure on personal/religious grounds are more likely to have their intentions known prior to their death.

We believe that in the event of a person’s death unless they have chosen to add themselves to a “do not remove” list any working organs should be available for transplant.

The capacity to opt out of donating is an important facet of any new legislation in this area, including a high standard of positive identification and a reliable register of non-donors. We also believe a sympathetic approach should be taken to next of kin who believe that the deceased may have wished to opt out, but who for some reason remain on the register.
Given the current waiting lists for organs it is a doubly terrible reality that of the many tragic deaths that happen everyday no good can come from them to benefit others. There is nothing more honourable than saving another life.

We urge you to include the presumption of a will to donate in any new legislation.

23 August 2007

Memorandum by Professor David Price

Presumed Versus Explicit Consent and the Role of Relatives

1. This submission contrasts the different types of consent “model” employed across Europe for the procurement of organs for transplantation, which in turn has implications for the role of relatives. Despite low procurement rates, some jurisdictions remain extremely sceptical regarding the notion of presumed consent. However, one needs to contrast the two systems as they actually work in practice in order to fairly represent them. In many societies, not only is the public ambivalent about presumed consent but so are professionals and healthcare staff. This is frequently a function of simplistic caricatures which require rectification following proper and full debate, or the central actors in the process will inevitably themselves undermine the scheme in any event.

2. In one sense, explicit consent is indeed the “ideal”. If one seeks informed first person agreement to organ donation, explicit consent from the preposthumous person, either by the person adding his name to the relevant organ donor register or signing an organ donor card, is the best unambiguous evidence that a person wanted and had decided to donate. It must be conceded that it is inevitable in various instances of presumed consent, even with a full and proper education process for the public in general, that organs will be taken and used for transplantation from some persons who did not want this to happen or at least had not decided that this should happen. Those at the margins of society are one cohort likely to be within this group, due to being outside relevant official and educational loops, and another would be those individuals who, due to some form of mental incapacity, are unable to reach a decision i.e. choose, whether to become an organ donor or not. Support for the explicit consent model seems to be principally premised on the notion that any such unwilling removal and use renders such a (presumed) system unethical and unacceptable. Yet even under current explicit consent systems such supposedly unethical removal will consistently occur also, in particular where relevant relatives are unaware of individuals’ wishes or act upon their own views.

3. Explicit consent is only “ideal” however where the wishes of the majority of now deceased persons have been reliably and directly recorded, or at a minimum have been conveyed to relatives with decision-making power at the time of death. In the United Kingdom only 24% of the population (14.6 million) have placed their names on the NHS Organ Donor Register (at 5.10.07) yet we know from opinion polls and other sources that this is considerably less than the percentage of individuals who are in fact inclined to donate. Partly it seems for this reason, the absence of such an explicit decision to consent to donate by the preposthumous person is not seen as a reason to conclusively decline organ removal for transplantation even though many such individuals clearly did not wish to become organ donors or had made no decision. In an explicit consent system, if we were to insist upon “first person” (preposthumous) consent in all cases the volume of transplants would slump to even lower levels.

4. Where the wishes of most individuals are not directly known, which is the position in all Member States, the issue is how we handle such uncertainty. In explicit regimes, relatives generally fill the void to one degree or other. Relatives are a valuable and important conduit for conveying the wishes of the now deceased person. In many situations though such a task is no more than guesswork. This is because even where the deceased had not prior to death nominated a relative or other person as a representative to make such a decision, relatives—“qualifying relatives” as they are labelled under the Human Tissue Act 2004—are permitted to decide whether to agree to organ donation or not. Yet, the available evidence suggests that no more than 50% of relatives in the United Kingdom know their deceased’s wishes at their death. Indeed, the European Commission’s Eurobarometer Survey revealed that across the Member States as a whole only 41% of individuals had even raised the subject with their relatives (43% in the UK).

5. In such an existing state of uncertainty, there are two profound objections to explicit consent. Firstly, it is not clear to all why, despite the knowledge that many people who have failed to explicitly consent to donate are nonetheless agreeable to becoming organ donors, it is considered better to allow such individuals to die “intact” with usable organs (as is the inherent impact of an explicit consent system) than taking organs from some apathetic, undecided or indifferent (and a very few objecting) individuals under a presumed consent system? The existence of a presumption of donation respects the preposthumous wish of individuals to donate
in a higher percentage of instances. This “neglected wish” in explicit consent contexts is no less a wrong to deceased persons, although rarely recognised or appreciated. The interests of those who will die or suffer compromised quality of life due to the absence of a transplant might also be seen to weigh in the balance in determining which scheme is to be preferred. Secondly, as stated, even under explicit consent regimes some organs will also be used for transplantation where the deceased was unwilling to donate or at least was undecided, apathetic or indifferent, where such wishes remain hidden or ignored. Moreover, to compound matters, there is often (although not invariably) no mechanism for recording objections apart from informing relatives to ensure that organs are not used where the deceased was unwilling. Yet, presumed consent regimes invariably have just such a register.

6. Thus, “error”, viewed in terms of the deceased’s actual wishes, is a concomitant ingredient in every system, not just presumed consent systems, and as shown above, in explicit systems there are two alternative potential sources of error, not just one. In a presumed consent system, where relatives views are solicited at all (ie in weak as opposed to strong regimes) relatives only add objections, as the silence of the deceased is itself an authorisation for donation. In an explicit consent system relatives can make decisions either to donate or not to donate, on any basis. Of course, the premise underpinning these contentions is that the wishes of the deceased are the central ethical and legal concern, not the personal views of relatives themselves (other than parents of deceased children insufficiently mature to formulate their own views). Thus, some would deny that any “error” occurs where the relatives agree to donate, whatever the deceased thought about the matter. However, the stance adopted here is that taken recently by most politicians, regulatory agencies and healthcare professionals in the United Kingdom and in Europe as a whole. The Human Tissue Act 2004 treats the wishes of the deceased as the principal factor, reinforced in the Human Tissue Authority Code of Practice, as does the Human Tissue (Scotland) Act 2006. Indeed even most relatives generally state that giving effect to the wishes of the deceased is their main function or role.

7. We know that most individuals in most States are inclined to donate, yet the UK Donor Audit, 2005–06 revealed rates of relative refusal of organs in the United Kingdom are hovering around 40%, 50% in some areas, leading ultimately to low rates of transplantation (Eurobarometer Report showed rates ranging within Europe from 6% to 42%). Thus, in societies where the evidence suggests that most individuals are willing to donate organs for transplant on their deaths, and where individuals’ wishes are generally not directly known, rates of “error” are seemingly much greater in explicit systems. Public opinion polls reveal that in the preponderance of Member States the majority of the populace are in agreement with donating their organs for transplantation after death. Whilst the Eurobarometer Report showed 56% of Europeans willing to donate (of course not all others were unwilling, many were undecided), there were wide jurisdictional variations. 63% of UK citizens were willing to donate, as well as 69% in three other explicit consent jurisdictions, Denmark, Germany and The Netherlands. Presumed consent regimes apparently better reflect most individuals’ true wishes as to the use of their organs in jurisdictions such as these.

8. We are therefore typically dealing with policies to handle doubt. The options are to either attempt to drastically eliminate such doubt, which in an explicit consent regime would in theory lead to many more organs being made available, or to otherwise handle such doubt in the most appropriate way. The first strategy would presumably have to be based around some system of mandated choice, which has not so far found favour either on account of the supposed coerciveness of forcing people to make a choice and/or the potential negative backlash towards organ donation of such a policy. Otherwise it seems we would typically need to invest extremely substantial additional resources into initiatives to increase organ registration and the adoption of donor cards, including further, productive opportunities for decisions to be made and recorded, probably following direct discussions with clinicians, etc, to make substantial inroads. To properly handle continued situations of substantial doubt it would seem appropriate though to start instead with a presumption which reflects the views of the majority; as far as we can tell.

9. There are various misperceptions surrounding presumed consent. Firstly, that it is simply the taking of organs by the state and, secondly, that organs will be taken despite the deceased’s objections. The first perception stems from a view of consent as always explicitly given despite the fact that our agreement is often reflected in our lack of objection, such as to the use of personal data for research or to medical students being present at in-patient examinations. If one opts out the state is not entitled to touch one’s organs to such ends. Thus, whilst presumed consent to donation may be less certain than an explicit consent it is not “no consent at all”, it is a tacit consent. Moreover, explicit consent is typically that of relatives not the deceased person.

10. Secondly, as noted above, where doubt exists organs will always sometimes be taken in some scenarios where the deceased was not a (preposthumous) willing party, no matter what colour of scheme is adopted. Whilst objections by the deceased are always respected in presumed consent systems with reliable communication mechanisms, the individual concerned nevertheless has to take actual physical steps to opt out. This means that only those who have real objections will be likely to do so ie if one can’t even be bothered
to go to the Town Hall or go online to register an opt out, this implies that the individual is not really anti-donation. Further, as noted earlier, in most explicit consent systems there is no dependable mechanism for recording objections to ensure that organs are not used. Thus, in reality it is less likely in a presumed consent system that organs will be removed from clearly unwilling persons.

11. There might seemingly be a risk of a public backlash to presumed consent, as there was in Brazil towards the end of the last millennium. But if deceased and relatives objections are solicited, recorded and acted upon in all cases, such a likelihood is minimal. Reliable and comprehensive processes are therefore essential. Thus, the BMA’s preference for weak presumed consent such as exists in Belgium is well founded. Of course, the introduction of presumed consent would need to be preceded by an extensive public education campaign and the setting up of easy to access means of opting out.

12. Relatives would not be excluded from influencing decisions with presumed consent, but they would not be the “decisionmakers”. They could add knowledge of known individual objections or indeed that the person concerned had insufficient capacity to make such a decision (although most individuals lacking such capacity at death will not have been permanently incapacitated during life) and veto removal by objecting. But the decision to donate would be essentially that of the preposthumous individual if he opted out he objected and if he failed to opt out he tacitly agreed to donation.

13. In the truly ideal system, one would have reliable knowledge of the wishes of all deceased persons, whether for or against donation. However, explicit consent may be an appropriate, may be even the best, system where reliable knowledge of the majority of deceased persons is accurately known. Whilst numbers continue to rise steadily, it will be some very considerable time before the NHS Organ Donor Register has a sufficient volume of registrants for this to be achieved in the UK, and a similar situation prevails elsewhere. Nor is it realistic to expect that in the short term individuals will share their (probably positive) views with relevant relatives to a very substantially greater extent than at present (Eurobarometer Survey suggests that this tendency is in fact generally declining). Thus, we are in many jurisdictions operating a much less than ideal system ethically, whilst simultaneously accepting the death and suffering of many patients.

14. Whether more organs are procured should be viewed as an important bi-product as opposed to the goal of any such change. Most importantly it is simply the ethically “right” interim scheme in situations of major uncertainty. In any event, on its own presumed consent would not an instant panacea to satisfy transplants needs, but it would tend to that end. Supported by other infrastructural, resourcing and educational changes, many of which require implementation in any event whatever system is chosen, a steady improvement can be confidently predicted. Whether an incidental effect or not, many existing regimes are dramatically failing to meet the needs of sick transplantable patients.

15. Whatever system is adopted an appropriate infrastructure is necessary to record the wishes of individuals. In view of their accessibility and reliability, registers are the preferred mechanism to this end. Donor cards are at best a supplementary strategy, as evidence shows that they do not generally achieve a wide range of coverage in addition to which they are often not available at or around the moment of death. Registers should in all cases be able to record (1) evidence of consent to donate (2) evidence of an objection to donation, and (3) where permitted by the jurisdiction concerned, allow for evidence of any individual nominated to make the relevant decision at the point of death.

16. This is not a communitarian proposal or approach per se; it is compatible with liberalism which can nonetheless be supportive of the value of community. Only where the evidence suggests that consent to donation runs counter to the views of the majority of the population is it necessary to underpin such a policy by a communitarian rationale.

5 October 2007

Memorandum by the Royal College of General Practitioners

1. The College welcomes the opportunity to comment on this Select Committee on the European Inquiry.

2. The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the “voice” of GPs on issues concerned with education, training, research, and clinical standards. Founded in 1952, the RCGP has over 31,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.

3. We believe that patient safety must be a key concern and therefore there should be EU-wide regulations on organ transplantation and donation to ensure a common standard of safety. Associated procedures should receive regulatory scrutiny to ensure that they meet set standards. However regulations should not be so
stringent that patients that badly need transplants are denied these, what is important that full and accountable information is provided with all donated organs.

4. Safeguards must also be taken to ensure that organisations or individuals do not profit from the transport of organs between EU member states.

5. I acknowledge the contributions of Mr Antony Chuter, Mrs Ailsa Donnelly and Ms Janet Radcliffe-Richards towards the above comments. While contributing to this response, it cannot be assumed that those named all necessarily agree with all of the above comments.

11 October 2007

Memorandum by the Royal College of Nursing

EU-wide Shortage of Organs Available for Transplantation

The UK appears to lag behind other countries in terms of rates of organ donation. Countries such as Spain manage donation rates of 35 per million population (pmp) compared to the UK with only 12 pmp\(^3\).

The UK has approximately 15 million people on the organ donor register, indicating widespread public support for organ donation. However, not all of those on the list suitable to donate are identified at time of death. If they were the transplant waiting list would be reduced significantly.

Organisation of Organ Donor and Transplantation Systems

Spain has introduced a system whereby all intensive care units in Spanish hospitals have an identified organ donation specialist whose role is to ensure transplantation is considered in all suitable cases. UK Transplant have identified this as good practice but in Spain such specialists are doctors however, in the UK they are more likely to be nurses. This may have an impact as the nurse’s opinion may not hold the same weight in discussions with colleagues and relatives as that of a doctor.

Another measure to increase organ donation rates from registers donors could include a centrally held database of all registered donors that can be accessed by all hospitals allowing quick identification of potential donors. At present the system relies on relatives making the donor’s wishes known or a donor card being found on their person. It is clear that the current arrangements for organ donation are not working effectively enough to deliver the number of organs required for transplants. 70% of the UK population have indicated that they would be willing to donate their organs after death but only 20% carry donor cards\(^4\).

Raising Public Awareness of Organ Donation

The RCN has been promoting organ donation cards and blood donation to its membership for a number of years. In particular we promote the blood transfusion service at our annual congress each year. We will continue to work with our members working in organ donation and blood transfusion to raise awareness within our membership.

Ethical Issues Relating to Organ Donation and Transplantation

Ethnic minorities continue to be over represented on transplant waiting lists but under represented as donors. Partly this is due to the differing blood and tissue types in ethnic groups that makes cross group transplantation difficult. This problem is exacerbated by the reluctance to release organs for donation due to religious beliefs about death. More needs to be done to increase cadaver and live donation from minority ethnic groups including:

- Increased education amongst ethnic minority groups.
- More use of peer support for those on waiting lists and their families.
- Greater engagement with local communities and their representatives on the importance of transplantation.
- Working with religious leaders to dispel myths about transplantation.

\(^3\) UK transplant statistics
\(^4\) Payne D (1994) Donation or Direct Debit?
THE NURSING ROLE IN ORGAN DONATION

If a “presumed consent” approach is to be taken in the future nurses will need to be equipped with the knowledge and support in dealing with relatives who may disagree with the policy. There is already a need for transplantation to have a greater role in nurse education and training. Most transplant coordinators are nurses who come from intensive care backgrounds but we would welcome a more structured educational approach for transplant coordinators which meets agreed national standards. This could be supported through professional organisations and forums and their training and development programmes.

ORAL QUESTIONS

What do you identify as the issues relating to organ donation and transplantation which are of greatest relevance to the RCN’s membership? Please would you describe the extent to which the RCN has sought to promote excellence and to shape health policies in relation to organ donation?

There are a number of issues relating to organ donation and transplantation which are important to the RCN membership. Nurses work closely with patients and their families and are very often the members of the healthcare team who would broach the subject of organ donation with distressed family members. Nurses also work in a variety of settings where donor organs may be in short supply and are a valuable resource. Therefore, RCN members are acutely aware of the importance of promoting and raising awareness of organ donation. Our members debated the issue of organ donation and an “opt out” system at our annual congress in 2000 and at this stage adopted a position opposed to an “opt out” system. However, at our annual congress this year we will again be debating the issue where members will have an opportunity to re-instate our existing position or push to change our position. Following congress the Royal College of Nursing will have a programme of work to promote discussions raised at congress to ensure our members views are adequately reflected in forthcoming policy debates.

What exchanges of information has the RCN had on issues relating to organ donation with professional colleagues in other EU member states? To what extent is your professional group supported and facilitated in making cross European connections to share good practice and research?

The Royal College of Nursing has forged a number of connections with European organisations such as the International Confederation of Nursing (ICN) and the European Federation of Nursing Associations (EFN) where our General Secretary, Dr Peter Carter, sits on the Executive Committee. These healthcare coalitions enable the RCN to share examples of professional best practice with healthcare colleagues and associations across the EU and discuss and debate policy which will impact on healthcare internationally. The RCN also participates in a number of European nursing and international forums such as the Royal Colleges International Forum and the Nursing and Midwifery Council European Forum in addition we also attend and contribute to policy debates through the European Public Health Alliance where we ensure that our member’s views are reflected and represented at an EU level.

In what way is the RCN taking steps to consult its membership on the issue of presumed consent? How essential would the support of the nursing community be to the effective implementation of such a system?

At this year’s RCN annual congress members have tabled a resolution which will generate a discussion about presumed consent. Following the resolutions discussion RCN Council will look at the debate; facilitate discussion with the relevant forums, networks and communities of practice with professional interests in organ donation and transplantation. Following these actions the RCN will adopt a formal policy on the issue of presumed consent and prepare work streams to ensure our members views are adequately reflected in all policy discussions.

As indicated earlier in this response nurses do work closely with donor’s families who can often be very distressed, and they are often the first people to broach the subject of organ donation. Similarly nurses working as transplant co-ordinators and in emergency care will have an important role to play in any organ donation system. It will be important to have support of the whole healthcare team in any decision to implement a new system of organ donation no matter what that system may look like.

March 2008
Memorandum by the Royal College of Physicians

The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 20,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

The RCP has a number of specialties with an interest in this issue, and our evidence has involved some of their views. We are pleased that the inquiry is addressing the key issues which are limiting the desired increase in organ donation. The following responses are based on opinion among a number of key specialties with an interest in this issue, including nephrology, lung transplant physicians, and a wider discussion at our Committee on Ethical Issues in Medicine (CEIM). Although there are many generic issues pertinent to organ transplantation, organ specific issues can be very different depending on which organ is discussed, and there are still a number of key ethical issues that the committee should consider.

Particular Issues Raised in the Commission’s Communication

EU-wide shortage of organs available for transplantation

It is acknowledged that there is a shortage of organs available for all forms of solid organ transplant and that this problem is both European and world-wide. In kidney transplantation, for example, this shortage can only be realistically met in by the continuing expansion of living kidney donation. It is also clear that, with regards to organ donation rates per million population (pmp), there is wide variability across Europe. This reflects differences in organisation of organ donor services between different countries and also represents different legislative arrangements in different member States. Some States use a presumed consent law, while others require next of kin consent even when an individual expressed a wish to be an organ donor before their death. In Spain, organ donation is managed in a very pro-active manner with dedicated donor co-ordinators in each major hospital and financial rewards to hospitals which identify donors. This approach means Spain has the highest pmp donor rate in the world. We believe that “best practice” from across Europe should be identified. This process should provide an opportunity for harmonisation of legislative approaches to consent for organ donation across the EU.

As well as a need to increase the number of donors, it is clear that there needs to be improved utilisation of existing donors. In lung transplantation the percentage of potential donor lungs actually used in transplantation varies widely between member states, from as low as 16% to 40%. There are a number of reasons for this observation. The lung is particularly susceptible to damage after death and caution on behalf of the transplanting surgeon to prevent early graft dysfunction means many donor organs are declined as unusable. Additionally, infrastructural problems at both a national and regional centre level, prevent maximal utilisation of available donors.

Organisation of organ donor and transplantation systems

In the United Kingdom the co-ordination of organ donation and allocation of organs to transplanting centres is performed by UK Transplant, an NHS body. Different systems operate for different organs, changing how waiting list patients are managed. For example, in kidney transplantation there is a national waiting list whereas for lung transplantation each centre manages their waiting list independently. Further consideration needs to be given to the benefits of national versus centre-controlled waiting lists as there are advantages and disadvantages to both approaches. There is some support for an expansion of the Eurotransplant system for donor organ distribution beyond the limited part of Northern Europe that it currently covers, and improve liaison, such as organ sharing with other parts of the EU.

In the United States the adoption of a lung allocation score to help prioritise patients on the lung transplant waiting list has led to a dramatic reduction in waiting list mortality and has meant the patients in most need have received the organs as they become available. It has also however meant slight worsening in early outcomes as more sick patients are now receiving transplants than previously. The merits of such a system should be investigated certainly at a national level and perhaps on a European Union wide basis.

The ability to perform lung transplants, even when organs are available, is not infrequently limited by infrastructural problems. If transplantation is to succeed as a recognised treatment, services need to be backed up by appropriate resources to allow simultaneous transplants to occur, sufficient transport by air to be
available for moving organs between centres and by the development of an organised and highly skilled organ retrieval service. These issues could be addressed on an EU wide level with minimum standards set for member states.

Raising public awareness of organ donation

It is the experience of our colleagues in renal medicine that sustaining interest with the public is very challenging. There should be an increase in resources available to obtain expert opinion and advice from PR and communications experts about this.

It is also broadly recognised that a huge amount of effort has gone into raising public awareness of organ donation through national organ donor registers in the UK, donor cards and maximising publicity on television, radio and in printed material. It is the opinion of the lung transplant community that this approach has now been exhausted and that to have a significant impact on the number of organ donors, a change to legislation to introduce presumed consent is needed. The fact that an individual can carry a donor card and yet still not be able to act as an organ donor due to refusal of the next of kin would seem to fundamentally undermine the value of pushing further with the donor card scheme.

However, our Committee for Ethical Issues in Medicine (CEIM) raise issues around the UK Chief Medical Officer’s proposal to change the law to an “opt out” system. The committee noted that the language used was misleading. So called “presumed consent” is not consent at all: it consists of the non-consensual removal of organs and tissues. Similarly, such organs are not “donated”: they are removed (or, rather less delicately, harvested). It is felt that the use of the terms “presumed consent” and “donation” should not be used in this context.

Use of organ donor cards, including the idea of a European organ donor card

The introduction of a European organ donor card is likely to require significant resource effort and yet unless there is a change in the law in the legal status of prior consent this is likely to yield little reward by producing more donor organs. (Please also note response above).

However, a significant body of our ethics committee did not believe that increased participation in the current donor card scheme represented an approach that had been exhausted. There had been no use of income tax forms or electoral registration forms, for example. The success in increasing donor card registrations from the Boots Advantage Card scheme suggested that similar approaches through banks or other commercial bodies might also be considered.

Some CEIM members were supportive of an opt-out scheme. However there was considerable doubt that a so called “soft opt-out” scheme, such as that supported by the British Medical Association, would improve the present donor rates—and could even make them significantly worse. Our understanding is that many practitioners approaching a bereaved family already introduce discussion of organ retrieval by inquiring if the family members are aware of objection, rather than of positive wishes to donate. The BMA proposal has little to offer beyond that and the public debate needed to achieve it could easily backfire with reduced donations. (The similarity to the opt-out arrangements for removal of organs post mortem in the Bristol and Alder Hey events was noted). Some members felt that if an opt out scheme is to be introduced, this would need to be the ‘tougher’ version which we understand to be in use in Austria, but there are other ethical issues relating to this kind of system.

There was a strong view in the CEIM that the provisions of the Human Tissue Act, which prevents a veto by the family where the potential donor has registered his/her wishes in the donor card scheme, should be supported in practice, without the possibility of being over-ruled as in the Human Tissue Authority Code of Practice 2, para 40. This states “It should be made clear that they do not have the legal right to veto or overrule those wishes . . . There may nevertheless be cases in which donation is inappropriate and each case should be considered individually.” The committee felt the latter sentence would be best withdrawn.
Use of volunteer living donors

In kidney transplantation, use of living donors is in many cases by far the best therapeutic approach.

It is the opinion of the UK lung transplant centres that this approach to donor organs for lung transplantation should be considered second choice to use of cadaveric or non-heart beating donor lungs. There is no survival advantage to patients undergoing lung transplantation using lungs from living donors. There are however, in addition, significant morbidity risks to the two living donors. This service should be available in UK centres, but perhaps to focus expertise it should only be offered in one or two centres nationally.

Ensuring the quality and safety of cross-border organ donation within the EU

Clearly the effective communication of donor details is essential in order to allow effective decision making on the suitability of a donor organ for transplantation. A minimum data set should be agreed when donor details are communicated and also a timely transfer of information between centres is essential. There are a number of laboratory based assessments which are an essential part of organ transplantation, including tissue typing, viral serology etc which must be robust and accurate if organs are to be safely used between member states of EU. Any member taking part in organ sharing would need to guarantee the standard of these.

Modern e-communication and rapid movements of organs should be explored to maximise opportunities for cross-border organ donation in Europe.

There is a need to explore the reasons for regional differences within the UK. It seems likely that EU member states may also demonstrate such differences. Such reasons may be capable of change.

Ethical issues relating to organ donation and transplantation

(i) Lung

There are a number of key ethical issues which face the lung transplant field at present. First is the issue of re-transplantation. Outcomes for re-transplantation of patients who have previously undergone lung transplantation can be as good as first transplants when patients are very highly selected. However, there is an ethical issue associated with giving individuals a second opportunity when those who are still waiting their first transplant may die on the waiting list. At present each centre assesses individuals for re-transplantation on their merits, but, as the number of lung transplant recipients increases, the demand for re-transplantation is also likely to increase. If there is not a significant increase in the supply of donor lungs then ethical issues about restricting access to re-transplantation may arise.

The second major issues relates to pushing the boundaries of donor lung acceptability. Very few donor lungs now fulfil the ideal selection criteria for use in lung transplantation. Many centres extend the acceptability of donor organs by using, for example, lungs from older donors, donors with a smoking history, donors where there may be signs of mild infection etc. It is imperative that more research is done to try and determine some objective measures of predicting outcome from different organ donors. It is also imperative that more research is done on trying to optimise potential donor organs to transform them from unsuitable to useable organs. Such research should be seen as a priority and integral to the provision of an EU wide transplant service.

(ii) General issues

As well as specific issues raised throughout this submission relating to points made by our CEIM, there are further points around ethical issues to organ donation and transplantation that are relevant here. There was a significant view within the CEIM that the proposal for mandated choice should be explored in more detail. Mandated choice means that it would be legally binding to make a choice whether to donate or not (or even whether or not to make a decision at the present time). This would have the advantage over opt out schemes of ensuring that all organ retrieval was consensual. It could be introduced in addition to the current donor card scheme and the documentation by which choice is recorded could be an addendum to either electoral registration papers or income tax forms or both. Special arrangements would still be needed for potential heart beating child donors. The view was expressed that this may be too cumbersome a proposal to be practical, but proponents argue that it has not been seriously explored. Ethically it has the benefit of putting consent at the heart of the process.
Health and social welfare benefits of organ transplantation

We feel that the benefits to health and social welfare are clear, in terms of reduced mortality as well as quality of life and health.

There are a significant number of studies now showing a dramatic improvement in quality of life associated with lung transplantation, but this improvement does vary between disease indications and with the age of the patient at time of transplant. However, many patients having undergone lung transplantation will return to work and will no longer be seeking welfare benefits.

Medical risks of organ transplantation

In many situations the medical risks are clearly outweighed by the benefits; but there is a substantial minority keen for live donor kidney transplant where the risks to both recipient and donor are substantial. The alternative situation in renal medicine is for the patient to remain on dialysis.

As experience increases both early and later outcomes from lung transplantation are also improving. A point will be reached where the major medical risk limiting quality of life after lung transplantation will relate to the side affects of immuno-suppression. This can cause significant morbidity to lung transplant recipients due to the development of hypertension, significant renal dysfunction, increased risk of malignancy and neurological toxicity. There is a significant need to develop newer generation immuno-suppressants which have fewer side effects and to develop new protocols where immuno-suppression can be weaned down to as low as possible in those individuals who have become tolerant of their organ. This would make sure that only those patients requiring higher levels of immuno-suppression receive more aggressive treatment.

The use of more heart beating donors and of greater use of marginal donors—(e.g. diabetic, older donors or even hepatitis B & C positive donors in particular cases)—should also be considered.

Illegal trafficking in organs

All UK lung transplant centres support patients’ rights to a second opinion. If a patient has been declined for lung transplant by a UK transplant centre, we are very happy to provide a second opinion at a second centre within the UK. Some patients however will seek private transplantation in countries outside the EU. Significant concern remains as to how donor organs are procured in certain countries. When patients return from these countries having undergone lung transplantation there is an expectation that they will be provided with on-going follow up care within UK lung transplant centres. This causes significant ethical dilemmas as clearly there is a duty of care to the individual patient yet there is also a wish not to be seen to condone illegal donor organ procurement in other countries. The International Society of Heart and Lung Transplantation recently published a position statement on this situation. Rigorous steps by the EU to minimise the risk of illegal trafficking are emerging in Europe, and to make plain our antithesis to such trafficking.

Other Issues of Relevance to the Commission Document

Questions which may arise in relation to organ donation and transplantation from a faith-based point of view

The UK experience in kidney transplantation suggests that faith-based perspectives are usually not the limiting factor for the expansion of kidney transplant services, but misunderstanding of the views of faith leaders among ordinary members of these faith communities often undermines progress in increasing donation rates.

12 October 2007

Memorandum by the Royal College of Physicians and Surgeons of Glasgow

The EU Commission has focused on three aspects of organ transplantation

— risks and safety issues;
— organ shortage and donation issues; and
— organ trafficking within the EU.
Risks and safety issues

The Commission focuses on the risks of disease (particularly viral) transmission from the transplanted organ. This is a risk, but within the UK screening of donors is excellent and the risk is absolutely minimal. The Commission’s concern is that with the expansion of the EU organs from “less well developed” countries may become available to patients throughout the EU and it is essential to ensure that these organs are adequately screened and of the same standard as those from the “more developed” countries.

Many of the new Member States have established transplant programmes and present their work at international professional meetings and publish in reputable transplant journals where their results are comparable to those from the older Member States. Transplant colleagues in these countries may be offended by the EU innuendo that they are not working to the same standards as the rest of us. There may be some countries where different standards apply and measures must be put in place to help these programmes not just so that organs exported to the rest of us are acceptable to us but so that the citizens of that country have good quality organs and transplantation services for their home needs.

Organ shortage and donation issues

There is acceptance that organ donor rates vary amongst the EU countries and measures need to be taken to increase donations in all countries because of the health and economic benefits afforded by transplantation compared with treatments such as renal dialysis or death.

The organ donor rate in the UK is a disgrace, with most European countries having a higher rate than us and some twice or even three times the rate in the UK!

I will deal more with this in addressing the specific consultation questions posed by the House of Lords Committee.

Organ trafficking within the EU

With free access to health care throughout the EU there is the possibility of people from one country seeking transplantation in another member state where they perceive a better/quicker chance of receiving an organ. In the West of Scotland we have one patient who moved to Spain to try to get a kidney faster but to date has been no more successful there than he was here. At present this is not much of an issue within the UK. For us there is more concern about our patients going to the Indian sub-continent for transplantation but that is obviously not dealt with in the European document.

The Impact Assessment, as well as setting out minimal standards for risks and safety issues, also stresses the need for high quality data collection and storage so that all the information about the organs etc is available for whoever may require it.

Comments about the particular issues on which the House of Lord’s Committee has requested responses.

EU-wide shortage of organs available for transplantation

Within the transplant community we believe there are adequate numbers of organs available if only we could get access to them. There are people dying everyday in ITUs and A&E departments who are not even considered as organ donors but who would be suitable to donate some if not all organs, and of the potential donors we are informed about in more than 40% donation is refused/rejected by the relatives. May patients have living family members etc who could donate an organ such as a kidney to them and this form of transplantation is inadequately embraced by the population. The deceased donor rate in the UK at 12–13 per million population is quite inadequate with a transplant waiting list of over 7,000 and many more people being added to the list per year than receive transplants in a year.

Organ shortage although an EU-wide problem is a particular issue in the UK! It is multifactorial—family refusal rates (> 40%), lack of ITU resources/facilities, lack of engagement of other health care professionals, social attitudes etc.

This issue is currently under review by the DofH Donor Task Force which is chaired by Elizabeth Biggins and is due to report within the next few months.
Organisation of organ donor and transplantation systems

This is the main remit of the DoH Donor Task Force. Preliminary communications show the way the Task Force is thinking and what its recommendations are going to be. There must be involvement of all health care professionals in identification of possible organ donors and facilitating the donation. It is not the sole responsibility of the transplant team to find donors. By definition we do not have any donors; it is only when a clinician in another specialty has a patient who dies and informs us about it that we can then try to bring it to organ donation. The Task Force report is expected to place organ donation as a responsibility for all “health care professionals”—doctors, nurses and anyone working within the health profession whether in primary, secondary or tertiary care, by identification of possible donors, facilitating the donation, and raising public awareness of the need for donated organs.

Another aspect of the report will deal with accountability and it is anticipated that the Chief Executives of Trusts and Health Board will be made ultimately accountable for the provision of donated organs from within their institutions. They will be required to ensure that all potential donors are identified (we know from audit that at present they are not) and that the facilities and will are there to progress the donation.

The report will also address the organisation of surgical donation teams which go to the hospital where the donor is to retrieve the organs. These teams will require to be adequately staffed with a robust structure rather than relying on good will as we often are forced to do at present. Scotland had a pilot scheme of a properly structured team of surgeons, theatre nurses, perfusionist and anaesthetist but despite a economic report of the cost benefit of having an anaesthetist on the team the Scottish Health Boards have not supported this service and so we are unable to provide a complete organ retrieval service since there are some donors who are lost to us because on the lack of specialist anaesthetic input.

I think it is essential that the House of Lords Committee takes heed of the Donor Task Force report when published and adds its weight behind the recommendations.

Raising public awareness of organ donation

It is essential to make everyone in our society aware of the difference that a successful transplant makes to a person’s life and the need for donated organs to achieve this. All ways of achieving this need to be embraced although from the transplant side we hope we have already engaged in all possible means of bringing this to the public via press and media advertising campaigns, inclusion in the school curriculum, talks to interested groups, distribution of information leaflets etc at public events. We are open to any suggestions that will get the message of the need for organs to a larger audience.

Use of organ donor cards, including the idea of a European organ donor card

The UK organ donor card was introduced nearly 30 years ago and for its time it was a major advance. It has now to a large extent been superseded by the Organ Donor Register. A card is only useful if it is with the potential donor when he dies and can be seen. I would, because of the amount to travel and the increasing possibilities of people dying in an EU country other that there usual country of residence, be in favour of a European system of registering their wish to donate organs when they die.

However, I consider a card to be a retrograde step and would favour an electronic system which could be “fed” from the electronic registers of individual countries and be accessible to ITUs, A&Es and transplant teams of all Member States.

Use of volunteer living donors

The laws within the UK now permit this and as long as the rights and health of the altruistic living donors are respected and upheld then I support this source of organs which has a lot to offer in renal transplantation in innovative ways of obtaining organs for people who are difficult to transplant.

Ensuring the quality and safety of cross-border organ donation within the EU

This is essential but it is also essential to ensure quality and safety of all organ donation within the EU (and the rest of the world) even when the organ does not cross a border. There may in some countries be the need for economic help and resources to achieve this. Viral and other infective risks do vary from country to country and there are some viruses prevalent in some countries that it would not be cost effective to routinely screen for in the indigenous UK population.
Ethical issues relating to organ donation and transplantation

If we are a European community ethically there has to be equity of access to transplantation throughout the EU. This is not achieved if different countries have different donor rates and differing disease profiles requiring different numbers of transplants. This has been addressed in the UK with an alteration to the organ allocation scheme where all organs are viewed as a UK resource not a local one so that each organ goes to the person in most need of it—allocated by a transparent system of points awarded to patients according to how long they have been waiting, age difference between donor and recipient, how easy it will be for them to be compatible with other organ donors, how immunologically sensitised they are etc.

All of the major religions are in favour of transplantation but often individuals site their religion as an excuse against donating their organs or those of a family member. Every donor must have their rights respected, which includes their wish to donate as much as any wish they have not to donate.

Health and social welfare benefits of organ transplantation

When considering the organs whose work can partly be done by machines eg kidneys, transplantation is proven to significantly improve not only the quality of the patient’s life but also the length of life compared with dialysis. For organs for which no substitute is available eg liver, heart etc transplantation enables the person to live and is a direct survival issue. The cost benefits of transplantation are well worked out, documented and published and there are numerous publications about the health benefits.

Medical risks of organ transplantation

Yes there are medical risks with transplantation as there are with any form of disease treatment. Some relate to operative risks as with any surgical procedure and some are immunological or infection related. Within the UK the benefits of transplantation far outweigh and medical risks if we comply with our professional standards and guidelines in relation to both donor and recipient acceptance criteria.

Illegal trafficking in organs

It is not illegal to go to another country to get a transplant. What is illegal is for non regulated money (or money in kind) to change hands and particularly for the donor or worse a third person acting as an agent to make money from it. There is debate within the transplant community about whether donors should receive payment for donating an organ. Those who favour this approach to increase donor numbers would stipulate that the money has to be at an agreed rate and paid by an authority such as a Health Board, not by the person who receives the organ.

Responses on Issues Relevant to the Commission Document

Questions which may arise in relation to organ donation and transplantation from a faith-based point of view

See my comments about this in the ethics issues above.

Questions which may arise in relation to organ donation and transplantation from the point of view of population subgroups within the UK

Different population subgroups are/were disadvantaged within the UK because of the mismatch between the proportions of the different blood groups between the donors and the recipients. This is recognised and the changes to the organ allocation system have helped to improve the system with some blood group O organs being made available to blood group B recipients without detriment to the blood group O recipients.

Most of the population subgroups have a lower donation rate than the indigenous British population and so if the allocation system is primarily driven by tissue type matching it is inevitable that more organs will go to “British” (ie white) people. This has been recognised and by changing the emphasis in the allocation system to waiting time with less commitment to tissue type matching more people from the population subgroups are now receiving organs.
The “presumed consent” approach for identifying organ donors

This appears to be favoured by English politicians but the health department in Scotland has ruled out a change in the law to accommodate this preferring to stick with the system in the present law of the donor’s expressed wishes while alive being carried out after death within an opting in system. Unfortunately it is very difficult to enforce this under the present law since although the donor may have legally registered his wish to donate organs after death which transplant surgeon when faced by the donor’s relatives saying that they do not agree to the organs being retrieved would be prepared to cross the relatives’ “picket line” and take the donor to theatre to take out the organs. The media backlash would further reduce organ donation.

The arrangements for taking into account the views or relatives about removing organs for transplantation from a deceased donor

See my response to the question above. Even with presumed consent in practical terms it is impossible to physically push aside relatives and wheel a donor into an operating theatre. All the countries with presumed consent in their laws still in effect ask the relatives. It is essential to adjust the thinking of all members of society so that it is accepted as the norm for organs to be retrieved from everyone after death unless there is a medical contraindication to the suitability of the organs for transplantation.

Views on the Need for an EU Role in the Field

To promote cooperation between Member States in order to share expertise and to expand the size of the potential pool in each Member State

At a medical level we already exchange expertise through our professional organisations and I don’t see that the EU would improve that. The EU with its “stick” could encourage governments and institutions to improve facilities etc. I don’t see what the EU can do to improve donor rates other than by providing ITU resources etc, but if it can I am all for it.

To provide a cross-border framework for the organisation of organ donation and transplantation, with harmonised rules that would provide EU citizens with higher standards for organ safety and quality than can be assured by the national legislations of Member States acting separately

Could be useful to “encourage” all countries to adhere to minimal acceptable standards and provide a form of quality assurance for organs being used outside the country of origin. Important to provide good quality transplantation for all citizens of the EU.

To enable more effective action across the EU to fight illegal organ trafficking

It is illegal; but if it is happening what more can the EU do about it if the countries involved are not enforcing the laws they already have?

8 October 2007

Memorandum by the Scottish Council on Human Bioethics

The Scottish Council on Human Bioethics (SCHB) is an independent, non-partisan, non-religious registered Scottish charity comprising doctors, lawyers, psychologists, ethicists and other professionals from disciplines associated with medical ethics.

The SCHB subscribes to the principles set out in the United Nations Universal Declaration of Human Rights which was adopted and proclaimed by the UN General Assembly by resolution 217A (III) on 10 December 1948. The SCHB is grateful to the UK House of Lords for this opportunity to respond to the consultation entitled Inquiry into the EU Commission’s Communication on organ donation and transplantation: Policy actions at the EU level. It welcomes the Committee’s intent to promote public consultation, understanding and discussion on transplantation.

In addressing the consultation, the SCHB has formulated the following responses, which can be made publicly available by the Committee.
CONSULTATION RESPONSE ON BEHALF OF THE SCOTTISH COUNCIL ON HUMAN BIOETHICS

Scottish Legislative Perspective

1. In Scotland, the Human Tissue (Scotland) Act 2006 has created a hybrid system between the explicit consent (opt-in) and presumed consent (opt-out) systems for the removal of organs from a deceased person for transplantation.

In other words, the proposed system in Scotland is of:

(i) informed consent (opt-in) for those who register their wish to donate a number of organs before death on the NHS Organ Donor Registry or by carrying an organ donor card (though their nearest relatives may greatly add to this number of body parts being donated after death, without the informed consent of the deceased person, in conformity with Section 7 of the Act), and

(ii) “soft” presumed consent (opt-out), similar to the Spanish system, when no prior wishes of the deceased person are known. Indeed, the general thrust of the opt-out system in Spain enables nearest relatives to agree to the presumed consent from a deceased person to the removal of organs when they have no “actual knowledge that the adult was unwilling for any part of the adult’s body . . . to be used for transplantation” (using the words of the Scottish Act in Section 7).

2. However, in contrast to all other systems of “soft” presumed consent in Europe in which nearest relatives usually tend to make the final decision, the Scottish Act does not enable persons, who wish to do so, to register their opposition to the removal of all or certain specific body parts after death. Indeed, the UK does not have a national register opposing general or specific organ donation.

In other words, a problem arises if a person does not know or trust, his or her relatives, characterised in Section 50 of the Act (and who may be just friends), concerning the decision to use his or her body parts after death. Indeed this person cannot stop his or her potentially unknown or unreliable relatives indicating that they have no “actual knowledge that the adult was unwilling for any part of the adult’s body . . . to be used for transplantation” after death in the present UK context (using the words of the Scottish Act in Section 7).

3. The absence of fail-safe mechanisms to allow people to record their wishes, be they positive or negative, in the Act is a cause of concern for the SCHB.5

4. Moreover, in the context of what is believed, by many, to be a gradual disintegration of family and social structures in Scotland it is very questionable whether the nearest relatives mentioned in Section 50 of the Human Tissue (Scotland) Act 2006 are even aware of the wishes of the deceased person.

5. Unfortunately, the present situation in Scotland has very serious ethical consequences and could lead to the undermining of the principle of informed consent in transplantation. As a result, it may undermine public confidence in the transplantation system and thereby reduce the number of organs available for transplantation.

6. The SCHB is already aware of a number of single persons who are considering taking their names off the NHS Organ Donor Register. This is because they do not have any appropriate close relatives, as characterised in Section 50 of the Act, on which they can really rely to implement their wishes after death.

Organ donor and transplant system

7. The SCHB has not taken a position on whether or not an “opting in” or “opting out” scheme would be preferable in possible future Scottish legislation. However, the SCHB considers it crucial that organs or tissue should only be removed from a deceased person if this person has given his or her prior informed consent to the procedure. In other words, if a system is put into place in which there is any uncertainty about the expressed wishes of the deceased person and body parts are removed, then the procedure can only be considered as unethical.

8. The possibility for the next of kin to authorise the retrieval of organs when an individual has left no wishes should not be possible in an “opting in” ie informed consent system. If body parts are removed without any explicit prior informed consent of the deceased person, then the procedure would be unethical. In the case of an “opting out” system, the next-of-kin could be able to authorise the removal of body parts. But this would

only be ethical if the next-of-kin was absolutely certain that the deceased person was aware of the “opting out” system and had not objected to the procedure.

9. The SCHB agrees that in relation to adults and mature children, the carrying of an organ donor card, or the registering of their names on the NHS Organ Donor Register should be sufficient indication of the individuals’ wishes. Verbally expressed wishes should be witnessed by two persons who are assured that the person has the capacity to make such a decision.

**Brain Stem Death**

10. The SCHB is of the view that specific provisions should exist which enable the physician removing the organs for transplantation to be satisfied that brain stem death tests have been performed adequately and duly recorded in an appropriate manner.

**Required Request**

11. The possibility of enabling “required requests”, in which staff in intensive care environments must always approach the family about organ donation when medical treatment has stopped and death has been confirmed by brain stem tests, should be supported. It may then encourage more positive attitudes within the NHS by taking away the feeling that complying with a request for organ donation should be done as a favour to the transplant unit.

**Paired Donation**

12. Since live kidney donation could be increased by paired donation, the SCHB notes that this procedure should be considered for any new legislation. Two potential pairs, hampered by blood group incompatibility, would then be able to exchange kidneys between pairs (for example, donor A, who is incompatible with recipient A, gives to recipient B, and donor B gives to recipient A).

**Altruistic Donation**

13. The possibility of “altruistic” donation, whereby a member of the public expresses a wish to donate a body part, such as a kidney, to the national pool of potential recipients should also be taken into account, provided the donor is not subjected to any serious harm to himself or herself and after (1) providing extensive counseling to the potential donor and (2) obtaining informed consent.

**Deceased Person’s wishes should be respected**

14. The SCHB supports the principle that the deceased person’s wishes should be respected as long as they reflect an “informed decision”, whether these have been expressed verbally or in writing (for example, using donor cards or a registration on the NHS Organ Donor Register). This principle implies that when the deceased’s wishes are clear, the nearest relatives should not have a right of veto.

15. However, the SCHB is concerned that persons are sometimes not adequately informed of what is involved when they consider donating their bodies or their parts after death for purposes such as transplantation, medical research and education or training. For example, the SCHB is aware that many individuals do not realise that this may include the dissection of a naked body in front of large number of undergraduate medical students. Thus the Council would like to see better information being available to the Scottish general public in order to enable the important principle of “informed consent” to exist.

16. Studies show that around 90% of the UK population would be willing to donate organs after their death, yet only 11.3 million out of a UK population of 59.2 million are registered on the NHS Organ Donor Register (as at May 2004). In this regard, questions can be asked relating to the reasons for this discrepancy. Moreover, should this discrepancy be respected as reflecting a difference between good intentions and actual decision making? This is a difficult question since the principle of informed consent does not relate to intentions but decisions.

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17. Even the Policy Memorandum of the draft Human Tissue (Scotland) Bill—when it was being discussed—accepted that nearest relatives were “changing their mind” with respect to what they believed were the wishes of the deceased person when these have not been communicated. Indeed, in paragraph 10 it stated that: “For reasons which are not entirely clear, but which may be related to the effect of issues surrounding retention of organs at post-mortem examination, in...Scotland, the relatives’ refusal rate where the deceased’s wishes are not known has risen from just over 30% in the early 1990s to around 49% now.”

18. The SCHB agrees that if there are no next-of-kin, organ and tissue retrieval should only take place on the basis that the deceased person carried a donor card or had registered his or her decision on the NHS Organ Donor Register.

No removal of body parts should take place when the wishes of the deceased person are unknown

19. Any decision that may go against the real wishes of the deceased person would enable a very unethical situation to exist. The removal or organs from a deceased person would only be acceptable if the nearest relative was absolutely certain that the deceased person was aware of the authorisation system, had not objected to the procedure and had very recently shared his or her wishes with his or her nearest relative. Any legislation which resulted in even only one decision being made by a nearest relative which did not reflect the real wishes of a deceased person could be considered as enabling unethical practices to exist.

20. The SCHB is extremely concerned about the potential for serious mistakes resulting from the possibility of a “nearest relative” authorising the removal of body parts from a deceased person who has not left any specific expression of wishes. This is because there is no certainty that the decisions of a “nearest relative” is a true reflection of the wishes of the person at the time of his or her death.

21. To go beyond the express and specific wishes of a person by letting others make important decisions on what they “assume” or “presume” are the wishes of this person is what specifically lead to the scandal at Alder Hey Children’s Hospital in Liverpool. At this hospital, body parts of children were retained after post-mortem examination when healthcare professionals “presumed” that this would be acceptable to parents without consultation.

22. The SCHB also agrees that it would be extremely difficult for absolutely everyone in Scotland to be aware of the system in place. Promises that advertising and publicity campaigns will be undertaken to promote the message that people should not simply carry a donor card or put their name on the Register, but also let their nearest relatives know of their wishes, will never be sufficient. Talking about death can still be considered taboo in many sections of Scottish society and members of the general public are entitled to not have to address this topic.

23. As with the present voting procedure at elections, people are entitled and have the right, in Scotland, not to make a specific decision. Thus, it would be unacceptable for electoral officers, after an election, to ask the nearest relatives of those who did not vote (either directly or using a proxy) to “presume” the wishes of those who did not vote and thereby cast a vote for them.

24. The only instances where authorisation from a nearest relative may be considered when the wishes of a deceased person are not known are when the person is a child or a person who did not have the capacity to consent to such a procedure while still alive. This would then reflect the provisions in the European Convention on Human Rights and Biomedicine whereby Article 6 (Protection of persons not able to consent) states that:

2. “Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorisation procedure.”

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8 Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10, http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf
9 In the Additional Protocol to the European Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin it is indicated that: “It is the expressed views of the potential donor which are paramount in deciding whether organs or tissue may be retrieved.”
10 Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 12, http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf
11 Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 13., http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf
250 INCREASING THE SUPPLY OF DONOR ORGANS WITHIN THE EUROPEAN UNION: EVIDENCE

25. If there are no nearest relatives and no expression of wishes by the deceased, there should be no role for the “person lawfully in possession of the body” to make a decision on organ retrieval since he or she cannot reflect the wishes of the deceased person. Therefore, in these circumstances, no organ retrieval should take place.

Organ Trafficking

26. The SCHB is of the view that the Scottish government should ensure that it respects the following international legislation.

UNITED NATIONS


In order to combat organ trafficking the SCHB supports extra-territorial provisions making it an offence for habitual residents in Scotland going abroad to undertake transplantation procedures which are prohibited in Scotland. Precedent has already been established in this regard with Article 4 of the UN Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography.

COUNCIL OF EUROPE


As with the Hague Convention on the International Protection of Adults (with Incapacity),13 the SCHB would like to see the United Kingdom ratify, as soon as possible, the above Council of Europe legal instruments on behalf of Scotland.

EUROPEAN UNION


5 October 2007

Memorandum by Dr Martin Smith

Thank you for asking me to clarify some of the current issues around the diagnosis of brainstem death.

The clinical criteria for the diagnosis of brainstem death in the UK were refined over many years in the 1970s by the Conference of Medical Colleges and their Faculties in the UK and published as a Code of Practice by the Department of Health in 1998. In the UK there is no statutory definition of death but English law has adopted these widely accepted criteria and considers death to be “the irreversible loss of the capacity for consciousness, combined with the irreversible loss of the capacity to breathe”.

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12 Legally binding if ratified by a country—The United Kingdom has not signed and not ratified this Convention.
13 Legally binding if ratified by a country—Adopted on 13 January 2000 but has not yet entered into force. The United Kingdom has ratified the Convention on 5 November 2003 (but for Scotland only).
The diagnostic algorithm in the UK has three sequential but interdependent steps. Certain pre-conditions must be fulfilled and potentially reversible cause of coma excluded before clinical tests of brainstem function, including an apnoea test, are performed. The UK criteria are robust, well established and used as the basis for the diagnosis of brainstem death in many other countries in the world.

An updated Code of Practice for the diagnosis of death has recently been agreed, following wide consultation, by the Academy of Medical Royal Colleges (AMRC) and, for the first time, includes guidance on the diagnosis of death by cardiovascular criteria. The updated Code is in two parts—Part 1 deals with the diagnosis of death and Part 2 with issues relating to organ donation. The guidance for the diagnosis of brainstem death (now called diagnosis of death by neurological criteria) will be essentially unchanged from the 1998 Code but additional clarification is provided for some of the areas that have previously been the cause of concern for some, eg clarification of serum electrolyte levels prior to testing.

I am aware that final draft of the Code was agreed by the AMRC some time ago and is currently with the Department of Health awaiting endorsement. There has been some delay in obtaining this endorsement and several groups in addition to the AMRC, including the Organ Donation Taskforce and the UK Transplant Donation Advisory Group, have been lobbying the DH to expedite its publication.

Dr Martin Smith
Consultant in Neuroscience Critical Care
Chairman, UK Transplant Donation Advisory Group
June 2008

Memorandum by Stuart Taylor and David Thewlis

1. We make this submission as having a profound interest in organ donation having been affected by the removal and retention of organs from babes which was contrary to our wishes as Christians seeking to live our lives according to the Truth contained in the Holy Scriptures.

2. In this submission we wish to respond specifically to three of the bullet points set out on page two of the paper. They are bullet points one, three and four of the section inviting responses on issues of relevance to the Commission document.

3. Bullet Point 1—Questions which may arise in relation to organ donation and transplantation from a faith-based point of view.
Response: Very simply, Scripture makes clear our concerns: “Ye are not your own. For ye have been bought with a price” 1 Corinthians 6 v19-20; As Creator and Redeemer, Christ has a claim on our bodies.

4. Bullet Point 3—The “presumed consent” approach.
Response: With “Informed or Explicit Consent” being the ‘cornerstone’ of the excellent Human Tissue Act recently enacted in this country, we would strongly urge the Committee to resist any changes whatsoever towards “Presumed Consent”.

5. Bullet Point 4—Arrangements for taking into account views of relatives.
Response: The present provisions in the Act are good namely that a person’s expressed, intelligent wishes should be carefully considered alongside those of the next of kin.

6. We are at a loss to understand why Article 152(4)(a) should be cited—are the Commission inferring that ‘harmonised measures’ would mean that every member state has to adopt the “Presumed Consent” approach to achieve harmony? The UK Government has a moral responsibility to stand by the excellent standard of the Human Tissue Act—“Informed Consent”.

5 November 2007

Memorandum by the Welsh Kidney Patients Association

1. EU-wide Shortage of Organs Available for Transplantation

There is no doubt that there is a severe shortage of organs throughout the EU. It is disappointing that the UK has a poor record on this issue and is second from the bottom of the league. Only Greece has a lower percentage donation rate than the UK.
2. ORGANISATION OF ORGAN DONOR AND TRANSPLANTATION SYSTEMS

There are several different methods of raising donor awareness and therefore different rates of organs retrieved across the EU countries. The infrastructure in each country differs. However, some countries, eg Spain, have higher donation rates. The methods and infrastructure used in these countries that have proven higher donation rates should be evaluated and good practice shared with those countries that do not have similar donation rates.

3. RAISING PUBLIC AWARENESS OF ORGAN DONATION INCLUDING THE IDEA OF A EUROPEAN ORGAN DONOR CARD

UK Transplant and the Dept of Health fund publications and donor registration cards, however, not enough is done to raise awareness of the benefits of organ donation. There should be a television and media campaign aimed at showing these benefits that are felt by donor families as well as recipients. This should lead up to introducing a law on “presumed consent” as advocated by the Chief Medical Officer of Health for England, the BMA and the Welsh Kidney Patients Association. A European donor card would be a welcome initiative and would lead to an increase in donated organs, but this should be in addition and not instead of Individual Member State organ donor cards.

4. USE OF VOLUNTEER LIVING DONOR

The Human Tissue Act introduced in September 2006 has allowed for altruistic living donation and pooled and shared living donation. This is strictly monitored and as such, should be free from abuse. No one should feel pressurised into donating an organ, either for financial gain or from emotional feelings towards relatives. However, those involved in the decision making to approve or not approve altruistic living donation should not be bound in too much red tape that the decision takes a long time to make.

5. ENSURING THE QUALITY AND SAFETY OF CROSS-BORDER ORGAN DONATION WITHIN THE EU

It is essential that the quality and safety of every organ used throughout the EU is monitored and robust systems of testing and checking the donor’s medical records should be in place in every EU country.

6. ETHICAL ISSUES RELATING TO ORGAN DONATION AND TRANSPLANTATION

An individual’s human rights and spiritual beliefs should be respected and taken into account at all times. The prospective donor family should be respected at all times. However, many ethnic groups have very low refusal rates due to religious beliefs, superstition or lack of understanding of organ donation. These groups should be approached with an education programme to inform and highlight the benefits of transplantation to the community as a whole.

7. HEALTH AND SOCIAL WELFARE BENEFITS OF ORGAN TRANSPLANTATION

There is no doubt that organ transplantation is the best treatment for end stage renal failure and the only treatment for heart, lung, and liver failure. Patients who have a good functioning graft are able to return to work, raise their children and contribute fully to society. This is an immense saving in benefits and state payments. With regard to kidney transplantation the saving on not having to provide dialysis is estimated as £10,000 per annum. With the average graft lasting 11 years, this is a saving of over £100,000 per patient. There is a rising need for haemodialysis of between 7% and 10% per annum in the UK. There is lack of dialysis capacity throughout Wales and many areas of the UK. Were there sufficient donated organs to transplant every patient who would benefit and was clinically able to have a transplant, the overall saving would be immense.
8. **Medical Risks of Organ Transplantation**

Recipients should be advised of all the risks involved during the operation and of rejection post transplantation. The side effects of the immuno suppressants should be fully explained to every patient. Any problems with the donated organs should be discussed with the recipients so that an informed choice can be made on whether or not to accept the organ. Strict criteria are in place in the UK when identifying possible donors. These or equally robust criteria should be practised throughout the EU to protect the prospective donors.

9. **Illegal Trafficking in Organs**

All illegal trafficking of organs throughout the EU and the world should be stopped. The trade in organs in the underdeveloped world is deplorable. There should be no need for residents of one EU Member State travelling to another member state, or any country throughout the world with an intent to “purchase” organs of vulnerable people. This also leads to the possibility of illegal traffickers hiding behind such trading. If there were sufficient cadaver or altruistic living donors there would be no waiting lists and there would be no market for illegal organs.

10. **Questions which may arise in relation to organ donation and transplantation from a faith-based point of view**

There are certain faiths that have objections to the principal of cadaver organ donation and these views must be respected. However, an educational programme could be devised to promote the benefits of organ donation specifically directed at individual faiths.

11. **Questions which may arise in relation to organ donation and transplantation from the point of view of population sub-groups within the UK**

The donation rate among some subgroups in the UK is very low and patients from these groups have had to wait longer than other patients for a suitable organ. UK transplant has developed new criteria to try to address this problem. However, some patients groups maintain that the “best matched” principle should not be over-ridden unless the recipient is in a critical condition.

12. **The “Presumed Consent” Approach for Identifying Organ Donors (under which a willingness to donate organs becomes the default position and people wishing to opt out from this need to make this known)**

Kidney patient groups were extremely disappointed that the government brought in the three line whip to stop the proposed law on “presumed consent” passing through parliament two years ago. BMA Cymru Wales has approached the Welsh Assembly government to introduce a law implementing “presumed consent” in Wales. The WKPA support this. Kidney Wales Foundation, with the support of the WKPA and patients, have met with the Minister of Health for Wales on 5 September 2007 and raised this issue. The Minister has said that the possibility would be “explored”. The Chief Medical Officer for Health for England stated in his report (July 2007) that “presumed consent” should be introduced in the UK. In Member States of the EU where “presumed consent” is the law, there is a noticeable higher rate of organ donation. The transplant infrastructure in the UK would need investment to facilitate the increase transplant operations if this law is passed. Before such a law is introduced there should be a wide ranged consultation and public awareness programme.

13. **The arrangements for taking into account the views of relatives about removing organs for transplantation from a deceased donor (both under the present system of “opting in” or under the “presumed consent” system for identifying donors)**

A. “Presumed Consent” As stated above there should be a wide ranged consultation involving the general public outlining what is involved in this issue. The public should be made aware that they have the right to opt out of this law if they wished. There should be a system in place at each hospital whereby a designated member of staff approaches the relatives of prospective donors and explains the process of organ donation in a sensitive way.
B. “OPT IN” The current system is evidently not producing enough organs for transplantation. It is known that 42% of relatives refuse permission for transplantation. (UK Transplant statistics). Some units are not “in favour” of organ transplant and there is often no dedicated staff member available to talk sympathetically to the relatives about organ donation. Although there is publicity on organ donation, this is not on the scale of government campaigns to promote obesity, cancer or the dangers of smoking. There should be an on-going television/radio/newspaper/web campaign to promote the benefits of organ donation. 70% of people want to donate their organs after death but only 20% are on the NHS Organ Donor Register. Clearly the current system of opt-in needs to be changed to one of “presumed consent” if lives are to be saved.

14. TO PROMOTE COOPERATION BETWEEN MEMBER STATES IN ORDER TO SHARE EXPERTISE AND TO EXPAND THE SIZE OF THE POTENTIAL DONOR POOL IN EACH MEMBER STATE

There is evidence that certain EU Member States have far higher rates of donation than others. Should the EU promote cooperation between Member States in the way described, the potential for increasing organ numbers would improve.

15. TO PROVIDE A CROSS-BORDER FRAMEWORK FOR THE ORGANISATION OF ORGAN DONATION AND TRANSPLANTATION WITH HARMONISED RULES THAT WOULD PROVIDE EU CITIZENS WITH HIGHER STANDARDS FOR ORGAN SAFETY AND QUALITY THAN CAN BE ASSURED BY THE NATIONAL LEGISLATIONS OF MEMBER STATES ACTING SEPARATELY

Where a Member State has an excellent infrastructure for measuring quality and ensuring organ safety this should be respected. However, a cross border framework for harmonising rules and procedures to safeguard the quality and safety of the organ should be in place to ensure that organs offered between countries are of high quality and are above all safe.

16. TO ENABLE MORE EFFECTIVE ACTION ACROSS THE EU TO FIGHT ILLEGAL ORGAN TRAFFICKING

The EU should take every action available to introduce methods to prevent /fight the illegal trafficking of organs.

27 September 2007
Letter from the Chair of EU Sub-Committee G

House of Lords inquiry into the issues raised by the European Commission Communication: Organ donation and transplantation—policy actions at EU level

You may be aware that the House of Lords EU Sub-Committee G (Social Policy and Consumer Affairs) is conducting an inquiry into the issues raised by the European Commission Communication: Organ donation and transplantation—policy actions at EU level.

The European Commission’s Communication proposes the following EU-level actions in the field of organ donation:

— The introduction of an EU Directive on the quality and safety of organ donation and transplantation—with the aim of providing a cross-border framework for the organisation of organ donation and transplantation, with harmonised rules that would provide EU citizens with higher standards for organ safety and quality than can be assured by the national legislations of Member States acting separately.

— The formulation of an action plan for strengthened cooperation on organ donation and transplantation between Member States—with the aim of sharing expertise and expanding the size of the potential donor pool in each Member State.

While we have already received some very valuable evidence from faith groups for our inquiry, the Sub-Committee would like to seek further evidence, and I am writing to you now in the hope that you will be able to help the Sub-Committee by supplying your own or your organisation’s views on some of the important ethical issues relating to organ donation.

It is our understanding that while the majority of the major faith groups support, in principle, organ donation, there are particular issues which might concern some of the members of certain of these groups. Furthermore, whilst religious leaders have broadly offered their support for donation, we have been informed of a substantial number of cases where individuals object to their own or their relative’s donation of organs on the basis of their own perception of what their religion requires of them.

Against this background, I would be most grateful if you could write to me setting out your own or your organisation’s views in response to the following questions.

Q1. Please would you describe any particular aspects of organ donation and transplantation which are considered ethically problematic within the context of your organisation’s religious beliefs—as these are perceived: (a) within the UK; or (b) in other EU Member States?

Q2. Please would you explain if there is any significant tendency for individuals from your faith group to oppose organ donation either for themselves or for a family member on the basis of their own interpretation of the religious teaching of the group, rather than on the basis of how that teaching is more generally interpreted. If so, how, if at all, do you think this tendency might best be addressed?

Q3. To what extent would a change to a system of presumed consent for organ donation in the UK (under which everyone would be assumed to have consented to donate their organs after death unless they explicitly opted-out from the system) be ethically acceptable for your faith group?

Q4. If presumed consent were to be introduced in the UK, what would be your views about the idea that members of any particular groups should be assumed to be opted out as a whole without the need for individual opt outs? (An example of this is the case in Singapore, where Muslims are assumed to have opted out unless they expressly opt in).

30 January 2008
Memorandum by the Board of Deputies of British Jews

The Board of Deputies, as the main representative body of the Jewish community, has noted recent calls for a change to an “opt-out” system of organ donation in the UK with considerable concern. Likewise there are also considerable concerns about any moves towards standardisation of European practices towards an “opt-out” approach, which has thus far been adopted in only a few European countries.

Therefore we welcome the opportunity to make a submission to the House of Lords Select Committee on the European Union Sub-Committee G (Social Policy & Consumer Affairs) about the proposals.

There are several factors which lie behind these concerns:

1. At present the UK Jewish community is very conversant of the wide variations which confront Jewish communities in different European countries in their approach to medico-legal issues that are relevant to organ donation. There are disparate approaches to ownership of parts of the body and/or of the whole body. Even within the UK to death certification and “coroner procedures” are not the same in Scotland as they are in England and Wales. Thus far the recent UK Human Tissue Act, and the associated Codes of Practice, has not been imitated in other countries. Hence any planned Europe-wide initiative about changes in the method of handling organ donation (as one specific form of tissue) is, we believe, premature and probably would be unworkable.

2. In the UK this Human Tissue Act, and the Human Tissue Authority which administers it, are founded on the principles of consent to the use of organs and tissues, and have regularised the previous haphazard structures which were shown to be open to neglect and abuse (as seen at Alder Hey, Bristol, and in the Isaacs case). The Jewish community has worked within this new system, which conforms broadly to Jewish views about the status of parts of the body and/or of the whole body. Amendment to this recent Act would have to be monitored closely to ensure that these views continue to be respected.

3. The Jewish community is aware of the difficulties faced by co-religionists in Austria (where autopsy was compulsory, and where “opt-out” has now been introduced), and Belgium. The most striking (and superficially successful) example of a European country where an “opt-out” organ donation system has been adopted recently is Spain. However, in a report on the situation in Spain, the leader of the programme commented that “the laws are necessary frameworks but they do not make organisations function... transplant organisations should be based on credibility, efficiency, impartiality and transparency for the health professionals, for patient associations, for the media, and for society in general”. This latter view is consistent with a Jewish religious view, and highlights how a balance between law and practice is essential. Thus it seems clear that changing the legal status, but without a strong commitment to education (including education about different faith attitudes) and development of a transplant co-ordinator network, would be futile.

4. The Jewish community has attempted to contribute in a constructive fashion to initiatives to increase donation rates. The general principles which underlie this approach are outlined in the accompanying memorandum (Appendix A). Asking doctors to persuade reluctant families, or to go ahead against family opposition, would betray the trust and confidence envisaged in this document.

5. The Jewish community believes that this contribution to the Select Committee deliberations has to be seen as closely linked to our ongoing work with the Department of Health on Spirituality and End of Life issues. Several pertinent comments have been raised in this work (Appendix B). There is some evidence from Israeli studies that reversion to religious practices in end of life situations (both in the dying and in their families) may occur and this may in turn influence organ donation decisions in either direction. An “opt-out” system would disturb this sense of individual autonomy, and it is not clear that it would increase transplant rates.

6. The Jewish community may be more aware of these issues because the topic was aired during the 1960-70s controversy in Israel about the family role in handling of body parts and bodies after death. At that time Israeli legislation did not require consent by relatives for an autopsy; this was considered totally unacceptable in the UK. The Israeli law was changed subsequently, motivated partly by a Jewish religious perspective, as outlined below, and partly by issues of autonomy and consent. However, during the same period, in Israel (in contrast with the UK), the fate of operative specimens was controlled. After analysis had been completed they could be sent for burial; likewise, there was a very rapid throughput of autopsy histology, and this too could be sent for burial. The “opt-out” system is analogous to a certain extent to the former Israeli autopsy system, and we believe that the combination of physician, patient and Rabbinic disquiet which resulted should provide a salutary warning to the advocates of change to “opt-out”.

These views are the outcome of internal discussions not only within the Defence and Group Relations Division of the Board but also within the framework of Jewish physicians that are involved in this field. If the select committee wishes to have further information, or is intending to pursue the matter with oral hearings, the
Board of Deputies would be willing to assist. In particular it may well be appropriate for the Board, together with the Office of the Chief Rabbi, to arrange for much fuller submissions relating to observant Jewish views about certain key and central issues such as autonomy, consent, definition of death, and trust.

We await further advice about submissions from the Select Committee, and hope that these concerns will be taken into account thoroughly during your deliberations.

2 October 2007

APPENDIX A

General Jewish principles relating to organ donation and transplantation:
(adapted from a presentation to UK Transplant—Multi-Faith Perspectives on Organ Donation)
“Judaism is a religion of life, not death”. [This may be self-evident, but the then head of the London Beth Din, Dayan Ehrenrteu, insisted that it was the starting point of the Jewish community presentation to the “Human Bodies Human Choices” discussions with the Chief Medical Officer, and it has served as an important preamble to the Jewish contribution to the debate about organ donation]

The Jewish community is not unique in its concerns about organ donation. This is common to all, and Jews are no different. At a time of stress and grief, often linked to sudden unexpected illness and death, talking about donation, and reaching a decision, can be difficult for a family.

The Jewish community, which has had the longest experience of the “non—Christian” faiths in discussion on medical issues with the UK Government, has a particular obligation to help other faiths get recognition for our mutual worries and concerns about biomedical issues such as organ donation.

There is no evidence to show that when confronted with the question at the time of possible transplant UK / European Jews are less likely to agree to organ donation requests than members of other faith (or ethnic) community.

The attitude of Jewish religious authorities to donation in general is positive. For example:

Blood donation is permitted.

Jews participate actively in bone marrow transplant registries. [In the UK in particular the Sue Harris Bone Marrow Registry worked closely with the Anthony Nolan Centre to recruit Jewish donors].

Jews have donated kidneys in “live related donor” programmes.

Jews donate corneas after death.

Organ donation has to be seen in the context of the strong Jewish tradition of caring for the sick: “Pikuach nefesh”—“saving of life”—takes priority. At the same time Jewish law poses questions about all new developments in medical treatment for serious illness:

Does the treatment indeed save life?

How do the beneficial effects balance with the risks?

Rabbinic authorities have discussed these issues in relationship to organ donation; a current consensus suggests that:

For the sick recipient, transplantation is life-saving.

The benefit of many types of transplant outweighs risk.

Thus organ donation (in fact, organ gift) falls clearly within an altruistic caring tradition. Hence:

Organ donation for “pikuach nefesh” is not forbidden in principle in Jewish law.

Some Rabbinic experts have expressed the view that there are circumstances where donation may be a “positive obligation”, or “mitzva chiyuvit”.

For observant Jews there are several resultant practical questions that may be raised concerning the actual act of organ donation. Judaism holds that:

The body of the dead person must be treated with the utmost respect, as in life

Any needless mutilation must be avoided

No benefit may be derived from a dead body.
In addition:
The process of interference with the body may cause undue distress to relatives
Taking an organ may delay burial.
Thus before advising donation, a Rabbi involved would help the Jewish family to address several questions:
Does the proposed organ donation fulfil the criteria of helping a “cholel lefanecha”—you must not stand idly
by when there is a sick patient before you? (To-day modern communications, with rapid transfer of organs,
means that “cholel lefanecha” does not mean a patient in the same hospital, town or country).
The concern that death of the donor, as defined in Jewish law, needs to have occurred before donation. Like
all other religions, Judaism has grappled with this problem in recent years. No organ may be removed from
a donor until death, as defined in Jewish law, has occurred. This may create specific problems where time is
of the essence.
The respect due to the body after death, and the balance between this respect and the concern for “pikuach
nefesh”.
The Jewish community role in organ donation includes:
To remember:
that there are two ways that one may be involved in organ donation:
as a donor
as the close family member whose opinion is sought.
that the donor does not participate in the decision at the time: in Jewish religious terms, the “mitzva”—
obligation—lies with the family, who are the agents of its fulfilment.
In addition:
Pre-discussion within families, and resultant better understanding of the Jewish approach to organ donation,
is very important.
An individual case approach, with discussion within the family, and with time for consultation, is central.
There are serious concerns about proposals to move to an “opt-out” system of organ donation, which would
conflict with these principles.
[The Office of the Chief Rabbi and the Beth Din have participated in initiatives by UK Transplant to educate the
public about organ donation, and believe that what is needed is an ongoing educational process, which needs to be
supported by Government—and not only for short term projects, as the expertise gained is soon lost, and as natural
personnel changes means that this must be a continuing process].
The requests of the individual Jewish family involved in organ donation are to be allowed:
Adequate consultation with Rabbinic authorities expert in this field during the decision making process.
To observe the principles of honouring the dead—“kavod hamet”
To ensure burial in a Jewish cemetery should follow as soon as possible after donation, without unnecessary
further procedures.
To take organs donated and not used (or rejected), for suitable burial.
In summary:
From a Jewish perspective each person is different, each donation is different—Judaism emphasises the
individual nature of donation.
Judaism stresses the importance of seeking competent halachic (religious law) guidance and advice to help in
the decision and implementation process.
[on the UK there has been a recent tragic case study where organs were donated by the family of Yonni Jesner,
an observant young British Jew, after he had been mortally wounded in a suicide bomb attack in Tel Aviv.
Subsequently his mother has made a television documentary about the donation process, which may be helpful
both in explaining about donation in general and about how an observant Jewish family responds to this dilemma]
Supplementary memorandum by the Board of Deputies of British Jews

Thank you for your letter of 30 January asking the Board of Deputies of British Jews for further comment following our earlier submission on this subject.

Although there are four specific questions posed, which we intend to address, we also believe that there are some underlying issues raised in your letter that need to be clarified.

The impression given (last paragraph, page 1) is that, while in general both the faith groups and their religious leaders support organ donation, there are particular issues which might be of concern to some members of the faith groups, which might make them reluctant to consent; and that this is then linked to self-perception of religious law. These comments tend to diminish the role that personal faith may play in the core decision making process, and to propound the view that total subjugation to religious authority should be the norm. Ignoring the personal faith dimension, and focussing entirely upon the pragmatic issues, does not do justice to the individual and their concerns. It is strange that these assumptions are stated at this point as your “understanding”, thus prejudging the responses to question 2.

There are two other issues which these same introductory comments raise. Firstly, it is unclear where the phrase “substantial number of cases” derives. One would need to know how many realistic potential donors there are in total, and how many refusals there are from amongst each faith group. The Board has the impression from your letter that it is the most observant parts of the Jewish community from which those who refuse might be presumed to be drawn. They may also be the least affluent. It would be of interest to know whether or not a control cohort of similar financial and social status will behave in the same way. There are also potential comparative Christian, Muslim and Hindu groups in the same socio-economic cohorts. Anger at the time of the Alder Hey investigation reflected a deep-seated sense of betrayal and mistrust which was not necessarily based upon religion. In earlier discussions it was made clear to the Jewish community that there are also racial issues and that it is the Afro-Caribbean donation rate that is the lowest.

Secondly not all Jews share the same view of this issue and other matters relating to organ donation. However, although for this reason widespread consultation amongst the Jewish community may be needed, there is a documented tendency amongst Jews to revert to certain religious “norms”, when confronting death, which can be based upon misunderstandings of the religious position, but which are nonetheless sincerely held, and should not be dismissed. For example, families will insist on immediate registration of death and facilities for early funerals, and then opt for cremation. Studies of Jewish opinion document that the reason why many Jews who oppose autopsy and cremation, and presumably donation, is based on the notion that “soft tissue” body parts will be necessary in the event of resurrection of the dead, despite the fact that there is Talmudic discussion reflecting that after a period of time only bones will remain. This pattern of reversion to religion, which might occur even amongst Jews who regard themselves as secular, will have an impact on donation rates. People change when confronted with mortality, and this can act as an impetus either for or against organ donation.

In answer to your specific queries, therefore:

**Question 1**

Religious beliefs are those of people, not of organisations. Thus this question is difficult, and probably inappropriate, for a representative organisation to answer, and would perhaps be so even if that organisation were to be composed solely of a group of synagogues. There is no difference between the UK and the EU in this context. Taking the observant Jewish view as the “median” norm there has been a continuous debate about problematic issues ever since transplantation was first suggested. Issues such as relative risk of the procedure, relative risk to live donors, how live donation should be regulated etc have all been posed and discussed in terms of religious law (“halacha”). The most major problematic area relates to determination of the death of the donor, and in particular to the definition and acceptability of brain death. Whether or not brain death defines the Jewish—legal moment of the death of an individual is debatable. Those who do not accept the definition of brain death cannot become organ donors until respiration has ceased, because this constitutes the killing a “still-alive” donor. One can foresee that this will pose problems if UK (or any other) authorities act without due consideration to the sensitivities of the donor and their families.

**Question 2**

The problems raised by this question have been noted already above. The “solution” which would help to address this tendency (without prejudice to a decision whether or not to donate) has already been formulated, with three main principles:
1. There must be opportunity for adequate consultation with Rabbinic authorities expert in this field during the decision making process.

2. There should be suitably trained transplant co-ordinators, fully conversant with issues of concern to Jews: as noted by the Spanish authorities “the laws are necessary frameworks but they do not make organisations function . . . transplant organisations should be based on credibility, efficiency, impartiality and transparency”.

3. The family must be reassured that they will be able to observe the principles of honouring the dead—“kavod hamet”; to bury the donor in a Jewish cemetery as soon as possible after donation; and to take organs donated and not used (or rejected), for suitable burial.

**Question 3**

In the light of the comments above, a change to a system of presumed consent would not be acceptable, as it would change the climate of the donation process radically. The concept of presumed consent that has been introduced in some European jurisdictions is only accepted by orthodox Jews because it is the law of the land, not because they regard it as the best way to regulate transplantation. The term “presumed consent” is in such instances factually wrong. The proposed change would not provide reassurance to the Board that the religious rights of a very significant number of Jews in the UK are protected along the lines suggested in our answer to question 2 above.

**Question 4**

This question moves entirely from issues of faith perspective to practicality. As noted above, Jewish views are not monolithic and Jews can change these views with time; how Jewishness is defined would be a problem; and the opportunities for stigmatization are considerable. The Select Committee may not be aware that the issue of religion and donation was brought to the fore for the first time in the UK when a newly-appointed renal physician was refused a place for a Muslim patient on a transplant list “because Muslims do not donate”. We are informed that there are also differences in the Muslim community on this issue. The opportunities for discrimination would be increased considerably in an “opt-out” system.

Finally, in preparation of these comments, it has been very helpful to have a memorandum at hand from Mr David Frei, Registrar of the Court of the Chief Rabbi, available to us, and therefore I am also attaching this memorandum for your consideration.

12 March 2008

**Memorandum by the British Sikh Consultative Forum**

The British Sikh Consultative Forum (BSCF) welcomes this opportunity to contribute to the House of Lords European Sub Committee G (Social Policy and Consumer Affairs) Inquiry on the European Commission Communication on Organ Donation and Transplantation COM (2007)0275.

BSCF welcomes the Commission’s proposal that European policy should concern itself primarily with guaranteeing the quality and safety of transplants and with the organization of cross-border cooperation. We welcome the recognition that the procedures for organ donation should continue to be determined by the Member States under domestic legislation. We also welcome the fact the Commission is proposing to act under Article 154 of the Treaty rather than the internal market provisions of the Treaty.

From a Sikh perspective the body after death has to be respectfully handled as per Sikh customs and tradition before cremation. Organ donation is permissible with the family’s consent if the deceased has not made a prior Will. The gift of organs from living donors is also permitted with consent. Many Sikhs may freely give consent for organ donation regarding it as an act of mercy and compassion.

There can be no question of payments being made to donors and families for this act of kindness. Organ trafficking should remain illegal and we welcome the Commission’s proposal to target and stop the trade in organs. We endorse the draft report of the European Parliament Committee on the Environment, Public Health and Food Safety (2007/2210(INI) which insists that altruism must be the guiding principle of organ donation and transplantation.

We have some reservations about a system of presumed consent. We are uncomfortable with the underlying logic of presumed consent which suggests that the individual and his/her body belong to the state. We also strongly believe that a system of presumed consent would only be acceptable to the extent it does not undermine the principle of informed and freely given consent. It would therefore be necessary to put in place
sensitive and confidential systems which would allow people to opt out without being subject to any form of pressure or embarrassment. One possible method of doing so would be for GPs to discuss the issue with their patients and make a record of their decision on opting out.

BSCF’s members believe that the major problem behind the low level of organ donation is the lack of public understanding of the issues involved, especially on the part of ethnic minorities. A public information campaign targeted at ethnic minorities would help to dispel fears and increase the level of organ donation from those communities. Such a campaign, highlighting the contribution of organ donation to society and encouraging the take-up of donor cards or other methods by which individuals can make their wishes known, would not be incompatible with the principles of Sikh.

We hope this statement of views will be of value to your Inquiry and will help to clarify the views of the Committee.

6 March 2008

Memorandum by Christian Medical Fellowship

1. INTRODUCTION

Christian Medical Fellowship (CMF) is interdenominational and has as members around 5,000 doctors throughout the United Kingdom and Ireland who are Christians and who desire their professional and personal lives to be governed by the Christian faith as revealed in the Bible. We have members in all branches of the profession, and through the International Christian Medical and Dental Association are linked with like-minded colleagues in more than 90 other countries. This includes formal links with the associations in 16 other European Union nations.

We regularly make submissions to Governmental and other bodies on a whole range of ethical matters (available on our website at www.cmf.org.uk/ethics/submissions/), and welcome this opportunity to comment to the House of Lords Select Committee on the European Union on their Inquiry into the EU Commission’s Communication on organ donation and transplantation: policy actions at EU level.

2. THE SCOPE OF THIS SUBMISSION

Some individual members of CMF, working in the field of transplantation, have already made submissions to the Inquiry in their professional capacities. We believe we can best contribute corporately by concentrating on ‘questions which may arise in relation to organ donation and transplantation from a faith-based point of view’ and from that perspective to comment briefly on some ethical issues.

3. CHRISTIAN SUPPORT FOR THE PRINCIPLES OF DONATION AND TRANSPLANTATION

3.1 Although surprisingly little has been written, Christians have since its advent generally been supportive of the principle of organ transplantation and see no major ethical problems per se. There was some initial concern when heart transplantation was first performed, in that the Bible speaks regularly of “the heart”. However, Scripture is referring to the totality of the identity, beliefs and character of the individual, and this confusion was rapidly dispelled as churchgoers came to realise that the heart being transplanted was only a sophisticated mechanical pump and had no special spiritual significance.

3.2 The Old Testament gives the over-arching themes that God is the Creator, Sustainer and Lord of all life and that we are accountable to him for what we do in the world. All human life is made in the image of God, belongs to God and should be treated with the utmost respect from its beginning to its end.

3.3 In the New Testament Jesus summarises the entire Law in the command to love, applied in two dimensions: “Love the Lord your God with all your heart and with all your soul and with all your strength and with all your mind” and “Love your neighbour as yourself”. The famous Parable of the Good Samaritan, recorded among the four gospels only by Luke the physician, makes clear that we should respond compassionately as best we can to anyone we come across in need, and has been taken by Christian health professionals as a paradigm for care. It is highly significant that the caring Samaritan was of an alien race to the victim; hence the love for neighbour which is advocated must cross national boundaries. This concept is relevant to the Inquiry in that it provides support for the principle of a European organ donor card.

This obligation to love is heightened when Jesus Christ says, just before giving his life for all mankind—“My command is this: Love each other as I have loved you”. He continues with the text that above all has inspired Christians to give sacrificially: “Greater love has no-one than this, that he lay down his life for his friends”.

6
Offering organs after one’s death or even offering live donation of a paired organ is compatible with this level of love that the Lord expects of his people.

3.4 As transplantation is such a clinically effective and cost effective treatment for organ failure, it fits well within our stewardship responsibility. The altruistic gift aspect of donation which arises from fully informed consent fulfils our Christian obligation to love our neighbour as ourself. Christians therefore support the principles of organ donation and transplantation.

4. Promoting Ethical Practice

4.1 Justice issues in allocation

Justice is an important concept throughout the Bible, and Christians must therefore strongly support principles of equity and equal access to scarce organs for those in need. Recognising that the necessary clinical prioritisation is contentious, CMF affirms that, regarding the patients themselves as people, we should “give effective service to those seeking our medical care irrespective of age, race, creed, politics, social status or the circumstances which may have contributed to their illness”.7 We have already emphasised that positive ‘neighbour love’ should cross boundaries.

4.2 Opting-in versus opting-out

We have not yet been able to hold a full debate within our membership about this difficult question. We are aware that the policy of the British Medical Association is to support an opting-out principle and are aware of figures in several EU countries that report increased retrieval rates after introducing opt-out policies.

However, in a preliminary discussion we placed much emphasis on the theological basis for our support for donation—namely that of altruistic free gift in a context of fully informed consent. A national opting-out policy would mean that at death the body effectively became the property of the state, and for many Christians this would conflict with the respect owed in biblical and church tradition to the dead body. We commented extensively on this perspective in 2002 in our submission to the Department of Health on “Human Bodies, Human Choices”.8 Pragmatically, there remains much concern in the UK about the retention of tissue and organs following the Alder Hey scandal, and this may have motivated Parliament when it recently rejected an opting-out policy.

We recognise though the low rates of organ transplantation in the UK. 68% of the public say they are certain or likely to donate their body (for research or teaching), their organs or their tissues but only 5% have already taken the necessary steps to do so.9 We understand why an opting-out system seems attractive and if the UK is to continue opposing it, we must all do more to increase rates of donation. We make some suggestions in 6 below.

5. Preventing Unethical Practice

5.1 Selling organs

Although some philosophers and ethicists argue that the current taboo on payment for organs is hard to justify, our preliminary view is that we have an over-riding Christian obligation to protect the vulnerable. The only people who would be attracted to sell their organs would be the poor and disadvantaged. They would not be making an autonomous choice but being exploited by the wealthy. Old Testament strictures support the poor, and checks and balances built in there to limit the buying and selling of private property10 may be relevant to this debate.

5.2 “Transplant tourism”

Like many others we raise the obvious questions about the source of the organs. Have they been donated willingly by people able to give fully informed consent? We therefore support all EU attempts to fight illegal organ trafficking.

In this context we note that, whatever individuals’ views on sexual behaviours are per se, there is widespread condemnation of the concept of “sex tourism”. We believe that measures against transplant tourism would receive widespread European support.
6. CAN THE CHRISTIAN CHURCH DO MORE?

We conclude that more teaching should be given within the Christian church to support the principles of organ donation and transplantation. Any outstanding questions should be answered. Such a policy should raise the numbers of Christians on the donor register.

To the extent that Christian teaching influences public choices we hope that this would increase national rates of organ donation, though we note that people dislike planning for death because they do not like intimations of mortality.

Some celebrities have lent their support to blood donation and bone marrow donation. Prominent Christian figures should join such role models in encouraging organ donation.

7. CONCLUSION

We are grateful to the Select Committee for this invitation to comment and are willing to help further if requested.

REFERENCES

7. Christian Ethics in Medical Practice—an Affirmation:
   www.cmf.org.uk/fellowship/doctors/cmf—ethics—affirmation.htm
8. Submission from the Christian Medical Fellowship to the Department of Health on “Human Bodies, Human Choices—the Law on Human Organs and Tissue in England and Wales”:
   www.cmf.org.uk/ethics/submissions/?id = 23
9. Dyer, C. Two thirds favour organ donation after death, but only one in 20 take steps to facilitate it. BMJ 2007; 335:533.
10 See for example Leviticus 25:8ff.

October 2007

Supplementary memorandum by the Christian Medical Fellowship

INTRODUCTION

Christian Medical Fellowship is a UK membership organisation comprising some 5,000 doctors in all branches of the profession and 1,000 medical students who wish their personal and professional lives to be governed by the Christian faith as revealed in the Bible. We are non-denominational.

This submission is made on their behalf, based on a broad consensus arrived at after discussions of our Medical Study Group, and we trust reflects the broad views of our membership. However, we do not claim to speak on behalf of any particular Christian church, denomination, or other grouping.

The Lords Inquiry has already received a general submission, and we respond here as requested to four supplementary questions.
Q1. Please would you describe any particular aspects of organ donation and transplantation which are considered ethically problematic within the context of your organisation’s religious beliefs—as these are perceived: (a) within the UK; or (b) in other EU Member States?

(a) We have already expressed strong support in principle for the concept of organ donation and transplantation, as an altruistic free gift in the context of fully informed consent, and have no fundamental ethical concerns with donation per se.

Some members are concerned about lack of transparency in the information provided to potential donors and their families about the issue of the timing of cessation of ventilation. Organs to be retrieved are in the best condition if well perfused with well oxygenated blood, so the practice is to leave the donor on the ventilator until all the organs to be retrieved have been removed, and then turn off the ventilator. Those with concerns here have reservations about the concept of brain stem death and would argue that it is the act of removal of organs which ends the donor’s life. They believe the ventilator should be turned off and removal of organs should not take place until classic criteria of death have been fulfilled—the donor stops any natural breathing and the heart stops.

Most members, fully aware of the situation about ventilation, accept the concept and criteria of brain stem death and have no such reservations. However, both sides would agree that consent by patients and families can only be truly valid if it is fully informed, and that information about this issue should be given transparently, even at the risk of lowering donation rates. The practice of organ donation must have public confidence and support.

(b) We cannot speak for other EU Member states, though would expect our sister organisations in those countries to mirror the position expressed above.

Q2. Please would you explain if there is any significant tendency for individuals from your faith group to oppose organ donation either for themselves or for a family member on the basis of their own interpretation of the religious teaching of the group, rather than on the basis of how that teaching is more generally interpreted. If so, how, if at all, do you think this tendency might best be addressed?

There has been surprisingly little teaching from the Christian church about donation and transplantation. We are not aware therefore that there is significant “religious teaching of the group” for individuals to interpret differently.

In our answer to Question 1 we have mentioned one difference of interpretation among those well informed about the details of practice—namely the questions: when does death occur? And what was its cause? We have suggested that transparency leading to fully informed consent is the way to address this.

Q3. To what extent would a change to a system of presumed consent for organ donation in the UK (under which everyone would be assumed to have consented to donate their organs after death unless they explicitly opted-out from the system) be ethically acceptable for your faith group?

We would expect this to cause significant ethical concern for Christians in the UK, and quote our previous submission:

“We have not yet been able to hold a full debate within our membership about this difficult question. We are aware that the policy of the British Medical Association is to support an opting-out principle and are aware of figures in several EU countries that report increased retrieval rates after introducing opt-out policies.

However, in a preliminary discussion we placed much emphasis on the theological basis for our support for donation—namely that of altruistic free gift in a context of fully informed consent. A national opting-out policy would mean that at death the body effectively became the property of the state, and for many Christians this would conflict with the respect owed in biblical and church tradition to the dead body. We commented extensively on this perspective in 2002 in our submission to the Department of Health on ‘Human Bodies, Human Choices’. Pragmatically, there remains much concern in the UK about the retention of tissue and organs following the Alder Hey scandal, and this may have motivated Parliament when it recently [2004] rejected an opting-out policy.

We recognise though the low rates of organ transplantation in the UK . . . We understand why an opting-out system seems attractive and if the UK is to continue opposing it, we must all do more to increase rates of donation”.

Our position is unchanged. We would point out that the language of “donation” becomes inappropriate when organs are “taken” rather than “given”.

Q4. *If presumed consent were to be introduced in the UK, what would be your views about the idea that members of any particular groups should be assumed to be opted out as a whole without the need for individual opt outs? (An example of this is the case in Singapore, where Muslims are assumed to have opted out unless they expressly opt in).*

We have already stated that we cannot speak for the whole Christian church, though our view is that no such assumption need be made about any particular Christian group.

(We are unaware of the position on donation and transplantation of the Jehovah’s Witness sect. We do not consider them “Christian”, but knowing their views on blood transfusion would expect them to reject donation and transplantation, as organs would inevitably contain blood.

We similarly do not consider Christian Scientists as part of the ‘Christian’ church, but would expect them to reject the medical treatments involved).

**CONCLUSION**

We trust these supplementary responses are some help to the House of Lords’ Inquiry, and wish you well in your deliberations about this difficult matter. We are willing to help further if requested.

**REFERENCE**


February 2008

**Memorandum by Christian Science**

I am very grateful for this opportunity to comment on the Inquiry about organ donation and transplantation.

The responses below are made in my capacity as a UK representative for Christian Science. My full title is District Manager for the United Kingdom and the Republic of Ireland, Christian Science Committees on Publication.¹

Q1. *Please would you describe any particular aspects of organ donation and transplantation which are considered ethically problematic within the context of your organisation’s religious beliefs—as these are perceived: (a) within the UK; or (b) in other EU Member States?*

A1. In Christian Science (for adherents in the UK and throughout Europe) all personal decisions, including organ donation and transplantation, are left to each individual’s own prayerful judgment. The Church of Christ, Scientist (ie, the Christian Science church) does not instruct its members on how to deal with healthcare options, including organ donation and transplantation issues.

It would be fair to say, though, that it is usual for Christian Scientists to prefer prayer-based healing—as fully explained in Mary Baker Eddy’s “Science and Health with Key to the Scriptures”—as their primary choice of healthcare, and so having an organ transplant would most likely not be as common an occurrence for them as it would be among other segments of society. However, while Christian Scientists feel that a spiritual approach to meeting their healthcare needs is effective, and therefore a desirable option to exercise, the teachings of Christian Science include no sense of there being biblical condemnation of any specific medical operation, such as blood transfusions and transplants. If these are eschewed it would be from a positive perspective of preferring a different approach, rather than from a negative perspective of rejecting the medical option available.

¹ The primary role of the office of the Christian Science Committees on Publication is to present accurate information to the media and government about Christian Science. The District Manager is appointed by The Christian Science Board of Directors to represent the practice of Christian Science to the Westminster Parliament. Christian Science Committees on Publication throughout the UK, and other European nations, are involved in communicating with the media, other religious bodies, civic organizations and government institutions about Christian Science. Christian Science is not linked in any way with Scientology.
Q2. **Please would you explain if there is any significant tendency for individuals from your faith group to oppose organ donation either for themselves or for a family member on the basis of their own interpretation of the religious teaching of the group, rather than on the basis of how that teaching is more generally interpreted. If so, how, if at all, do you think this tendency might best be addressed?**

A2. As explained above, the Christian Science church leaves each member to turn to God, the Bible and the Christian Science textbook (“Science and Health”) to prayerfully seek his or her own answer regarding personal issues, including organ donation. In Christian Science, the relationship between God and each individual is sacred. From this holy relationship, realized in prayer, stem the decisions taken for one’s life. The Christian Science church honours this relationship and trusts each member’s prayerful choices on life issues, without intruding on those choices.

Q3. **To what extent would a change to a system of presumed consent for organ donation in the UK (under which everyone would be assumed to have consented to donate their organs after death unless they explicitly opted-out from the system) be ethically acceptable for your faith group?**

A3. Individual choice is paramount in Christian Science and just as Christian Scientists have appreciated the ways in which their own choices have been accommodated in government policy, so they would not want to interfere with the choices of those who wish to approach their healthcare needs through organ donation, so long as rigorous safeguards are in place ensuring that each individual opt-out would be properly honoured. We would also suggest that all efforts should first be exhausted to encourage sufficient opt-in donations to meet the need, before the change to a system of presumed consent for organ donation in the UK is made. Should this occur, though, it would be workable to those in our faith group. However, it is fair to say that Christian Scientists would be concerned if this is taken as a green light for a broader presumption that traditional Western medicine is the assumed norm, especially in this time when so many more people are gravitating towards alternative medicines, as well as prayer-based spiritual healing, such as that practised by Christian Scientists.

Q4. **If presumed consent were to be introduced in the UK, what would be your views about the idea that members of any particular groups should be assumed to be opted out a whole without the need for individual opt outs? (An example of this is the case of Singapore, where Muslims are assumed to have opted out unless they expressly opt in).**

A4. Should the presumed consent system, including rigorous safeguards ensuring that an individual opt-out would be honoured, be introduced in the UK, there would be no need to provide for an assumption that Christian Scientists would opt-out of organ donation. Moreover, we would not be in favour of an assumed opt out for Christian Scientists because individual Christian Scientists are free to make their own decisions with respect to health care matters.

29 February 2008

**Memorandum by Church of England Mission and Public Affairs Division**

**INTRODUCTION**

1. The terms of reference of the Church of England’s Mission and Public Affairs Unit require it to assist in the Church in making a constructive and informed response to issues facing contemporary society. The Unit reports to the Archbishops’ Council and, through it, to the General Synod, the Parliament of the Church of England.

2. The Mission and Public Affairs Division warmly welcomes the opportunity to respond to the House of Lord’s Committee’s call for evidence on organ donation and transplantation. In particular we would like our responses to be seen as addressing your request to consider questions that may arise from a Faith-based point of view, even though they also largely address the issues raised in the first part of your call for evidence. We would like to emphasise that Christian faith is a positive motivation for organ donation and a powerful incentive for many people to donate.
CONSENT TO ORGAN DONATION

3. For Christians, acts of mercy are a part of the self-sacrifice that God requires of us. Christ is the paradigm of self-giving. Giving oneself and one’s possessions voluntarily for the well being of others and without compulsion is a Christian duty.

4. Christians have a mandate to heal, motivated by compassion, mercy, knowledge and ability.

5. The Christian tradition both affirms the God-given value of human bodily life, and the principle of putting the needs of others before one’s own needs. Organ donation is a striking example of this.

6. Whether organ donation should be arranged through an “opt-in” or an “opt-out” system is not a question on which Christians hold a single set of views. The opt-in system reflects our concern to celebrate and support gracious gifts, freely given. The opt-out approach stresses Christian concern for human solidarity and living sacrificially for others. We are also concerned to understand moral questions like this in their wider social and political context and, here, the undoubted need for more organs to be donated for the healing of others has to be weighed against the changed relationship between persons and the State which moving to an opt-out system might entail.

COMMERCIAL ARRANGEMENTS FOR ORGAN TRANSPLANT

7. Selling organs for commercial gain would never follow from a Christian ethic. It confuses the notion of an organ as gift and turns it into a commodity.

LIVING DONORS

8. However, altruistic organ donation from a living donor would flow from a Christian ethic, provided there was no coercion, no commercial gain, and above all no harm to the living donor. That the organ might go anonymously to a recipient, unknown and unrelated to the donor, only heightens the self-giving of the donor.

PUBLIC AWARENESS

9. If the present opt-in system is to continue, it will need to be backed by a properly resourced programme of public awareness-building and education.

RESPECT FOR THE DEAD

10. Our experience as pastors at the time of the Bristol and Alder Hey enquiries has shown us that the body is crucially important to bereaved parents and friends. There were numerous requests for burial services for body parts of children that had already been buried. The body is to be respected and the continuity between life and death in the form of what is done with the body matters. The body at its burial or cremation should ideally be recognizably the body of the person who has died.

11. However, though body parts must always be treated reverently, they should not be mistaken for the person him or herself. The reverence is perhaps expressed best in the use of body parts only and always for healing others. The harvesting of organs should not be such as to violate this continuity or to cause unnecessary distress to the mourners.

12. It is extremely important to be clear about the point of death, particularly when there is a pressure to maintain organs in a healthy state before harvesting them. This, again, is of vital importance to the bereaved.

EUROPEAN-WIDE ORGANIZATION OF TRANSPLANT SERVICES

13. We welcome the potential for Europe-wide organization of organ transplant services if a just system can be devised: member states will need to ensure that there is a balance between the organs they can provide and those their citizens need for transplant, otherwise some nations will be jeopardized and worse off than hitherto. For example, all member states would need to adopt the same opt-out or opt-in approach to consent for organ donation.

4 October 2007
Supplementary memorandum by the Church of England

In response to Baroness Howarth’s letter of 30 January with additional questions to Faith groups about organ donation, we should like to answer as follows:

Q1. No specific aspects, providing consent is in place, and there is adequate opportunity for considered ethical reflection by all parties.

Q2. Rather the contrary: we would expect all Christians to consider ensuring they are registered organ donors.

Q3. There are differing views within the Church of England on presumed consent; for principled reasons on both sides, some favour it and others do not. There are hesitations about the potential for “opt-out” to change the relationship between individual and State. However it is recognised that there is a need for more organs and a mismatch between the percentage of people overall who believe they should donate their organs and the percentage who actually register as donors, hence the need for more and better public education and campaigning.

Q4. We would not expect members of the Church of England to be treated as a discrete group, opting out or opting in, but would want members to make up their own minds and act accordingly.

Thank you for giving us the opportunity to revisit these important ethical issues in relation to organ donation.

29 February 2008

Memorandum by the General Assembly of Unitarian and Free Christian Churches

I am writing to you in my capacity as Chair of the Faith and Public Issues Commission of the General Assembly of Unitarian and Free Christian Churches, in response to your letter of 30 January 2008 concerning the House of Lords Inquiry on organ donation and transplantation. I offer the responses to your questions after having discussed them with my fellow-Commission members and the Chief Executive of the General Assembly, the Reverend Steve Dick. Together, we operate as a representative group of the wider body which we serve.

I respond to your numbered questions:

Q1. There are no particular aspects of organ donation and transplantation that are considered ethically problematic within the context of the religious beliefs of the Unitarian and Free Christian tradition, either in the United Kingdom or in other EU Member States.

Q2. There is no significant tendency for individuals to oppose organ donation either for themselves or for a family member on the basis of their own interpretation of the religious teaching of the Unitarian and Free Christian tradition.

Q3. The Unitarian and Free Christian tradition places the highest value on the authority of individual conscience. For this reason, a change to a system of presumed consent for organ donation would not be any more or any less ethically acceptable than the status quo.

Q4. According to the value system which is upheld by the Unitarian and Free Christian tradition, in which the conscience of the individual is paramount in matters of belief and personal ethics, it would be fully acceptable for members of any particular group(s) to be assumed as opting-out of any presumed consent arrangement.

Thank you for your inclusion of this faith group in your consultative process. It is appreciated.

22 February 2008

Memorandum by the Ipswich Hindu Samaj

Thank you for sending us the letter of Baroness Howarth of Breckland, Chairman of the Sub-Committee G concerning organ donation and transplantation—policy action at EU level.

We have consulted our members, who had no objection for the use of organs for medical research and transplantation, both from ethical and Hindu Faith points of view.

According to Hindu Philosophy and faith, the body comprised of five elements ie earth, fire, air, ether and water, and when a person dies and the body cremated or buried it mix with these five elements. It is the Soul that remains, which leaves one’s body and goes into another.

In Shrimad Bhagvat Gita, the Hindu holy book, Chapter 2, verses 19 & 20, Lord Krishna says to Arjuna, who does not want to fight to kill his teachers and relations:
“He who thinks this soul a slayer
And who thinks this soul can be slain
Are both ignorant?
This soul neither slays nor can be slain
Neither it is born nor does it die
Nor having come to be will it ever cease to be
Unborn, eternal, everlasting, this primeval one
Is not slain when the body is slain”

Lord Krishna further added:
“As a man shedding worn out garments, takes new ones
Likewise the embodied soul, casting out worn out bodies
Enters into others, which are new
Weapons cannot cut it, nor can fire burn it
Water cannot wet it nor can wind dry it”

(Bhagvat Gita Chap 2 verses 21–22)

Members of the Ipswich Hindu Samaj felt, that if parts of their body could be used for the benefit of mankind, there is no objection to use of organs for transplantation or for medical research. However, they felt, that the immediate family members must be consulted and asked before the organs are taken either for transplantation or for medical research.

23 February 2008

Memorandum on behalf of the London Beth Din
(Court of the Chief Rabbi)

Q1. Jewish Law in principle supports any measure that preserves life including organ donation. However there may be practical restrictions with the donation of some organs given the determination of death in Jewish Law. The Court of the Chief Rabbi, in line with leading Jewish legal authorities, rule the definition of death as being that of cessation of respiration rather than brain stem death alone. One may not terminate the life of a living person in order to save the life of another.

Q.2 We are not aware of any such tendency. Obviously, however, the issue of organ donation is of a very personal nature and individuals will have their own feelings and views. General education and promotion of the need for organ donation should prove helpful.

Q3. It would not be acceptable. In addition to the “halachic” (Jewish Law) issue referred to above, the right to donate organs must at all times remain with the donors and their families and may not be presumed by others.

Q4. We have concerns that a group that differs substantially from the general norm could be prejudiced. Accordingly this option is not acceptable.

March 2008

Memorandum by Sue Mottram

The e-mail containing questions from Baroness Howarth was forwarded to me by our Secretary to Churches together in Dorset. I am replying to it as an individual Quaker, albeit as one who has consulted Quaker Faith and Practice [our book of discipline], staff at Friends House, and as many local Friends as has been possible.

Friends as a whole have no religious objection to organ transplants. Many welcome the move to assume consent if an individual has not opted to dissent.

The concerns expressed have been about ensuring that there should be no coercion of vulnerable relatives, and that the need to harvest healthy organs should not override the patients need for a comfortable death.

Most Friends would not regard organ donation as a matter of Faith, but should they seek help in their decision making we have appropriate processes in place for them to discern their way forward.

25 February 2008
Memorandum by the Muslim Burial Council of Leicestershire (MBCOL)

Q1. Please would you describe any particular aspects of organ donation and transplantation which are considered ethically problematic within the contact of your organisation's religious beliefs—as these are perceived: (a) within the UK; or (b) in the EU Member States?

1. The interference and or the violation of the human body, whether living or dead, are prohibited in Islam. This concept has been applied in many differing ways by the Muslim community with regard to matters that relate to organ donation and transplantation.

The application of this concept has in some cases been more rooted in cultural attitudes than strict application of Islamic (Shariah) Law.

One fundamental aim of Shariah Law is the positive injunction for believers to save life. Islam places a very high value on life.

As with some of the prohibitions there is a balance that needs to be struck. This balance is achieved by the prohibition being waived in some instances. These are in cases of necessity; to preserve the life of others and of one self. This is the Islamic legal maxim of “al-darurat tubih al-mahzurat” (necessities overrule prohibition). This has great relevance to organ donation. This can be seen in the Quran when Allah declares:

“Whosoever saves the life of one person it would be as if he saved the life of all mankind”.

Holy Qur'an, chapter 5 vs 32

Many Scholars in Islam have examined this issue and the points that flow from opinions appear to be as follows:

(a) Medical professionals should be entrusted in defining “death” by clinical criteria and this is a question of medical fact rather than one of religious analysis.

(b) We should accept brain stem death as the proper definition of the end of life.

The ethical questions in transplantation relate to the source of donor organs eg anencephalic donors, cadaveric donation which is still controversial in some countries, paid living donors, donation under coercion or by minors, and by patients in a persistent vegetative state as well as organs from animals (xenotransplantation). The other major ethical issue has to do with equitable distribution of organs.

For these opinion makers the facts point to the fact that organ donation is permitted.

The issue therefore would also require analysis of all cultural perspectives in the UK.

Q2. Please would you explain if there is any significant tendency for individuals from your faith group to oppose organ donation either for themselves or for a family member on the basis on the basis of their own interpretation of the religious teaching of the group, rather than on the basis of that teaching is more generally interpreted. If so, how, if at all, do you think this tendency might best be addressed?

2. The tendency for opposition to organ donation tends to be based on both individual application of what individuals believe and what some Muslim scholars say about the human body and parts. The human body is a trust (amanah) that has been given to us by God as such; it will be impermissible for one to donate any organs of his body. In view of the above and other evidences, according to these scholars, it is unlawful to donate and transplant organs, whether it be of a living person or a dead body, and whether there is a need or otherwise. In other words, there is no permissibility whatsoever for the transplantation or donation of organs.

One way to address this would be for institutions to engage with the Muslim community in order to clarify the particular aspects of Sharia (law) relating to this area. It must be understood that, even in this instance, people will still want to exercise their own personal right to refuse for their own personal reasons. This personal choice of course may be true of all people regardless of their faith.
Q3. To what extent would a change to a system of presumed consent of organ donation in the UK (under which everyone would be assumed to have consented to donate their organs after death unless they explicitly opted-out from the system) be ethically acceptable for your faith group?

3. We do not believe that a system of “presumed consent” would be appropriate. The idea of people having to “opt out” is in our view inappropriate when we look at the fact that ones organs are being used. Personal and cultural feelings about ones body are intrinsically very problematic. We can envisage families raising legal, moral and ethical challenges against the medical profession when they are opposed to one of their loved ones bodies being used in this way. We all sensed that extreme concern and discomfort when we learnt of the Alder Hays organ retention scandal. It would not be ethically or religiously acceptable to us.

Q4. If presumed consent were to be introduced in the UK, what would be your views about the idea that members of any particular groups should be assumed to be opted out as a whole without the need for individual opt outs? (An example of this is in the case in Singapore, where Muslims are assumed to have opted out unless they expressly opt in).

4. We do not accept that the concept of “opting in” or “out” would be acceptable. What we would recommend is that all GP’s and Hospital Doctors should be placed under an obligation to get each of their patients to declare their decision as to organ donation. There also has to be a distinction between those donations that are for the purpose of helping to save a life and organ donations for the purpose of clinical research only. There should be a clear instruction as to what part of the body or organ (or part of an organ) is being donated. The patient should be able to withdraw any such consent given at any time and this can also be determined in any testamentary document such as a Will. Lawyers should be encouraged to advise their clients to draw up Wills and to address this issue in it. This is creating a system where people are encouraged to apply their minds to the issue of donating their organs and to make an informed decision, which is what Islam requires. The intent of the deed is paramount, rather than the issue being determined on your behalf by others. It also follows that we firmly believe that organ donation must be given freely, without reward, and trading in organs is strictly prohibited.

21 February 2008

Memorandum by Sukyo Mahikari

Thank you very much for the opportunity to respond to the questions related to the ethics of organ donation and transplantation and the matter of “assumed consent”.

QUESTION 1

According to the teachings of Sukyo Mahikari, death does not occur in an instant but progressively over time, sometimes even over several days. It is hard to define an instant of death. As well as this, we believe that the soul of a person continues to exist after “death”, not in the physical world, but in the unseen world of spirits (astral world).

According to our teachings, a human being is a trinity of a spiritual body, astral body and physical body. When a person dies, the soul, that is the spiritual and astral bodies withdraw from the physical body and continue to exist in the astral world. After a period of time, the soul will reincarnate into another physical body.

In a living person, the spiritual, astral and physical bodies function together in a closely interwoven and interconnected manner whilst occupying the same physical space.

According to our belief, the spiritual and astral bodies may not have completely left the physical body at the time when organs are removed from the human body. This is even after the person has stopped breathing. This may cause spiritual problems for both the donor and recipient. It may take 24 hours for the spiritual body and astral body to fully withdraw from the physical body.

There are accounts of people who have had near death experiences where the soul has left the physical body and later returned within that period of time.

Our concern, as part of an international organisation with members in almost all EU Member States, is that the ethics of organ donation and transplantation have not yet been fully explored particularly with respect to the spiritual aspect. It is, therefore, essential that government agencies, NGOs and the general public maintain an on-going debate about the ethics of organ donation and transplantation.
QUESTION 2
Members of Sukyo Mahikari are very likely not to want to donate an organ automatically for all the reasons outlined above. Nevertheless, according to our teachings, we would not simply decide that all transplants are not acceptable. A person wishing to be a donor or to receive the donation of an organ from another would therefore be very likely to seek to discuss the matter seriously. It is, therefore, almost unthinkable that a member would wish his consent to being an organ donor be assumed without consultation with himself (or with those who shared or at least knew of his spiritual beliefs, in a case where he was not able to express them for himself).

QUESTION 3
It is likely that a member of Sukyo Mahikari would consider it unethical that either he or she is assumed to be a potential organ donor unless he or she specifically opts out. We are of the opinion that members would wish it to be both UK and EU policy that anyone willing to be a organ donor be given the option of positively choosing to be a donor rather than being a situation where everyone is regarded as a potential organ donor and anyone not wishing to be a potential organ donor has to actively opt out. In other words, there should be a positive choice to be an organ donor rather than a negative choice not to be one. In some circumstances, we envisage that a member may indeed wish to express his or her compassion for the suffering of another person, by electing to be an organ donor.

QUESTION 4
Although it may seem convenient to have a blanket exemption for members of our organisation or any other organisation, as a general policy we believe that each person, whether they are living in the UK or any other EU country, should have the positive option to opt in when it comes to the matter of consent to be an organ donor or recipient. People should have the right to choose and they should base their choice not on any form of coercion, or assumed expectation of the state, but on informed opinion and their own beliefs (including spiritual and religious beliefs) and personal experience. However, it is very understandable that people of goodwill would seek to address the suffering of others by organ transplants. The approach of Sukyo Mahikari is to address the issues that underlie this suffering and to seek to reduce the number of people who suffer. We do this through our spiritual practice of the art of True Light.

Thank you very much for allowing our organisation to express our views concerning organ donation and transplantation. If we can be of any further help, please do contact us.

25 February 2008

Memorandum by The Christadelphian

I refer to the letter from Baroness Howarth of Breckland and thank you for the courtesy extended to the Christadelphians in affording us the opportunity to comment on these issues.

QUESTION 1
Christadelphians seek to adhere to the statutes and conventions of the countries (and European States) in which they reside wherever possible, except where these are believed to be in conflict with the laws of God. In the absence of specific instructions in the Scriptures about organ donation, the Christadelphian movement has not legislated on the issue. In this, as in a number of other matters (eg donation of blood and receiving blood transfusions) the matter is left to individual members to apply Scriptural principles in accordance with their own consciences. Consequently, organ donation and transplants are not at present considered ethically problematic within the context of Christadelphian religious beliefs.

QUESTION 2
Because organ donation is an individual matter that has not been formally discussed by us, it is difficult to be certain about opinion. But it is believed that there would be a significant proportion of Christadelphians— and almost certainly over half—who would find organ donation ethically problematic and who would oppose it for themselves and their families on grounds of conscience and their interpretation of the Scriptures. This opposition would be based on the Christadelphian understanding of God being the author of life, on the
accepting of God’s will in our lives (to varying degrees), on the Scripture that our bodies are not our own but are for the glory of God and on our belief in a physical (bodily) resurrection at the second coming of the Lord Jesus Christ.

QUESTION 3
You will appreciate from the comments above that, as a “Faith Group”, Christadelphians could not object to a system of presumed consent in relation to organ donation provided that there was provision for individuals to exercise their conscience and choose to opt out.

QUESTION 4
In view of our response to Question 3, whilst it is felt that a majority of Christadelphians may wish to opt out, many would wish to opt in. There is not perceived to be any great advantage in the possibility of a Group opt out and there may be potential practical problems in such a system depending on how it was to operate.
In summary, therefore, many Christadelphians would have concerns about the restrictions on freedom that legislation governing organ donation would bring, but as an organisation, could not seek special treatment in the matter as long as legislation allowed for the exercise of an individual’s religious conscience.

20 February 2008

Memorandum by The Greater World
As far as The Greater World is concerned it is an individual decision as to whether members participate in the donation and transplantation system. Many of our members are/were Card carrying Donors and are not averse to transplantations because many of them have benefited from this process or have had family who have benefited.
In itself it is beneficial to those who have no other recourse for an extended life, ie kidney or heart. Cornea grafts give sight to many, especially the young who would otherwise perhaps go blind.
What some people have said to me is that they are concerned that if they were ill and near death they would not like their organs harvested before time. This comes within the scope of Q3. and relies completely on the integrity of the individuals carrying out the work in the system. Are the procedures secure enough, “policed” enough and would the public be kept informed as to the rules that are laid down?
Q4. Should any group or religion choose to opt out of the system they should be required to make it public. If individuals of those groups/religions that do opt out wish to participate they can make it known by carrying a card or by any means made available to the public. There is always a possibility that some members of these groups/religions may require assistance in this particular way!
11 February 2008

Memorandum by The Pagan Federation
Q1. There are no particular aspects of organ donation and transplantation which are considered ethically problematic within the context of our members religious beliefs.
Q2. There is no significant tendency for individuals from our faith group to oppose organ donation either for themselves or for a family member on the basis of individual interpretation of religious teaching.
Q3. Our members would find a system of presumed consent for organ donation (unless they had specifically opted out) in the UK ethically acceptable.
Q4. Our members do not hold any specific views regarding a presumption that members of any particular group should be assumed to be opted out as a whole.
22 February 2008