



HOUSE OF LORDS

European Union Committee

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17th Report of Session 2007–08

**Increasing the supply  
of donor organs  
within the  
European Union**

Volume I: Report

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NOTE: References in the text of the Report are as follows:  
(Q) refers to a question in the oral evidence  
(p) refers to a page of written evidence

The Report of the Committee is published in Volume I (HL Paper 123-I) and the Evidence is published in Volume II (HL Paper 123-II)

## **FOREWORD—What this Report is about**

In recent years, the transplantation of organs has continued to develop as a successful form of treatment for life-threatening conditions resulting from organ failure. The transplantation of a kidney is now the most cost-effective form of treatment for renal failure and is almost always preferable to kidney dialysis. Unfortunately, it has not been possible to realise the full potential of advances in transplantation surgery because of the severe shortage of donor organs both in the UK and, more widely, across the European Union as a whole.

In May 2007, the European Commission issued a Communication relating to organ donation and transplantation. This made a number of proposals for actions, at Community and Member State levels, which were designed to help increase the supply of donor organs across the EU. The two major elements were: first, the introduction of a directive aimed at setting standards for the quality and safety of organ donation and transplantation across the EU; and, second, the establishment of an action plan for closer cooperation between Member States in sharing experiences and best practice.

This Report brings together evidence relating to the Commission's proposals and draws conclusions about their merits. In order to put these conclusions in context, the Report also sets out the evidence we received about a range of matters relating to organ donation which are not within Community competence but which are, nevertheless, of central relevance to the main issue which the Commission's Communication addresses, namely, the shortage of organs for donation.

During the inquiry, the Department of Health's Organ Donation Taskforce published a number of recommendations for the re-organisation of the health infrastructure in the UK which had the aim of increasing the supply of donor organs available for transplant. The inquiry also coincided with the publication of a proposal, by the Chief Medical Officer for England, that current legislation in England should be changed in order to create a "presumed consent" or "opt-out" system for organ donation in place of the existing "opt-in" system. The Report covers the evidence we received in relation to both these issues.

Our conclusion is that the proposals set out in the Commission's Communication would help to raise the numbers of organs available for transplantation as well as the overall safety and quality of those organs. We see it as important, however, that the proposed directive on the quality and safety of organs should not be overly bureaucratic and that it should not inhibit the application of expert clinical judgement and informed patient choice.

While the scope of Community competence in relation to organ donation is limited, we take the view that the Commission's proposals usefully stimulated our inquiry to assess a wider range of important, closely related issues. We hope that this Report, in addition to its primary purpose of contributing to the future development of sound proposals at Community level, will make a valuable contribution to the aim of improving the performance of organ donation and transplantation activities in the UK.

# Increasing the supply of donor organs within the European Union

## CHAPTER 1: SETTING THE SCENE

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### The purpose of our inquiry

1. The first successful kidney transplant, between identical twins, was carried out in the USA in 1954, but much more widely remembered is the first successful transplant of a human heart performed by Dr Christian Barnard, in South Africa, in 1967. In the years which have passed since then, the medical techniques required for successful organ transplantation have advanced considerably and this is now a widely used form of treatment. In fact, kidney transplantation has now become the most cost-effective form of treatment for cases of renal failure and is almost always preferable to kidney dialysis.
2. Unfortunately, many of the patients who potentially could benefit from receiving an organ transplant cannot be treated in that way as a result of the severe shortage of available donor organs both in the United Kingdom (UK) and, more widely, across the whole of the European Union (EU).
3. In his Annual Report for 2006<sup>1</sup>, the Chief Medical Officer (CMO) for England quoted figures produced by UK Transplant showing that, while the number of patients waiting for an organ transplant in the UK had risen from around 7,200 in 2002/03 to around 8,400 in 2005/06, the proportion of these for whom a transplant operation had been performed had fallen, during the same period, from 39% to 34%. In 2005/06, directly as a result of the shortage of organs, the number of transplant operations carried out had been limited to 2,794.
4. The CMO estimated that 1,000 patients on the transplant waiting list were dying every year for lack of a transplant; and that others who were not put on transplant waiting lists “because doctors know there is no hope of them getting treatment” were “dying silently” (Q 44).
5. In May 2007, the European Commission issued a Communication<sup>2</sup> which made a number of suggestions for actions at Community and Member State levels designed to help increase the supply of donor organs across the EU. The Commission commented that, across the EU as a whole, over 40,000 patients were on waiting lists for a kidney transplant. It concluded that, “the severe shortage of organ donors remains the main challenge that EU Member States face with regard to organ donation”.
6. Our inquiry had the principal aim of taking evidence in order to assess the merit of the suggestions for action at EU level which were put forward in the Commission’s Communication. In order to address these issues in a fully informed way and to put them in context, we found it necessary to take

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<sup>1</sup> Department of Health, *On the state of public health: Annual report of the Chief Medical Officer 2006*, July 2007.

<sup>2</sup> European Commission Communication, *Organ donation and transplantation: policy actions at EU level*, May 2007. [http://ec.europa.eu/health/ph\\_threats/human\\_substance/documents/organs\\_com\\_en.pdf](http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_com_en.pdf)

evidence also about matters relating to organ donation and transplantation in the UK which went beyond the scope of any potential EU involvement. We report also on this additional information.

### What the Commission's Communication says

7. The Communication proposes three main areas of action at EU level in relation to organ donation and transplantation:
  - The introduction of an EU directive on the quality and safety of organ donation and transplantation;
  - The introduction of an Action Plan for strengthened cooperation between Member States; and,
  - Continued vigilance to combat trafficking in human organs.
8. The Communication proposes that an EU directive, setting standards of quality and safety for organ donation and transplantation, could serve a similar purpose to that served, in a related field, by the existing Directive on quality and safety standards for blood, tissues and cells<sup>3</sup>. The Commission argues that, based on further cooperation with the Member States, an appropriate and flexible European legal framework for this would be provided by Article 152(4)(a) of the Treaty of Rome<sup>4</sup>.
9. The Commission also proposes to develop an action plan for the sharing of expertise among EU Member States designed to help maximise organ donation rates and to promote greater access to transplantation. This approach should be based on: the identification and development of common objectives for which it is agreed that a Community response is necessary; agreed quantitative and qualitative indicators and benchmarks: regular reporting; and identification and sharing of best practices.
10. In relation to organ trafficking, the Communication refers to existing international legal instruments and envisages that it will closely monitor any developments in the organ trafficking field both inside the EU and worldwide.
11. Further details of the Commission's proposals are set out in chapters 2, 4 and 5 of this Report.

### Relevant developments during our inquiry

12. An important development which occurred during our inquiry was the publication of a report<sup>5</sup> by the Department of Health's (DH) Organ Donation Taskforce which made recommendations about how to re-organise the health infrastructure in the UK in order to increase organ donation rates.

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<sup>3</sup> Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ L102, 7.4.2004, p. 48–58

<sup>4</sup> *Treaty establishing the European Community*: Article 152(4)a. "The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting: (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures."

<sup>5</sup> Department of Health, *Organs for Transplants: A report from the Organ Donation Taskforce*, January 2008



The issues addressed by the Taskforce report were also central to the subject matter of our inquiry and we heard a great deal of evidence from our witnesses which related to the recommendations it made. Our evidence and conclusions on this issue are reported in chapter 6.

13. We were delighted to hear from Elisabeth Buggins, Chair of the Organ Donation Taskforce that the Government had allocated, in full, the funding needed for implementation of the recommendations of the Taskforce report (Q 489).
14. We were pleased also to hear from Ann Keen MP, Parliamentary Under-Secretary of State for Health Services that a new National Clinical Director for Transplant had been appointed in April 2008 with the responsibility of taking forward delivery of the Taskforce recommendations (Q 490).
15. The timing of our inquiry also coincided with a great deal of publicity, arising from the proposal set out in the CMO's report<sup>6</sup>, that current legislation in England should be changed in order to create a "presumed consent" or "opt-out" system for organ donation in place of the existing "opt-in" system. The EU has no competence in this area, and the Commission has shown no intention of suggesting what model for consent Member States should adopt. Nevertheless, the potential advantages and disadvantages of presumed consent are so central to the assessment of how the supply of donor organs might be increased, that our inquiry needed to take account of the arguments both for and against the CMO's suggestion. Our evidence and conclusions on this issue are reported in chapter 8.
16. In September 2007, the Organ Donation Taskforce was requested by the Secretary of State for Health to explore the issue of presumed consent. We understand that the Taskforce report will be published in summer 2008 so there has been no opportunity to take account of its findings in our inquiry. We hope, however, that our Report will provide a useful input to the work of Taskforce on this issue and we have sent it to the Taskforce Chair drawing her attention to the relevant sections.

### How we conducted the inquiry

17. The Members of our Social Policy and Consumer Affairs Sub-Committee (Sub-Committee G) who conducted the Inquiry, showing their declared interests, are listed in Appendix 1.
18. We are most grateful for the evidence that we received for our inquiry; the witnesses who provided it are listed in Appendix 2. In particular, we thank those witnesses who gave us evidence in person. The Calls for Evidence we issued are shown in Appendices 3 and 4, and the evidence we received in response is printed in a companion volume to this Report.
19. We acknowledge with considerable thanks the expertise and hard work of our Specialist Adviser for the inquiry—Professor Bobbie Farsides of the Brighton and Sussex Medical School—who played a key role in helping us to prepare the Report.
20. **We make this Report to the House for debate.**

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<sup>6</sup> op. cit.

## CHAPTER 2: THE EUROPEAN COMMISSION'S PROPOSALS

21. The European Commission's Communication<sup>7</sup> on organ donation and transplantation was published in May 2007. A substantial amount of work has been done since then by the Commission, in consultation with Member States, to develop their proposals in relation to: the introduction of an EU directive on the quality and safety of organ donation and transplantation; the introduction of an action plan for strengthened cooperation between Member States; and continued vigilance to combat trafficking in human organs.
22. Dr Eduardo Fernandez-Zincke, Medical Officer in the European Commission's Directorate of Public Health and Risk Assessment, told us that the Commission was planning to publish its firm proposals by the end of 2008 (Q 2).
23. The Commission's proposals in the field of health are subject to a co-decision procedure under which both the Council of Ministers and the European Parliament need to agree them. In April 2008, the European Parliament adopted a resolution<sup>8</sup> on organ donation and transplantation which put forward a number of views about the Commission's Communication.

### EU Directive on the quality and safety of organ donation and transplantation

24. Dr Fernandez-Zincke pointed out that cooperation between EU Member states to exchange organs across national boundaries was a valuable way of increasing the size of the donor pool. This was especially helpful for smaller Member States for which available, suitable organs may not readily be found when needed for transplant (Q 20). The evidence we received relating to cross-border exchanges of organs within the EU is set out in chapter 3.
25. At present the five Member States that comprise the Eurotransplant area (Austria, Belgium, Luxembourg, the Netherlands and Slovenia) have entered into collaborative agreements relating to organ exchange. While the Commission has not suggested that this area should be extended to include any further Member States, it does argue that a Community framework would be desirable for setting quality and safety criteria with respect to the procurement, transport and use of organs across the Community. In the Commission's view, such standards would help to facilitate exchanges of organs across internal EU boundaries.
26. Dr Fernandez-Zincke confirmed that the Commission would wish to introduce a legal framework—a directive—in order to put in place such standards across the EU saying, "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" (Q 21).

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<sup>7</sup> op. cit.

<sup>8</sup> European Parliament resolution of 22 April 2008 on organ donation and transplantation: policy actions at EU level—see <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+20080422+SIT+DOC+WORD+V0//EN&language=EN>

27. Box 1 in chapter 4 shows the content of the Communication which sets out the key principles to which Dr Fernandez-Zincke referred.
28. The European Parliament's resolution<sup>9</sup> on this matter recognises that it is "vitally important to ensure the quality and safety of organ donation and transplantation" and acknowledges that "actions on quality and safety could have an effect on organ availability". The resolution calls on the Commission to "help Member States develop their capacity to create and develop national regulations and a regulatory framework to enhance quality and safety, without this having a negative impact on the availability of transplant organs".
29. It seems likely also that a consensus will be reached among Member States in the Council of Ministers that a directive will be acceptable as a way of ensuring high quality standards in relation to organ donation across the EU. Ann Keen MP, the responsible DH Minister, lent weight to this view when she told us, "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" (Q 467).
30. We heard little evidence opposing entirely the introduction of an EU directive relating to organ quality and safety. However, we did hear a wide range of views about the potential problems that such a directive could cause if care were not taken to ensure that it did not inhibit in any way existing beneficial medical practice, and did not cause an unacceptable administrative burden.
31. A more detailed account of the evidence we received relating to the Commission's ideas about a directive on the quality and safety of organ donation and transplantation is given in chapter 4.

### **Action Plan for strengthened cooperation between Member States**

32. The motivation for the Commission's suggested action plan for strengthened cooperation between Member States is its perception that this would be a positive way of improving the supply of available donor organs across the EU. The Commission observes in its Communication<sup>10</sup> that organ donation rates vary widely between different EU Member States for reasons which cannot easily be explained.
33. The Commission concludes from this that some of the national models used to organise organ donation and transplantation services perform better than others in generating a supply of donor organs. It suggests, therefore, that sharing expertise between Member States would help the Community as a whole to "identify the best of the models and support its application throughout the EU, while respecting cultural and organisational diversity."
34. The Commission envisages that this cooperation between Member States would be based on the identification and development of common objectives, agreed quantitative and qualitative indicators and benchmarks, regular reporting, and the identification and sharing of best practices.

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<sup>9</sup> op. cit.

<sup>10</sup> op. cit.

35. The Communication highlights three areas in which such action could be beneficial: increasing the availability of donor organs; raising public awareness of organ donation and transplantation issues; and improving the effectiveness of organ donation and transplantation services.
36. In relation to the availability of donor organs, the Commission points out that, in some Member States, many potential donors are lost because taking organs for transplantation is never seriously considered by the medical staff responsible for the patient. As a result, the option of donation is never presented to the patient's relatives, and no evaluation is made of the suitability of the patient's organs for donation. Sharing information about how to raise the profile of organ donation in the medical context would address the problem.
37. The Communication suggests that public awareness should be raised by improving the knowledge of both health professionals and the media of transplantation issues. People should be encouraged to talk about organ donation within their families and to ensure that their relatives are aware of their wishes about organ donation. According to the Commission, the evidence shows that the members of families who have discussed these issues among themselves tend to be more likely to be willing to donate organs.
38. The Communication goes on to suggest that the creation of a European organ donor card, indicating the willingness of the holder to donate organs, would be a positive factor in raising public awareness and in raising organ donation rates.
39. Health service systems differ widely between Member States, the Commission comments, as a result of their different origins and history. However, even among those countries which have well-developed systems, there are wide differences in the ways they organise organ donation and transplantation services. The organisational models adopted in some Member States seem to stand out for their success in achieving high rates of organ donation and successful transplantation.
40. The Communication comments that the most effective organisational approach appears to be to combine a decentralised network, formed by local organisations which have the roles of promoting organ donation and of procuring donor organs, with a centralised organisation which focuses on ensuring cooperation between local areas in sharing organs and on other matters. Again the sharing of information, about how such models achieve relative success, would be beneficial across the EU.
41. We heard evidence indicating that the Commission's ideas for an action plan for information sharing were widely accepted. The European Parliament's resolution<sup>11</sup> on organ donation and transplantation looks forward to the Commission's action plan, stating that the Parliament "strongly believes that there is significant potential for sharing expertise between Member States in order to increase donor rates and equalise access to transplantation across the EU".
42. Support for the concept of an action plan from the Council of Ministers also seems likely. Ann Keen MP, the responsible UK Minister, told us, "I believe that we can learn from each other" and added, "looking at best practice and

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<sup>11</sup> op. cit.

promoting that is also something that I believe we are very keen to follow and to do” (Q 471).

43. A more detailed account of the evidence we received in relation to the Commission’s proposals for an action plan on organ donation and transplantation is given in chapter 5.

### **Combating organ trafficking**

44. In relation to the issue of combating organ trafficking, the Commission refers to Article 3 of the EU Charter of Fundamental Rights<sup>12</sup> (which states that everyone has the right to respect for his or her physical integrity) and to a range of existing international legal instruments which ban trafficking in human organs and tissues. The Commission states that it bases its actions on these important international instruments and that it will closely monitor any developments in the organ trafficking field both within the EU and worldwide.
45. Few of the witnesses for our inquiry saw the issue of organ trafficking as a serious problem within the EU. In fact, Dr. Eduardo Fernandez-Zincke, Medical Officer in the European Commission’s Directorate of Public Health and Risk Assessment, told us that the cases of this which had been reported in the EU were rare (Q 22).
46. Dr Adamos Adamou MEP, rapporteur to the European Parliament’s Committee that produced the resolution on organ donation, however, did regard this as a problem that the EU should not underestimate. His view was that, in large part, trafficking arose as a result of poverty and deprivation in countries outside the EU, but that the demand for trafficked organs resulted from the shortage of donor organs in both EU countries and elsewhere.
47. Further evidence that we received in relation to organ trafficking and the related phenomenon of “transplant tourism” is reported in chapter 5.

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<sup>12</sup> Charter of fundamental rights of the European Union (2000/c 364/01) Official Journal of the European Communities, 18.12.2000

## CHAPTER 3: SHORTAGE OF DONOR ORGANS ACROSS THE EU

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### Organ transplantation as a medical treatment

48. The Chief Medical Officer for England, Sir Liam Donaldson, told us that organ transplantation had now become an important area of healthcare and medical practice. He added that it was likely to become increasingly important as the population ages and develops more chronic diseases which precipitate the failure of organs. Sir Liam noted, however, that “the disappointment is that it has not been able to fulfil its full potential because of the shortage of donors” (Q 44).
49. Sir Liam referred to three areas of research into possible future means of creating replacement tissue or organs; the use of animal organs, modified genetically or otherwise; the development of mechanical organs; and the prospect of stem cells being produced which could yield tissue capable of being turned into the architecture of an organ (Q 44). He considered, however, as stated in his 2006 Annual Report<sup>13</sup>, that the immediate priority was to increase the supply of donor organs suitable for transplant.
50. When anticipating future demand in a UK context, the Organ Donation Taskforce reported<sup>14</sup> that waiting lists for organ transplants were rising by 8% per year, and that at least 50% more organs were needed than were currently available. Given the ageing of the population, a surge in diseases related to organ failure was anticipated, for example Type 2 diabetes. As a result, a further increase was to be expected in the demand for organs for transplantation.
51. The gap between supply and demand of organs for transplantation is particularly large amongst specific groups within the UK, notably amongst patients of South Asian and African Caribbean origin. Within these groups relatively high levels of need, arising from a high incidence of such diseases as Type 2 diabetes, are coupled with low levels of donation. This issue is discussed in chapter 9.
52. A shortage of organs for transplantation was also acknowledged to be a problem across the EU as a whole. The consequences of this shortage were clear. Dr Eduardo Fernandez-Zincke, Medical Officer at the European Commission, put the total EU figure for people on transplant waiting lists in 2006 at approximately 58,000 (Q 9).

### Organ donation rates

53. Table 1, published by the Commission in the Impact Assessment which accompanied their Communication<sup>15</sup>, compares organ donation rates in 2004 across the 27 EU Member States, as well as in Iceland and Norway. The rates vary from 0.8 donors per million population in Bulgaria to 35.1 donors per million in Spain. In the UK, the donation rate was 12.8 per million. Dr Fernandez-Zincke pointed out that the EU average donation rate of 18.8 per million compared unfavourably with the USA, where the average donation rate was 25.5 per million (Q 8).

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<sup>13</sup> op. cit

<sup>14</sup> op. cit

<sup>15</sup> op. cit Impact Assessment (ps. 22,23)

**TABLE 1****Organ donor rates in EU Member States: 2004 (per million population)**

Austria	24.8	Greece	8.1	Poland	14.5
Bulgaria	0.8	Hungary	18	Portugal	19
Belgium	23.8	Iceland	6.8	Romania	0.5
Czech Republic	20.3	Ireland	17.6	Slovak Republic	12.1
Cyprus	8.9	Italy	21	Slovenia	10.5
Denmark	11.9	Latvia	20	Spain	35.1
Estonia	26.9	Lithuania	10.2	Sweden	14.2
Finland	16.2	Luxembourg	6	The Netherlands	14.6
France	22.2	Malta	10	United Kingdom	12.8
Germany	14.8	Norway	16.5		

Source: European Commission Communication on Organ Donation and Transplantation: Policy actions at EU level: Impact Assessment (page 23).

54. Table 2, also shown in the Commission's Impact Assessment<sup>16</sup>, puts the organ donation rates listed in Table 1 in context by showing the numbers of patients in each country who, in 2005, were waiting for a kidney transplant.

**TABLE 2****Kidney transplant waiting lists in EU Member States: 2005**

Austria	826	Greece	775	Poland	1105
Bulgaria	36	Hungary	939	Portugal	N/A
Belgium	955	Iceland	N/A	Romania	1512
Czech Republic	343	Ireland	N/A	Slovak Republic	741
Cyprus	N/A	Italy	8688	Slovenia	81
Denmark	384	Latvia	354	Spain	4152
Estonia	29	Lithuania	434	Sweden	503
Finland	272	Luxembourg	11	The Netherlands	1088
France	5932	Malta	N/A	United Kingdom	7126
Germany	8853	Norway	174	TOTAL	45313

Source: European Commission Communication on Organ Donation and Transplantation: Policy actions at EU level: Impact Assessment (page 21)

55. Despite the variation in donation rates across the EU, the Commission makes clear in its Communication that, even in Member States where there have been sustained increases in the number of donors, it is very difficult to reduce the numbers of patients waiting for transplants and the time they spend on waiting lists. It concludes, therefore, "The severe shortage of organ donors remains the main challenge that EU Member States face with regard to organ transplantation".

<sup>16</sup> op. cit Impact Assessment (p. 21)

### Acquiring organs for transplant

56. Organs for transplantation can be acquired via three routes—live donation, post mortem donation after brainstem death (DBD) and donation after cardiac death (DCD—also referred to as non-heart beating donation). Table 3, published by UK Transplant, shows the numbers of transplants in the UK from each category of donor during 2006. The Table also shows the total numbers of patients on the active national transplant list who were waiting for transplants.

**TABLE 3**

**Numbers of patients on waiting lists for transplants; numbers of transplants from deceased donors (shown separately for heartbeating and non-heartbeating) and from living donors: UK, 2005 and 2006**

Organ	United Kingdom			Rep of Ireland		
	2005	2006	% change	2005	2006	% change
<b>Patients on waiting lists for transplants</b>						
Kidney	5660	6190	8	-	-	-
Kidney & Pancreas	76	141	86	-	-	-
Pancreas	53	53	0	-	-	-
<b>Total Renal*</b>	<b>5789</b>	<b>6384</b>	<b>10</b>	<b>-</b>	<b>-</b>	<b>-</b>
Heart	96	83	-14	-	-	-
Heart & Lung	41	37	-10	-	-	-
Lung(s)	257	272	6	-	-	-
<b>Total Thoracic*</b>	<b>394</b>	<b>392</b>	<b>-1</b>	<b>-</b>	<b>-</b>	<b>-</b>
Liver	360	326	-9	24	29	21
<b>Total List</b>	<b>6543</b>	<b>7102</b>	<b>9</b>	<b>24</b>	<b>29</b>	<b>21</b>
<b>Transplants from Deceased Donors</b>						
Kidney	1197	1240	4	121	137	13
Kidney & Pancreas	102	138	35	5	4	-
Pancreas	15	25	67	0	0	-
<b>Total Renal</b>	<b>1314</b>	<b>1403</b>	<b>7</b>	<b>126</b>	<b>141</b>	<b>12</b>
Heart	147	156	6	11	14	27
Heart & Lung	8	3	-	0	0	-
Lung(s)	129	119	-8	3	9	-
<b>Total Thoracic</b>	<b>284</b>	<b>278</b>	<b>-2</b>	<b>14</b>	<b>23</b>	<b>64</b>
Liver/Liver Lobe	584	616	5	55	64	16
Other Multi-organ	15	22	47	1	1	-
<b>Total Solid Org. T/plants</b>	<b>2197</b>	<b>2319</b>	<b>6</b>	<b>196</b>	<b>229</b>	<b>17</b>
Cornea	2443	2479	1			



	2005	2006	% change	2005	2006	% change
<b>Transplants from Living Donors</b>						
Kidney	543	671	24	2	4	-
Heart (domino)	0	0	-	0	0	-
Liver/Liver Lobe	8	9	-	0	0	-
Lung Segment	0	0	-	0	0	-
<b>Total Transplants</b>	<b>551</b>	<b>680</b>	<b>23</b>	<b>2</b>	<b>4</b>	<b>-</b>
<b>Deceased Donors</b>						
Heartbeating	630	633	0	71	85	20
Non-heartbeating	122	146	20	0	0	-
<b>Total Donors</b>	<b>752</b>	<b>779</b>	<b>4</b>	<b>71</b>	<b>85</b>	<b>20</b>
Cornea only	1683	1927	14			

Note: Cardiothoracic and renal transplant lists for the Republic of Ireland are not routinely reported to UKT. The statistics are those recorded on the National Transplant Database as at 30 May 2007 and might be subject to slight modification.

Source: UK Transplant Active national transplant list: Yearly up-date to end 2006

[https://www.uktransplant.org.uk/ukt/statistics/calendar\\_year\\_statistics/pdf/yearly\\_statistics\\_2006.pdf](https://www.uktransplant.org.uk/ukt/statistics/calendar_year_statistics/pdf/yearly_statistics_2006.pdf)

### Living donation

57. The Communication recommends 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.”
58. Dr Chris Rudge, of UK Transplant, informed us that living donor kidney transplantation has been established in the UK for many years, as is the case in most EU Member States. The number of such transplants had more than doubled in the UK in the past 5–6 years, to approximately 700 per year (pp 26–30). Dr Anthony Warrens, British Transplantation Society, added, “the outcome following living donation is better than the outcome following cadaveric donation, even if the living donor is not particularly well matched” (Q 243).
59. The Human Tissue Authority (HTA) explained their role in managing living donation in the UK. Under the Human Tissue Act 2004<sup>17</sup>, all donors and recipients had to be individually assessed by a local independent assessor, who was trained and accredited by the HTA to act on behalf of the donor. The independent assessor ensured that the donor and recipient had an appropriate relationship; that the donor fully understood the risks which donation involves; that the donor was not under any pressure to donate; and that consent had been given freely and voluntarily (Q 359, pp 145–148).
60. The British Transplantation Society (BTS), the National Kidney Federation and the Royal College of Physicians all stressed the importance of developing live donation as a response to the shortage of certain organs, kidneys in particular (pp 94–97, pp 227–228, pp 239–242). The BTS thought that

<sup>17</sup> See [http://www.opsi.gov.uk/acts/acts2004/ukpga\\_20040030\\_en\\_1](http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1)

support should be given to altruistic, unrelated donation including “paired” donation, “pooled” donation and “non-directed” donation (pp 94–97). These terms were explained as follows.

61. “Paired” donation, according to the HTA, occurred when a donor and recipient, who are connected to each other, but whose blood groups or tissue types were mismatched or incompatible, were paired with another donor and recipient in the same situation. (pp 145–148).
62. “Pooled” donation, according to Mr Rigg of the BTS, occurred when more than one pair of donors was involved (Q 220). He said that at least 30 to 50 pairs of donors were needed in a “pool” in order to generate a reasonable chance of finding successful organ matches for transplantation (Q 245).
63. “Non-directed altruistic” donation, according to the HTA, involved a donation by a person who did not have a relationship with the recipient. In such cases a psychiatric assessment of the donor was required (pp 145–148).
64. UK Transplant commented on paired donation and drew attention to the potential benefit of EU cooperation in relation to this approach in the case of kidney transplants. Such cooperation could generate more pairs of donors in a pool which would increase the chances of finding a suitable exchange (pp 26–30).
65. Mr Peter Lemmey, Director of Policy at the HTA, pointed out that, while different forms of living donation were a means of increasing the supply of donor organs, such donations were never likely to be numerous. He added, however, that the “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 50 per year” (pp 145–148).

### Donation after brain stem death

66. The mainstay of donation in the UK has been donation after the diagnosis of brain stem death (DBD). However, the January 2008 report of the Organ Donation Taskforce<sup>18</sup> stated that, between 2000 and 2006, the annual number of such donations in the UK fell from 739 to 633.
67. The medical criteria for identifying brain stem death are well established, and Sir Liam Donaldson, Chief Medical Officer for England, supplied us with a document, prepared on behalf of the Intensive Care Society (p 40), which set out guidelines for the certification of death by brain stem testing<sup>19</sup>. This document stated that, in addition to their wide acceptance by the medical profession across the world, “the criteria for the diagnosis of brain stem death have also been adopted by the courts in England and Northern Ireland for the certification of death”.

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<sup>18</sup> op. cit

<sup>19</sup> According to the Intensive Care Society document, brain stem death is diagnosed in three stages:

1. It must be established that the patient has suffered an event of known cause resulting in irreversible brain damage with apnoeic coma, i.e. the patient is deeply unconscious, mechanically ventilated with no spontaneous respiratory movement.
2. Reversible causes of coma must be excluded.
3. A set of bedside clinical tests of brain stem function are undertaken to confirm the diagnosis of brain stem death.

68. Despite this background, there are still a limited number of groups and individuals who disagree with this way of defining and confirming death as a replacement for the traditional process of establishing that there is no heartbeat and that breathing has stopped. Dr David Hill, a retired consultant anaesthetist, put it like this, “death can only be assured by complete cardio-pulmonary failure over a period of time and at normal temperature” (pp 223–225). Dr David Evans, a consultant cardiologist, also took this view, asserting that “so-called ‘brain stem dead’ patients who are designated as organ donors are self-evidently alive” (pp 213–216). The views of faith groups on this issue are reported in chapter 10.
69. A view, more in line with the mainstream of opinion, was expressed by the Patient Liaison Group of the Royal College of Surgeons (England), who identified the need for more public education about the concept of brain stem death in order for organ donation from such patients to be more widely accepted. They took the view that “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” (pp 48–52).
70. Mr Keith Rigg, British Transplantation Society, told us that the Academy of Medical Royal Colleges (AMRC) was working on an up-dated Code of Practice for the diagnosis of death (Q 241). We subsequently heard from Dr Martin Smith, a consultant in neuroscience critical care at University College London Hospitals who was involved with this work, that the AMRC code had been agreed some time ago but was awaiting the endorsement of the Department for Health before it could be published (pp 250–251).
71. Dr Smith explained that the code agreed by the AMRC consisted of two parts: the first dealing with the diagnosis of death; and the second with related issues affecting organ donation. While the code did not alter any essentials of the existing guidance for the diagnosis of brain stem death, it did provide additional clarification in some areas which had been a cause for concern. Dr Smith added that the code also included, for the first time, guidance on the diagnosis of death by cardiovascular criteria.

### **Donation after cardiac death**

72. Donation after cardiac death, or non-heart beating donation, takes place from donors who have suffered a cardio-respiratory arrest sometimes, but not always, subsequent to the withdrawal of treatment. The Organ Donation Taskforce reported<sup>20</sup> that, after specific support from UK Transplant, between 2000 and 2006 there was an increase in the annual number of such donations from 38 to 146.
73. Dr Paul Murphy, Leeds General Infirmary, told us that post cardiac death organ donation (NHBOD) most commonly occurred after the planned withdrawal of life-sustaining therapies for patients in intensive care units, for whom there was no prospect of recovery. In order for a donation to occur, a surgical team had to be assembled (usually from another hospital), and only when they were ready could treatment be withdrawn. This inevitably meant

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<sup>20</sup> op. cit

that the patient might have to be maintained on therapies, which would otherwise have been withdrawn because there was no hope of preserving life, purely to maintain the organs in a suitable state for transplantation (pp 122–132).

74. Against this background, Dr Murphy emphasised to us, “The committee should recognise that many ICUs are resistant to the introduction of NHBOD—certainly in the absence of a binding and authoritative statement on the ethico-legal probity of the process”.
75. Once again, the situation across the EU differs widely with regard to donation after cardiac death, with the UK having one of the most permissive regimes in this regard. According to the Impact Assessment which accompanied the Commission’s Communication<sup>21</sup>, Croatia, Germany, Hungary and Poland legally prohibit the practice. Moreover, while it is legally permitted in other Member States, some countries have not developed any programme to implement such donations, notably, Italy, Portugal, and France.

### Cross border donation

76. Dr Chris Rudge, UK Transplant, supplied us with the statistics shown in Table 4 which show the extent to which organs were exchanged between the UK and other countries during a recent 12 month period.

**TABLE 4**

**Solid organs exchanged between the UK and other countries:  
April 2006 to March 2007**

	Ireland	Other countries	Total
(a) Overseas to UK			
Organs offered to the UK by other countries	95	118	213
Organs transplanted which were offered to the UK	34	13	47
(b) UK to Overseas			
Organs offered by the UK to other countries	219	14	233
Organs transplanted which were offered by the UK	12	6	18

*Source: Based on tables supplied by UK Transplant from the National Transplant Database*

77. Responding to the Commission’s view, which we report in chapter 2, that the exchange of organs across internal EU borders was a good way to increase the size of the donor pool, Mr Keith Rigg, British Transplant Society, identified the problem of transporting such shared organs. He told us that “one of the concerns, if you start to share between more countries, is the actual time that is involved ... 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” (Q 220).

<sup>21</sup> op. cit (see the table on p. 34 of the Impact Assessment)

78. Dr Adamos Adamou MEP, rapporteur to the European Parliament Committee commenting on the Commission's proposals, took a similar view, but suggested that there was scope for neighbouring countries to cooperate. He explained, "There is a time limit. It does not make any sense to transport one organ from Cyprus to London or to Sweden. What we are 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" (Q 443).

### **The human and economic cost of organ scarcity**

79. Several witnesses provided powerful accounts of the human cost of the current shortage, as well as inspiring stories of lives saved and enhanced by donation. The National Kidney Federation, for example, pointed out that "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" (pp 227–228).
80. Mr Gordon Nicholas, who described himself as "a patient of some 30 years, on dialysis and then transplanted, for 12 years now back on dialysis", wrote to tell us of the way his life had been transformed by transplantation, saying, "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. Transplantation gave me back my life; dialysis gives me eight years to live" (p 233).
81. The Organ Donation Taskforce's report<sup>22</sup> of January 2008 included an assessment of the economic case for increasing donation rates. They reported that in the UK the average annual cost for treating kidney failure by dialysis is £23,177 per year. This compared with an initial cost of £42,025 for a kidney transplant followed by annual costs for care of £6,500.

### **Conclusions**

82. The shortage of organs available for transplant both in the UK and across the EU is a serious public health problem which has significant human and economic costs. (paras 48–52; 79–81)
83. In the UK, the organ donation rate lags substantially behind not only the best achieved in the EU, but also the overall EU average rate. (paras 53–55)
84. All forms of donation—living donation, donation after brain-stem death and donation after cardiac death—have the potential for increases in volume, although brain-stem death donation is the principal source. There are ethical and legal uncertainties relating to donation after cardiac death which limit its acceptability among medical practitioners. (paras 56–75)
85. While the criteria for the definition of brain stem death are widely accepted across the medical profession, there are some aspects on which clarification would be valuable. The work of the Academy of Medical Royal Colleges (AMRC) to develop an up-dated Code of Practice for the diagnosis of death is therefore most timely, although its publication appears to be awaiting endorsement from the Department of Health. (paras 69–71)

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<sup>22</sup> op. cit

86. There are practical limitations, largely arising from the deterioration in the quality of a donated organ during its travel from donor to recipient, to the practical extent of cross-border donation within the EU. Nevertheless, there is a potential for expanding the numbers of such donations between neighbouring Member States. (paras 76–78)

### **Recommendations**

87. **We recommend that the Government should support the work of the European Commission in seeking to raise the profile of organ donation issues across the EU and in seeking ways to reduce the shortage of organs for transplantation.**
88. **We recommend also that the Government should act urgently to address the shortage of organs for transplantation in the UK by taking measures which will significantly increase organ donation rates over the next five years.**
89. **We recommend that the Government should address the ethical and legal issues which currently limit the extent to which donation after cardiac death is accepted across the medical profession.**
90. **We recommend that the Commission should pursue their ideas for increasing the supply of suitable organs for transplantation by encouraging Member States to improve the arrangements for donation across internal EU borders. These arrangements should take account of the impracticality of successful donation in cases for which the time to transport the organ between donor and recipient would be too long.**
91. **We welcome the completion of the work by the Academy of Medical Royal Colleges (AMRC) to produce an up-dated Code of Practice for the diagnosis of death. We urge the Government to expedite the publication of this badly needed new guidance and to draw it to the attention of the European Commission.**

## CHAPTER 4: PROPOSED EU DIRECTIVE RELATING TO ORGAN QUALITY AND SAFETY

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### Quality and Safety

92. In 2004, an EU Directive<sup>23</sup> was introduced in order to provide assurance on quality and safety standards in relation to the medical use of blood, tissues and cells. The Commission's Communication envisages that this approach would be taken also in relation to organ donation and transplantation.
93. Ms Triona Norman, Transplantation Policy Lead at the Department of Health, described the Commission's work to develop firm proposals for a directive as being in a "pre-publication phase where we are still looking to see what could go in the minimum standards" (Q 113). Box 1 outlines the framework currently envisaged by the Commission for a directive.

### BOX 1

#### Proposed framework for a directive on the quality and safety of organ donation and transplantation

- A number of measures can be introduced into every stage of the transplant process in order to improve the quality and safety of organs.
- 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.
- The maintenance of donor records and quality systems has been identified as key steps towards quality and safety. Standard procedures for procurement and requirements for organ preservation and transport must be in place.
- Effective transportation of organs which minimises ischaemic times<sup>24</sup> and avoids organ damage must be ensured. While maintaining medical confidentiality, the organ container must be clearly labelled and must contain the necessary documentation.
- The transplant system must ensure traceability from donor to recipient(s). The system must have the capacity to alert of an unexpected complication. A system must be in place to detect and investigate serious or unexpected adverse events.
- Many times an organ donor is also a tissue donor. Quality and safety requirements for organs shall complement and be linked with the existing community system for tissues and cells. An adverse reaction in the recipient of an organ should be traced and reported on the tissue vigilance system if needed.
- The key role of national competent authorities in ensuring the quality and safety of this process has been stressed, as well as the importance of establishing systems for the authorisation of establishments and programmes of organ donation and procurement based on common quality and safety criteria. This system would provide a complete list of authorised centres throughout Europe, accessible to the public and professionals.
- Binding safety and quality criteria should not have as a consequence a reduction in the actual number of donors. It is important to have a clear understanding of the disease transmission risk inherent in each case. Although a definition of risk based upon the donor's profile is critical to rational decision-making, each decision also depends upon the recipient's characteristics. In every case there is a balance of risks and benefits to be considered: the risk associated with the organ versus the consequences of not getting a transplant.

*Source: Commission Communication: Organ donation and transplantation: policy actions at EU level, May 2007*

<sup>23</sup> op.cit

<sup>24</sup> The periods during which donated organs are deprived of an oxygen supply during their transportation to the transplant recipients

94. Dr Fernandez-Zincke, EU Commission, stated that the risks of spreading disease through organ donation were real as opposed to theoretical, and reported that Europe had already witnessed the transmission of Human immunodeficiency virus (HIV), Human T-lymphotropic virus (HTLV), malaria, rabies and malignant neoplasms from donor to recipient. He argued that to address these risks a legal framework was necessary that would establish basic levels of quality and safety at Community level (Q 2).
95. Dr Fernandez-Zincke went on to assure us that “the intention of the Commission is not to interfere in the clinical decision” relating to organ donation (Q 5). He explained that the Commission recognised the enormous shortage of donor organs for transplantation in all EU Member States and emphasised that “quality and safety principles which are basic and which are important should always take this into account in the area of organ transplantation” (Q 2).
96. Ms Norman accepted the case for an EU directive stating, “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” (Q 112).
97. Ms Norman went on to say, however, that the Department of Health (DH) did have concerns about the level of detail that a directive might contain and about its possible incompatibility with current UK arrangements and operating procedures. They had drawn these concerns to the notice of the Commission. She emphasised that any directive needed to be the minimum necessary to achieve its purpose and that it should not “gold plate” what the UK was trying to do (Q 112).
98. Ms Norman explained that the Department recognised that implementation of a directive would add to costs of regulation and stated that, “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” (pp 41–42).
99. The introduction of an EU directive was supported by Lord Patel, Chairman of the National Patient Safety Agency (NPSA), who reported that the NPSA received a significant number of reports of patient safety incidents relating to organ donation and transplantation. He considered that it was important to introduce an EU-wide safety checklist “so that every time there is a donation or recipient, that checklist is gone through”. He also saw the value of an EU-wide reporting system of all patient safety incidents in relation to donation and transplantation (Q 344).
100. The Royal College of General Practitioners also saw merit in a directive stating, “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” (pp 236–237).
101. While Dr Adamos Adamou MEP agreed that standards of safety were not the same across the EU and that measures to bring them all up to the best standard would be a good thing (Q 433), he thought it “a bit unfair to pinpoint certain Member States and blame their health systems and praise others” (Q 432).



### Balancing safety and quality standards with increasing organ donation

102. A number of witnesses expressed the view that there should be a balance between the potentially competing requirements of imposing new standards of quality and safety and of increasing the donor pool.
103. UK Transplant pointed out that whereas a sufficient supply of blood, tissues and cells can be maintained at the same time as applying the highest levels of quality and safety, for organs there is a potential conflict between these two aims. For organs, the available supply falls short of the demand for transplantation, with the result that, across the EU, thousands of patients die each year because an organ is not available. If standards of quality and safety which are too high had to be applied in order to conform to the provisions of an unsuitable directive, then some organs judged clinically acceptable for donation might have to be rejected (pp 26–30).
104. UK Transplant went on to say that, in the UK, there is clear guidance on the risks that may be associated with donated organs, but a recognition that the final decision about whether to transplant a particular organ must rest with the clinician, the patient and the patient's family. Their view was that, while 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 the introduction of a directive which gave excessive priority to safety and quality at the cost of reducing further the number of available organs that are suitable, according to clinical judgement, for transplantation (pp 26–30).
105. UK Transplant emphasised that the risks associated with a given organ may be deemed unacceptable for one recipient, who can afford to wait for a better quality organ, but entirely acceptable for a second recipient for whom the almost inevitable alternative, if the organ is declined, is death (pp 26–30).
106. Mr Keith Rigg, on behalf of the British Transplantation Society, considered that it was important to be able to learn from each other across the EU, and to learn from good practice in relation to quality and safety. However, he emphasised the need to focus on increasing the supply of organs for patients waiting for transplants, stating, "I think there are minimum standards for quality and safety and we all need to maximise knowledge about organ donation so that people can make a choice and hopefully we can meet the needs of the many people who are waiting for organs" (Q 254).
107. Dr Magi Sque, Senior Lecturer, University of Southampton School of Nursing, expressed a different reservation about the suggested directive, stating that it was important that this should be enabling rather than constraining, and that it should take account of cultural sensitivity. She felt that "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 this could waste precious organs" (Q 208).

### Safety and quality within the UK

108. Several witnesses, including Mr Peter Lemmey of the Human Tissue Authority, and Dr Vivienne Nathanson, Head of Science and Ethics at the British Medical Association (BMA), felt that safety and quality standards in the UK were already high (QQ 369, 388).

109. Mr Lemmey stated, “I do not think that there 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 National Patient Safety Agency (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” (Q 369).
110. Dr Nathanson shared this view and asked, in reference to the introduction of a directive, “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?” (Q 388)

### “Gold plating”

111. Mr Lemmey argued that the directive should be both practical and flexible (pp 145–148). On the basis of his experience with the Tissue and Cells Directive he believed that that “too much detail in Directives can sometimes be a hazard” (Q 370). Mr Lemmey also stated that his experience with the dual licensing system, which had been required in the UK in order to make it possible to implement the EU Tissue and Cells Directive alongside the UK’s 2004 Human Tissue Act, suggested to him that the Commission could, and should, make more effort to develop a future directive on organ donation in a way that would be compatible with the legislation of individual Member States (Q 374).
112. Clinicians expressed concern that the approach taken to imposing and monitoring levels of quality and safety could theoretically jeopardise the supply of organs. The British Transplantation Society (BTS), while accepting the need to ensure safety, did not want “inappropriately onerous restrictions” to result in more deaths on the waiting list (pp 94–97). The British Medical Association was also concerned about the potential administrative and regulatory burden a directive might impose. If this were too great, they thought, it might unhelpfully divert resources away from transplantation and patient care (pp 165–169).
113. These views were supported by Ms Norman, Department of Health, who told us, “Many Member States, including the UK, already have high quality systems for the identification, testing, procurement, allocation and distribution of organs procured for transplant” (pp 41–42).
114. Ms Norman acknowledged that the appropriate level of detail that a directive should usefully include would be an issue to negotiate with EU colleagues. She expressed confidence that she had established good working relationships within which to do this (Q 112).
115. Dr Adamos Adamou MEP pointed out that common safety standards could have the effect of increasing organ availability by encouraging confidence in a greater volume of cross-border organ donations between Member States. However, he shared the caution expressed by others regarding the exact content and implementation of a directive (Q 431).

### Clinical judgement

116. A number of witnesses, including clinicians working within the transplant field, were particularly keen to stress that clinical judgement and the ability of the patient to make an informed choice should not be inhibited by the introduction of an over elaborate directive. Individual clinicians and patients

should be allowed to make the final decision regarding the suitability for donation of a particular organ in a particular case.

117. Mr John Forsythe, an experienced surgeon, wrote, “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” (pp 216–223). Dr Vivienne Nathanson, BMA, acknowledged the value of some EU directives but warned, “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’” (Q 386).
118. Dr Nathanson’s concerns were echoed by Ms Lesley Bentley, Lay Chair of the Patient Liaison Group of the Royal College of Surgeons, who, while emphasising that it was important for patients to be able to assume acceptable levels of safety and quality (Q 152), suggested that, if a patient has a lot of difficulty in finding an organ, an organ of less than the highest quality might be considered (Q 154). She emphasised that the patient should have the opportunity to talk through this type of issue with the doctor (Q 157).
119. The DH Minister, Mrs Ann Keen MP, recognised clearly the concern that, in the context of applying a directive relating to quality and safety, it would be important to maintain the flexibility for clinicians to exercise their medical judgement. She told us, “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 judgement for themselves and not necessarily follow the directive” (Q 469).
120. Dr Adamou MEP was able to confirm that these concerns were shared by his European Parliament colleagues. He explained the position in the following terms. “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” (Q 439).

### Conclusions

121. We are persuaded that the introduction of a European directive, on the quality and safety of organ donation and transplantation, would be a valuable measure for helping potential organ recipients to feel confident in the basic quality of an organ and the safety of procedures wherever in the EU an organ had been donated and wherever transplantation was to take place. Given the relatively low levels of cross border donation, for most recipients this would translate into confidence in their national systems, but for hard-to-match recipients or patients living in countries other than their own, it would mean that they should feel confident to accept any organ offered by an EU Member State. (paras 92–101)

122. We share and underline the concerns of several of our witnesses, however, that a directive should not introduce stringent or overly-bureaucratic requirements beyond those which are clinically justified. There needs to be sufficient flexibility in a directive to allow scope for clinical judgment and informed patient choice to be applied, particularly where existing systems are working well. (paras 102–115)
123. In particular, we were convinced by the case made to us that clinicians and patients together must have the freedom to make informed decisions about the balance between the acceptable quality of organs to be transplanted and the medical needs of the patient. An organ deemed of insufficient quality for a patient who can afford to wait longer for a transplant may be judged suitable for transplant to a patient who, without it, would have a high risk of imminent death. (paras 116–120)

### **Recommendations**

124. **We recommend that the Government should support the introduction of an EU directive on the quality and safety of organ donation and transplantation in a form which provides minimum standards across the EU, but is not overly bureaucratic and which does not impose requirements beyond those which are clinically justified.**
125. **We recommend further that the Government should seek to ensure that the directive allows sufficient flexibility for decisions, about the quality of organs to be used for transplantation, to be informed by soundly based clinical judgement of the medical urgency of need of the patient and informed patient choice.**

## CHAPTER 5: PROPOSED EU ACTION PLAN FOR COOPERATION ON ORGAN DONATION

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126. While, as described in chapter 4, there were mixed views about the need for an EU directive on quality and safety, and significant concerns about its exact content, there was a greater degree of consensus about the potential benefits of an EU action plan for cooperation on organ donation across the Community.

### Greater cooperation between EU Member States

#### *Best practice*

127. UK Transplant took the view that there would clearly be advantages in greater cooperation across the EU in the sharing of experience and the more general introduction of best practice. While the scientific and clinical communities internationally already share knowledge and expertise regularly and constructively, there would be clear benefits to extending this collaboration (pp 26–30).
128. Professor Margot Brazier, Centre for Ethics and Social Policy, University of Manchester, stated, “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” (pp 161–164).
129. She went on to observe, “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 organ donation (e.g. 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” (pp 161–164).

#### *Potential donors*

130. UK Transplant drew specific attention to the benefit of sharing good information, in a standardised format, on the identification and referral of potential donors and the consent rate for donation stating, “this is one of the many areas where accurate and comparable data are essential”. They felt, “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” (pp 26–30).

#### *Diagnosis of death*

131. UK Transplant thought that consideration should be given to standardisation of the diagnosis of death by neurological and cardiovascular criteria across the EU stating, “This would prevent national differences in

diagnosis impeding cross EU cooperation in organ donation.” UK Transplant also suggested that 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 Member States (pp 26–30).

#### *Transplant outcomes*

132. Dr Magi Sque, University of Southampton, shared Mr Rudge’s view about the benefits of information sharing, stating, “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” (Q 208).

#### *Management information*

133. Mr Peter Lemmey, HTA, commented on the need for the sharing of management information relating to organ donation services. He said, “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. I think 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” (Q 377).

#### *Action plan overall*

134. A dissenting view was put forward by Dr Nathanson of the BMA who stated, “The truth is that we see very little benefit from having a European centre of bureaucracy around this” (Q 391). Dr Jackie Long, of the Royal College of Physicians and Surgeons of Glasgow, shared this view when she wrote, “At a medical level we already exchange expertise through our professional organisations and I don’t see that the EU would improve that” (pp 242–246).
135. In contrast, the DH Minister, Mrs Ann Keen MP, saw the action plan as an opportunity for the UK to both educate and learn from other Member States. In response to our question about whether an action plan would add value for the UK, or whether the UK would just pass information to others, she replied: “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 high quality, a very high standard, of which we are very proud. But there is always scope, I am sure, in particular for the training of professionals, and how other cultures might look at it is something we should be open to” (Q 472).

#### *Public Awareness*

136. We found significant support for increasing public awareness of organ donation both to encourage donation across the EU and to inform potential donors and their families of what was entailed in donation. There were

differences of opinion as to how this could best be achieved, and it was recognised that there might be a tension between these two goals.

137. Drs Sque and Long, University of Southampton, argued, “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” (pp 75–79).
138. The Cystic Fibrosis Trust’s view was that “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” (pp 212–213).
139. UK Transplant also strongly advocated the need for raising public awareness, stating, “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” (pp 26–30).
140. The BMA agreed that “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” (pp 165–169).
141. In considering their own role in increasing public awareness, the Christian Medical Fellowship concluded that, in order to raise the numbers of Christians on the donor register, “more teaching should be given within the Christian church to support the principles of organ donation and transplantation” (pp 261–263).
142. Dr Paul Murphy, Leeds General Infirmary, while he felt that the evidence for the sustained effectiveness of publicity campaigns in the UK was not convincing, thought that efforts to increase public understanding of donation and transplantation were to be encouraged, particularly when incorporated into educational programmes such as the National Curriculum (pp 111–113). The need to focus on education in schools about organ donation was also a key element of the evidence from the Jeannette Crizzle Trust (p 43).
143. Based on his experience in Spain, Dr Rafael Matesanz believed that while he did not oppose publicity campaigns, they were expensive and his view was that any available funding in relation to organ donation would be better invested in the hospital system and in skills and training (QQ 332, 334).
144. Despite these reservations, we took the view that previous Government publicity campaigns relating to health issues, for example those addressing AIDS and cigarette smoking, had made a significant impact. We recognised, however, that a publicity campaign relating to organ donation could only be effective if the organisational infrastructure were in place to take advantage of any impact that a campaign might have in increasing donation rates.

145. Against this background, we pursued the issue of whether a campaign relating to organ donation would be funded by the Government. Ann Keen MP, the DH Health Minister, felt that this was a very important issue and Elisabeth Buggins, Chair of the Organ Donation Taskforce, confirmed that a budget of £4.5 million over two years had been allocated for raising public awareness as part of the funding for implementation of the recommendations<sup>25</sup> of the Organ Donation Taskforce for the re-organisation of services in the UK (QQ 503, 504).

### Organ trafficking

146. Dr Sque and Dr Long drew attention to the Council of Europe's<sup>26</sup> report<sup>27</sup> on organ trafficking<sup>28</sup> in relation to collaborative European action in this area. That report stated that Council of Europe Member States had a common responsibility to deal openly with the problem of organ trafficking nationally, but also through multilateral cooperation at the European level. Drs Sque and Long suggested that EU level intervention to develop a "rigorous and orchestrated" response to organ trafficking would be welcome (pp 75–79).
147. Dr Sque went further in giving her opinion on how organ trafficking might be tackled, stating, "I think that certainly both within 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" (Q 210).
148. The British Transplantation Society (BTS) shared the concern of the Commission about organ trafficking. It took the view that the best response to this problem, and the related problem of transplant tourism,<sup>29</sup> was to improve the supply of organs within the high quality, regulated health care systems of the EU so that the incentive for people to travel abroad for organs was greatly reduced (pp 94–97).
149. The BTS went on to advise that "All Member States should develop appropriate protocols to eliminate the possibility of undue inducement or coercion and ensure informed donor consent" (pp 94–97).
150. The National Kidney Federation, however, expressed the view that people involved as patients in illegal trafficking should not be made criminals "as they do it to save their own lives—or at least try to" (pp 227–228).

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<sup>25</sup> See Box 2 in chapter 6.

<sup>26</sup> The Council of Europe is a distinct non-EU body and should not be confused with EU European Council. Founded in 1949, it has 47 members and seeks to develop throughout Europe common and democratic principles based on the European Convention on Human Rights and other reference texts on the protection of individuals.

<sup>27</sup> Council of Europe Parliamentary Assembly Doc. 9822, 3 June 2003, *Trafficking in organs in Europe*, Report of the Social, Health and Family Affairs Committee, Rapporteur: Mrs Ruth-Gaby Vermot-Mangold

<sup>28</sup> The Commission Communication (op. cit.) provides an explanation of the context in which the term "organ trafficking" is defined stating, "Article 3 of the EU Charter of Fundamental Rights states that everyone has the right to respect for his/her physical integrity. Moreover, the Charter contains the prohibition of making the human body and its parts as such a source of financial gain (Article 3(2)), and the prohibition of trafficking in human beings (Article 5(3)). As part of the general phenomenon of trafficking in human beings, trafficking for the purpose of the removal of organs constitutes a serious violation of the freedom and physical integrity of its victims"

<sup>29</sup> The practice whereby citizens needing a transplant travel outside the EU to obtain organs



151. Chris Rudge, UK Transplant, drew a clear distinction between organ trafficking and organ tourism and the legitimate and proper situation in which some patients now resident in this country travel to their country of origin for a transplant from a family member as a donor (Q 127). In the case of illegal trafficking, however, he agreed that the EU had a role to play in spreading good and correct practice, both in legal terms and in structural terms (Q 126).
152. Dr Fernandez-Zincke, EU Commission, did not see organ trafficking in the European Union as a major problem. He considered that the first priority of the Commission in this area was to collaborate with the competent authorities in the Member States. He went on to say that the Commission recognised the problem of organ tourism by EU citizens. It was working together with the World Health Organisation and with the Council of Europe in order to monitor the extent of this. He concluded, “Probably where we can play a role is to try to agree with Member States common national positions regarding this problem” (Q 22).
153. Dr Adamos Adamou MEP took the view that “a mechanism of traceability should be put in place so as to prevent trafficked organs from entering the European Union” (Q 456). The Impact Assessment which accompanied the Commission’s Communication addressed this issue stating, “It is important to ensure that all transplanted material can be traced forward to recipients and back to the donor. It is mandatory to inform the relevant contacts of donors or other recipients about potential problems coming to light after transplantation, when relevant to their health. Twenty-five of the countries surveyed have a national register containing data on the origin and destination of the organs; in 18 of these countries this register is legally binding”.<sup>30</sup> A mechanism for ensuring a comprehensive system for ensuring the traceability of organs from donor to recipient across all Member States forms part of the proposed framework for a Community directive on organ quality and safety.<sup>31</sup>

### European Donor Card

154. The Welsh Kidney Patients’ Association and the Kidney Wales Foundation supported the Commission’s proposal for a European Donor Card<sup>32</sup> believing that this could lead to an increase in the number of donated organs (pp 43–46, pp 251–254.). The Welsh Kidney Patients’ Association felt, however, that this “should be in addition to, and not instead of, individual Member States’ organ donor cards” (pp 251–254).
155. Dr Adamos Adamou MEP reported that the European Parliament had given support to the idea of a European donor card in its resolution<sup>33</sup> on the Commission’s Communication as something which should be complementary to the existing systems of Member States (Q 446). Dr Adamou’s colleague Ms Pavlou stated, however, that “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” (Q 447).

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<sup>30</sup> op.cit. Impact Assessment p.19

<sup>31</sup> See Box 1 in chapter 4

<sup>32</sup> An organ donor card in a format that would be recognised across all EU Member States

<sup>33</sup> op. cit

156. A rather less positive view of the benefits of an EU donor card was taken by Mr Chris Rudge, UK Transplant. In relation to the UK's NHS Organ Donor Register and its predecessor the donor card, his view was that "both 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)" (pp 26–30).
157. Mr Rudge went on to question how an EU donor card could sit easily alongside national systems, particularly in those Member States with presumed consent legislation. His view was that such a card might be most effective as a simple record of the wishes of the individual. If it were intended as proof of legally valid consent, however, he thought, "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" (pp 26–30).
158. Other witnesses also had little enthusiasm for the idea. Dr Paul Murphy, of the Leeds General Infirmary, for example, who was an advocate for the retention of the donor card at a national level, doubted that this would meet with public approval in the UK (pp 111–113).
159. The BMA was less firm in its opposition saying, "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" (pp 165–169).
160. The BMA went on to say that they felt it was not clear whether the intention of a European organ donor card would be that organs would be routinely shared throughout Europe, rather than throughout the UK as at present. Their view was that routine sharing across Europe might make people less, rather than more, inclined to sign up for donation. They felt also that such a system, requiring the transmission of "full donor records" across the EU, would raise issues about confidentiality (pp 165–169).
161. The British Transplantation Society's view was that a donor card might achieve maximum acceptability by aligning it with something with which the public most closely identified and that this might be more likely to be their own community than the EU or even the Member State. The idea would be to promote the idea of donation through the means of a donor card in a manner which dealt explicitly with some of the concerns of their own community, not to suggest that donors should donate organs only to members of the same community.
162. The BTS quoted the example, in the USA, of the Orthodox Jewish community's development of their own card which had adopted this approach (pp 94–97). When we followed up this reference, we found that it referred to an initiative by the Jewish Halachic Organ Donation Society. This organisation stated on its website<sup>34</sup> that it had the mission "to save lives by encouraging organ donation from Jews to the general population (including non-Jews) by educating them about the different halachic and medical issues concerning organ donation".

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<sup>34</sup> Website of the Halachic Organ Donation Society <http://www.hods.org/index.shtml>

### Information and research

163. A number of witnesses, including Dr Warrens (British Transplant Society), Professor Brazier (Manchester University), Professor Gurch Randhawa (University of Bedfordshire) and Kidney Research UK, were enthusiastic for an EU action plan to clarify the Commission's role in, and commitment to, encouraging and funding research in the area of organ donation.
164. Dr Warrens thought that the Commission could help in the field of social science research relating to organ donation, for example in understanding attitudes within the communities with which people identify. He wanted the Commission to recognise the need to increase knowledge in this area and to allocate funding to it (QQ 225, 226). He made the point that "an EU-wide approach to research across national boundaries would have value in determining common themes in attitudes to organ donation" (pp 94–97).
165. Professor Brazier made the point that there was a wealth of evidence across the EU about what worked and what did not. She thought that the best approach to obtain the information needed to prepare guidance on best practice would be to conduct EU-wide research (pp 161–164).
166. Professor Randhawa, University of Bedfordshire, thought that the EU could help by coordinating the collection of data across the Community in relation to the attitudes of different population sub-groups, including ethnic minority groups, towards organ donation issues. At a recent international conference he had formed the impression that there was no appetite among major EU countries to collect such data. He thought that an action plan could help to promote EU-wide understanding that there was a need for such data in order to develop EU-wide strategies for handling the issues which arise in different groups in relation to organ donation (Q 184).
167. Kidney Research UK agreed with this view, arguing that "Research needs to be 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". They identified a number of other areas which could benefit from cross-EU research and concluded that "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" (pp 225–227).
168. Ms Norman, Department of Health, agreed that it might be useful for the Commission to spend money on research that might enhance work that was going on across Europe in all countries on organ donation (Q 488).

### Conclusions

169. We support the proposal for an EU action plan to promote cooperation between Member States on organ donation in the interests of increasing the supply of organs. Our view is that the exchange of information via this means would be valuable over a number of areas including: best practice; the identification of potential donors; the diagnosis of death; information about transplant outcomes; and management information. (paras 126–134)
170. We recognise the need for public awareness and understanding of organ donation and transplantation issues to be increased, and we welcome the Government's commitment to fund this in the UK over the next two years. Given the scepticism expressed by some key witnesses, we would, however,

like to see work done to establish a basis for assessing the effectiveness of such awareness raising in increasing donation rates. (paras 135–144)

171. While we understand that organ trafficking and organ tourism are not currently major problems in the EU, we agree that there is a need for the Commission and Member States to be vigilant in monitoring and tackling any cases which may occur. While we note the view that it would be desirable to have in place a mechanism for tracing trafficked organs, we are not clear how such a mechanism could operate in practice. (paras 145–152)
172. The balance of views we have heard is that a European Organ Donor Card would not command public support and would not add value to national donor card systems already in place. We were concerned that it would be difficult for carriers of a standardised European Organ Donor Card to understand that their wishes regarding donation would be interpreted differently in Member States according to the arrangements for consent in place in each country. Nevertheless, we do see some merit in the idea of introducing a common format for the donation cards used by each Member State, providing that these are designed to be consistent with the donation consent process which is in force in the Member State of the holder's origin. (paras 153–159)
173. We heard of, and were interested in, suggestions for community-related donation card schemes which would be worth pursuing. (paras 160–162)
174. We were impressed by the evidence we received of the benefits which may be gained through cross border information exchange and research in relation to organ donation issues. In particular, experiences with the success of donation services in Spain (which we discuss further in chapter 6) have had considerable influence both in the UK and across the EU as a whole. We recognise the support for the Commission to help fund cross-EU based research in relation to the attitudes to organ donation of different population sub-groups. (paras 163–168)

### Recommendations

175. **We recommend that the Government should support the Commission in its development of an Action Plan relating to organ donation and transplantation. The action plan should provide financial and infrastructure support for information exchange and research collaboration between Member States, both reinforcing and expanding existing successful collaborations, and enabling the development of new initiatives which will address the shortage of organs for donation across the EU.**
176. **We recommend that the Commission should support Member States in developing and auditing public awareness campaigns suited to their own socio-economic and cultural contexts. We would particularly encourage the development of campaigns designed to engage hard-to-reach groups. Such work should be accompanied by provision, where possible, to assess the effectiveness of such campaigns in increasing donation rates.**
177. **We recommend that the Commission should explore the options for the introduction of a common format for the donation cards used by each Member State which are designed to be consistent with the donation consent process which is in force in the Member State of the**

**holder's origin. We recommend also that the Commission should encourage Member States to develop effective processes for donors to express their wishes in the context of their own consent systems.**

- 178. We recommend that the Government should give active consideration to investigating the merits of cooperation with local organisations, businesses and others to establish the scope for the introduction of community-based donor card schemes.**

## CHAPTER 6: ORGANISATION OF ORGAN DONATION AND TRANSPLANTATION SERVICES

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179. The way in which health services, including organ donation and transplantation services, are organised and delivered is a matter for individual Member States, and the Commission does not have a role to legislate or set down guidelines in this area. However, the Commission's proposal for an Action Plan to strengthen cooperation between Member States in relation to organ donation has received some considerable support in the UK, as is described in chapter 5.
180. A key element of cooperation under this Action Plan would be for Member States to share information about what aspects of organ donation and transplantation services worked best in order to raise donation rates, thereby maximising the number of patients who were able to benefit from an organ transplant. To investigate how advantageous this element of the Commission's proposals might be, it was therefore most important for our inquiry to take evidence about the organisation of organ donation services in the UK and in Spain, where, as our evidence showed, the greatest degree of progress had been achieved in this field.

### The UK Context

181. This inquiry took place during a period of intense activity relating to organ donation in the United Kingdom. As we commenced the inquiry, the Department of Health (DH) Organ Donation Taskforce chaired by Mrs Elisabeth Buggins was midway through a study of the issues affecting the insufficient supply of donor organs in the UK. It had been charged by the DH to make recommendations for the re-organisation of organ donation services which would have the effect of increasing this supply. The Taskforce reported on organisational issues in January 2008.<sup>35</sup>
182. The issue of how individuals might indicate their consent to donate organs (which forms the subject of chapter 8 of this Report) was outside the scope of the Taskforce's initial study, although this formed the subject of a second Taskforce study initiated by DH in September 2007.
183. While much public attention focussed upon the call of the Chief Medical Officer for England, Sir Liam Donaldson, in his 2006 Annual Report,<sup>36</sup> for the introduction of a system of presumed consent for organ donation, Sir Liam made clear to us that the way in which organ donation services were organised was crucially important. Speaking to this point he commented, "Let us imagine you introduce presumed consent and did very little to change the organisation of services ... you would suddenly have a flow of additional organs. If the services were not equipped to receive them, deal with them and allocate them to patients, there would be a serious problem" (Q 59).
184. In written evidence at the outset of this inquiry, prior to the publication of the Taskforce report, Mr Chris Rudge, UK Transplant, referred to the system of organ donation services which had been successful in achieving a much higher rate of organ donation in Spain than in the UK. He emphasised

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<sup>35</sup> op. cit

<sup>36</sup> op. cit

that, to achieve such success, it was “of absolute importance for States to have a national organisation with responsibility for the donation system”. He set out as follows what he saw as the key components of a successful donation system (pp 26–30):

- 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;
- Efficient and fully-resourced organ retrieval teams;
- Accurate data to monitor all steps of the process and robust performance management; and
- High level political commitment.

### **The “Spanish Model” for organ donation services**

185. The Committee was most grateful to Dr Rafael Matesanz, Director of the Organización Nacional de Trasplantes (ONT)—which is the Spanish National Transplant Organisation—for coming to London to give evidence. Dr Matesanz gave a clear account of the organisational changes that had taken place in organ donation services in Spain, and the extent to which he felt these had contributed to the increased rates of donation. He explained that the changes had been initiated in 1989, when the organ donation rate in Spain was 14 per million (Q 300). This is comparable with the present day UK donation rate of 12.8 per million (see Table 1 in chapter 3).

186. Dr Matesanz explained that the key elements of the re-organised Spanish system were as follows:

- Establishment of a centralised office for coordination – the ONT;
- Appointment of regional organ donation coordinators; and
- Appointment of coordinators in each hospital.

The coordinators were medical doctors with clinical authority inside hospitals, who worked full-time on championing organ donation issues and interacting with both intensive care and transplant teams (Q 300).

187. Dr Matesanz commented on the present level of organ donation rates in Spain which had resulted from the organisational changes he had described, “we have at this moment 34, 35 donors per million ... and there are seven regions which have over 40 donors per million” (Q 306). A particular success had been seen in the La Rioja region of Spain, where the appointment four years ago of a new enthusiastic coordinator had led to the achievement of a donation rate of 72 per million (Q 306).

188. Dr Matesanz explained that, on the basis of what had been achieved in the La Rioja region, the ONT had launched “Plan 40” with the aim that all Spanish regions should achieve an organ donation rate of 40 per million population. This would be done by identifying the best practice in each region in order to: improve donor identification; develop post cardiac death donor programmes; reduce family refusal rates; and involve more effectively immigrants from North Africa and Asia (QQ 306, 307).
189. Commenting on his work outside Spain, Dr Matesanz argued that the application of the approach he had developed could be successful in other national contexts, “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” (Q 331).
190. Several witnesses acknowledged with admiration the effectiveness of the organisation of donation services which had been developed in Spain (pp 26–30, pp 94–97, pp 111–113, pp 148–151, pp 216–223, pp 256–258,). Professor Brazier and Dr Quigley, of the University of Manchester, observed, “It was the introduction of an organisation to coordinate all aspects of donation activity, the ONT, 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” (pp 148–151).
191. Dr Rudge of UK Transplant was also very clear about the success of the Spanish system, “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”. Dr Rudge was equally clear in his view of the reasons for this success, “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 [Dr Rafael Matesanz] changed the system” (Q 124).
192. Responding to questioning about the relative importance for increasing organ donation rates of organisational change and changing the law relating to consent for donation, Dr Rudge commented, “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” (Q 124).

### **Employment and training of staff**

193. Dr Matesanz explained that in the Spanish organisation of services, about 80% of hospital coordinators were selected from the intensive care speciality. In order to avoid burn out, coordinator posts were held for two to three years at a time, and the post-holders could easily move back into other jobs (Q 303). He felt that this avoided the problem experienced in many other countries where people in the coordinator role were kept in it for too long and became a problem for effective organ donation (Q 300). He explained that, in appointing hospital co-ordinators, there was a “functional link



between the hospital, the regional and the national co-ordination” and that this interface was the key to the system (Q 304).

194. Dr Matesanz stressed the importance of the multi-disciplinary nature of the services involved in organ donation and told us that, since the present system had been introduced in Spain, a great deal of effort and most of the budget of the ONT had been devoted to training doctors, nurses and all other professionals involved in the system (Q 302). Expanding on this, he said, “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” (Q 301).

### Donor identification and audit

195. Mr Simon Bramhall, a consultant liver transplant surgeon, drew attention to the UK Potential Donor Audit<sup>37</sup> which had revealed that up to 1,288 patients per year, who were potentially suitable for organ donation, did not come to fruition, largely as a result of the absence of brain stem death testing. He asserted, “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 ... the organ donor rate in the UK would mirror that of the US and would become close to the rates achieved in Northern Italy and Spain” (pp 204–207).
196. Mr Bramhall took the view, “This adds further weight to the argument that there is the potential in the UK for significantly increasing organ donation with an appropriate approach” (pp 204–207).
197. Dr Paul Murphy, an intensive care consultant at Leeds General Infirmary, reinforced the point about the missed opportunities for organ donation that arose as a result of brain stem death tests not being carried out. He also quoted statistics from the Potential Donor Audit<sup>38</sup> showing that there were between 400 and 600 patients each year in intensive care for whom the diagnosis of brain-stem death was likely, in the opinion of the auditors, but that diagnosis was not made. For around 30% of these Dr Murphy’s own investigation had shown that there was no reason why brain stem death testing had not been carried out (Q 265).
198. For another 30% the diagnosis was not made because the patient’s heartbeat and breathing were unstable and the clinicians felt it inappropriate to correct the instability. Dr Murphy said, however, that in his experience such instability was “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” (Q 265, pp 122–132).
199. Mr Chris Rudge, Director of UK Transplant the organisation that compiles the Potential Donor Audit, confirmed these points, explaining that the lack of brain stem death testing revealed by the Audit was one of the reasons why organ donation rates in the UK fell well below Spanish levels. Referring to the Audit he asserted, “It shows that potential donors are not subjected to

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<sup>37</sup> UK Transplant: Potential Donor Audit—a source of information which covers every single patient in the UK who dies in intensive care—see website page [https://www.uktransplant.org.uk/ukt/statistics/potential\\_donor\\_audit/potential\\_donor\\_audit.jsp](https://www.uktransplant.org.uk/ukt/statistics/potential_donor_audit/potential_donor_audit.jsp)

<sup>38</sup> *ibid.*

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 donor co-ordinators every time” (Q 108).

200. Against this background, Dr Murphy concluded that European Commission’s proposals for sharing information across the EU would be advantageous for improving donor identification methods in the UK. “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” (Q 271).

### **The Organ Donation Taskforce’s proposals**

201. When publishing the report<sup>39</sup> of the Organ Donation Taskforce, on 16 January 2008, the Department of Health announced<sup>40</sup> that it accepted all the recommendations made, and that these should lead to a 50% increase in organ donation rates in the UK within five years. The 14 recommendations of the Taskforce are set out in Box 2.

## **BOX 2**

### **14 recommendations made by the Organ Donation Taskforce**

- R1. A UK-wide Organ Donation Organisation should be established.
- R2. The establishment of the Organ Donation Organisation should be the responsibility of NHS Blood and Transplant.
- R3. Urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice. Additionally, an independent UK-wide Donation Ethics Group should be established.
- R4. All parts of the NHS must embrace organ donation as a usual, not an unusual event. Local policies, constructed around national guidelines, should be put in place. Discussions about donation should be part of all end-of-life care when appropriate. Each Trust should have an identified clinical donation champion and a Trust donation committee to help achieve this.
- R5. Minimum notification criteria for potential organ donors should be introduced on a UK-wide basis. These criteria should be reviewed after 12 months in the light of evidence of their effect, and the comparative impact of more detailed criteria should also be assessed.
- R6. Donation activity in all Trusts should be monitored. Rates of potential donor identification, referral, approach to the family and consent to donation should be reported. The Trust donation committee should report to the Trust Board through the clinical governance process and the medical director, and the reports should be part of the assessment of Trusts through the relevant healthcare regulator. Benchmark data from other Trusts should be made available for comparison.
- R7. BSD testing should be carried out in all patients where BSD is a likely diagnosis, even if organ donation is an unlikely outcome.

<sup>39</sup> op. cit

<sup>40</sup> DH Press Notice 16 January 2008 “Fifty per cent increase in organ donation possible within five years”

R8. Financial disincentives to Trusts facilitating donation should be removed through the development and introduction of appropriate reimbursement.

R9. The current network of DTCs should be expanded and strengthened through central employment by a UK-wide Organ Donation Organisation. Additional co-ordinators, embedded within critical care areas, should be employed to ensure a comprehensive, highly skilled, specialised and robust service. There should be a close and defined collaboration between DTCs, clinical staff and Trust donation champions. Electronic on-line donor registration and organ offering systems should be developed.

R10. A UK-wide network of dedicated organ retrieval teams should be established to ensure timely, high-quality organ removal from all heart beating and non heart beating donors. The Organ Donation Organisation should be responsible for commissioning the retrieval teams and for audit and performance management.

R11. All clinical staff likely to be involved in the treatment of potential organ donors should receive mandatory training in the principles of donation. There should also be regular update training.

R12. Appropriate ways should be identified of personally and publicly recognising individual organ donors, where desired. These approaches may include national memorials, local initiatives and personal follow-up to donor families.

R13. There is an urgent requirement to identify and implement the most effective methods through which organ donation and the 'gift of life' can be promoted to the general public, and specifically to the BME population. Research should be commissioned through Department of Health research and development funding.

R14. The Department of Health and the Ministry of Justice should develop formal guidelines for coroners concerning organ donation.

*Source: Organ Donation Taskforce Report Organs for Transplants, January 2008*

202. Dr Murphy, who was a member of the Taskforce, acknowledged, as did other witnesses, the influence of the Spanish model within Europe and the extent to which the UK Taskforce had been influenced by its success. "I am not saying that we have taken the Spanish model off the shelf and put it into the 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" (Q 271).
203. Mrs Elisabeth Buggins, Chair of the Taskforce, confirmed that the Government were giving full funding support to the implementation of all the Taskforce's recommendations (Q 489).
204. The Minister announced during her evidence that Professor Sir Bruce Keogh had been asked to chair a committee overseeing work on implementing the Taskforce recommendations. She announced also that Chris Rudge, then Director of UK Transplant, had been seconded to the Department of Health to lead this implementation as National Clinical Director for Transplant (Q 490).
205. Dr Matesanz was very positive about the Taskforce's recommendations for changing the organisation of donation services in the UK. He felt, however, that "The problem is probably how to develop all of these points ... so I fully agree with the 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" (Q 337).

206. In Dr Matesanz's view, the main problem for the UK, and other EU countries wishing to implement change in the interests of increasing transplantation rates, could be resistance to change (Q 338). He predicted that it might be quite difficult to change existing practices in well-established health systems, including that in the UK, which had existed for many years (Q 339).
207. Despite Dr Matesanz's concerns about resistance to change, Elisabeth Buggins reported that she was delighted with the enthusiasm with which the Taskforce's proposals had been received by the medical profession and others (Q 489). This was confirmed by Dr Vivienne Nathanson, British Medical Association, who told us that doctors were aware that it was essential to get the right infrastructure for donation services. She commented that one of the reasons why the BMA welcomed the Taskforce report so much was that it challenged many of the ways in which donation services in the UK were currently organised (Q 385).
208. Dr Anthony Warrens and Mr Keith Rigg, British Transplant Society, also expressed strong support for the recommendations of the Taskforce referring to this as an "excellent document" and saying, "we hope that all parts of the Taskforce recommendations will be implemented" (QQ 213, 227).

### Conclusions

209. We are convinced, largely from what we heard of the experience in Spain, that the effective organisation of organ donation services is key to success when addressing issues of the scarcity and the quality and safety of human organs for transplant. (paras 185–192)
210. We recognise that a key factor leading to the success of the Spanish system has been the strong emphasis given to the selection and training of the staff involved in organ donation services. (paras 193–194)
211. We recognise that potential donors are lost within the UK system as it is presently organised. In particular, we note the evidence, based on the Potential Donor Audit carried out by UK Transplant, that the omission of brain stem death testing for all potential organ donors leads to a significant loss of donor organs. (paras 195–200)
212. We welcome the Organ Donation Taskforce's recommendations to address the barriers to organ donation in the UK through the reorganisation of organ donation services. (paras 201–208)
213. We consider that the Taskforce's use of the experience of the Spanish system for organising donation services is a good example of how cross-EU cooperation can benefit individual Member States, and we are convinced that there are key components of an effective organ donation organisation that could be implemented to good effect in most individual Member States. (paras 199, 200, 202)

### Recommendations

214. **We commend the success of the system, introduced by Dr Rafael Matesanz and his colleagues, for the organisation of organ donation and transplantation services in Spain. We welcome the fact that, in the UK, the Organ Donation Taskforce drew considerably on the Spanish experience in formulating their recommendations for**

changing the UK system; and we recommend that the European Commission advises Member States also to draw appropriate lessons from the Spanish success in introducing changes to the systems in place in their own countries.

215. We recommend, in particular, that the Commission should draw attention to the key role that has been played in improving Spanish organ donation rates by the priority given to the selection and training of the staff involved in organ donation services.
216. We acknowledge the merits of the approach (as adopted by the UK Government) of setting up a Taskforce of qualified experts to study the issues relating to organ donation services, learning from experience elsewhere in the EU, in order to produce proposals suited to a specific country's health care system and to its social, economic, cultural and ethical environment. We recommend that the Commission should encourage Member States where there is a need to improve organ donation rates, as in the UK, to assess whether this type of approach would be helpful.
217. We recommend that the Government gives a clear and strong commitment to funding the full implementation of the recommendations of the Organ Donation Taskforce for the re-organisation of organ donation and transplantation services in the UK, both during the crucially important first five years and beyond.
218. We recommend also that the Government puts in place mechanisms to monitor the effectiveness of changes being made as a result of the implementation of the Taskforce proposals. This would have the aim both of ensuring progress within the UK, and of facilitating the exchange of relevant information with other EU Member States which face similar challenges and are considering or implementing similar responses.

## CHAPTER 7: PATIENT CARE ISSUES—ORGAN DONORS AND ORGAN RECIPIENTS

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219. Patient care issues fall within the area of the organisation of organ donation and transplantation services, an area in which the Commission does not seek to lay down any legislation, or even guidelines, which Member States should follow. The Commission does, however, as is explained in chapter 5, seek to promote the exchange of information between Member States as part of its action plan for cooperation across the EU.
220. With the future prospect of such information exchange in view, we set out the evidence about the UK background in relation to patient care issues which we received. We found this to be valuable in helping us to understand fully the context in which the Commission's proposals for an EU role had been put forward.
221. Both organ donors (while they are alive) and organ recipients are patients, and an equal duty of care is owed to each. Witnesses acknowledged the tensions which can arise when seeking to pursue the best interests of both parties, particularly in the context of donation after cardiac death. The point was made that potential donors (other than living donors) were likely to be seriously ill when the issue of donation became imminent and that, in such circumstances, it was important to recognise the role of the donors' families and to consider the care they might require.

### Living donation

222. Dr Warrens, British Transplant Society, told us that most living donors were probably the partners of the recipients of the organs, and that living with somebody who was on kidney dialysis had an impact on the partner's own quality of life. In consequence, in cases of donation from one partner to another, the donor would often have the benefit of improving his or her own quality of life as well as that of the partner who received the organ. He confirmed that "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" (Q 243).
223. In the case of the living donation of organs other than kidneys, particularly lungs, some witnesses expressed caution about living donation. The Royal College of Physicians reported that, "It is the opinion of UK lung transplant centres that this approach to donor organs for lung transplantation should be considered second choice to use of cadaveric or post cardiac death 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" (pp 239–242).
224. This view was shared by the Cystic Fibrosis Trust, despite their membership being the most likely beneficiaries of this form of transplantation. They underlined the point that the donation of two lungs from two living donors could lead to the death of three people, of whom two were not ill in the first place (pp 212–213).
225. Tom Butler, Bishop of Southwark, on behalf of the Church of England, believed that altruistic unrelated organ donation from a living donor would flow from a Christian ethic, provided there was no coercion, no commercial gain, and above all no unnecessary harm to the living donor. He thought that

- the fact that the organ might go anonymously to a recipient, unknown and unrelated to the donor, would “only heighten the self-giving of the donor” (pp 266–267).
226. The Welsh Kidney Patients Association recognised that altruistic living donation and pooled and shared living donation were strictly monitored in the UK and, as such, should be free from abuse. However, they argued that no-one should feel pressurised into donating an organ, either for financial gain or from emotional feelings towards relatives (pp 251–254).
227. The British Kidney Patient Association, however, did not favour living donation as a first option and actively opposed the concept of unrelated living donation. They expressed these views as follows, “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 [in relation to the shortage of organs for transplantation]. 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” (pp 209–211).
228. Dr Muireann Quigley and Professor Margaret Brazier, Manchester University, were in favour of the promotion of donation from living donors, but questioned the assumption that organ donation by living donors should always be purely altruistic. Their view was that practical obstacles to such donation, in particular by non-related altruistic donors, such as loss of earnings while the donor is in hospital and during their recovery from the operation, had not been addressed due to an “overriding fear that this type of donor is seeking ‘financial reward’” (pp 148–151).
229. They went on to advocate the reimbursement to living donors of costs incurred and losses attributable to the transplant donation process. Going even further, they took the view that, “living 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” (pp 148–151).
230. Commenting on the European Commission’s views on this matter, Professor Brazier and Drs Quigley stated, “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.” They said that they 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 it (pp 148–151).

## Donation after Brain Stem Death

### *(a) Brain stem testing*

231. The scope for better identification of potential donors through wider use of brain stem death testing was discussed in chapter 3. In terms of patient care, witnesses argued that it was in the interest of patients, irrespective of their

donation intentions, that tests be carried out to confirm brain death in appropriate cases.

232. Mr Simon Bramhall, a consultant liver transplant surgeon, argued that it is good medical practice to perform brain stem death tests for suspected brain stem dead patients, not just for potential heart-beating organ donors. He took this view because, if brain stem death is confirmed, then continued intensive care is futile. He added that, if brain stem death is confirmed, then the families of the deceased should be offered the option of organ donation (pp 204–207).
233. The Scottish Council on Human Bioethics took 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” (pp 246–250).
234. The Patient Liaison Group of the Royal College of Surgeons believed that “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” (pp 48–52).

*(b) Conflict of interest*

235. Dr Murphy, Leeds General Infirmary, commented on the conflict of interest between the duty of care towards patients who are potential donors and towards patients who need a transplanted organ. “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 interest of that patient but rather in the best interests of a third party; that is, a recipient down the line.” He raised the question of what the patient’s “best interest” actually would be in this context. “Is it restricted to the physical or does it rather embrace 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?” (Q 265).
236. Kidney Research UK also identified this conflict of interest, stating, “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” (pp 225–227).
237. Similarly, the British Transplantation Society (BTS) observed, “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” (pp 94–97).

**Donation after cardiac death**

238. The BTS felt that insufficient emphasis to the development of donation after cardiac death had been given in the Commission’s Communication on organ donation. While they recognised that such donations are labour intensive, and may be culturally unacceptable in certain parts of the EU, they took the view that these had the potential to make a significant impact on the organ



shortage. The BTS encouraged the Committee to press for more detailed consideration of this approach (pp 94–97).

239. Dr Warrens of the BTS emphasised, however, that “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” (Q 240).
240. Dr Rafael Matesanz, Director of the Spanish National Transplant Organisation, also drew attention to the point that the arrangements which needed to be made in the case of post cardiac death donations were very complicated and required a large amount of attention from medical staff (Q 310).
241. Dr Jane O’Brien, Assistant Director in the Standards and Fitness to Practice Directorate of the General Medical Council, commented on the issue of how the provisions of the Mental Capacity Act affected the circumstances in which a person who is not brain stem dead, but who has major neurological trauma, can be considered as a potential organ donor.
242. She said that, if a decision were made that the patient would donate organs, then some time, usually a matter of hours, would be needed to organise the transplant teams to undertake the necessary tests and to get things in place. As a result, she continued, treatment that was simply prolonging the process of dying, which would normally be stopped with the patient dying soon afterwards, might be continued for up to 6 hours. Dr O’Brien added, “It is very unclear that that is lawful under the Mental Capacity Act” (Q 414). She emphasised that clarification in this area would be most helpful (Q 415).
243. The Organ Donation Taskforce recognised this issue and recommended (see Box 2 in chapter 6) that outstanding legal, ethical and professional issues should be resolved in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice. They recommended also that an independent UK-wide Donation Ethics Group should be established.

### **The role and needs of families**

244. The refusal of consent for organ donation by the relatives of potential donors is a significant barrier to raising the level of donation rates in the UK, yet this problem is not found to the same degree across the EU as a whole.
245. Dr Matesanz reported that the family refusal rate in Spain overall was only 15% compared with about 40% in the UK. Moreover, among the 100 to 120 British people resident in Spain who came to the state of brain death during 2005 and 2006, every one of the families agreed to organ donation. “So the family refusal rate of the British in Spain is zero” (QQ 307, 326).
246. Witnesses were able to identify a range of issues that families found difficult and it was acknowledged that donation decisions are necessarily made at a time of great distress. Dr Magi Sque, a researcher with considerable experience of working with donor families, told us, “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” (Q 192).

247. Dr Sque went on to emphasise the importance of handling sensitively families’ bereavement, but was keen to stress that even at this difficult time many relatives wished to be approached about the issue of organ donation. She advised, “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 care professionals that are tasked with this discussion as they realise it must be difficult for them” (Q 192).
248. Dr Tracy Long, Dr Sque’s research collaborator, went on to discuss some of the questions which relatives often put to health care staff at this time such as “is my relative really dead?”; “is s/he going to be treated with dignity?”; “are her/his organs going to be used?” Her view was that, ideally, staff should take the initiative in addressing these concerns with relatives in case they felt uncomfortable raising them. She advised “You need someone who will say, ‘Some people have these concerns, is that an issue for you?’” (Q 196).
249. Other witnesses identified what they saw as more deeply rooted reasons for relatives to object to donation. Lesley Bentley, Chair of the Patient Liaison Group of the Royal College of Surgeons, believed that it was often difficult for families to discuss and reach decisions on matters relating to organ donation. She thought this might be because, “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”. She saw this as adding to the traumatic experience of relatives who faced a donation decision (Q 149).
250. Ms Jayne Fisher, Chair of the UK Transplant Coordinators’ Association, reported the view, based on her own experience and that of colleagues, that one of the main fears of relatives was that taking organs would mean the “mutilation” of the donor (Q 290).
251. This view was supported by Dr Sque, who thought that a cultural distaste for having the body interfered with after death was to be found across the whole population, not only among ethnic minority groups (Q 195).
252. Dr David Evans, who opposed the donation of organs from patients whose death had been determined on the basis of brain stem death testing, found it completely understandable that a family should not be willing to agree to the donation of organs from a relative who was still breathing and whose heart was still beating (pp 213–216).
253. It was acknowledged by many witnesses that families played an important role in facilitating donation, not only by allowing donation to proceed but also by providing information about the donor. Both patient groups and health care professionals took the view that it was most important to treat the families with care, and to respect any decision not to donate.
254. Reflecting this general view, Dr Sque and Dr Long were keen to stress the additional advantages of a family having a positive experience in the context of donation. “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”. Based on reported experience in the USA, she advised that, given the right circumstances, families “appear motivated by what their deceased family member achieved through donation, illustrated by the heroic status which is attributed to them” (pp 75–79).

### Conclusions

255. We understand that the living donation of an organ, most often of a kidney, is an admirable gift which often has advantages not only medically for the recipient but also, in other ways, for the donor, especially when she or he is the carer of the recipient. While we see it as most important that such donations should be freely given, with no coercion of the donor, we do see the case for considering whether some reimbursement should be provided to living donors of the costs they incur which are attributable to the transplant donation process. (paras 223–231)
256. We support the view that brain stem testing should be offered for all patients in whom brain stem death is suspected, and that this is in their interest irrespective of their donation wishes. (paras 232–235)
257. We understand the potential for a conflict of interests to arise for medical staff when caring for people who are identified as potential organ donors. We are persuaded that it is essential, for the maintenance of trust in health services, that all such people should be dealt with as patients in the first instance. They should be provided with appropriate treatment and care, in line with their best interests, until the point at which it is agreed that withdrawal of treatment is medically justified. (paras 236–238)
258. We acknowledge the difficulties faced by clinicians who might wish to maintain a patient’s stability, in the interests of maximising the chances of donation, when the steps which need to be taken to do this are not directly in the patient’s medical best interest. We understand also that the legal uncertainty surrounding this issue causes problems for clinicians and results in organs being lost to donation (paras 239–244)
259. We are impressed by the evidence we have received about how important it is, in attempting to increase the supply of organs for donation, not to lose sight of the needs and concerns of patients and families. (paras 245–255)

### Recommendations

260. **We recommend that the Government should explore the merit of making provision for the reimbursement to living donors of the costs they incur which are attributable to the transplant donation process.**
261. **We recommend that the Government should seek to ensure that brain stem testing becomes standard practice for all patients in whom brain stem death is suspected.**
262. **We recommend that the Government should take steps to ensure that, for a person who has clearly stated their desire to donate organs, it is recognised legally that it is in their best interests to facilitate donation through the appropriate maintenance of their organs prior to or immediately after death. When the patient’s wishes are unknown, but**

**the family have agreed to donation, the same approach should be taken.**

- 263. We recommend that the Government should ensure that in all cases of organ donation, sufficient staff resources are made available for caring and informed support to be given to the relatives of the donor.**

## CHAPTER 8: ALTERNATIVE FORMS FOR DONOR CONSENT

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### Consent to organ donation and the EU

264. Dr Fernandez-Zincke, of the European Commission, made clear that the issue of consent to organ donation was not one on which the Commission intended to legislate or lay down guidelines. He stated, “It is not the intention of the Commission to say how consent should be organised in the different Member States but, as we have done with the Tissue and Cells Directive, it is important to stress the need for consent, however the Member States organise this consent” (Q 24).
265. Dr Fernandez-Zincke emphasised, “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” (Q 26).
266. Nevertheless, the issue of consent is inextricably linked with the issue of the cooperation among Member States on an action plan to help raise the level of organ donation rates across the EU, which forms a key element of the Commission’s proposals (see chapter 5). It is only by sharing experiences between Member States that it is possible to assess how different forms of consent, in combination with different forms of organisation of donation services, may affect donation rates.
267. In order to understand properly the arguments put forward by witnesses about the value of cooperation across the EU on matters related to organ donation, we therefore needed to take evidence about donor consent in the UK.

### Consent to organ donation in the UK

268. The present system for consent in the UK is often referred to as “explicit consent”. This term describes an “opting-in” system for consenting to donate organs, under which a person expresses a clear wish to donate organs after death, often by joining an organ donation register or by carrying a signed donor card.
269. There has been some discussion about a future switch in the UK to a different system for consent known as “presumed consent”. This term describes an “opting-out” model for consent, under which all citizens are presumed to be willing to donate organs after death unless they actively register a wish not to do so.
270. In England and Wales and Northern Ireland, consent to organ donation is governed by the Human Tissue Act 2004<sup>41</sup>, which covers both living and post mortem donation. In Scotland the Human Tissue (Scotland) Act 2006 is the relevant legislation which, as Mr Peter Lemmey of the Human Tissue Authority (HTA) pointed out, contains one or two differences including the replacement of “consent” with “authorisation” (Q 366). Mr Lemmey stressed, however, that “consistency of approach across the UK has been the watchword” (Q 366).
271. In regulating organ donation, Mr Lemmey believed that the HTA was guided by three important factors (Q 368):
- The ethical principles which underlie the 2004 Act, i.e. ideas of the degree of individual autonomy, the primacy of consent in the process, the importance of consent being properly informed, no trafficking and no coercion;

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<sup>41</sup> op. cit

- The key principles promulgated by the Better Regulation Commission i.e. accountability, proportionality, being targeted and transparent; and,
  - The need to support the Secretary of State for Health’s objective to maximise transplantation rates, without compromising on the HTA’s remit to regulate the process according to the 2004 Act.
272. Many witnesses were clear that consent should be explicit, with Patient Concern, for example, rejecting presumed consent as “no consent at all” (pp 46–48). Professor David Price, a medical lawyer, argued that explicit consent—obtained either by the person adding his or her name to the relevant organ donor register or by signing an organ donor card—could provide the best unambiguous evidence that a person wanted and had decided to donate (pp 234–236).
273. However, Professor Price went on to say that explicit consent could only be effective if the wishes of the now deceased person had been reliably and directly recorded or, at a minimum, had been conveyed to the relatives who would have decision-making power at the time of death. Where this was not the case, he suggested that the family would usually have to rely on guesswork about the deceased’s wishes, which would weaken the system (pp 234–236).

### **UK donor cards and the Organ Donor Register**

274. UK citizens can register their willingness to donate an organ after their death by joining the Organ Donation Register (ODR), by carrying a donor card or by making any other form of advance statement that would be recognised under the terms of the Mental Capacity Act 2005. Mr Chris Rudge, Managing Director of UK Transplant, reported that 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” (Q 101). He expressed his regret that there was only a limited budget available to UK Transplant for promoting the register (Q 107).
275. Views on the effectiveness and significance of carrying a donor card or registering with the ODR differed. Patient Concern thought they were little known to the general public. They cited the Bishop of Southwark who “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’”. Patient Concern added, “That is our experience too” (pp 63–66).
276. However, Dr Paul Murphy, an experienced intensive care doctor who dealt regularly with the families of donors, felt that the donor card was an important and direct means for the family and clinician to share an understanding of a potential donor’s consent. He thought, moreover, that “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, eBay, YouTube etc.” (pp 111–113).
277. There was further support among patient groups for working to enhance the donor card system. The Patient Liaison Group of the Royal College of Surgeons, for example, said that “Information held must be accurate and easily accessed—time is of the essence. The national register seems a good idea for the public and clinicians when in urgent need of a donor” (pp 48–52).
278. The Royal College of Physicians was keen that other options than the use of a donor card should be explored. They took the view that “The success in

















































































