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The Use of New Medical Technologies within the NHS

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Oral and written evidence

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The Health Committee

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Footnotes

In the footnotes of this Report, references to oral evidence are indicated by 'Q' followed by the question number. Written evidence is cited by reference to Volume II of this Report, in the form 'Ev' followed by the page number.

Witnesses

Thursday 3 March 2005

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Additional papers have been received from the following and have been reported to the House but to save printing costs they have not been printed and copies have been placed in the House of Commons library where they may be inspected by members. Other copies are in the Record Office, House of Lords and are available to the public for inspection. Requests for inspection should be addressed to the Record Office, House of Lords, London SW1. (Tel 020 7219 3074) hours of inspection are from 9:30am to 5:00pm on Mondays to Fridays.

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Saysell & Hargreaves (MT 4)
British Society of Echocardiography (MT 5)
BHTA (MT 7)
Mr Eddie Chaloner (MT 9)
Professor Sam H Ahmedzai (MT 11)
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Oral evidence

Taken before the Health Committee

on Thursday 3 March 2005

Members present:

Mr David Hinchliffe, in the Chair

Mr David Amess	Jim Dowd
John Austin	Dr Doug Naysmith
Mr Simon Burns	Dr Richard Taylor

Memorandum by Professor Carl May (MT 03)

1. Background

1.1 Since 1997 we have undertaken a series of studies, supported variously by the NHS Executive (North West); NHS Modernisation Agency; Department of Health; and the Economic and Social Research Council. These studies have investigated the factors that promote and inhibit the effective design, evaluation and implementation of telemedicine, telehealthcare and telecare systems. Our work includes observational studies of professionals and others deploying telehealthcare systems in practice; surveys of patient satisfaction, focus groups and a citizens' panel related to users' views of telehealthcare systems; and systematic and other reviews of policy, evaluation methodologies, patient satisfaction and economic evidence for the effectiveness of telehealthcare.

1.2 Our work has also included collaborations with colleagues at the Royal Free Hospital and UCL Medical School (Professor Paul Wallace, Dr Robert Harrison); National University of Ireland (Dr Anne MacFarlane); University of Liverpool (Professor Simon Capewell, Dr Robert Angus) University of Manchester (Professor Linda Gask, Professor Christopher Griffiths, Dr Aneez Esmail); and Michigan State University (Professor Pamela S Whitten). Taken together these studies form one of the most comprehensive programmes of work of its kind in Europe.

2. Definitions: In this Memorandum we Define Telemedicine, Telehealthcare and Telecare in the Following Way

2.1 Telemedicine: is electronically mediated interaction between doctor and patient either as synchronous telemedicine, using real-time video-conferencing systems (often with parallel transmission of physiological or other clinical data), or asynchronous telemedicine using store-and-forward systems where images and other data are captured and transmitted for onward review by clinicians. The former is commonly used for management of patients' problems (eg psychiatric interviews) and the latter for diagnosis or diagnostic advice (eg review of digital images of skin lesions in dermatology).

2.2 Telehealthcare: is electronically mediated interaction between patients and health professionals, often nurses. Once again this may be asynchronous or synchronous in form, but involves a different kind of health care work. This is primarily work to collect diagnostic or other data for doctors, to manage an illness by means of advice, or triage work intended to decide whether a patient warrants admission to hospital.

2.3 Telecare: Highly portable telecare systems for monitoring the health status of people with chronic (eg diabetes and asthma) and degenerative (eg respiratory and cardiovascular) diseases are now widely available (eg the Doc@Home system developed by Docobo Ltd). Such devices measure physiological status and other data, present this data to individual users, and transmit it for review by service providers using either mobile or conventional telephony. They promise accurate self-surveillance, (which may lead to improvements in compliance with treatment regimens and users' expertise in self-care); and remote monitoring of individual health status by service providers to enable early intervention and reduce hospital admissions.

3. The Utilisation of Telemedicine (Including Telecare) and its Future Potential for Improving Services

Telemedicine and telehealthcare systems have had a limited impact on NHS provision, in stark contrast to the apparent success of telephone triage and advice services like NHS Direct. Despite significant support framed in policy documents, and very active clinical champions, these systems have largely failed to become integrated in routine health care delivery. We call this failure to normalise, and our work has investigated the reasons for this. Our work suggests four main reasons for the failure of telemedicine and telehealthcare to normalise in NHS practice

3.1 Telehealthcare systems fail to normalise when there is no positive link with a policy sponsor. When such a link does exist, telemedicine is organisationally defined as an appropriate means of delivering care and organising clinical work. What stems from this is the direction of resource allocation and infrastructure development. The absence of a central source of concrete policy sponsorship, and thus a central funding stream, has played a crucial role in retarding the development of telemedicine and telehealthcare. In this context most developments in this field are fragmentary, disconnected, and often of short duration. Many of those services that we have seen in the course of our work have relied on R&D funding, and have ceased once trial or evaluation funding has run out.

3.2 Telemedicine systems fail to normalise when they are not properly integrated into existing structures of healthcare delivery within specific organisational settings. When such integration does take place, telemedicine systems cease to become alternatives to traditional models of health care, and become embedded as routine models of service delivery. The reliance of much development in this field on R&D funding means that many developments have taken the form of alternatives to "conventional" medical encounters and have been structured through clinical studies aimed at demonstrating the existence of strong clinical evidence. These services are rarely integrated into "real" service delivery, and when they are, our work suggests that they deal with low patient volumes. The organisational requirements of integrating telehealthcare systems into hospital and primary care settings are rarely considered in R&D contexts.

3.3 Telemedicine and telehealthcare systems fail to normalise when the people needed to make them work in practice are not enrolled into cohesive networks. Telemedicine and telehealthcare systems tend to emerge when there are specific clinical champions at work, rather than as mainstream developments. This means that small groups of staff tend to take responsibility for them, and these groups are often oriented towards R&D. When co-operative functional groups exist, and when they have have management support, the new ways of organising service delivery that are necessary for fully operational telemedicine systems can come into being and maintain direction.

3.4 Telemedicine and telehealthcare systems fail to normalise when the models of clinical practice that are derived from them are unstable, and when the pressure opf conventional workload makes them unattractive alternative modes of delivering care. If such stability exists, then individual clinicians can stabilise the new kinds of knowledge and practice that are required, and re-engineer these to meet the demands of a new mode of service delivery. Remote diagnosis and management of patients requires different skills to traditional face-to-face models of care, and present different kinds of risks and governance issues. These new modes of care change professional roles and responsibilities, if this is not anticipated and accommodated in advance then inter-professional conflicts can occur. Even in well designed services and R&D projects, it is often the case that little consideration is given to training around skills and identifying and solving novel problems.

4. Professional Resistance and Patient Satisfaction

4.1 Professional "resistance" is often claimed to be a key problem in integrating telemedicine and telehealthcare services into NHS provision. But this resistance is often a product of failure to attend to reasonable concerns about (a) the safety and effectiveness of new systems, and (b) the organisational problems noted above in developing and implementing new models of service delivery.

4.2 It is important to note that patients and other service users are rarely consulted in any meaningful way about the development and implementation of such systems, and it is often assumed that the needs of NHS service providers and those of patients are the same, when this is by no means always the case. In our work we have found that participatory design of telemedicine and telehealthcare systems is notably absent. In its place we have found abundant studies (often very poorly designed) of patient satisfaction. These show high levels of support for new systems but often represent highly selected patient groups, and often focus on "hotel" aspects of care rather than important questions of diagnostic confidence and quality of life. Users' concerns about security and confidentiality are rarely addressed.

5. The Speed of, and Barriers to, the Introduction on New Technologies

5.1 Clinical and other proponents of telemedicine and telehealthcare are to some degree demoralised by (a) the widespread failure of these systems to normalise in practice, and (b) the degree to which they are rapidly being overtaken by more advanced telecare and ehealth applications. The major focus of innovation and spending in NHS ICTs is within NPfIT, and our work suggests that other forms of innovation are seen as inherently risky because of the potential for incompatibility with new IT systems, but also because there is

a shift from clinically focused innovation to innovation in the organisation of service delivery. In this context telecare systems are presented as chronic disease management solutions. Some patient groups and clinicians see the emerging field of telecare as a means of distancing people with chronic illness from the NHS rather than as a means of closer engagement between them.

5.2 Telecare systems are rapidly developing, but they present similar organisational problems of implementation and integration to those faced by telemedicine and telehealthcare systems. These need to be resolved. It is worth noting that while the NHS is often spoken of as a single organisation it is in fact a federation of more than 700 Trusts, with different and often inconsistent policy and practice perspectives on new technology development and application. The absence of a central policy sponsor and central funding stream for R&D, procurement, and service development is the key barrier to these new developments. It is worth contrasting this with the rapid development and delivery of mechanisms for telephone triage, advice and service delivery (NHS Direct, NHS 24).

5.3 Little is known about how useful telecare systems are to patients and other service users. Small scale development studies show problems of compliance even in heavily managed trials. It is important to note that the needs of service users are often assumed rather than demonstrated, and that they are expected to fit with new technologies rather than be engaged in participatory processes of design and service delivery. There is little practical engagement with other policy processes (eg the Expert Patient programme). There are key opportunities here for citisens to be involved in deciding and designing telecare services that are genuinely relevant to their needs, but this window of opportunity is rapidly being lost.

5.4 The manufacturers and suppliers of telecare systems face an additional problem. They sit outside of the procurement and implementation structure of the National Programme for Information Technology in the NHS. Suppliers are often small to medium sized enterprises with little capacity to endure long development and procurement lead times: difficulty in funding their own R&D, in engaging with purchasing and procurement structures centrally in the NHS, and in dealing with large numbers of trusts as potential customers, all interact to make their routes to market difficult.

6. The Effectiveness and Cost Benefit of New Technologies

6.1 Effectiveness: The clinical effectiveness of telemedicine and telehealthcare systems has been established largely by quantitative evaluations that show diagnostic accuracy and which are intended to contribute to the development of evidence based practice in the field. These evaluations are generally positive but the benefits of many systems remain assumed rather than adequately demonstrated, and definitions of effectiveness remain limited. The assumption is that they are effective in limited clinical contexts (in many telecare systems this is still only an assumption), rather than being effective in solving patients' problems, or effectively integrated into real services. Demonstration projects that trial specific devices and systems are also generally positive. The same caveats apply to evaluations of telecare systems, and already problems with user compliance have been noted in some studies. A key problem in the evaluation literature is pressure to publish positive rather than negative results, this is especially so because of the funding relationship between some R&D groups and system manufacturers.

6.2 Cost benefit: high quality economic evaluations of telemedicine, telehealthcare and telecare systems are few and far between. Systematic reviews reveal few studies where adequate evaluation methods have been used. The economic benefits of new systems have been claimed by many of their proponents, but in the absence of real evidence these are currently assumed rather than actually demonstrated. Because patients and other service users are almost never involved in service development and design, the main focus of economic evaluation is at the level of health care provider (often US insurance based services where the organisation of funding is radically different to that in the UK), and questions of cost benefit are rarely applied to service users. This is important because the policy shift in the UK is likely to mean that telecare systems are employed in relation to people with chronic diseases. With these comes a shift in the burden of social costs to often disadvantaged people. Telecare systems are likely to change the cost structure of health surveillance in primary care, perhaps shifting some routine clinical checks on patients in general practice to automated and remote monitoring minimum patient data sets in call-centres. The cost-benefits of this are not yet proven.

Memorandum by the Queen Victoria Hospital NHS Foundation Trust (MT 10)

1. Summary

1.1 The Queen Victoria Hospital NHS Foundation Trust (QVH) in East Grinstead is a tertiary acute centre receiving a significant number of acute trauma calls from hospital A&E Departments and Minor Injuries Units (MIUs) in the South East. A Telemedicine system has been developed by the QVH over recent years, which enables referring hospitals to transmit images and clinical information in a secure manner to the QVH to facilitate informed discussion between clinicians at both sites in order to assist the clinical decision making process. The system has also been extended internally within the Trust and now offers a central repository for all clinical images taken by the Photographic Department.

1.2 Few telemedicine projects in the UK have progressed from pilot study to mainstream activity. At QVH, we have followed a common sense approach of implementing a practical simple system, keeping the system with clinicians and IT support staff, enabling users to drive the system, and maintaining consistent support. We believe these are the reasons why our system has been welcomed by clinical staff at the QVH and external locations and is becoming increasingly accepted as part of the Trust's trauma management processes.

1.3 We believe that the tele-medicine facility at QVH will play an integral role in future service development at the Trust. In particular, the facility strongly supports the establishment of the QVH burns unit as a UK Burns Centre. The ongoing National Burns Care Review is currently reviewing this decision.

2. Introduction

2.1 The QVH is a specialist acute unit providing services in plastic surgery (including burns and hand surgery), maxillofacial and corneo-plastic surgery for a wide catchment population across the South East. The Trust is one of the UK's largest plastic surgery units and has one of the most advanced Burns Units in the UK.

2.2 QVH employs Consultant staff in the specialties of Plastic Surgery, Maxillofacial Surgery, Orthodontics, Ophthalmology and Anaesthetics, together with Radiology and Pathology. The Trust also provides a range of medical services including Rehabilitation and Elderly Medicine for a more localised community under the management of a Trust Consultant Physician, with a number of inpatient beds being managed under the care of local GPs. A further range of services is provided by several visiting Consultants in specialties which include Cardiology, Dermatology, General Surgery, Gynaecology, Orthopaedics, Paediatrics, Respiratory Medicine and Urology.

3. Tele-Medicine at QVH

3.1 *Tertiary referrals from other sites*

The Trust receives substantial numbers of tertiary referrals from other sites with regard to its specialist services. A large volume of trauma referrals are received from A&E Departments and Minor Injuries Units situated throughout Kent, Sussex and Surrey. The Trust receives around 100 such calls every week in respect of acute plastic surgery services. The management of trauma referrals (both complex and simple) has been complicated in the past by the fact that the type of injuries concerned such as burns or hand trauma can be particularly difficult to describe over the telephone. This has led to situations occurring where patients have been transferred to the QVH on the basis of a verbal description of an injury, but following examination on arrival at the hospital, the priority of the referral can be seen to be very different. This change in priority can be both upgrading and (more commonly) downgrading the urgency of intervention or treatment. Use of the Trust's Telemedicine facility now means that almost 20 A&E Departments and MIUs are able to send photographic images of injuries which can be reviewed immediately by specialist staff at the QVH and can therefore assist in the clinical decision making process. The development of the Telemedicine Service is summarised in the following section.

3.2 *Development of Telemedicine at the QVH*

The Telemedicine project was initially established in 1999, and involved three local A&E Departments which regularly referred patients to the Trust. A digital camera was provided for each of these, together with associated training and support. Digital images were then taken of appropriate trauma cases and these were sent to the QVH as email attachments. This early approach was generally successful and additional sites began to be included. After a relatively short time, however, a number of shortcomings began to emerge, including the following:

3.2.1 Firstly, although the emailed images were being sent via the NHS network, neither encryption nor added form of security was being employed which restricted the amount of accompanying data which could be sent. Moreover, the photographic images themselves were often of an identifiable nature (eg facial).

3.2.2 Secondly, a number of technical problems frequently emerged regarding the ease of use of the system. For example, email attachments were sometimes received in an indeterminate format, which then needed to be converted to an appropriate format before they could be viewed.

3.2.3 The Trust therefore took the decision to commission the development of a bespoke Telemedicine system, which would be both easy to use and meet appropriate security requirements. The Distar (standing for Digital Storage and Retrieval) system was therefore produced by GCP Systems and was implemented within the Trust towards the end of 2000. The system has two distinct elements, the first of which is client based and as such, is installed within A&E Departments and MIUs of referring hospitals. The second is the host software, which takes the form of an internal web page at the QVH. Staff within referring Departments take photographic images of appropriate cases and then send these to the QVH via an easy-to-use five step process which results in the

appropriate images being selected, encrypted and then transmitted securely. Since the entire message including the images is encrypted before transmission, identifiable details of patients can be included, together with confirmation of patient consent. The host software at the QVH incorporates a facility which checks for the arrival of incoming emails containing photographic images, decrypts them on receipt and then posts them to the internal Telemedicine website, where they can be viewed immediately by staff with the appropriate level of authorisation to do so.

3.2.4 During the development of the system, it became apparent from an early stage that a Clinical Coordinator was required to promote the system both internally and externally, and to train staff in its use. The first two Clinical Coordinators had extensive experience as junior doctors within the Trust, and were therefore ideally suited to train staff in the use of the system, both within the trust) and at other hospital sites. A permanent Clinical coordinator has since been appointed. As a qualified nurse, his experience greatly assisted the process of dealing with other clinicians and provided an invaluable link to non-clinical support staff especially in IT to facilitate prompt troubleshooting.

3.3 *Results from Tele-Medicine at QVH*

3.3.1 Access to Images

Since the Telemedicine (and digital photographic) system has been introduced, a substantial number of changes have occurred in the management of clinical activity. For example, the trauma board in the theatre complex has had a wall mounted computer installed. This allows surgeons to communicate more objectively with each other when planning interventions, and allows junior surgeons to gain valuable feedback from senior colleagues. Similarly computers have now been located within outpatient consulting rooms, thereby enabling clinical staff to access images during patient consultations. The system has a number of features to assist these processes; for example, by entering the unit number of a specific patient, the system will display thumbnail images of all photographs taken. Clicking on any one of these thumbnails displays the full image for enhancement and viewing.

3.3.2 Proof of Effect

We have conducted several large studies. In 2002 we looked at the use of the system over 10 weeks, covering almost a thousand patients. The system was found to be simple and easy to use. In 2003 we looked at similar number of patients and found a significant difference in the way we managed their cases. Fewer patients needed to come to the Queen Victoria Hospital for an extra assessment after the phone referral (6.5% decrease) and more patients could be booked directly to the day surgery unit (10.5% increase). The decision to refer a patient from the non specialist to the specialist is rarely inappropriate, but gauging the urgency of intervention or review is fraught with difficulty and miscommunication. The accuracy of triage was assessed on arrival at the Queen Victoria Hospital, and was found to be significantly improved. This appears to be due to the extra information provided by the objective digital image.

3.4 *Cost considerations*

The cost of the system has not been recouped by extra income to the Trust, since the National Tariff does not allow for an activity of "providing specialist opinion" if the patient is not admitted, and hence the costs of providing such an advice service are unlikely to be covered. This could be considered an overhead on the cost of those who are admitted but puts a Trust offering this service at a financial disadvantage compared with those who do not. As we await the impact of the new tariff arrangements for surgical episodes, the use of a telemedicine system to increase the accessibility of the surgical service is likely to be one tool to increase the efficiency of a surgical unit, thereby allowing a greater number of patients to be treated. The lack of financial benefit has been shown consistently elsewhere in a variety of health care environments, including Australia, Canada, the USA and Europe.

Memorandum by the Association of British Healthcare Industries (MT 24)

1. Summary

1.1 The ABHI is delighted to submit written evidence to this inquiry and welcomes the investigation into this vital, and often under-acknowledged, sector of the NHS. It is estimated that approximately 38 million people in the UK have contact with a medical device in any one day.

1.2 The ABHI whole-heartedly supports the findings of the Healthcare Industries Task Force (HITF) report and endorses its outputs. Given the breadth of the HITF report, we believe it is important to prioritise the report's outputs and proposed actions. Questions remain over the report's implementation and the processes that are still to be developed to ensure that these recommendations come into force. In addition, the recommendations do not address all of the barriers to the introduction of effective technology to patients

in the NHS. We continue to have concerns over the procurement processes of the NHS. These urgently need to be addressed if patients and clinicians are to be assured of equal and fair access to the best available treatments and medical devices.

1.3 As a monopoly buyer, the Department of Health has a dual responsibility to ensure that the NHS gets the best value for money from suppliers while ensuring that a healthy market is in place. The ABHI understand the need to contain the costs of the NHS and would welcome a commercial extension of the HITF programme where government and industry engage to jointly explore and introduce methods of evaluating the cost effectiveness of treatments for both primary and secondary care as opposed to an arbitrary "lowest unit price". ABHI believes that the UK should follow the example of the USA and introduce legislation to proscribe anti-competitive purchasing behaviour in the healthcare sector.

2. The Association of British Healthcare Industries (ABHI)

2.1 The ABHI is the lead trade association for the medical technology and devices industry. This sector comprises not only manufacturers of medical devices, equipment and consumables, but also service companies, distributors, professional groups and other suppliers to the medical community. Medicines are not included. All these products and devices are regulated under the European Medical Devices Directives. The ABHI has nearly 200 member companies, many of which are small to medium sized enterprises.

2.2 The healthcare technology industry plays a vital role in meeting the needs of an increasingly health-aware population. The industry's composition is diverse:

- plasters to MRI scanners;
- walking sticks to implantable defibrillators;
- autologous cartilage implants to tape; and
- DNA probes to tongue depressors.

2.3 The UK healthcare technology industry also makes a significant contribution to the economy. The industry is made up of approximately 2,000 companies, employs in excess of 55,000 people, and has combined annual sales of £6 billion.

3. Healthcare Industries Taskforce Report (HITF)

3.1 ABHI was closely involved in HITF and worked to develop the programme of action as outlined in the final Report. The programme is an exciting blueprint that—if implemented—could lead to major medical breakthroughs, improve quality of care for patients and herald a new era of co-operation between the NHS and the medical technology industry.

3.2 The report contained five major outputs:

- A new device-evaluation service to make it easier to identify new devices and accelerate the process of getting these used across the UK.
- A modern approach to NHS regional procurement so that the best technology is bought for the best value.
- An Innovation Centre to pull together all the innovative work done in the NHS and link this to the existing networks around which the Medical Devices Faraday operates.
- The building of a new research and development capacity that gives more prominence to developing new medical devices.
- Activity to assess the needs, capacity for delivery and benefits associated with a more structured approach to training and development, especially in relation to the use of medical devices.

The ABHI fully supports these recommendations as the foundation of a programme of action for the next two to three years. In addition, exports are of importance to the medical technology industry in the UK. HITF recommends that UK Trade and Investment focuses its strategic activities and resources in favour of the United States, Germany, France, Japan and China in relation to the devices industry.

3.3 ABHI believes there are a number of threats to the successful implementation of the HITF report, however, which may prevent fair and appropriate access to treatments and technologies for patients. There are two key threats:

- unclear accountability for each output's implementation (4.4); and
- an NHS preference for short-term savings to be made, at the expense of long-term advantages for patients (4.5).

3.4 While the report has been developed with the consultation of over 200 individuals and organisations and a taskforce has been established to monitor implementation, there is a lack of clear accountability within government departments or an impetus to ensure that the outputs are achieved. ABHI remains concerned by the risk of implementation drift.

3.5 ABHI is concerned by the inherent preference within the NHS to purchase technology and medical devices at the lowest cost—regardless of whether the chosen products are the best treatment solutions for patients in the long run. While the HITF report acknowledges these challenges, little action was suggested to address this challenge directly. Further information on this point is included in section 5.

4. Introduction of New Technologies

4.1 Effective procurement by the NHS is at the heart of successful delivery of medical technology to patients. There are a number of barriers within the NHS, however, which prevent this effective procurement from taking place—and which slow or prevent the introduction of new technologies to the NHS and its patients. With the NHS spending around £15 billion a year on goods and services (£3.5 billion through PASA), the ABHI believes the purchasing function within the NHS is currently under-resourced and under-skilled.

4.2 *Price*

Several fundamental weaknesses exist within the purchasing process at PASA and elsewhere in the NHS: there is often a lack of clinical involvement in the buying process; many products are purchased only if they meet certain limited criteria—even if they are more effective products available; but most importantly, lowest price is predominantly chosen as the most important procurement factor. If lowest price is prioritised, several consequences occur. These include:

- The best technologies for patients do not reach the NHS. Products that offer huge benefits to the patient, efficiency and effectiveness of healthcare delivery will simply not be available in the UK.
- A barrier to innovation develops. The industry has little incentive to invest in R&D for new products and devices. Larger companies will re-locate activities away from the UK, while many SMEs may move out of the market altogether.
- Opportunities for partnership with the NHS disintegrate. Suppliers will not support their products but will simply sell them into the market on an opportunistic basis.
- Choice in the NHS will become limited. Clinicians, and therefore patients, will be restricted in the choices of technology and treatment available to them.
- Patient safety could be compromised. Restricting the availability of the very technologies, which can deliver improved performance, would prevent hospitals from being as clean and as safe as they need to be. In addition, UK industry will not be in a position to respond to NHS requests to design safer technologies.

4.3 *Budgets*

The NHS market itself also prevents the successful use of medical technology. The budget silos that characterise NHS funding can often lead to inefficient management of the patient pathway. An example of this is the use of insulin pumps and monitors for diabetes. While they may initially be more expensive than needles—and therefore far less likely to be favoured by procurers—they are far more effective both for diabetics and for the NHS in terms of cost effectiveness. Their use means fewer patients present with hypoglycaemic episodes at A&E and many avoid serious long-term issues, such as amputations or even blindness. The NICE guidelines for diabetes clearly state that pumps and monitors should be the first choice treatment—but few have been purchased by the NHS.

4.4 *Payment by Results (PbR)*

4.4.1 The reforms to NHS financial flows under PbR will affect NHS procurement, including the purchase of medical technologies. The tariffs for medical technologies are to set according to the national reference cost for each Healthcare Resources Group (HRG). The derivation of the current HRG list and tariff is not clear and some procedure payments appear to be so inadequate, they would fail to cover the cost of the technology alone. Many of our members are already undertaking bottom-up costing exercises and this assessment is intended to highlight where industry can work effectively with the Department of Health to ensure a good and effective system. It is hoped that this collaboration will continue in order to be sure that Payment by Results will not have an adverse impact on the introduction of new technologies to the NHS.

4.4.2 ABHI is concerned that if PbR is not implemented with great care, perverse incentives will operate to:

— further slow the availability of choices for new innovative technology; and

— in the worse case scenario, reduce the number of options available for clinicians and patients for existing technology based treatments.

4.4.3 For example—in a bottom-up costing exercise, for cardiac resynchronisation therapy (CRT), industry has estimated that the average tariff shortfall for these procedures will be in the region of £3,000–£5,000. This means that the hospital will lose money for every CRT procedure administered; making it likely that services will be withdrawn. Other similar examples can be viewed in Appendix 3.

4.5 *Reverse E-auctions*

Reverse e-auctions have recently been introduced as a procurement process for the NHS. In a reverse auction, a buyer specifies a set of goods to be purchased. Suppliers then bid the price down to win the contract. Reverse e-auctions therefore work on the principle that lowest cost is the final judging factor. As section 5.2 and 5.3 illustrate, this leads to serious negative consequences for the introduction of existing and new medical technologies and devices to the NHS.

4.6 See Appendix 4 for a case study on the introduction of new technologies.

5. Cost Effectiveness of New Technologies

5.1 The potential benefit for patients from equitable and fast access to medical technology is obvious. New devices can diagnose and treat conditions quicker and better, drastically improve quality of life and in many cases, even save lives.

5.2 New technologies can also improve productivity. In the last 20 years, medical technology has accounted for around two percentage points of the annual growth of NHS spending. The Wanless Review projected that under the "fully engaged" scenario, this would rise to 3%. It also stated that this growth in medical technology could help achieve a growth in NHS productivity.

5.3 See Appendix 5 for a case study on the cost-effectiveness of new technologies.

6. Tele-Medicine

6.1 Tele-medicine is one of a number of technologies, which can help to improve the quality of care for patients. In particular, tele-medicine has been shown to improve diagnosis, choice of treatment and management of referrals between healthcare providers in the NHS. Remote monitoring and management of patients in the community offers enormous potential for shifting the burden of care away from expensive hospitals. Telemedicine offers patients an enhanced quality of life.

7. ABHI Recommendations

7.1 The ABHI has a number of recommendations for the improved management of medical technology within the NHS. All of these are integral to the effective use of technology and to ensure patients have access to the best available treatment and technology. These recommendations are as follows:

7.1.1 The HITF outputs must be followed through with clear accountability across government for delivery.

7.1.2 The new arms-length body—"The NHS Institute for Learning, Skills & Innovation"—needs to quickly establish its role as a focus for driving innovative service development.

7.1.3 Both industry and clinicians need to be fully engaged in the process of HRG tariff development.

7.1.4 Reverse e-auctions should be eliminated as a method for procuring medical technologies.

7.1.5 The Government should deliver on its Wanless Report commitment to increase the level of purchasing of medical technology as a key driver for improved patient care and NHS productivity.

7.1.6 The ABHI believes that the UK should follow the example of the USA and introduce legislation to proscribe anti-competitive purchasing behaviour in the healthcare sector.

APPENDIX 1

EXAMPLES OF IMPACT OF PAYMENT BY RESULTS ON MEDICAL TECHNOLOGY

Example 1

UNCODED ACTIVITY: CARDIAC RESYNCHRONISATION THERAPY

Example: Impact Analysis, Elective Procedures Only

HRG	*Tariff, 2005–06, Electives*	*Specialised Uplift 2005–06? (Yes: 19%)*	*MFF Adjustment: Low (88.5%)*	*MFF Adjustment: High (128.4%)*	*Industry Estimate: Total Cost of Care*	*Payment Shortfall, (Low MFF)*	*Payment Shortfall, (High MFF)*
(a)	*(b)*	*(c)*	*(d)*	*(e)*	*(f)*	*(g)*	*(h)*
E07	2,909	3,462	3,462	4,843	8,483	−5,021	−3,640
E08	2,975	3,540	3,540	4,952	8,483	−4,943	−3,531
E09	2,623	N/A	2,623	3,670	5,081	−2,458	−1,411

Example 2

UNCODED ACTIVITY: IMPLANTABLE LOOP RECORDERS

Example: Impact Analysis for Implantable Loop Recorders, Elective Procedures Only

HRG	*Tariff, 2005–06, Electives*	*Specialised Uplift 2005–06? (Yes: 19%)*	*MFF Adjustment: Low (88.5%)*	*MFF Adjustment: High (128.4%)*	*Industry Estimate: Total Cost of Care*	*Payment Shortfall, (Low MFF)*	*Payment Shortfall, (High MFF)*
(a)	*(b)*	*(c)*	*(d)*	*(e)*	*(f)*	*(g)*	*(h)*
E31	949	1,129	1,129	1,580	2,000	−871	−420
E32	542	645	645	902	2,000	−1,355	−1,098

Example 3

UNCODED ACTIVITY: VAGAL NERVE STIMULATORS

Example: Impact Analysis for Vagal Nerve Stimulators, Elective Procedures Only

HRG	*Tariff, 2005–06, Electives*	*Specialised Uplift 2005–06? (Yes: 12%)*	*MFF Adjustment: Low (88.5%)*	*MFF Adjustment: High (128.4%)*	*Industry Estimate: Total Cost of Care*	*Payment Shortfall, (Low MFF)*	*Payment Shortfall, (High MFF)*
(a)	*(b)*	*(c)*	*(d)*	*(e)*	*(f)*	*(g)*	*(h)*
A01	1,580	1,770	1,770	2,476	13,000	−11,230	−10,524
A02	3,456	3,871	3,871	5,415	13,000	−9,129	−7,585
A06	4,285	4,799	4,799	6,714	13,000	−8,201	−6,286

Hospitals typically charge £11,000 to £15,000 for the complete service.

This product is sold by a sole-product manufacturer and would likely cease to be available in the English market under the tariff for 2005–06.

Example 4

UNCODED ACTIVITY: NEUROSTIMULATORS

Example: Impact Analysis for Neurostimulator of the Brain

HRG	*Tariff, 2005–06, Electives*	*Specialised Uplift 2005–06? (No)*	*MFF Adjustment: Low (88.5%)*	*MFF Adjustment: High (128.4%)*	*Industry Estimate: Total Cost of Care*	*Payment Shortfall, (Low MFF)*	*Payment Shortfall, (High MFF)*
(a)	*(b)*	*(c)*	*(d)*	*(e)*	*(f)*	*(g)*	*(h)*
A03	4,849	N/A	4,849	6,784	22,750	−17,901	−15,966
A04	7,126	N/A	7,126	9,969	22,750	−15,624	−12,781
A06	4,285	N/A	4,285	5,995	22,750	−18,465	−16,755

Example 5

CODED ACTIVITY: ENDOSCOPIC PROCEDURES

Example: Impact Analysis for Endoscopic Procedures, Elective Procedures Only

HRG	*Tariff, 2005–06, Electives*	*Specialised Uplift 2005–06? (???)*	*MFF Adjustment: Low (88.5%)*	*MFF Adjustment: High (128.4%)*	*Payment Shortfall, Partial Estimate (Low MFF)*	*Payment Shortfall, Partial Estimate (High MFF)*
(a)	*(b)*	*(c)*	*(d)*	*(e)*	*(f)*	*(g)*
M14	502	502	502	702	−1,413	−1,413

Other endoscopic procedures are used in HRGs F04, F15, F35 and G15 and have similar payment shortfalls.

APPENDIX 4

CASE STUDY—THE INTRODUCTION OF NEW TECHNOLOGIES

1. Cartilage damage to the knee is often very painful and can carry long-term adverse effects. It leads to knee swelling and knee locking or giving way at the knee joint. Untreated, it can lead to osteoarthritis.

2. The Royal National Orthopaedic Hospital has estimated that 17,000 out of 29,000 patients with knee defects who obtain surgery would benefit from chondrocyte transplantation (Briggs, *The Times*, 12/5/98).

3. Autologous cartilage transplantation (ACT) enables the regeneration of articular cartilage at the end of the bones, thereby restoring normal function. It consists of two surgical procedures—the first to harvest the cells, the second to implant the cultured chondrocytes (the cellular component of "hyaline" cartilage).

4. The National Institute for Clinical Excellence's guidance in 2000 stated that ACT should only be performed as part of a properly structured clinical trial, which, wherever possible, is randomised. This had had the effect of discouraging the NHS from making greater use of ACT, often against the views of consultants and patients, and has effectively limited such treatment to around 500 patients a year. The result is that companies concerned with ACT are working with other countries where innovation is promoted, not discouraged.

APPENDIX 5

CASE STUDY—THE EFFECTIVENESS AND COST BENEFIT OF NEW TECHNOLOGIES

1. Over the last 15 years Deltex Medical, based in Chichester, has developed the technology of Oesophageal Doppler Monitoring ("ODM"). It manufactures and sells a monitor, the CardioQ, together with a range of disposable ultrasound probes which are inserted into the oesophagus through the mouth or nose to determine the amount of blood being pumped around the body—"circulating blood volume". Reduced circulating blood volume is known as hypovolaemia and means insufficient oxygen is delivered to the organs. This causes medical complications including peripheral and major organ failure; the latter often leads to death. Hypovolaemia, which is akin to severe dehydration, affects virtually every patient having surgery because of the combined effects of pre-operative starvation, the impact of the anaesthetic agents and trauma from the surgery itself. Using fluids and drugs, guided by the CardioQ, to optimise the amount of circulating blood significantly reduces post-operative complications allowing patients to make a faster, more complete recovery and return home earlier.

2. Some 100 clinical papers have been published on ODM, variously showing that it is safe, accurate, reliable, easy to use and highly effective. As a body, this constitutes Level 1A clinical data—the most compelling possible.

3. Because all ODM patients feel a bit better after surgery than others, and, because many of them avoid complications, which would otherwise keep them in hospital, the clinical benefit translates into shorter hospital stays. The results of randomised controlled trials published in peer review journals over the last 10 years show reductions in length of hospital stay for ODM patients of 25% to over 40% across a range of surgical specialties. The clinical evidence encompasses procedures undertaken on circa one million NHS patients each year.

4. The latest UK study from Worthing was funded by the Department of Health. The results were announced in September 2004 and show that fluid management significantly improves patient outcomes, that you get much better results using flow-based early indicator monitors (ie the CardioQ) than existing pressure-based monitors, and that the CardioQ pays for itself several times over. Another study whose results were announced in 2004 from the Middlesex Hospital in London showed that nurse-led ODM protocols at suitable stages of the patient journey also deliver significant reductions in hospital stays.

5. To assess whether the benefits shown in the clinical studies could be delivered in the day-to-day working environment of a typical busy District General Hospital, The Medway Maritime NHS Trust conducted an extensive post-procurement audit of the impact of the technology after it purchased 10 CardioQ monitors in March 2004. On 23 September 2004 the Trust chief executive announced the conclusions from this audit:

> "We have used the CardioQ in around 200 operations in the last four months and have had very good results. It has improved quality of care for patients as they are healthier when they leave theatre, need less post-operative care and get home quicker. In addition to improving patient experience it improves efficiency and saves the Trust a considerable amount of money. We are able to treat more patients because they stay in hospital for shorter times. It is a win, win situation. The saving of about £1 million a year is the equivalent of the running costs of a ward for a year."

6. At the Medway Maritime NHS Trust the system reduced the average length of stay after surgery by three days, approximately 30%, for the range of moderate and major risk surgery where it was used. This equated to an approximate saving of £800 per patient. The probes used cost the NHS £50 each and the monitors £6,000 each. Based on the Medway experience, full payback on the cost of the monitor is achieved after eight patients—for the average NHS Trust treating its share of the one million patients with existing clinical evidence, full payback on the capital investment would be achieved within between one and two days per monitor.

Memorandum by the Royal College of Pathologists (MT 12)

The Royal College of Pathologists (RCPath) welcomes the opportunity to contribute to the evidence submitted to the House of Commons Select Committee on Health, specifically on The Use of New Medical Technology within the NHS.

Submissions were invited under the following (italicised) headings:

1. The Utilisation of Telemedicine (Including Telecare) and its Future Potential for Improving Services

1.1 Telemedicine is an important development in the support of all pathology disciplines. In those pathology specialties where patient samples are analysed in a laboratory to produce numerical measurements (haematology, chemical pathology, microbiology and immunology), remote access to the laboratory data is an essential adjunct to the diagnosis and management of patients by all clinical staff.

1.2 Electronic transfer of laboratory data is already routine between some secondary care centres and between primary and secondary care. The introduction in the near future of secure network technologies either through wired or wireless networks will increase access for clinical staff working from home or in the field and significantly benefit the delivery of patient care.

1.3 Current technology goes far beyond the facility to exchange numbers and text electronically. Telemedicine in pathology (often referred to as telepathology) has the potential to allow a pathologist to view images of a specimen remotely. These may be still images, video of the field of view of a microscope, or in some cases a complete digital scan of the slide at range of magnifications. At this point telepathology moves beyond the straightforward transmission of factual data; it becomes a tool to assist the formulation of expert opinion. It is essential to recognise that it is the expert interpretation of the image in telepathology that is the basis of the diagnosis. The diagnosis is therefore highly dependent on the appropriate provision of the image by the referring pathologist and on the quality of the image that is displayed to the receiver.

1.4 Electronic methods of image transfer have been used in some limited settings so far, but use is likely to increase over the next few years. Currently the most promising area is probably expert consultation, which is becoming more necessary as pathologists specialise in increasingly narrow fields. Telepathology provides

the pathologist with the ability to seek the opinion of one or more experts anywhere in the UK or even further afield. This is particularly useful when diagnoses are difficult or where a second opinion may be required with some urgency, for example during organ transplantation.

1.5 Telepathology also has enormous potential in developing systems of laboratory quality assurance, multidisciplinary team meetings in cancer diagnosis, staff training and education.

1.6 The use of telepathology in routine primary diagnosis is also possible but it raises additional problems, some of which may not be obvious to those who do not work in the field.

1.6.1 It is well recognised by all of those involved in the care of patients that accurate laboratory diagnosis can often be achieved only by correlation of the laboratory findings with the clinical presentation and history of the patient. Reaching the correct diagnosis is often an iterative process underpinned by a close dialogue between all those involved in the care of the patient and comparison with previous specimens. This process includes the pre-analytical phase (eg advice on what specimen to take, how it should be fixed and transported to the laboratory) the analytical phase (where exchange of clinical information between laboratory and physician is often vital, and it is often essential to have ready access to previous samples from the same patient for comparison) and the post-analytical phase (translating laboratory findings, which may be relatively subjective or semi-quantitative, into valid treatment options and prognostic information).

1.6.2 This collaboration and review process has been well developed in the multidisciplinary team (MDT) meetings that are now a core part of cancer care in the UK. MDT meetings are often very successfully supported by telemedicine. Nevertheless, if telepathology is used as a "quick fix" to provide cheap services in isolation from a collaborative environment there is a significant risk that it prevents, or does not allow for, adequate discussion between the clinician and the pathologist and patient care will suffer.

1.6.3 For simple cases, this may not matter and may be cost-effective. But the wholesale replacement of local pathology services by a distant telepathology service would be the laboratory equivalent of believing that NHSDirect could take over the role of the entire NHS. Patients with problems that are not straightforward would suffer.

1.7 The introduction of telepathology therefore has risks that will need to be addressed. These problems are discussed further below under "regulatory framework".

2. The Recommendations of the Healthcare Industries Task Force (HITF) Report, Published 17 November 2004

2.1 The Royal College of Pathologists is committed to maintaining and improving the standards of laboratory diagnostic services. It therefore strongly supports the aims of the HITF report "Better healthcare through partnership" and affirms its wish to assist in realising the "key outputs" identified in that document.

2.2 A closer relationship between the healthcare industry and the Department of Health and the healthcare industry is to be welcomed. It is essential that the professionals who use the industry products are involved with and can advise this partnership. The RCPath is keen to provide this involvement and advice.

2.3 There are four main areas where the interests of the RCPath coincide with the introduction of new medical technology and the contents of the HITF report. These are:

2.3.1 the introduction of point of care testing (POCT) and over the counter (OTC) diagnostic devices instead of tests which are currently laboratory based (discussed further in paragraph. 3.2)

2.3.2 the introduction of new diagnostic techniques which are supplementary to (or in some circumstances render obsolete) existing diagnostic tests. The development and implementation of new molecular diagnostic techniques is particularly relevant here (discussed further in paragraph 3.3).

2.3.3 the facilitation of healthcare research and development, including method validation (discussed further in paragraph 3.4)

2.3.4 the development of a coherent and efficient regulatory framework. This must protect patients from inappropriate and poor quality devices and techniques, but it must not damage patients by causing an unnecessary delay in the implementation of innovations and improvements (discussed further in paragraph 3.5).

2.4 The RCPath is supportive of the aims of the HITF report and many of its members are already involved in related work. However, we are concerned to alert the Select Committee to potential problems with and barriers to implementation, some of which we believe are not made sufficiently explicit in the HITF document.

2.5 The RCPath wishes to assist in overcoming these problems and barriers.

3. The Speed of, and Barriers to, the Introduction on New Technologies

3.1 *Telemedicine (telepathology)*

3.1.1 There are three significant barriers to the introduction of telemedicine in pathology: financial, technical and a lack of expertise.

3.1.1.1 While it is accepted that telepathology will benefit niche areas, if these are to be successful they will often require dedicated allocation of funds, because the benefits are distributed across the NHS rather than being realised by one Trust. The provision of a national on-call histopathology service to transplant retrieval teams is an example.

3.1.1.2 Technical limitations are a barrier to the introduction of telemedicine in the short to medium term. Disparate laboratory systems, some of considerable age, are present in laboratories throughout the country, while many Trusts have only limited capacity network connections to NHS net. We anticipate that these constraints should be reduced through the National Programme for Information Technology, with the introduction of the new NHS network and with the modernisation of pathology systems, but these are unlikely to be in place within the next five years.

3.1.1.3 Lack of expertise in the use of new technologies also poses a barrier to their introduction. Diagnosis using an image on a screen is very different from looking down a microscope and navigating a virtual slide on a computer is different skill from moving a slide on a microscope stage. This is discussed further below under Regulatory Framework. We have previously found that busy NHS staff may be very reluctant to spend time learning how to use telepathology systems unless they can see an immediate, obvious and easily realisable benefit.[1] It is often easier, if slower, to put the relevant diagnostic material in the post.

3.2 *Point of care testing (POCT)*

3.2.1 The main drive to the introduction of POCT is the development of new devices which can rapidly deliver sufficiently high quality diagnostic services in a cost-effective way.

3.2.2 The HITF report identifies several barriers to implementation, including financial constraints. We believe that where it is appropriate for POCT to replace an existing method of laboratory-based testing a full cost-benefit analysis will promote, rather than hinder, its implementation. Problems lie in objective comparison of non-financial benefits (such as increased speed) with financial costs.

3.2.3 The RCPath is however concerned that issues of quality and governance are not overlooked in this change. It is regrettable that independent organisations specifically concerned with these issues (such as the United Kingdom National External Quality Assessment Schemes organisation, www.ukneqas.org.uk, and Clinical Pathology Accreditation Ltd, http://www.cpa-uk.co.uk/) were not represented on the Task Force.

3.2.4 The Medicines and Healthcare products Regulatory Agency has recently reiterated its advice on the implementation of POCT (DB 2002(03) "Management and Use of IVD Point of Care Test Devices", and "Point of care testing—top 10 tips", issued July 2004). The MHRA advises that POCT services should be linked to and supervised by staff in a local NHS diagnostic laboratory, and that POCT users should participate in appropriate external quality assessment schemes. In our experience, problems with POCT technology usually arise because staff (or patients) using the machines make mistakes or do not recognise machine malfunction when it develops. For this reason external assessment schemes and oversight are very important.

3.2.5 We have previously expressed our concern that POCT services and OTC diagnostic kits are being supplied without due regard to these MRHA recommendations. For example, if an assay for a blood cholesterol level is undertaken in an NHS laboratory, the laboratory is obliged to participate in an external quality assessment scheme for cholesterol analysis and the laboratory must enrol for external inspection and accreditation with an organisation such as CPA Ltd. If the same measurement is performed in a high-street retail outlet these safeguards are rarely if ever in place. We are currently in discussions with the MRHA, the NPSA, the RCGP and the Pharmaceutical Society to resolve this issue.

3.2.6 Most observers will accept that members of the public have little understanding of the quality controls needed to produce accurate and precise[1] laboratory measurements. However, it is a regrettable and little-recognised fact that most doctors similarly have little or no knowledge of the "behind the scenes" work which is necessary to maintain the quality of the laboratory results upon which they rely.

[1] In this context, "accurate" means the proximity of a result to the "true" value, or to that given by an accepted reference procedure; whereas "precise" refers to the level of reproducibility of the result. They are not interchangeable terms.

3.2.7 We therefore suggest that EITHER a single regulatory framework must be applied to all diagnostic tests, whether POCT or laboratory based, OR that tests provided outside a "laboratory standard" regulatory framework should be clearly identified as screening tests, where abnormalities require confirmation under the supervision of an accredited laboratory. To do otherwise risks misleading consumers, patients and doctors.

3.2.8 We are concerned that the transfer of the Device Evaluation Service from the MHRA to the NHS Purchasing and Supplies Agency must not mask this issue.

3.3 *New diagnostic techniques, particularly those involving molecular biology and molecular genetics*

3.3.1 The RCPath supports the view that numerous new and improved diagnostic tests are likely to become available in the near future, and believes that many of these will be based on the techniques of molecular biology, especially molecular genetics. For example, we note and agree with the comment at paragraph 4.15 of the HITF report, that "common cancers in reality consist of many distinct forms of the disease, which require entirely different drug types". These distinct forms require new diagnostic techniques for their detection, often including genetic analysis.

3.3.2 The HITF report correctly identifies resource issues as one of the barriers to the implementation of such new techniques.

3.3.3 We believe that another important barrier is a lack of certainty as to when a new technique can be regarded as sufficiently well validated and clinically proven (a) to permit its introduction and (b) to permit withdrawal of any older technique which it may render obsolete. These are two separate issues; both have resource implications and therefore both impact on implementation.

3.3.4 This problem, especially the withdrawal of outdated methods, is exacerbated by the fear of litigation if a patient is harmed by a change in practice which is in retrospect judged to be premature. It is also inhibited by a lack of agreement between different professional groups. For example, the RCPath recently published a document entitled "Histopathology of limited or no clinical value", in an attempt to reduce the futile use of NHS resources. The implementation of its recommendations has been less extensive that we had hoped, at least partly because of lack of agreement with other professional groups. Where there is uncertainty or disagreement, even if it is ill-informed disagreement, the old test usually continues to be performed.

3.3.5 For this reason we would welcome the introduction of an agreed national system of evaluation, not only for new devices, but also for new diagnostic approaches. At present, NICE evaluates new therapeutic interventions and the MRHA evaluates new medical devices. The National Genetics Reference Laboratories (*www.ngrl.org.uk*) provide advice on clinical genetics, but there is no equivalent system for the evaluation of other new diagnostic techniques. Rather than being invariably prescriptive, this central evaluation agency should (as appropriate) provide evidence to assist local cost-benefit analyses. As part of this work it should specifically attempt to produce authoritative advice on circumstances where outdated diagnostic tests can be withdrawn.

3.3.6 A further barrier to the implementation of new genetic techniques is the lack of public understanding. Patient consent and autonomy are central to the provision of healthcare, but there is a widespread concern and mistrust especially of any technology which is described as "genetic". The RCPath is keen to assist with measures intended to improve public awareness and understanding of modern medical developments.

3.4 *The facilitation of healthcare research and development*

3.4.1 The development and validation of new diagnostic techniques is an area of intensive research activity. The RCPath therefore shares the concern expressed in the HITF Report that although the UK has a worldwide reputation for R&D, business investment in R&D is beginning to decline (HITF report paragraph 3.12.2).

3.4.2 This is paradoxical, because we agree with the HITF report that "Our largest asset is the NHS itself" (HITF report paragraph 4.35). The size of the NHS should allow unparalleled access to large study populations, even where the disease under investigation is rare. The introduction of the National Program for IT (NPfIT) and the NHS Information Spine ought to enhance this potential.

3.4.3 We believe that one of the main barriers to this work being undertaken in the UK is the climate of the current regulatory framework. New requirements have been introduced, sometimes without the introduction of adequate mechanisms to satisfy those requirements.

3.4.4 Recent changes in the regulatory framework relevant to the interests of the RCPath include the Data Protection Act 1998 and the Human Tissue Act 2004. The RCPath welcomes these changes, which are necessary and have been largely driven by the recognition of the importance of patient consent.

3.4.5 New diagnostic approaches which are relevant to patients' samples are often best investigated using "residual" material, left over from real diagnostic samples after tests are complete. This is material which would otherwise be incinerated. In this context obtaining consent becomes a problem, simply because the patient is not present in the laboratory where the "residual" tissue is held. We know that over 97% of patients

give consent to this sort of work if they are asked,[2, 3] and that historically such research has very rarely caused any harm to the tissue donor. Nevertheless, in the absence of documented consent, research often becomes difficult or impossible.

3.4.6 This can result in the paradox of research into a specific disease being prohibited, supposedly to protect patients who are suffering from that disease, but without those patients ever having their wishes sought. We can supply specific examples of this paradox.

3.4.7 We therefore urge the introduction of a scheme whereby all NHS patients are asked to express their wishes regarding involvement in research, whether it be in clinical trials, using their data, or using "residual" samples of blood or tissue. We note with regret that although with the introduction of the Human Tissue Act the Government identified resources to improve consent processes at the time of bereavement, no such resources were made available in relation to the new consent requirements for living patients.

3.4.8 It is regrettable that the NPfIT does not propose to include data fields in the "NHS information spine" specifically for the storage of patient preferences in relation to research. If it did so, it would open the possibility of identifying all the patients in the NHS who fitted a specific disease and ethnographic definition, and who had stated a willingness to participate in research (or to allow their data and samples to be used in research). We believe that if such a system was available it would represent a major incentive for investment in healthcare R&D in the UK.

3.5 *The regulatory framework*

3.5.1 Telepathology has risks that will need to be addressed by a regulatory framework. For example:

(a) There may be limitations in the technology that impair the quality of the image seen by the remote pathologist, which may make it unsuitable for diagnosis. Current systems of medical laboratory accreditation will therefore need to be extended. There is the need for device evaluation (HITF Report 5.10) which should be combined with a programme of establishing internationally recognised standards (HITF Report 5.15) for image capture, storage and transmission of pathology images, similar to DICOM used in Radiology. At present the use of digital slide scanners is limited to very few academic groups in the UK and the recommendation of the Task Force report to establish the Health Technology Co-operative (5.14) and enhance the R&D capacity (especially the New and Emerging Technologies Programme) in the NHS (5.13) is to be welcomed.

(b) Primary diagnosis by telepathology raises particular regulatory problems. To address the issues discussed in paragraphs 1.6 (above), a distant pathologist involved in primary diagnosis must have excellent communication channels to the referring clinical team. This is needed to facilitate clinico-pathological correlation in the formulation of a diagnosis and management plan, much as happens currently in a multidisciplinary team meeting. There must also be adequate access not only to the clinical history but also to previous samples from the same patient, and access to further tests (such as immunohistochemical stains) as indicated by the clinical problem.

(c) Pathologists must be trained in the use of telepathology for diagnosis, as distinct from the use of conventional microscopes for diagnosis. This is crucial, but it is a more subtle point than it may seem. Even pathologists often assume that diagnosis based on using a microscope and diagnosis based on viewing computer screen images are interchangeable skills. There is solid evidence that this is not so, from the published literature[4] and from trials in the examination system run by the College of American Pathologists. Even experienced pathologists need training and revalidation before making this switch. The Royal College of Pathologists has already recognised the training needs of future pathologists in using this new technology and will be making digitally scanned slides available to trainees across all the SHO training schools. A programme of continuing professional development will be needed for senior staff to ensure that they are skilled to use this new technology and aware of its limitations.

(d) Remote pathologists would need to be authenticated to ensure that their accreditation is verified and they are not practising outside their area of competence. This may be difficult if the remote pathologist is based outside the UK.

(e) Issues of liability need to me resolved to address a situation where the negligence of a pathologist who is working outside the jurisdiction of the British legal system causes harm to an NHS patient.

(f) Where the remote pathologist's first language is not English, the remote pathologist must be sufficiently competent in the English language to ensure that misunderstanding does not arise as a result of language barriers.

(g) Protocols must be agreed to ensure the security and confidentiality of patient information.

3.5.2 We note and agree with the emphasis placed by the HITF on the need for an improved regulatory framework and device evaluation service (eg HITF recommendations 1, 2, 9 and 10).

3.5.3 The views of the HITF report in this respect accord closely with those developed recently by a joint working group of the Royal College of Pathologists, the Association of Clinical Biochemists and the Association of Clinical Pathologists.

3.5.4 We have already provided further arguments supporting the need for a coherent efficient and authoritative national system for device evaluation, and the need to extend this system to new diagnostic techniques (paragraph 3.3.3–3.3.5).

3.5.5 We have already provided arguments for a national system to record the wishes of all NHS patients, in order to comply with appropriate consent requirements (paragraph 3.4.6–3.4.7).

3.5.6 The transfer of the device evaluation agency from the MRHA to the NHS Purchasing and Supplies Agency should not be allowed to result in the loss of the expertise which has developed in the present system.

3.5.7 We believe that the current system of research ethics evaluation (under COREC) is cumbersome. It imposes on small laboratory-based projects using residual tissue samples or clinical data a bureaucratic load which is appropriate to a clinical trial of a potentially dangerous experimental therapy. Many of the requirements seem irrelevant to studies where the patient is not actually present. We believe that this is an additional factor which is encouraging industrial R&D to relocate elsewhere in the world. We hope that the current Ministerial Review of COREC will result in an improvement.

3.5.8 The RCPath will be pleased to assist by identifying relevant professional expertise to facilitate the development of a safe and efficient regulatory framework.

4. The Effectiveness and Cost Benefit of New Technologies

4.1 We anticipate that most decisions on the implementation of new medical technology within the NHS will be made locally, based on local cost-benefit analyses. If these decisions are to be consistent and based on sound evidence it is essential that Trusts must have a source of reliable information and advice from an efficient, authoritative and comprehensive central evaluation service.

4.2 In relation to telepathology, the greatest benefits to patient care will be achieved by:

(a) the introduction of interoperable laboratory systems capable data exchange to a common format across all pathology disciplines;

(b) a high bandwidth network linking all NHS sites; and

(c) the targeting of new technologies at niche areas such as transplantation and for remote consultation with experts.

Benefits (a) and (b) should be delivered through the National Programme for Information Technology, but will require appropriate funding, especially for the modernisation of laboratory systems. Benefit (c) could be developed through a specific funded programme as recommended through the Health Industries Task Force and combined with the current pathology modernisation

References:

[1] Bamford WM, Rogers N, Kassam M, Rashbass J, Furness PN. The development and evaluation of the UK national telepathology network. *Histopathology* 2003;42(2):110–9.

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Memorandum by Tunstall Group Ltd (MT 32)

Summary

1. Simple technology, well made and configured to produce effective outcomes, is with us now, and increasing evidence confirms the benefits of the use of such technology primarily to patients but importantly to both health and social care agencies. The technology is cost effective relative to residential care and hospital admission.

About Tunstall Group

2. Tunstall is Europe's leading supplier of telecare products and services for older, disabled and other vulnerable people. Established in 1957 and based in Yorkshire, the company has sales of circa £70 million per annum, employs around 750 people and operates in Europe, North America and Australasia. It works with 90% of local authorities in the UK and spends some 5% of revenue on R&D.

The utilisation of telemedicine (including telecare) and its future potential for improving services

3. Hospitals are great places for people who need to be there, but are dangerous and often unhappy places for people who no longer need acute levels of care. Properly supervised, many people can receive rehabilitative care (or indeed often preventative care) away from locations where the specialist facilities are provided. By managing and monitoring risk many people can receive services in their own homes or in community based nursing homes, with costs now demonstrably much lower than the cost of a place in an acute sector hospital. Shorter stays in hospital, or avoidance of admission altogether, can mean that waiting lists can be reduced and as has happened in at least one instance numbers of acute sector beds reduced.

4. Key features of the sorts of technology now being used in various parts of the country and the world are:

- They are simple, so have very high levels of reliability at relatively low cost.
- They can be installed quickly without the need for expensive hard wiring, so that decisions to discharge can be implemented quickly.
- The infrastructure to manage the provision of services already exists in the UK so "on costs" are lower.
- Units can be supplied in flexible configurations so that they reflect the needs of the patient.
- Risk can be managed, with individual parameters set to reflect the health of each individual patient.
- Records can be maintained electronically both in terms of the well-being of the patient but also when a service is provided and who provides it.

The recommendations of the Healthcare Industries Task Force (HITF) Report, published 17 November 2004

5. We welcome the publication of the above report which states that "the case for an alternative model which focuses on early diagnosis and prevention is gaining momentum". Furthermore "remote monitoring technologies will allow the health of at-risk patients to be monitored as they go about their daily lives and treatment to be provided when there is an indication of need emerging. All of this will be done via intelligent systems which analyse streams of data, looking for patterns which indicate if intervention is required."

6. The report also highlights the role of assistive technology in the integration of health and social care. "DH recognises that increasingly it is beneficial for patients and service users to receive health and social care services in the community where appropriate. For instance, in the management of chronic disease and to support older people, which is a growing need as the age profile of the population lengthens, solutions often need to be implemented in the community or home environment to meet people's expectations and enable them to live as normal a life as possible, maintaining their independence. Increasing emphasis on home care has meant closer co-operation between health and social care and an expansion of resources in this area. By 2006 a further 100,000 people each year will be supported to live independently at home. Whilst there are a number of issues to resolve in delivering integrated services, caring for people close to their home environment is a pressing objective for the future." The availability of telecare is therefore consistent with the recommendations of the HITF report and can help deliver the desired outcomes

The speed of, and barriers to, the introduction of new technologies

7. The announcements made by the Chancellor last July in respect of additional funding are very welcome, and will hopefully lead to an extension of the use of technology in this way in other parts of the country. However, unless there is good joint working between the NHS acute sector, primary health care, social services and in many instances the local housing authority, progress will be limited. All too often the fact that it is the patient who primarily benefits is lost sight of as the various agencies argue about finance. Shorter waiting lists will benefit primary care services and social services. Reductions in pressure for acute sector places will financially benefit primary care trusts. Housing providers who often already have the basic infrastructure in place can make their services more cost effective, and workforce pressures can be reduced both in the primary care sector and social services.

8. As the new money contained in the Comprehensive Spending Review could point to a new model for funding care, direction will be needed from central government to social services to avoid diversion of funds into other local authority spending priorities. There will be a need for policing to ensure that all the money intended for telecare does indeed reach the front line.

9. In the feedback the company receives from those individuals who now receive services based on our technology not only do recipients of the service feel more confident that their health and well being is being constantly monitored, but relatives and carers also feel reassured that if the patient does experience a deterioration in the health it will be identified quickly so that appropriate medical interventions can take place.

10. As our technology develops the range of conditions where it can be used is increasing. Many cardiac conditions can be managed without the need for regular visits to the doctor or outpatients department. This is particularly effective in rural areas, as has been demonstrated in the monitoring of women who are having complicated pregnancies in the Outer Isles, where expensive trips to specialist clinics in Glasgow have been reduced.

11. There remains a need to remind policy makers at regional and local levels of the benefits of the use of telehealthcare and telecare, with clearer direction centrally. We remain convinced that if all the agencies work together money becomes a non issue as the benefits to all become obvious.

12. We wish to emphasise also the need for systematic deployment of telecare against national standards with for example a single national care assessment and a model for delivering telecare as needed, on the same day as the assessment if possible. There is potentially a big role here for the NHS Care Record System (NCRS) combined with a desktop telecare application system.

The effectiveness and cost benefit of new technologies

13. Telecare technology is cost effective relative to other forms of care. A basic system costs in the order of £200 to £400, less than the cost of one week in a residential care home (typically £450) and one day in an acute hospital bed (typically £600). A fuller system for more complex needs costs in the order of £500 to £800, less than two weeks in residential care or two days in an acute setting.

14. Telecare technology was endorsed in the Audit Commission report of February 2004, which concluded that there was sufficient evidence to recommend mainstream deployment of telecare. The Audit Commission stated "the potential of AT to promote independence and save money across public services is not in doubt." According to the Commission there were 648,000 A&E attendances and 204,000 admission to hospital for fall related injuries in people aged 60+ in 1999. Falls cost the Government £981 million of which the NHS incurred 59%. They also suggest that by utilising telecare the NHS could save £63 million for COPD and £118 million in CHF alone (1).

15. This strong endorsement is supported by the increasing body of evidence emerging from more than 20 telecare pilot projects across the UK.

West Lothian

16. One of the most well established is in West Lothian in Scotland, which is being independently evaluated by the University of Stirling. The results to date have shown that there are real cost benefits both to the NHS and the local authority, whilst rates of recovery have not been jeopardised, but rather have improved.

17. The objectives of the West Lothian project are to:

- provide a rapid response service which aims to prevent hospital admissions and reduce the length of stay;
- offer a home safety service to support people in their own home for as long as possible;
- provide a housing with care model to replace institutional care, which sustains independent living through housing design, individually tailored care services and the efficient use of new technologies.

18. The results for the first phase of the project are as follows:

- the number of hospital bed days saved was 3,364 (full year equivalent) with the service getting people home quicker or preventing admissions in the first place;
- the level of delayed discharges for people over 65 in West Lothian was reduced by around one third to 2.14 per 1,000 people, compared to 4.33 in the rest of the Lothian area;
- the length of stay in nursing homes in West Lothian has dropped from approximately three years in 1999 to 1.8 years by the end of 2002.

Carlisle

19 In Carlisle patterns of healthcare delivery have been changed through the use of telecare. The project aims to develop and provide a range of community based services that prevent avoidable acute admissions and facilitate the transition from hospital to home and support continued independent living at home, utilising modern telecare technology.

20. Since the scheme was introduced in February 2002, 420 individuals have received care packages in 13 months. Most packages (60%) were put in place to support a transfer of care, with 20% of packages instigated to monitor clients at risk of falling, and 20% actually preventing admission to hospital.

21. An important aim of the project is to release hospital beds and the major resources benefit of the project is derived from the savings produced by this one aspect of the project. The comparison of £5,100 for six weeks in hospital (based on a minimum cost of £850 per week for a hospital bed) and £154.28 for the care package cost speaks for itself.

22. The project has achieved its aims of delivering an effective intermediate care programme through partnership working, and fulfilling many of the standards set out in the NSF. The project has demonstrated that telecare plays a key role in delivering effective, client centred services, at the same time releasing funds to be used for other vital services. The technology sustains independence and promotes healthy ageing in a safe, home environment, in line with both Government policy and the wishes of the vulnerable.

Northamptonshire

23. The project explores the use of telecare technology in the homes of people with dementia in Northampton, with the aim of preventing admission into hospital or residential care, supporting carers, promoting independence and reducing perceived and actual risks. Assistive technology is installed following a careful assessment of need. The project is currently actively exploring ways of achieving a transition from project to service by mainstreaming its practice.

24. The objectives are;

— To assess if assistive technology can help people with dementia to remain living in their own homes.

— To delay or prevent the need for them to enter residential care.

25. Results

— The costs of residential and hospital provision amongst a comparator group over the 15 month evaluation period were £66–68,000 higher (based on 14 service users).

— Telecare technology was a contributing factor in enabling individuals to maintain existing levels of independence.

Fold Housing, Northern Ireland

26. The Going Home Staying Home Project is a partnership between Fold Housing, Foyle Health and Social Services Trust and Northern Ireland Housing Executive. The three-year project ends in April 2005 and generated funding from the Northern Ireland New Directions funding programme.

27. The aim of the project is to offer support to older people in the Foyle Trust area by supplying a range of telecare and assistive technology, monitoring and support services. The results to date show that:

— 320 people have received telecare packages in the Foyle Trust Area.

— 356 people have successfully returned home after leaving hospital with the most appropriate care package, having spent six weeks in intermediate care.

— 15 people have received monitoring for Chronic Obstructive Pulmonary Disease at home which has enabled them to return home seven to 10 days earlier.

28. A study by Professor Mark Hawley (2) has shown that deployment of Lifestyle Monitoring would have a major impact on health and social care costs. A cost model has been developed for a city such as Birmingham with 11,000 users. Based on reduced hospital bed days, delayed entry to residential care etc, at the end of 10 years, £8.3 million would be saved, 47% by the NHS, 49% by social services.

Recommendation

29. Central Government should issue strong direction to social services departments to ensure that the new money (Preventative Technology Grant) allocated in the 2004 Comprehensive Spending Review should be spent as intended and not diverted by local authorities into other priorities.

Oral Evidence

30. We would be delighted to give oral evidence to the Health Committee if required

References

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2 Hawley M S (2003) Implications for Health and Social Care, in Brownsell S and Bradley D, Assistive Technology and Telecare, Policy Press. ISBN 1-86134-462-7.

Witnesses: **Professor Carl May,** Centre for Health Services Research, University of Newcastle upon Tyne, **Mr Baljit Dheansa,** Consultant Burns and Plastic Surgeon, Queen Victoria Hospital NHS Foundation Trust, **Mr John Wilkinson,** Director General, Association of British Healthcare Industries, **Professor Sir James Underwood,** President, Royal College of Pathologists and **Mr Tony Rice,** Chief Executive, Tunstall Group Ltd., were examined.

Q1 Chairman: Can I apologise for the slight delay and can I congratulate those of our witnesses who have managed to make it through the snow, from wherever you have to come, as some of you have had to travel some distance, and we appreciate it. We have one witness who is stuck on a train and who hopes to be here as soon as possible, but we felt it important to make a start. Can I thank you for your cooperation with this short one session inquiry; we are most grateful to you. As you appreciate, we have two short sessions this morning, so I hope our questions will be reasonably concise and I would appeal for reasonably concise answers. I think in some respects, because the area that we are looking at is so wide ranging, that perhaps we are looking at common things which we can pull out of the two sessions that might be helpful in any report that we produce. Can I begin by asking you each to briefly introduce yourselves to the Committee, starting with you, Professor May?

Professor May: My name is Carl May; I am Professor of Medical Sociology at the University of Newcastle. Over a period of several years now we have undertaken different kinds of evaluation work on telemedicine, telehealthcare and telecare systems, which we have enjoyed greatly and which we hope have made a contribution to debates about policy and practice in this field.

Mr Rice: I am Tony Rice, Chief Executive of Tunstall. We are the leading company in the UK on telecare, with one and a half million systems installed in the homes of the elderly, those with chronic conditions, and who are frail and at risk.

Professor Underwood: James Underwood, President of the Royal College of Pathologists. Our responsibilities are for professional training and standards in pathology.

Mr Wilkinson: I am John Wilkinson. I am Director General of the Association of British Healthcare Industries. We represent businesses producing and distributing everything from sticking plasters to MRI scanners. We represent in excess of 500 companies, and we acted as the Secretariat for the Healthcare Industries Taskforce.

Q2 Chairman: Does your remit include companies of the kind that Mr Rice has, the telecare section as well, or are you primarily on the medical side?

Mr Wilkinson: Not specifically. We have a broad reach. There are companies in our remit that cover specific telecare, but we have a broad reach.

Mr Dheansa: My name is Baljit Dheansa, I am a burns and plastic surgeon based at the Queen Victoria Hospital Foundation Trust, which is a Trust that has a significant input in the practical use of telemedicine for the management of burns and plastics format. It is currently going under review for its critical care burns service and the telemedicine that we use is an essential part of that.

Q3 Chairman: Thank you very much. Can I ask a broad opening question about where we fair in terms of telemedicine and telecare in international terms? One of the advantages of being on this Committee is that we get the chance to look at other healthcare systems in various parts of the world, and I have always been very struck by other countries making much greater use of new technologies compared to ourselves. I was conscious of the Wanless Report's comments some time ago about the way we have been historically slow to adapt to these new technologies and we have had figures presented to us showing that we are more or less at the bottom of the European league on percentage of healthcare spent on medical technologies. Why is this when we have some brilliant ideas—some of the people I meet, some good companies are in the forefront of world technology advancing ideas—that we as a country are so slow to take advantage of these innovations? I do not know who wishes to start on that? Mr Wilkinson.

Mr Wilkinson: Could I perhaps introduce a perspective from the Healthcare Industries Taskforce, which we were heavily involved in last year, which was really addressing these issues and trying to work our way through with the Government and a number of stakeholders in the sector as to why things were not happening? I think one of the key elements is the propensity for budgets to be held in silos in the UK, and it is quite difficult to demonstrate value across silos and treatment pathways, if you like. Let me give you an example. Insulin pumps are a technology which has been well adopted in other countries—40,000 people use them in Germany and less than 2,000 use them in the UK. Why is this important? Type 1 diabetics, if not managed effectively, suffer substantially later in life and cause huge costs to be brought on to the system. An investment up front in managing diabetes effectively can downstream, bringing huge benefits in avoiding blindness, amputation, ulceration and all sorts of unpleasant consequences. So I think there is a silo issue. I think also there is an issue relating to the engagement of the involvement of clinicians in the procurement process and particularly the evaluation of technologies and translation of those through every day use. Again, the Healthcare Industries Taskforce has been working very hard to try to work on the mechanisms which can join these bits up and pull technology through the system.

Q4 Chairman: I am assuming that if we were, for example, to make a recommendation suggesting the integration of our health and social care systems that might be helpful in advancing the cause of telehealth and telecare.

Mr Wilkinson: I think increasingly the location of treatment and management of patients is becoming less hospital-centric.

Q5 Chairman: So a more integrated system would be helpful?
Mr Wilkinson: It is integrating the passage of the patient from first presentation at the GP through to management in the community afterwards, potentially after a surgical intervention, is clearly the way the world is going. So I think integrating those activities clearly has value.

Q6 Dr Naysmith: Can I just come in on that? You still have not answered the question the Chairman asked you. Let us say there were 40,000 using these insulin pumps in Germany and less than 2,000 here.
Mr Wilkinson: As I say, there are a number of issues. There are clinical practice issues and how do we get best practice consistently applied across the country? I believe that there are issues in terms of funding reaching the front line, so certain PCTs are happy to fund this sort of activity whereas a neighbouring one may not be. So there are many issues.

Q7 Dr Naysmith: Nobody is saying it is a waste of money, are they?
Mr Wilkinson: I do not think so. I think the challenge is recognising the value effectively and translating that across the system so that people can make wide decisions. People are hard pressed to manage their individual budgets.

Q8 Chairman: I know that Mr Rice and Professor May may want to come in on that general point, but can I throw in another question arising from your answer? One of the things that struck me in looking at how we can advance this whole area within the health service is the way in which increasingly both the current Government and the previous Government have moved in the direction of devolving decision making and devolving budgets, so perhaps in a sense reinforcing the silo concerns that you have pointed to. Is that a factor in some of the concerns you have about the inability to move things forward? Mr Rice, do you want to come in?
Mr Rice: Yes. The answer is absolutely, unequivocally yes. The role of telecare is to effectively keep people where they want to be, in their own homes, and remove the routine load from the acute sector, the hospital sector essentially, and bearing in mind that the routine load is largely centred around the elderly who are the people who mostly have the chronic conditions, although obviously Type 2 diabetes is a much younger condition. Everyone contracts MRSA but the elderly are the ones who tend to die, they are the more frail and vulnerable and therefore we want to keep them away from hospital. So telecare fulfils that role. Telecare of course is preventative and it is funded by social services and acute care is funded by the Department of Health and therefore the removal of people from the acute sector, which saves the Department of Health money, imposes an additional cost burden on social services, and until we find a way to pool those budgets—and there are initiatives underway to do that—then I think the budgets and responsibilities being divided will continue to mean that we are sub-optimal in our utilisation of new technologies.

Q9 Chairman: Professor May?
Professor May: It seems to me that one of the errors we fall into is viewing the National Health Service as a unitary organisation, when it is actually a federation of several hundred NHS Trusts, each of which have often incompatible and inconsistent procurement policies and which have different political interests. This places a huge obstacle to industry in negotiating its way through the procurement pathway. So relatively small companies and quite large ones find it very, very hard to engage with the National Health Service because it is not a National Health Service, it is many different health services. There is a second problem, which is something that we have noted many times in our own studies, which is the incompatibility of two key policy streams: the modernisation stream which seeks to use technological innovations to move services forward very rapidly and to develop their patient centre services, services which have a degree of local participation and which cross organisational boundaries, and the policy stream that demands evidence-based practice because the production of evidence always takes a very long time if it is going to be formed in a way that will satisfy the demands of clinicians and budget holders. Those three things come together to make it very hard for the private sector to negotiate with the NHS.

Q10 Chairman: The areas that you are concerned with really look at the relationship between primary care, secondary care and obviously social care. How satisfied are you currently in local discussions—and my area is a good example, we have a major PFI capital scheme for a new hospital in Wakefield, and that scheme has been called a "whole district" scheme because it has looked at not just one hospital but three hospitals and also links with primary care—that evaluation of schemes of that nature and moving schemes of that nature forward are taking account of where we are now on the areas that you are concerned with, and certainly where we will be in 10, 20 years' time when these facilities will be up and running and serving people? The frustration I have had with my own scheme is there has not been sufficient vision, particularly about the relationship between primary and secondary sectors, as to what telemedicine can achieve in terms of reducing the current reliance upon your acute hospital sector? Professor Underwood, would you like to take that?
Professor Underwood: I cannot comment on that but can I throw in another factor, which is geography and population density? In my own field of pathology, telepathology—that is the transmission of diagnostic images of human tissue—is well established in Scandinavia. That is because the population is so sparsely distributed and there are many hospitals that do not have on-site pathology services. If a patient has a breast lump which necessitates intra-operative diagnosis by what we

call frozen section, in this country that is dealt with by the pathologist on-site in the hospital because we have a dense population and every hospital in this country has on site pathology services. But in Scandinavia that is not the case and the image is transmitted from a small hospital with no pathology service to a large hospital with an expert pathology service where the diagnosis is made. So there is the necessity factor, which is driving the implementation of telepathology in some countries. That is less of a pressure here because although we do not have enough pathologists we do have more pathologists, more widely distributed than in Scandinavia.
Chairman: That is very interesting because I was actually in Tromso, in the north of Norway, where there is a centre of the work in Norway doing exactly what you are describing, and I thought at the time, Richard, that with what they are doing there you do not need Kidderminster Hospital, so over to you for your questions!

Q11 Dr Taylor: Thanks Chairman. I should like to declare two interests. First, a personal interest because my wife is a quite severe insulin dependent diabetic who ought to be on a pump, and I shall be campaigning for insulin pumps; and secondly, I do have a very few shares in Smith & Nephew. I now want to follow up with Professor Underwood. Going down to basic telemedicine as far as laboratory data is concerned, the electronic transfer of data is fairly well developed when you talk about just pathology results. Is that universal across the country?
Professor Underwood: It is quite well established. I know you do not want to talk about the National Programme for Information Technology, but our concern is the interface between our laboratory information systems and NPfIT. We do have concerns about the lack of seamlessness at the interface between our laboratory systems and the National Programme.

Q12 Dr Taylor: So there are very real concerns on that?
Professor Underwood: Yes.

Q13 Dr Taylor: We will be raising that with the Department's representative in the second part. In the broadest terms, what do you think are the advantages to patients and to professionals of telehealthcare in the broadest terms?
Professor Underwood: I think in this country the place of telepathology—that is what I have been describing in Norway—is in seeking an expert opinion on particular features of a case, particular aspects of a case. Not the overall diagnosis, because I think in my field of histopathology the overall diagnosis is best made when you can see the specimen that has been removed from the patient, you can talk to the surgeon who has removed that specimen, you can look at the X-rays and you can have access to all sorts of additional clinical information that contributes to the diagnosis. I do not think that in this country we are confident that telepathology, the interpretation of the image on a screen from a hospital 100 miles away, is necessarily the best way to make the diagnosis, but it is a good way to seek an expert opinion on a specific feature or aspect of the case.

Q14 Dr Taylor: If the expert is not with you on the same site?
Professor Underwood: Yes.

Q15 Dr Taylor: So it is a form of video conferencing?
Professor Underwood: It is, yes.

Q16 Dr Taylor: And that is in wide use?
Professor Underwood: No, it is not. There is a lot of enthusiasm for it in the profession but it is not widely used.

Q17 Dr Taylor: I think you were quoted yesterday talking about imaging in some way taking the place of post mortems?
Professor Underwood: I was mentioned in the Press yesterday as a result of a briefing, yes.

Q18 Dr Taylor: Is that a realistic hope because the post mortem rate, as we have discovered on a different inquiry, is dropping alarmingly.
Professor Underwood: It is, yes.

Q19 Dr Taylor: Is this a realistic way forward?
Professor Underwood: I think we could do more to make the post-mortem examination more informative by capturing digital images taken at autopsy and showing them the same day or the following day to the surgeon or physician who has requested the examination. The problem with post mortems at the moment as you, as a doctor, will know is that often a long interval elapses between doing the post mortem and the issuing of the report of the examination, by which time the surgeon or physician has seen hundreds of other cases and they have lost, in a sense, interest in that case.

Q20 Dr Taylor: It is particularly with examination of the brain where that has to be fixed for weeks and weeks?
Professor Underwood: Yes.

Q21 Dr Taylor: So could that speed up examination of the brain?
Professor Underwood: No, not of the brain but it could make the post-mortem examination more informative and therefore motivate physicians and surgeons to request them more often.

Q22 Chairman: Professor May wants to come in.
Professor May: I think one of the things that we need to remember is that incorporating these new technologies into clinical practice actually requires that the hospital departments re-engineer their business processes. For example, in some work that we did on a telepsychiatry service we found that the pressure on consultants to be in a particular place at a particular time to see a patient on a video link

created real problems in the distribution and organisation of other work. So a problem for NHS departments that want to use these systems is thinking about how to integrate the hidden work of delivering healthcare, the things that none of us think of in terms of professional practice because we see a doctor at work on a patient and we neglect the work that goes on to deliver that service in a flexible way. Some of these systems can be quite inflexible for clinical users and that has led to some resistance. One further point to make of course—and I know also that you do not want to discuss the National Programme—is that for many IT professionals in the NHS a real problem with these systems (and there are many of them) is concern about whether they will be compatible, whether they can be compatible with the new information spine and the work that different contractors are doing on NPFIT clusters,

Mr Dheansa: At the Queen Victoria Hospital we have successfully introduced a telemedicine system which is a store and forward system, which looks at plastics trauma patients and burns patients, and it has been successfully introduced and it has been incorporated into the daily use of the hospital because it has changed the way that we manage patients, to avoid the unnecessary transfer of patients, to safely triage patients at a distance and to plan their appropriate surgery without unnecessary visits to our hospital. Because it is a regional trauma centre it covers a population of four million people, and patients may have to travel up to 80 miles to see a plastic surgeon. With the use of telemedicine pictures one can make much more appropriate decisions, thus avoiding late night transfers, which can sometimes be unsafe and also make appropriate operative decisions, such that a patient can come directly to theatre rather than making a visit and then having to wait unnecessarily.

Q23 Chairman: Just before you carry on, I was very interested in what you have done because I have a burns unit, as you know, in my part of the world. In 1999 what actually kicked off the idea of introducing this approach? What were the factors that resulted in huge interest?

Mr Dheansa: It basically stemmed from patient safety. We had a patient who was referred to us, we were informed that they had a very large burn, they needed to have immediate transfer to enable their safe management, intravenous fluids and what have you. On the information we were given from the referring hospital we felt that the only way to get them to us quickly was to use a helicopter. Helicopters are very useful in transferring patients quickly but they are also very, very cold and relatively unstable. If a patient becomes very unwell in a helicopter transfer then it is much more difficult to manage them. This patient came over, we assessed them and they did not have a burn; they went home in a taxi that day.

Q24 Chairman: In other words, if you could have seen them it would have avoided all the expense.

Mr Dheansa: That is right. To some extent the cost to us was not significant but the cost to the NHS as a whole was massive.

Q25 Dr Naysmith: If I could just come in here, Richard? It is a question I was going to ask Mr Dheansa later on but this is a very good point to ask him. One of the criticisms often made is that it is quite hard to produce links between primary care and secondary care and between specialists and non-specialists. You seem to have solved that problem at the Queen Victoria; you have very good relationships with everybody you need to have a relationship with. Why have you managed that and are there lessons that other people can learn later on?

Mr Dheansa: The first thing was identifying the problem and the problem was that patients were travelling long distances and sometimes unnecessarily. We then found the means to avoid those unnecessary trips, and at the same time we had an increasing number of referrals and we were filling up to capacity, so we needed a safe way of triaging and changing our practice to enable a vast number of patients to come through, and explaining this to our colleagues in the Accident & Emergency Departments and then providing a clinical champion. So we provided support in the form of a clinical champion and also identified the clinical champion within those Accident & Emergency Departments. Providing that support enabled doctors in those units to see the benefits of those cases where telemedicine was useful, and in fact it has become so useful now that patients' photos are sent to us before they actually get on the phone, to make it even easier for us. It is the constant support so at that A & E Departments do not have to worry about having to maintain the system because we will provide that support and, equally, legitimising its benefits. The doctors and the nursing staff can actually see the benefits of doing that because it means that their referrals are quicker and easier and it means that patients are happier because they do not feel unhappy about travelling long distances when they do not need to.

Q26 Dr Naysmith: Forgive me, Richard, this will be the last one. Is that because you have a very specialised area of medicine that you are involved with in burns surgery, and that sort of thing, or could it work with other things too?

Mr Dheansa: It works in two ways. For instance, in burns critical care, where we have a very large burn, someone has had smoke inhalation, where they have potentially life threatening conditions, it is a situation that A & E doctors do not come across very often and it is something with which they need as much help as possible. So it means that I can start managing the patient right from the beginning. I can say, "This patient may well be safe for transfer with the clinical information you provided over the telephone and the photographic evidence I have before me." So in situations where doctors feel out of their depth and rarely treat a situation it is very, very useful. Equally, there are situations where there

are benefits to be had from much more common injuries, so finger injuries where some specialised treatment may be necessary in certain situations but not in others. Equally, it is also useful within the hospital because it means that consultants who are, for instance, in an operating theatre can also help manage patients in the rest of the hospital whilst still in theatre. A good example would be that I was operating on a large burn the other day, I had a patient who had a wound break down in dressing clinic and I also had an outside burns referral, all of which needed expert opinion, which the junior doctor wished me to be involved in, and I was able to do all three to some extent without leaving theatre, without compromising any of their care. These sorts of things are quite useful, not just outside of hospitals but within. So transferring pictures of wound breakdowns for general surgeons, for instance, or for orthopaedic surgeons and X-rays.
Dr Naysmith: Thank you very much.

Q27 Dr Taylor: I think your specialty is one that lends itself ideally to this sort of work. In your memorandum, Professor Underwood, you said that there was often a reluctance to use the new technologies; that it was more difficult to look at a section on a video screen rather than down the microscope.
Professor Underwood: Yes.

Q28 Dr Taylor: How can you overcome that reluctance?
Professor Underwood: Through training. We train with microscopes and I daresay that in 50 years' time histopathologists like me will be using flat screens on which the images will be projected, perhaps the histology slides will be digitised and therefore transmissible more widely. The other thing is that, in seeking second opinions, it is much easier in this country to put the histology slides into a padded envelope with a referral letter and send them by post and to get a full and reliable expert opinion than to get a partial opinion more quickly by telepathology. Often the opinion that we are asked for does not have to be given so quickly that it needs telepathology. It is not like burns, which is a very acute situation. We are dealing with cancer diagnoses, which, apart from the intra-operative situation, do not necessarily have to be made within a few hours—often a day or two to get a very reliable interpretation is better for the patient.

Q29 Dr Taylor: To someone who was not used to looking down a microscope it would appear to me to be far easier to look at a huge screen with everything magnified even more times than just peering down a microscope.
Professor Underwood: Yes, I suppose it is like the difference between driving a car and flying a plane. I can drive a car but I would find it impossible to fly a plane, but pilots have no problem with that because they have been trained to do it. If we are confident that in 10 or 20 years' time colleagues of mine will be diagnosing off flat screens then we had better start training them to do that now. The other thing is that the technology has improved considerably over the last decade or so, the resolution that one can achieve with digital microscopy is far superior now to what it was even five years ago. So it makes it more realistic and feasible to consider diagnosis off screen.

Q30 Dr Taylor: So it is a question of training, practice and usage?
Professor Underwood: Yes, and developments in technology that make it feasible.

Q31 Dr Taylor: I want to move on to regulation because POCT—Point-of Care-Testing—
Professor Underwood: Or Near Patient Testing, it is often called.

Q32 Dr Taylor: You are suggesting *either* a single regulatory framework must be applied to all diagnostic tests, whether Point-of-Care Testing or laboratory based, *or* that somehow laboratories have to somehow take the responsibility for controlling the point of Point of Contact Testing.
Professor Underwood: Yes.

Q33 Dr Taylor: What do you want us to recommend on those lines?
Professor Underwood: It is important to bear in mind that point-of-care testing includes a wide spectrum of patient testing. Your wife is a diabetic, so is mine; so our wives do blood glucose tests frequently, and that is point-of-care testing—the patients test themselves. We do not envisage that that test ought to be regulated by a local pathology service and quality assured and that sort of thing. But where in a hospital testing is being done at the bedside or in the operating theatre, we believe it should be done to the same quality assurance standards as the same test done in the laboratory. It is perhaps even more important it should be quality assured to the same standard because if it is being done at the bedside the clinical action that is likely to result is going to be very immediate, so we need to make sure that that action is based on the most reliable result.

Q34 Dr Taylor: What about chemists' cholesterol levels?
Professor Underwood: I have concerns about that, from the pre-analytical, analytical and post-analytical aspects. On the pre-analytical aspect I went into *Boots* recently and I found a leaflet that said on it that three out of four adults over the age of 45 have high cholesterol. What does the ordinary man in the street conclude from that: that only 25% of people have a normal cholesterol? I think that is grossly misleading information that is given to patients, motivating them to have a test, which is 75% likely to show that they have, by *Boots'* standards, a high cholesterol, which then results in over-the-counter sale provision of simvastatin. So I am concerned about the probity aspects of that and the quality assurance aspects.

Q35 Dr Taylor: So it is a very good way of increasing sales?
Professor Underwood: I am not unhappy for you to say that. Then there is the test itself and its quality assurance. If the patient has a high result it could be because they genuinely have a high cholesterol or because there is a problem with the test itself. In hospital-based testing we know whether it is a genuinely high cholesterol or a wrong result because we quality assure the method. I do not know if *Boots* and other high street chemists do that.
Dr Taylor: Thank you; that is very clear.

Q36 Chairman: Could I ask one more question before I bring in Doug Naysmith. Going back to Dr Dheansa, one concern that I have had raised with me about down the line consultations—and frankly this is nothing new, I can recall 35 years ago when I was training in social work I was going into hospitals where we were doing sessions where a consultant psychiatrist interviewed a psychiatric patient in front of a camera and a roomful of people saw the outcome, and we discussed the diagnosis and all this sort of stuff, so this has been going on for a long time—is that where you have people going down the line, maybe in primary care, and someone like you in a tertiary hospital or wherever, looking at that patient, there is some anxiety on behalf of the patient about who is seeing them down a camera, particularly if they are showing their more private parts, shall we say. Is that an issue that you have addressed and how do you deal with those anxieties?
Mr Dheansa: It was actually integral to our development of the whole system because we have certain regulations, Data Protection Act, Human Rights issues and what have you, which we pull together with the general act of patient dignity and privacy that we all need to address, and we have developed quite a comprehensive photographic and video recording policy, which includes getting the patient's consent but explaining to the patient where those images are going to be used.

Q37 Chairman: I appreciate that this is quite a complex area and if it is possible for you to give us some follow-up information on exactly what is given to patients, that would be very, very helpful.
Mr Dheansa: If you would like I can actually forward the policy we have developed.
Chairman: That would be very helpful; I am most grateful.

Q38 Dr Naysmith: I want to follow up with Mr Dheansa an aspect of the fact that you are giving advice fairly widely to people who ask for it, and you have good links with other Trusts, and so on, partly because of the success of what you have done at the Queen Victoria. But do you suffer a financial disadvantage in any way because you are offering this service? How is it paid for?
Mr Dheansa: To some extent we have had a financial disadvantage. We have been very cost efficient in developing this system. To date, since 1999, we have spent £85,000 on developing a system that has transformed our management of 3,000 patients a year, and we have not been reimbursed for that cost. The advantages that it gains to the Trust in terms of efficiency and appropriate theatre and bed utilisation is such that we can treat more patients; and also to the NHS in general in terms of avoiding inappropriate transfers, and more importantly to the patients. So although there are cost benefits the hospital itself has not realised those cost benefits except by more efficient usage of the facilities that they have already.

Q39 Dr Naysmith: Is this then an inbuilt disadvantage or disincentive to do things because spending money on developing new systems means that you actually spend the money and you do not get any reimbursement for it? So some Trusts are making use of your facilities and not paying for them.
Mr Dheansa: There is and certainly that is an issue in terms of payment by results issues, in terms of commissioning for patient care. To some extent we feel that it is important that those costs are reimbursed because on a wider scale it would be cost inefficient and even in the States, where telemedicine is utilised on a wider scale, those costs are not reimbursed and it is detrimental.

Q40 Dr Naysmith: Have you anything to offer in this area on how it might be done because I know that usually when I speak to clinicians about this sort of thing they say they do not want bits of paper flying around the system and charging each other. Although it is coming in in in some centres.
Mr Dheansa: I think it may well be in the form of recognition. So, for instance, with payment by results, where care at a particular facility is paid for, I think when one is actually organising tariffs for patients one ought to introduce a cost within that for telemedicine and telecare because it is the simplest and most efficient way of doing things.
Dr Naysmith: Thank you.

Q41 John Austin: I think everybody can point to the long-term potential benefits of various new technologies, but it is quantifying the risks and balancing the risks and I think that Professor May was talking about some of the problems about lack of a central sponsorship or procurement, and I think Professor Underwood was talking about the lack of compatibility with other systems. We have also had some evidence that sometimes there is a problem with patient compliance as well, even in some of the well and heavily managed trials. How do you balance the benefits of the risks, are they clearly understood and how they are managed, particularly when we are talking about a proliferation of potential commissioners and purchasers of these services?
Mr Rice: Just an observation, which is that it is very easy to go for a number of high technology solutions that are incompatible. It is really important, certainly in the teletechnology field, that the solutions are relatively simple, the clinician still has

complete control of the process and where more complex solutions are needed then they are delivered in an institutional setting where the quality of the assessment, for example, can be higher. I always have a concern about non-compatible systems. One of the interesting things about telecare is that we already have an installed base of telecare systems and monitoring systems which can be used for simple monitoring. That really just removes, if you like, the bread and butter workload from the clinicians so that they are free to do the more higher quality work in an institutional setting or, indeed, by using teletechnology if they want. I do think that with the National Programme for IT and the desktop applications that are overlaid on that in terms of teletechnologies that it is very important that they are compatible, they are simple and they work in a mass market, because the savings are immense and the qualitative benefits are huge. To give you a very quick example, the example we always use for telecare, which is similar to my colleague at the end, is pregnant women in the outer isles. We install vital signs monitors there because at present—or until two years ago—they had to fly to Glasgow for assessment, stay overnight after assessment and fly home, and arrange childcare if they could not arrange childcare on North Uist, or whatever. Now we have vital signs monitors where they can be assessed and a nurse in Glasgow looks at it and says, in 99% of the cases, "Fine, same time next month," and in 1% of the cases, "You need to come over here." But actually that is not the mass market, the mass market is Mrs Smith, aged 82, who has a routine visit to her local hospital or her clinic, and for her it is much more arduous to get from the south of Leeds to the north of Leeds by public transport for a monthly assessment when she could go to a local health centre or indeed the common room of her sheltered housing development to have an assessment. So I think there is a simple market and there is a complicated market; the complicated market I am happy to leave to my clinical colleagues, who know a lot more about it.

Q42 John Austin: I think Professor May wants to come in.

Professor May: I was going to echo that point, which is that it is very important to separate the different kinds of service. Telemedicine is usually a very specialised clinical service and telecare is a much more general field. It is worth contrasting the failure of the NHS to invest in telecare systems with the massive investment in teletriage which you have with NHS Direct and NHS 24 in Scotland. Those have been very successful; they were rigorously piloted; good quality data was collected about successes and failures and, lo, we now have the National Teletriage Service which will provide advice and referral and will call you an ambulance if it transpires that you need one. The failure of the NHS to engage with telecare systems comes back to the problem where the benefit lies. The benefit for telecare lies largely, as Mr Rice has said, in the field of social services because it manages often elderly, often disadvantaged, often very vulnerable people remotely. It has very clear parameters for calling in specialised or expert help and that means it can be very cost effective. The cost effectiveness of telemedicine systems is sometimes in doubt and that cost effectiveness is in doubt largely because of the poor quality of most of the economic evaluations that have been done. The truth is that we do not know whether these systems are cost effective—not that we say that they are not cost effective—and that is because the economics of the National Health Service are really some of the most extraordinarily byzantine things in the history of humanity.

Q43 Chairman: Can I pick you up on that point? What you are saying is that the kind of stuff that the telecare aspects of this inquiry are more beneficial to financially is social services. My recollection of the last time I visited Tunstall Telecare, Mr Rice's company, was probably last year some time—and I cannot remember whether you were actually there, Mr Rice—and you gave somebody from the Treasury and myself a presentation on the cost implications for the NHS of avoiding elderly people falling in their own homes, and in particular fracturing their hips which, as we all know, is a common problem that leads to other difficulties and is hugely costly for the NHS, and we had a presentation which enabled us to understand a series of quite simple mechanisms that can be fitted into a person's home that enables elderly people to be less susceptible to falls of the kind that result in broken hips. Basic, simple straightforward things like when you get out of bed to go to the loo during the night, when your foot hits the mat the light goes on and you can actually see where you are going. Simple, straightforward, commonsense things like that. The figures that his company gave us showed a direct impact upon NHS costs of saving the person having that serious accident. So I think I would disagree with you—unless I have misunderstood what you are saying—that I think there can be huge cost savings for the NHS in telecare.

Professor May: I cannot comment on that particular case but what I can say is that the published evidence about cost effectiveness is often of methodologically very poor quality. Individual companies can produce service specific evaluations, as can individual NHS Trusts. To go back to what you were saying, there are some even more simple ways of stopping elderly people breaking their hips, using hip pads and using cushioned underlay—Duralay make a cushioned underlay for carpets—that will negate some of those problems.

Q44 Chairman: The point I was concerned about was that the outcome of that meeting with Mr Rice's company, with this Treasury person, who was involved by the way, and I took to see, and what I thought was interesting stuff was that in the budget statement last year we got some additional resourcing for investing in telecare, which in a sense will save huge amounts of money in the NHS, and

it is commonsense, and it frustrates all of us that we cannot see these connections more often. There are all sorts of hands going up. Mr Wilkinson.

Mr Wilkinson: The point I was going to make is actually telecare, investments in IT, investments in all manner of technologies only work if they are integrated into a system of care and you re-engineer, as my colleague said, the whole way that you manage patients. I think most of these technologies are enablers of significant changes. We have had lengthy discussions about telemedicine. Implantable devices, a lot of them are very active, produce information; pacemakers produce information about the status of the patient. That, while the patient is walking around, can be transmitted back to a computer which can analyse what is going on and flag up problems. That is, one, very good for the patient; but, two, it potentially eliminates regular checkups because you can actually pick up the patient's call when the need is there. This principle applies to most of the technologies. They have to be applied across the system and that is about evaluation methodologies, getting the value appreciated across the system and re-engineering the patient pathway and the way the patient is cared for. That is where the real value is.

Q45 John Austin: I wanted to go on to the evidence that we had from the Medical Technology Group, and I understand that Ms Lobban is stranded somewhere, but perhaps Mr Wilkinson might be able to answer the point, because in their submission they were talking about slippage between the national guidelines being issued by NICE and the introduction of the new medical technologies, and really saying that what happens on the ground, particularly with PCTs, that if there was something within the National Service Framework there was more likelihood of implementation, whereas there was a real slippage if there was not.

Mr Wilkinson: It is a shame that Trudie is not here because she could speak very clearly from a patient's perspective, but I will attempt to cover the issues.

Q46 Chairman: We understand that she is stuck in Oxford, so she has made every effort to get here.

Mr Wilkinson: The issue she is talking about is very much about that there are centres in the UK which take, adopt and use new technology as fast as anybody in the world. The challenge we face is getting that translated and being available for patients broadly across the country, particularly in relation to NICE recommendations. We have seen some recent work done on the implementation of NICE recommendations and concerns that these technologies just do not get out and do not get propagated and are not available to large portions of the population. So this is real postcode, not prescribing but availability of technologies. I think I have already alluded to that in the context of diabetic pumps. You can look at many technologies; if you are in the right place at the right time you can get access to these things and if you are not then you cannot. Clearly there are a number of mechanisms that drive towards that. NICE is one. Just creating the atmosphere in the environment for innovation and encouraging doctors and systems to become informed and pull innovation in the ways that patients are treated would be an encouraging move forward. The Department has just announced the establishment of an Institute for Learning Skills and Innovation and if that works well—and we hope it does—that will be crucial to supporting this process of getting good practice, good ideas out, and that means that patients get access to the good stuff that is available in parts of the country.

Q47 John Austin: Much of the examples that have been given have been about technologies which are used outside of a clinical setting, possibly in the patient's home, involving very much the patient or the carer of the patient. Does this prevent new risks and what are the implications for patients, and also what use is being made of user groups in terms of learning about new technologies and designing them so that they are patient friendly?

Mr Wilkinson: If you transfer the focus of care from a highly controlled environment into a less controlled environment, if you like into a domestic environment, then you need to build new quality systems to manage that, particularly if patients are involved, and then patients are intimately apprised of the challenges of managing their situation and need to be full stakeholders. Medicine is not being done to people the way it was 25 years ago. People are increasingly being engaged in their care and I think engaging patients, patient groups to help set up the systems which effectively manage the use of these technologies in these new environments is crucial to their success.

Q48 Dr Naysmith: If we can return to the discussion that was going on about on about five minutes ago about the economic benefits of some of these new technologies and looking in a wider sense, not just about telemedicine, although it is included here, there is a feeling—and it was in the MTG memorandum and I am sure you have read it, Mr Wilkinson—it talked about the traditional approaches to measuring the benefits often fail to address quality of life and productivity dimensions in the way new techniques are assessed. I suppose it draws to mind the old joke about the surgeon—I apologise, Mr Dheansa—saying, "The operation was a success but unfortunately the patient died," and just evaluating things from the purely medical and clinical may not reveal all the benefits to patients. Is there something in that?

Mr Wilkinson: Perhaps I can give you a couple of examples which might illustrate the situation. Potentially fatal cardiac arrhythmias, ie random stopping of the heart in young children, is sadly not as rare an event as many of us might like to think. Can you imagine the situation where you, as a parent, have a child who is susceptible to this complaint, it has been identified and you have been present when your child has dropped to the floor lifeless, you have administered CPR or whatever and

brought your child back to life. The stress of living with that sort of tension for the child, for the family, for anybody engaged with that child, the teachers, is enormous; it does not bear thinking about. I have fortunately never had to experience it. The technology is available to implant a device which monitors the heartbeat and when it starts behaving badly it effectively gives it a jolt and gets the thing going, so that the fear of going to bed one night and kissing your child goodnight and waking up the next morning and finding him a lifeless corpse is eliminated; it is very profound. Another example, if I could quickly burden you, I met a patient who had severe Parkinson's Disease, shuddering severe Parkinson's Disease, of the sort in which the physical manifestations are profound but the psychological effect is even more profound and you become a social leper effectively and really do not want to present yourself to the world. One of our member companies has a technology which allows you to implant electrodes in the brain and provide minute electrical stimuli, and you can walk up to this chap who is standing at a bar with a pint in his hand, rock solid, shake his hand and have a conversation and you would not be able to distinguish him from any of us sitting in this room. It has profound impact on that person's life; he has a productive job, he is engaged in normal life. I think those sort of criteria are often lost and they have, I suspect, profound economic consequences as well as social consequences.

Q49 Dr Naysmith: Why do you think that is? Is it—because I was suggesting that these things are looked at in the purely medical and clinical effects—that not enough attention is paid to what it allows patients to do? Is that a factor in it?
Mr Wilkinson: I think often technologies are looked at as very technical solutions by technical people to specific problems and I think further engagement with patients and understanding the real impacts of these technologies on their lives can only be good.

Q50 Jim Dowd: I wanted to press that a bit further with Mr Wilkinson. I accept the point he is making, but what kind of formula, what kind of uniform calculation could be made of such abstract notions about quality of life and impact?
Mr Wilkinson: There are many models for life adjusted quality of life. It is all very esoteric and rather complex, I am afraid, to most lay people including myself in that context. I think there is scope to work on methodologies to evaluate these impacts. Certainly the economic impacts are profound. The difference between somebody getting work and earning the average wage and paying taxes like the rest of us, rather than being a burden on society, is a very simple number to calculate. I think some of the quality of life issues are much more difficult, but there is scope for methodological research in that area.

Q51 Jim Dowd: But you run up against the practicality of public spending, which it is that it is better under the system we operate to spend a pound from now until infinity than to spend £5 now once off.
Mr Wilkinson: I think that is where the evaluation methods need work and it needs to engage patients, clinicians, economists who can capture some of those things, so that we get a mechanism for making decisions with the annual budgetary cycle or even the five-year political cycle because some of these technologies have profound benefits long-term. We have to find methodologies that achieve that and some of the stepping-stones are in place to do that. The effectiveness of NICE is clearly one, the HITF report alludes to the Device Evaluation Service, a lighter on its feet mechanism for looking at the value that various technologies can produce. I do not think there is a perfect answer but I think there is scope for much more rounded input from a variety of stakeholders in the process.

Q52 Dr Taylor: We have talked quite a bit about cost effectiveness. You have just mentioned, Mr Wilkinson, Payment by Results. I am very bothered when in your submission you say that the present tariffs' arrangement is not clear "and some procedure payments appear to be so inadequate they would fail to cover the cost of the technology alone" and you have given us a table of uncoded activity and the huge payment shortfalls. Could you expand on this a little bit?
Mr Wilkinson: I think, broadly speaking, the industry is supportive of Payment by Results. Because if the quality agenda attached to Payment by Results and the flexibility agenda which allows flexibility in the way that patients are cared for and treated come to fruition, I think that would be very good for all concerned—and, most importantly, patients. We do have some concerns, however, in terms of implementation and the capacity of the system at the moment to generate accurate, reliable tariffs. There is also a concern that if this massive process of generating large numbers of tariffs is slow then new technologies will not be reflected in the tariffs, or they will be reflected very late, so we have made some very specific proposals regarding mechanisms to try to circumvent some of these less than ideal outcomes in the process. As an industry, many of my members have experienced payment-by-result type schemes coming in in other countries, so we have seen a lot of the problems. I think we are very heartened by the fact that the Department of Health is keen to engage us in helping to resolve some of those problems.

Q53 Dr Taylor: Will it be possible to have tariffs for virtually everything, including the implantable defibrillators that you mentioned?
Mr Wilkinson: The view is that tariffs are targeted to be aggregates of a number of procedures. In some cases, there is no aggregating. There is a need for very specific tariffs for technologies which do not fit comfortably into the buckets which might have been

created in the system. The key thing is to have a system which is light on its feet, which engages very much with clinicians, industry and other stakeholders, and is not just an accounting exercise, because there are profound impacts of getting this wrong. If we get that sort of engagement, we may get the system to work rather more rapidly and effectively than we have seen in other countries.

Q54 Jim Dowd: If I could go back to the theme I was exploring earlier, triggered by Dr Taylor's mention of the implantable defibrillator. In an earlier inquiry we were told that this cost about £30,000 for unit and the procedure. The difficulty we were faced with was evaluating the benefit of that for one individual—for whom it is crucial: literally a matter of life and death—when you can employ a nurse for £30,000 a year. How do you evaluate the contribution he or she could make to a number of people over the course of that year compared to the benefits for one person?

Mr Wilkinson: If I were to use an industry analogy: companies that do not invest in technology and look at new ways of doing things, get drowned with trying to do the same thing over and over again more effectively more often. I think there is a balance between human resource needs in delivering healthcare and using technology effectively to minimise the increase in human resource. I wish I could give you a clear answer, but clearly every individual treatment and situation has a different set of dynamics to it.

Chairman: I am very conscious that this has been an extremely short session and I think all of us would like to have pursued the various avenues we have touched on at much greater length. I apologise that it has been brief, but it has been very valuable from our point of view. It may be that you would wish to follow up with further written comment on issues that we have touched on and we would be very pleased to hear from you. Could I place on record our thanks to all of you for coming along today.

Memorandum by the Department of Health (MT 1)

Contents

Annexes

1. Introduction

1.1 The term "new medical technologies" embraces a wide range of products, systems and techniques used in health and social care. There is no readily accessible definition of this term—it is usually applied to new and emerging technologies in any field which may be have a medical application. Examples of technologies that offer potential for better healthcare solutions include digitalisation, tissue engineering, nanotechnology (particularly bionanotechnology), robotics, information and communication technologies (ICTs), materials engineering, pharmacogenetics and pharmacogenomics and point of care testing devices (miniaturisation). Technological advances in these areas are being utilised to develop higher quality imaging equipment, tissue implants and wound management products, tumour destruction techniques, precision surgery, genetic screening tests, tests to predict adverse drug reactions, and more rapid turnaround times for a variety of pathology tests, moving diagnostics closer to patients.

1.2 The producers of these medical technologies are loosely grouped together according to the technology within the healthcare industries sector. Further information, compiled by the Department of Trade and Industry (DTI), about the scope of the UK-based sector and its characteristics is at Annexes A and B.

1.3 Technology has never evolved more quickly than at the present time and it is increasingly at the centre of innovation in the field of human health, as well as in other industrial and social areas. The medical technology industry operating in the UK is highly diversified and innovative. It is a significant component of the national economy and has considerable potential for growth. It also has the capability of transforming the way in which health and social care services are delivered.

1.4 For all these reasons, Government is pleased to note the Committee's interest in this area.

2. Government Policy Objectives

2.1 The Government's policy objective in relation to the use of new medical technologies is to harness the benefits that they can bring to all stakeholders. This means provision of improved healthcare for patients and service users, whilst continuing to safeguard public health, and fostering a vibrant commercial environment in which the industry can grow, increase its competitiveness and its contribution to the UK economy.

3. Context for Change

3.1 The *Wanless report*[2] stated that the NHS was a "late and slow adopter of medical technology". Since its publication in April 2002 DH has been considering the reasons for this and developing ways of improving patient access to new technologies. Up to 2003–04 expenditure on the NHS has increased by an average of 6.2% in real terms each year since 1997 and is set to further increase by an average of 7.2% in real terms over the period from 2003–04 to 2007–08. This investment is resulting in increases in workforce numbers and NHS capacity, new and better treatments for patients, shorter waiting times and greater choice. By 2008 there will be increases above the September 2001 staffing figures of 15,000 more consultants and GPs, 35,000 more nurses, midwives and health visitors, and 30,000 more therapists and scientists.

3.2 The changing demographic profile is another significant factor which influences health and social care needs. People are living longer and surviving some previously life-threatening illnesses, due in part to advances in medical science. The proportion of older people is growing and they need a different range of services eg to help manage long term conditions and to support independent living.

3.3 DH is also in the process of developing policies to ensure that patients and services users are at the heart of the health and social care system. Strategies are underway to devolve NHS decision-making, budgets and commissioning of services to front-line staff and to drive forward a programme of service modernisation eg increasing the number Foundation Trusts, integrating health and social care services, introducing specialist Independent Treatment Centres (ITCs), decreasing waiting times for some operations through the establishment of local day surgery units, extending the role of pharmacists in the community, etc. Combined with other central and local initiatives, the aim is to deliver responsive, patient-centred services within a flexible framework capable of providing speedy, convenient and modern healthcare solutions.

3.4 Changes to central structures are also necessary to reflect the new balance of power. The DH review of its Arm's Length Bodies (ALBs)[3] which is already starting to take effect, will ensure that the Departmental structure reflects and supports the new roles and ways of working centrally, in the remaining ALBs and in the NHS.

3.5 Alongside developments in public policies and structures, an explosion is taking place of new technologies which have considerable potential in the medical field to improve treatments. Information and Communications Technology (ICT) already has many recognised medical applications and continues to evolve as further advances are made. Similarly, tissue engineering promises to bring improved therapies in a range of medical conditions, as do breakthroughs in pharmacogentics, nanotechnology, robotics and new device/drug combinations. It is necessary to keep up-to-date with all these developments to help ensure that patients have access to better treatments.

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[2] *Securing our Future Health: Taking a Long-Term View* written by Sir Derek Wanless for HM Treasury, examined future health trends and the resources necessary to run a publicly funded, comprehensive and high-quality health service over the next 20 years (accessible on www.hm-treasury.gov.uk).

[3] *Reconfiguring the Department of Health's Arm's Length Bodies* (July 2004) and *An Implementation Framework for Reconfiguring the DH Arm's Length Bodies* (November 2004)—www.dh.gov.uk/publicationsandstatistics/publications/pulicationspolicy.

4. Meeting the Challenge of Change

4.1 The Government aims to meet its objectives in optimising the benefits of new technologies for all stakeholders via a number of processes and initiatives.

4.1.1 *DH research in the NHS*

The DH budget for NHS research and development is over £600 million in 2004–05, of which £480 million is allocated to NHS providers. Some 75% of the money from these allocations meets the service costs to the NHS of research funded by research councils and charities.

Research is fundamental to the introduction of new products, technologies and services to the health and social care system. DH funds research specifically to support policy initiatives through its Policy Research Programme, and provide the evidence needed to underpin quality improvement and service development in the NHS through three main national programmes:

- New and Emerging Applications of Technology (NEAT).
- Health Technology Assessment (HTA).
- Service Delivery and Organisation.

Both the HTA and NEAT programmes have commissioned work of relevance to the Committee's Inquiry.

Policy Research Programme

The Policy Research Programme aims to underpin policy development by commissioning high quality research-based evidence. Its remit extends across the full range of DH's responsibilities, including health and social care services, healthy living and well-being, disease prevention, the role of the environment in health, the organisation of the NHS and strategies for treating particular diseases and conditions.

Horizon scanning reviews of both telemedicine and telecare were commissioned in 1997 and 1998, and these informed a developing research agenda within DH. This built upon earlier involvement in European research programmes *(Technology Initiative for Disabled and Elderly People, and Advanced Informatics in Medicine)*, and was closely linked to policy making in a number of areas, including the potential for the technologies to support elderly and disabled people. In 2000 DH commissioned a report on *The Use of Information and Communication Technologies (ICTs) in Assistive Technology*.[4]

Further research is being planned that will provide evidence in relation to the most cost-effective approaches. Some of the more sophisticated electronic technology options will be studied further within a wider programme of research currently out to tender and aimed at investigating technological support for chronic disease management, for self-care and for healthy living. The invitation to tender has been timed to coincide with the latest call by the DTI in their Technology Programme, and we are encouraging joint proposals to the DH call and to the pervasive computing section of the DTI call. The Department has also been discussing with the Engineering and Physical Sciences Research Council and Economic and Social Research Council their interest in joint research in this area.

NEAT

The HITF report *Better health through partnership: a programme for action* (see also section 5) recognised that an NHS aiming to innovate should capture the benefits of emerging technologies and, in so doing, provide an engine for industrial development based on the knowledge economy. NEAT aims to promote this concept by supporting applied research and development that will apply recent advances in fundamental knowledge and technology to the development of new products and interventions for improved health and social care or for disease prevention and treatment.

The NEAT programme provides funding for applied research and development in all areas of the medical sciences where new or innovative technological approaches can be used to enhance the quality, efficiency and effectiveness of health and social care. The research is strategic and applied in nature, and has the potential (although not necessarily the direct aim) for generating both intellectual property and cost reducing products and interventions. Its outputs are general; they have wide applicability and are capable of exploitation.

Projects supported by NEAT have for example been concerned with the use of new technology in quantitative 3-D ultrasound breast imaging, speech recognition for people with severe dysarthria, and the development of a practical recycling device to permit cost effective application of Xenon anaesthesia.

The NEAT programme has been in operation for some five years and has an annual budget of approximately £1.5 million. As indicated in the HITF report, this commitment is to be increased by DH through the UK Clinical Research Collaboration (UKCRC) (see paragraph 5.5.4). The NEAT programme

[4] "Assistive technology" is a term generally used to describe aids for the disabled eg in the home, to help mobility etc.

is open to all research providers in the academic and NHS communities. It aims to overcome the funding gap for research that is basic in nature and fundable by the Research Councils, and that which is towards market and driven by industry along commercial lines. The NEAT programme helps to fill this gap and support speculative applied research which may have benefit to the NHS but which does not have immediate commercial application and return.

HTA

The aim of the HTA programme is to ensure that high quality information on costs, effectiveness and broader health impact of health technologies is produced in the most effective way and is bought to the attention of those who use, manage and work in the NHS. The HTA programme considers the effectiveness and appropriateness of technologies by asking four fundamental questions:

— does the technology work?

— for whom?

— at what cost?

— how does it compare to alternatives?

Examples of HTA findings and the uses to which they have been put are given in Annex C.

LINK collaborative research

The Department has used the LINK collaborative research scheme (formerly overseen by the Office of Science and Technology) as a means of sponsoring the pre-commercial or strategic development and assessment of new technology. The MedLINK programme, which ran from 1996 to 2001, supported projects with the potential to lead to new medical devices for prevention, diagnosis, monitoring or treatment of illness or injury. A total of 48 projects received Government support of £15 million.

The LINK Health Technology Devices programme is currently supporting the research into innovative healthcare technologies needed to develop new medical devices. A further £15 million of government funding will be available throughout the programme to support collaborative R&D projects involving industry, universities and the NHS. Public investment will be matched by industry. As well as medical devices, the programme covers healthcare devices for use in the community and the home.

National Horizon Scanning Centre (NHSC)

The NHSC, funded through the NHS R&D Programme, aims to provide advance notice to DH of new and emerging health technologies likely to impact on the NHS. Where such technologies require evaluation, including consideration of clinical and cost effectiveness, they are passed to the Health Technology Assessment Programme for prioritisation. Where there are implications for the development or modification of clinical guidance, topics are referred to NICE.

Assistive technology

A report on Research and Development Work Relating to Assistive Technology is prepared annually for Parliament under Section 22 of the Chronically Sick and Disabled Persons Act 1970. The report is funded by DH and currently prepared by the Foundation for Assistive Technology, whose database of research projects is used both to highlight gaps and to identify funding sources.

4.1.2 *The National Institute for Clinical Excellence (NICE)*

NICE has made a positive contribution to improving NHS understanding of the clinical and cost effectiveness of new medical technologies and has led to faster uptake where there is evidence of benefits. DH recognises that more needs to be done to improve implementation of NICE guidance and work is ongoing to address this. (See also section 8.)

4.1.3 *Regulation of medical devices*

The regulations and controls on medical devices provide a stable framework for product development and use. They derive largely from EU legislation.

European Directives

A series of five European Directives regulating the marketing of medical devices throughout the EU started to come into effect from 1 January 1993:

— the Active Implantable Medical Devices Directive (AIMD) covers powered implants (such as pacemakers) or partial implants which are left in the body. This Directive was transposed into UK law by the Active Implantable Medical Devices Regulations (SI 1992 No 3146, as amended), subsequently consolidated into The Medical Device Regulations (SI 2002 No 618);

— the Medical Devices Directive (MDD) covers a broad range of products from sticking plasters to X-ray machines and was transposed into UK law by the Medical Devices Regulations (SI 1994 No 3017, as amended), subsequently consolidated into The Medical Devices Regulations (SI 2002 No 618);

— the In Vitro Diagnostic (IVD) Medical Devices Directive covers test kits and instruments used in vitro for examining specimens taken from the human body (eg blood grouping reagents, pregnancy and Hepatitis B test kits). It was transposed into UK law by the In Vitro Medical Devices Regulations (SI 2000 No 1315), subsequently consolidated into The Medical Devices Regulations (SI 2002 No 618); and

— the Directive amending the MDD to include medical devices which incorporate stable derivatives of human blood or human plasma (eg albumin, thrombin, fibrinogenor immunoglobulin) which can be incorporated into medical devices such as stents, leads, heart valves, vascular grafts, catheters, filters and haemostats) was transposed into UK law by the Medical Devices Regulations 2002 (SI 2002 No 618).

These Directives are single market measures designed to remove technical barriers to trade by harmonising safety and performance requirements for medical devices. The Directives replace former national controls of Member States. The CE mark is applied to devices to denote conformity with the requirements of the Directives and manufacturers may then market their products freely throughout the European Community without having to abide by any further national controls.

Key features

— the Competent Authority (CA) in each Member State must ensure effective implementation. In the UK, the CA is the Secretary of State for Health acting through the Medicines and Healthcare products Regulatory Agency (MHRA). The main responsibilities of the CA involve enforcing compliance with the implementing regulations, maintaining a register of manufacturers, assessing notifications for clinical investigations, monitoring and designating Notified Bodies (NBs) (independent organisations responsible for assessing the conformity of certain classes of devices) and authorising use of non-CE marked medical devices on humanitarian grounds;

— the Directives seek to match the level of control to the perceived risk associated with the product. In the MDD, this is achieved by a classification system whereby devices are grouped into one of three classes according to a series of rules. Class I covers products generally regarded as low risk such as spectacles, bandages and non-invasive products. Manufacturers of these devices are required to assess themselves that they comply, make a declaration to this effect and register their details with the CA. For medium risk products (Class II a and b), eg contraceptive devices, contact lens care products and for high risk products (Class III), eg intra-uterine contraceptive devices and devices combined with a medicinal product, the manufacturer must apply to an NB to assess conformity. Only when the NB certifies that the manufacturing processes or the products meet the requirements may the manufacturer CE-mark these devices and place them on the market. A similar system based on risk applies in the IVD Directive which groups IVDs into four categories reflecting an increasing risk. These are general IVDs; those intended for self-testing, that is for use by lay people; Annex II List B—which amongst others includes test kits for German measles, toxoplasmosis and phenylketonuria test kits as well as self-test kits for blood glucose; and Annex II List A—which includes test kits for HIV, HTLV I and II, most hepatitis viruses, and some blood grouping products, including those used to test donated blood. As the risk increases through these categories, so too does the involvement of the NB in ensuring that the devices have met the relevant requirements of the Directive before they are placed on the market. All devices covered by the AIMD are regarded as being high risk and subject to the highest conformity assessment controls. All devices covered by the AIMD are regarded as being high risk and subject to the highest conformity assessment controls; and

— a vigilance system which requires serious adverse incidents to be reported to the relevant CA where they are evaluated and, if appropriate, the results communicated to other Member States and the European Commission to help prevent similar incidents from occurring elsewhere in the Community.

The medical devices Directives do not include controls on advertising.

MHRA

In the UK, the MHRA is responsible for ensuring manufacturers comply with the Regulations. It investigates all allegations of non-compliance received and carries out a pro-active compliance exercise on selected manufacturers from the Class I Register and on focussed projects selected because of some safety concern. Member States have the power to withdraw from the market any device which it considers is a danger to public health.

Clinical investigations

To place their product on the market in the EU, manufacturers must demonstrate that it complies with relevant Essential Safety Requirements. To demonstrate such compliance, it will sometimes be necessary to carry out a specifically designed clinical investigation. The clinical investigation must be designed to establish that the performance claims of the manufacturer can be adequately demonstrated, and that the device may be judged safe to use on a patient, taking into account any risks associated with its use when weighed against the expected benefits.

Before a clinical trial can be held, the manufacturer must notify the CA of his intention and submit a detailed trial protocol. The CA has 60 days to assess the notification and raise any objections on grounds of public health or policy. In the absence of a formal objection from the CA, the trial may be held.

4.1.4 *Procurement*

Part of the wider Government agenda includes ensuring efficient public procurement which also allows for innovation. Relevant reports include DTI's Innovation Review *Competing in the Global Economy: The Innovation Challenge*[5] published in December 2003, the Office of Government Commerce (OGC) report *Capturing Innovation: Nurturing Suppliers' Ideas in the Public Sector published in May 2004,*[6] Sir Peter Gershon's Efficiency Review of the Public Sector[7] published in July 2004, OGC's report to the Chancellor of the Exchequer *Increasing Competition and Improving Long-term Capacity Planning in the Government Market Place* published in December 2003[8] and the OGC and Cabinet Office report *Making a Difference—Reducing Bureaucracy in Central Civil Government Procurement* published in December 2003.[9]

NHS procurement is being brought into line with Government policy with the aim of ensuring the purchase of high-value products that perform effectively. The sharing of best practice between local purchasers and commissioners is improving the quality of decision-making, and the development of regional procurement hubs is enabling better value-for-money procurement. Centrally-managed procurement of high investment medical equipment continues to ensure that the NHS benefits from such programmes.

To underpin this more professional approach to procurement, NHS budgeting arrangements are being reformed so that funding is directly linked to the treatment provided to the patient. The new system is designed to take account of the costs and savings throughout the complete care programme, wherever they occur.

4.2 Most recently, bringing many of these streams of activity together and initiating new collaborative work, government and industry have published the Healthcare Industries Task Force (HITF) report (see section 5 below).

4.3 Following on from the HITF report and as a result of the DH ALB Review, the NHS University (NHSU) and the Modernisation Agency are to be merged to create a new NHS Institute of Learning, Skills and Innovation (NILSI). This new organisation will manage the Innovation Centre proposed under HITF.

[5] www.dti.gov.uk/innovationreport/index.htm.
[6] www.ogc.gov.uk/embedded_object.asp?docid=1001717.
[7] Releasing Resources to the Frontline: Independent Review of the Public Sector—www.hm-treasury.gov.uk.
[8] www.ogc.gov.uk/embedded_object.asp?docid=10013941.
[9] www.ogc.gov.uk/embedded_object.asp?docid=1001426.

4.3.1 *NHS Institute of Learning, Skills and Innovation (NILSI)*

NILSI will promote excellence and innovation across the health and social care system. It will enhance service delivery in the NHS by focusing on innovation, learning and leadership development in an integrated and efficient manner.

The institute will assume a leadership role in the implementation and delivery of change in the NHS and manage the new Innovation Centre. It will aim to engender a culture of innovation within front line staff by developing linked training and modernisation programmes for new medical technologies.

An advisory board, under the Chairmanship of Sir David Brown (Chairman of Motorola), has been established to support the development of this new organisation. This board is to be advised by a Transition Team, who will manage the process of developing, reconstructing and merging the three entities into a single operational body by July 2005.

5. Healthcare Industries Task Force (HITF) and its Recommendations

Background to HITF

5.1 HITF was the first venture of its kind in this country at a strategic level between Government and the healthcare industries. It was a year-long initiative which was launched in October 2003 by the co-chairmen, Lord Warner, Under Secretary of State at DH, and Sir Christopher O'Donnell, Chief Executive of Smith & Nephew plc. Task Force members included Lord Sainsbury, Minister for Science and Innovation at the Department of Trade and Industry (DTI), Mike O'Brien (later succeeded by Douglas Alexander), Minister of State for Trade & Investment and Foreign Affairs, senior public policy makers and leading executives from the healthcare industries. The terms of reference are at Annex D, and the industry sector and products covered are defined in Annex A.

5.2 The broad aim was to develop a better understanding of how Government and the industry interact and to identify opportunities where closer co-operation would benefit all stakeholders. Its agenda was wide-ranging and complex, but the key issue was how to improve patient access to healthcare products, particularly beneficial new medical technologies. The Task Force recognised that solving this particular issue would unlock ways forward in other areas of mutual interest—developing practical measures to stimulate more innovation in the industry and in the NHS, and modernising NHS procurement would underpin the central objective.

The HITF process

5.3 The Task Force established four Working Groups to study the areas identified in the terms of reference:

- market access;
- R&D and the industrial base;
- regulatory issues;
- international trade.

5.4 The Working Groups comprised representatives from industry, government and its agencies, the NHS, academia, patient groups and other key stakeholders. They identified the issues and barriers in each of the four areas, and in June 2004 put forward over 50 recommendations to the Task Force.

HITF recommendations

5.5 The Task Force focused on nine key areas for action to optimise their impact across HITF's agenda:

5.5.1 *Development of an enhanced Device Evaluation Service (DES)*

To provide independent, expert guidance on performance of devices and their value to purchasers. The existing service is to be transferred from MHRA to NHS Purchasing and Supply Agency (PASA) with effect from 1 April 2005, subject to any necessary amendments to legislation, where links to procurement will be strengthened. The new DES will establish a consistent "once-only" approach to evaluation, will be more responsive to industry and public health needs, disseminate expert advice to purchasers, be supported by strengthened horizon scanning so that it knows what developments are in the offing and in what area useful new medical applications are likely to appear. The new DES will be at the hub of a wide-ranging network, joining industry with NHS clinicians and purchasers, with access to expertise in the field, paving the way for patient access to modern healthcare solutions.

The Task Force considered this new departure to be the cornerstone of its outputs, connecting NHS purchasers more closely to informed evaluations of novel products and medical technologies on the market and helping to promote the uptake of innovation.

5.5.2 *Innovation Centre*

To stimulate innovation in the NHS and in the global industry, this new institution will be developed to provide a pathway into the NHS and the social care system for beneficial new products and ways of working. It will cover more than medical devices and technologies, and promote a more entrepreneurial culture in the NHS. It will co-ordinate the work programmes of the NHS Innovations Hubs, stimulate innovation within the NHS as well as the global industry, and develop a brokerage service and a "route-map" to signpost the pathway for successful product development. It will also work towards building up a fund for translational research to fill what is currently a gap in funding streams and why a number of useful ideas are not progressed. The Innovation Centre will be a visible portal to the NHS with expertise to advise NHS staff and private companies on how best to proceed with their inventions.

5.5.3 *Procurement processes*

Ensuring that procurement of healthcare products in the NHS is modern and based on informed advice, will help ensure that patients get faster access to better treatments. Procurement processes are already being modernised in line with HITF outputs, DH and wider Government policies on procurement, developing a regional focus to reduce market entry points, a professional approach including significant clinician involvement so that health professionals' needs are taken into account, more transparent procedures to help overcome bureaucracy and improve understanding. Decisions will be informed by device evaluations from the new DES, and more interaction with suppliers is taking place, eg consultation on procurement plans, the development of National Service Frameworks (NSFs), development of best practice models, and the new NHS budgeting arrangements Payment by Results (PbR) which is currently being phased in. The aim of the latter initiative is that hospitals receive an agreed sum for a particular course of treatment, rather than via a broad service agreement which may not appropriately reflect the level of activity. The result is that funds follow the patient, incentivising better patient care and underpinning implementation of patient choice. This combined with a DES assessment of the value of a product, will help overcome "silo budgeting".

5.5.4 *Building R&D capacity*

The UK Clinical Research Collaboration (UKCRC)[10] will encompass new medical technologies within its programme. Embedding research on medical devices and technologies into the UKCRC networks will help increase the number of clinical trials with medical devices, make the NHS more accessible, and exploit its potential to help generate high quality clinical data on safety and performance. UKCRC will promote a better understanding of the conditions needed for the conduct of clinical trials with new medical technologies and help create more opportunities for trialling innovative products and procedures. Unlike medicines, development of new healthcare products and technologies is generally a continuous process involving incremental enhancements. Therefore, the products have relatively short life-cycle. It is important that the environment for clinical investigations and device evaluation are responsive to this (whilst continuing to protect patient safety) ie uses rapid, simple procedures supported by effective dissemination networks. UKCRC will facilitate this approach and co-ordinate efforts to streamline approval processes.

5.5.5 *Development of Healthcare Technology Co-operatives (HTCs)*

The Task Force appreciated the need to develop academic specialist centres, bringing government, universities and industry together to pioneer and test out new medical techniques and products. A pilot is to be designed to inform the future development of this project. The NHS working in partnership with other stakeholders in the field of innovation and trialling new products will help overcome barriers of resistance to adopting new technologies and will provide another means of support for product development.

5.5.6 *UK as the regulatory lead in the EU and internationally*

Maintaining and building on the UK's high standing in regulatory matters will be important in ensuring that future legislation for new and emerging technologies is appropriate, so that patients safety is paramount whilst innovation is not unnecessarily stifled.

[10] UKCRC is tasked with speeding up the development of new medicines and treatments from the laboratory to the patient by expanding the number and range of clinical trials. Its aim is to help bring together clinical teams, primary care trusts, the voluntary sector and industry to increase the number of patients participating in clinical trials. Its work will initially be targeted on five therapeutic areas. It is chaired by the Director of DH R&D and the Board comprises representatives of the main UK funding bodies for clinical research.

5.5.7 *International trade*

Exports are important to this sector and agreements were struck on how to focus government support to improve performance in overseas markets. Part of the solution lies in ensuring that the NHS is a showcase for leading-edge technology and innovation, and the other HITF outputs will clearly contribute to helping companies to sell their products abroad.

5.5.8 *Communication with patients/public to improve understanding of benefits and risks of medical devices*

Educating patients and the public about the important part medical devices play in their daily lives, communicating their risk:benefit profile and the regulatory system that governs them will help promote their safe use within our health and social care system.

5.5.9 *Training and education*

Improvements in the training and education of NHS and social care staff in the use of medical devices are to be made via the development of learning programmes and tools to expand opportunities for professionals to acquire practical skills and competences. This will facilitate career development and improvements to training records systems will help ensure that workforce skills are kept up-to-date. These initiatives will underpin the introduction of new medical technologies and be an essential element in speeding up patient access to modern treatments.

5.6 HITF agreed two further actions to improve understanding of the dynamics of UK-based industry, given its scope to help the NHS with innovation and its industrial potential :

— The complex nature and fragmentation of the industry has made it difficult to gather accurate and consistent data in the past. To address this the Government decided to undertake a regular data collection exercise. DTI reviewed existing statistical data on the sector and reached a consensus with DH and the industry on what statistical indicators should be collected on the industry in future years (see Annex A). This exercise will ensure that a clearer picture of the sector and its performance is made available on a regular basis.

— DTI also commissioned an independent sector competitiveness analysis of six key sub-sectors of the industry. The sub-sectors were chosen on the basis that they would offer in-depth insight into a range of high-technology and fast-moving disciplines, and provide the opportunity to assess UK strengths and weaknesses in each case. The study is currently being finalised and the report will be published in the early part of 2005. More information about the interim findings is at Annex B.

Implementation plans

5.7 The process of developing implementation plans was started once there was a consensus in principle on the nine key HITF outputs and, where possible, set in train. This involved identifying the necessary resources, and preparing the ground for establishing new structures and procedures. The nine key recommendations, together with an update on implementation strategies, were presented to the Task Force at its final meeting in October 2004. The Task Force gave its full backing to the recommendations and framework for action. An account of the work of the Task Force and its conclusions are detailed in its final report Better health through partnership: a programme for action[11] published on 17 November 2004.

5.8 Work is continuing to refine the HITF outputs and implementation plans. Resources in some areas still need to be identified, eg to identify funding for the development of the new DES, the Innovation Centre and the pilot HTC. Government is committed to meeting its HITF undertakings and is working with other stakeholders to complete its action plans. In addition, DH and industry are in the process of establishing a new strategic group to monitor implementation of HITF outputs. The new group is to be led by the former HITF co-chairmen, Lord Warner and Sir Christopher O'Donnell, and its members will be key players from both government and industry who will champion the delivery of the commitments given under HITF.

Conclusion

5.9 Taken together, the key HITF outputs constitute a coherent action plan which, once the various elements are brought into operation, should significantly increase NHS uptake of useful new medical technologies. The new joint group being formed will oversee implementation and address any unforeseen issues that arise from this. HITF has also provided a platform for the development of constructive relationships between manufacturers representatives and government at all levels. This is seen as a very important legacy—one which will provide mechanisms for ongoing communication so that policy makers, clinicians and innovators can share their knowledge and harness the industry's capability for innovation to meet the health needs of the nation.

[11] www.advisory.bodies@doh.gov.uk/hitf.

5.10 The HITF report has been received enthusiastically by interested parties, both in the UK and overseas. As the issues addressed are common to other countries, it is hoped that HITF and its ongoing work will provide a model for others to follow.

6. The Utilisation of Telemedicine (Including Telecare) and its Future Potential for Improving Services

6.1 Two of the technologies which can have a significant effect on a wide range of care environments are telemedicine and telecare.

What are telemedicine and telecare?

6.2 Telemedicine and telecare have a long history. In 1906 the Indonesian-born Dutch cardiologist Willem Einthoven experimented with using telephones to try and send early electrocardiogram recordings as the first attempt at exchanging information at a distance. The first specific references to "telemedicine" start in 1959, at the University of Nebraska, where microwave video links were used for medical consultations and continuing education.[12]

6.3 It may be helpful to make some distinctions between the terms "telehealth", "telemedicine", "telemonitoring" and "telecare", although they overlap conceptually and, as technology advances, they will overlap in reality.

"Telehealth" is a generic term used to cover both "telemedicine" and "telehealth monitoring (telemonitoring)".

"Telemedicine" covers systems that help doctors and other health professionals to diagnose and treat patients over a distance, typically linking geographically remote health premises such as a GP surgery and a hospital. As well as being able to provide more convenient access to patients, there is significant value for healthcare professionals in terms of continuing professional development and providing expert support when dealing with complex or less common conditions.

"Telemonitoring" covers equipment that allows remote monitoring of symptoms, such as heart functions and blood oxygen. A more accurate record of variations in a patient's condition can be created, improving the ability to spot changes in conditions, and unnecessary clinic visits are avoided. These systems are best if located in the patients' homes, possibly sharing communications infrastructure with telecare devices. Other future developments could see help for improved patient compliance with medication regimes.

"Telecare" includes systems that incorporate electronic devices (eg movement sensors, fall alarms, monitors for unlit gas) that can alert the occupant of a house, or a care response system, on the occurrence or non-occurrence of predetermined events, such as the fridge not being opened for a long time. By better managing the "risk" of letting disabled and older people live independently at home, telecare systems have the potential to enhance the lives of individuals and to postpone admission to residential care and to hospital.

6.4 Examples of telemedicine and telecare currently in operation are given in Annex E.

DH policy

6.5 DH's policy on telemedicine and telecare covers relevant health and social care services.

6.5.1 Telemedicine

Telemedicine is referenced in both the NHS Plan and the NHS Improvement Plan. The underlying principle of using Information and Communications Technology (ICT) to support and transform the delivery of healthcare by connecting delivery of the NHS Plan with the capabilities of modern information technologies is at the heart of the Government's vision for the NHS in the 21st century. Under the National Programme for IT in the NHS for England a national broadband network is being implemented across the NHS in England which will support the capability for telemedicine and telecare, including the transfer of medical images. Future possibilities include telemedicine in GP surgeries for electrocardiograms and skin disease, ambulance telemonitoring in emergency response vehicles, and home telecare.

6.5.2 Telecare

Modern, responsive electronic community alarm-type devices can do much more than alert a carer or call centre to an event that needs investigation to ensure that a person is safe. They may, for example, remind the person of things they should do. This allows them to stay in control of their lives for longer and gives them and their carers reassurance owing to reduced risk of untoward events. In time, technologies for the

[12] Centre for Health Informatics Aberystwyth.

remote monitoring of health conditions could share the same infrastructure as telecare technologies, and many people would benefit from both types of monitoring. Technical advances mean that the devices are easy to install and that they are relatively unobtrusive.

As well as the improvements in quality of life, efficiency gains to the health and social care systems are possible because "just-in-case" admissions of older people to hospital and residential care are still common. Telecare and related health technologies can therefore contribute to a number of important agendas such as:

- avoidance of unnecessary hospital admission and timely discharge;
- falls prevention strategies;
- saving lives through more reliable fire/smoke detection for older people;
- timely information to inform people's care package reviews;
- improving quality of life and reducing care costs for people with long term conditions and with strokes; and
- better monitoring of people with chronic obstructive pulmonary disease (COPD) and diabetes which can alert to changes in condition and significantly reduce out-patient attendances.

A number of influential publications referenced research in this area and influenced policy development by the Government. The Audit Commission's *Fully Equipped* reports in 2000 and 2002, followed by *Older People—Independence and Well-being* (February 2004) and particularly the sub-report on assistive technology, are notable examples.

Telecare enables older and disabled people to remain in their own homes—rather than in hospital or residential care—with increased safety and reassurance. It gives reassurance to the service user that help can be summoned quickly; to the informal carer that their friend or relative is safe and that they will be called in the event of an emergency; and to the professional that there is cover when they are not present. Telecare may most usefully be provided as part of a care package.

Community equipment services play an important part in helping people to develop their full potential and to maintain their health and independence. A wide range of equipment and adaptations can now be provided from 138 services in England with the majority of items being provided within seven days of a professional decision being made.

The Government has set out to increase the number of people benefiting by this integrated approach to meeting their needs. It is making a significant investment in modernising and expanding these services. The NHS Plan and National Service Framework for Older People set out the main targets.

In July 2004, as part of the 2004 Spending Review, The Chancellor announced £80 million funding for a social services' Preventative Technologies Grant over two years from April 2006. This is to extend the benefits of new technology community alarms (telecare), with the aim of reducing the number of avoidable admissions to residential care and to hospital.

These funds will be distributed through social services' baseline funding which means that councils and their PCT partners will need to have in place before April 2006 plans to take forward the implementation of the Government's policy to expand the uptake of these technologies.

The service implications

6.6 The use of ICT offers significant opportunities to improve the quality of care and meet patient expectations:

- efficiency and streamlining the work of professionals;
- monitoring, performance management (clinical and non clinical) and clinical governance, dissemination of evidence based best-practice;
- convenience;
- joined-up working throughout the NHS and social care; and
- reduction in human errors (eg computerised checking of dispensed medicines).

6.7 ICT enables the separation of location between patient and professional and between professional and hospital. Telemedicine and telecare will enable patients to be treated outside hospital settings, and support GPs and Primary Care teams in providing much greater opportunity for independent living for the elderly and chronically ill. ICT has tremendous potential to help transform the way healthcare is delivered and realise the vision of care tailored to patients' needs and responsive to their wishes and that of their carers. It is important however to remember that technology is only part of the solution.

6.8 Substantial investment will be required in training and IT skills for all staff, as well as investment in infrastructure and system design. This will need to place the patient at the centre of IT system design to ensure that technology developments enhance the patient experience of care.

6.9 Confidentiality and security are recurrent issues. ICT can enable and facilitate (for example) home telecare and home telemonitoring and alert care teams to a health problem with a patient—but that has to be balanced against patients' rights to privacy.

6.10 While there are clear benefits to the use of telemedicine, formal studies have indicated that it is by no means a panacea. For example, one study in the NHS into telemedicine in an Accident and Emergency setting in East Gloucestershire looked at the safety and clinical effectiveness of a telemedical system and its cost-effectiveness. The telemedicine system was formally evaluated through a prospective, randomised and blinded study, and a wide range of data, incorporating clinical, financial and satisfaction outcomes were collected. The results showed that telemedicine enjoys an acceptable safety profile, with overall clinical outcomes similar to conventional practice. However it also found that telemedicine is more expensive than conventional alternatives, and that there are a number of important process issues that must be adequately addressed if telemedicine is to succeed.

6.11 This view is reinforced by a study[17] into the perceptions of general practitioners (GPs) towards teledermatology, that demonstrated the importance of linking the use of telemedicine effectively into the clinical process. There was a general perception that teledermatology would result in quicker diagnosis and treatment, decreased referral rates and improved medical education and training. The study also indicated that unless the telemedicine system was quick, easy to use, efficient and reliable, and crucially, did not increase GPs' workloads, it would be unlikely to find widespread acceptance.

Key issues

6.12 The introduction of telemedicine and telecare into mainstream delivery of health and care services has been limited by the need to understand the key issues that distinguish them from more traditional approaches, and the implications for patient healthcare outcomes and service organisation. Valuable lessons can be learnt from the demonstration and pilot projects that have taken place to date and generalisations made about the principles and practicalities of implementing telemedicine and telecare services in line with Government policies.

6.13 Telemedicine and telecare should be implemented only as part of an integrated package developed in conjunction with appropriate business process re-engineering. Clinical engagement is essential to ensure that there is robust adherence to the highest clinical standards and that there are no compromises affecting patient safety. Above all, telemedicine and telecare facilities must be seen as complementing, not replacing, more traditional forms of healthcare delivery.

6.14 Legal and ethical issues that need to be addressed include:

- Who is responsible for telemedicine and telecare interventions ? Is it the clinician or agency directly interacting with the patient, or the remote clinician or agency, and how is the responsibility shared? Where services are provided across national boundaries there may additionally be jurisdictional issues.
- Does the concept of "consent" in a telemedicine/telecare context differ from a face-to-face context? If so, how is this to be managed so that patients understand what it is they may be consenting to and the implications of that. For example, there is a fundamental tension between the application of telemonitoring and a citizen's right to privacy.
- Protocols for use of telemedicine and telecare—have they been clinically proven? In a telemedicine/telecare context, what impact does the intervention of ICT equipment have on the clinical judgement of clinicians ? What are the implications of malfunction or misoperation of equipment being used in a clinical context for which it was never designed and may not have been formally certified as a "medical device"?
- A fundamental principle of the NHS is that healthcare provision should be on the basis of clinical need, and that, in general, the same levels and types of service should be available nationally. The implications of providing telemedicine and telecare services, that, by definition, are not locality based, has far-reaching implications for NHS service organisation, which traditionally has been focussed on serving the needs of local communities.
- Does professional training for telemedicine and telecare differ from traditional clinical practice? If so, how does this get integrated into health and social care training?

What the future holds

6.15 Developments in medical technology will continue as will the convergence between medical devices and traditional ICT systems. An increasing number of medical devices, particularly diagnostic devices, will have ICT capability and will be configured for connection to networks as part of the standard manufacturing process. All of this will facilitate their inclusion in telemedicine and telecare applications as well as raising the expectations that they can be used for this purpose. All administrations across the UK have strategies in place to implement comprehensive Electronic Health Care Records which will be used in

[17] K Collins *et al.* GPs' perceptions of asynchronous teledermatology; *Journal of Telemedicine and Telecare* 2004; 10: 94-98.

all health care interventions. As the use of electronic records becomes the norm, the necessity for the patient to be physically present on all occasions will diminish. Coupled with advances in telemedicine technology generally, this combination of events will open up many new possibilities to exploit telemedicine and telecare for the better delivery of health services.

6.16 Looking further ahead, "intelligent technologies", medical devices that can self-monitor and call upon expert/professional help automatically will play an increasing role in care. Miniaturisation of diagnostic and monitoring tools is likely to be significant, making these available in local or home settings. Professionals could be making much greater use of "intelligent devices" expert systems software to support clinical decision making, for example. There will be increased use of "data mining" and systems that can infer "rules" based on experience of previous events. Techniques such as "teleimmersion"—enabling users in different locations to collaborate in a shared, simulated environment as if they were in the same physical space; and "telepresence"—using remote sensors and manipulators to enable operations to be controlled in real-time from a distance, and virtual reality tools will increasingly make the physical location of services less important. Patients will be able to interact with and discuss their case specialist consultants from their homes or GP practice supported by their local GP. (Early pilots are already taking place, eg Chorleywood, NHS Digital TV referred to in Annex E.)

Conclusion

6.17 Health technologies are a rapidly developing area. The aim of developing health technologies is to improve the quality of care by promoting cost-effective technology and to protect the patient from less effective or less convenient health interventions. Failure to respond to new opportunities may result in the persistence of ineffective and obsolescent technologies to the detriment of the patient or client and possibly greater expense to the healthcare system.

6.18 The past two decades have seen a rapid rate of development in information and communications technologies as evidenced primarily by the arrival of the internet. The developments in the communications technologies in particular have generated a flurry of activity in many industry sectors. The potential for such as services as internet banking and on-line shopping are well understood and are being widely exploited. The potential of technologies which facilitate the delivery of health and medical services at a distance—telemedicine and telecare—are similar.

6.19 Geographical location will not necessarily imply health and social isolation. Delivery of appropriate care services through a variety of electronically enabled support mechanisms, thus sometimes avoiding the need to visit the GP surgery or local hospital, will be possible. In adopting even a small range of telemedicine and telecare initiatives, opportunities such as changing skill mixes of staff to deliver services more effectively thus giving more meaningful and rewarding work will also be possible.

6.20 Telemedicine and telecare offers the potential for a wider range of safe, effective, high-quality care to be offered and opens up a new range of possibilities for localised services. This includes increasingly sophisticated day surgery, exploring networking between hospitals, including the potential of telemedicine, and exploring new ways of providing services at night, for example as at the Princess of Wales Hospital in Grimsby where telemedicine technology enables links to be made between the Grimsby radiology department, Hull and Scunthorpe hospitals, consultants' homes and other external sites. At any time of day or night, consultant radiologists can diagnose remotely from their home.

6.21 The UK is taking a leading role in the use of ICT to support the delivery of healthcare. In England the National Programme for IT, one of the world's largest IT projects, is putting in place a national information infrastructure which will support telemedicine and telecare, help change the way the NHS works and improve the experience for both healthcare professionals and patients. The health services in the other UK countries (which are the responsibility of the devolved and Northern Ireland administrations) are also fully committed to making full use of ICT.

6.22 The electronic NHS in the 21st century will help deliver better, safer and higher quality care. The opportunities offered by new information technology, telemedicine and other new technologies that are coming on stream will enable the design of modern services.

7. The Speed of and Barriers to the Introduction of New Technologies

Barriers

7.1 The barriers to the speedy uptake of useful new medical devices and technologies were identified as part of the HITF process (see section 5 above). The main ones were :

- multi-entry points to the NHS for companies marketing products
- no formal mechanism to disseminate device evaluation advice and guidance, or to share experience and best practice amongst purchasers—leads to risk-averse purchasing decisions
- insufficient data available to purchasers about cost and value of new products and technologies

— NHS budgeting arrangements can act as a disincentive to uptake of innovation where initial costs are high/higher than existing products and encourage a risk-averse approach to innovative ideas, particularly where the benefits of new technology do not fall into the budget holder's domain

— not enough sharing of information between purchasers/clinicians/industry, which can result in ill-informed purchasing decisions

— NHS culture is not entrepreneurial enough—needs to be a driver of innovation

— lack of financial and technical support for companies in translating promising new ideas into marketable products

— bureaucracy around procurement procedures and instigating clinical trials in the NHS

— reluctance/difficulty in changing the current configuration of health and social care services inhibits the introduction of disruptive technologies

— NHS staff need to be better trained in the use of new medical technologies and products

7.2 A lot of these issues are interlinked. The Task Force therefore concentrated on finding practical ways to overcome or reduce the most important barriers and weaving these into an integrated strategy that would impact on all the key areas. The specific measures agreed by Task Force are covered under section 5.

Role of healthcare scientists

7.3 In addition to the range of measures proposed under HITF, the introduction of a range of new technologies into the NHS and the continual evaluation of performance are integral to the function of many healthcare scientists working in the constituent disciplines of the NHS workforce and associated organisations such as the National Blood Service and the Health Protection Agency (Life sciences and Genetics; Physiological Sciences; Clinical Engineering and Physical Sciences). Most of this is achieved as part of routine scientific service provision, rather than as part of formalised and funded R&D studies, and is part of the usual process of developing and improving scientific services. In some instances, equipment manufacturers and other diagnostic and therapeutic manufacturers may provide kits/equipment for trial and evaluation (alongside the current service provision) which often leads to purchase and introduction into the NHS as part of the usual capital replacement programmes or service improvement business planning processes. Additionally, some healthcare scientists will as part of their NHS function work with industry at the developmental stage of new technologies in a partnership approach.

7.4 Healthcare scientists within the life science disciplines (pathology, genetic and embryology) would routinely be introducing new in vitro diagnostic testing kits which can, for example, take what has been a research tool into a full NHS diagnostic service which includes the measurement of new parameters (eg BNP—a cardiac protein which is an important marker in heart failure). Within the field of applied molecular genetics (which is an integral part of many life science disciplines), there is an ongoing adoption of new technologies, especially those that can speed up processes or provide greater accuracy. Equipment in the Life science disciplines is evolving rapidly and recently robotic platforms have been introduced for the rapid processing of blood samples for biochemistry, haematology and for immunology, an extended range of point of care testing devices (eg for blood glucose monitoring), state of the art tandem mass spectrometry and the introduction of liquid based cytology.

7.5 Within the physiological science disciplines where tests and investigations are made directly on patients, a range of new equipment and technologies has been adopted that includes those to introduce new techniques or ways of measuring function (eg using sound waves to detect changes in airflow) or to make it easier for patients to comply with the measurement requirements. A wide selection of more portable and sometimes hand-held devices has been introduced that has enabled measurements to be provided in a range of healthcare settings, including primary care (variety of cardiac monitors eg echo machines, ECG event monitoring, spirometers, hand-held blood gas analysis, hand-held vascular scanners) and in some instances to enable patients to make the measurements themselves at home and transmit via telemetry. In addition, new technology has been introduced that has enabled improved treatment (DH investment in digital hearing aids, local funding of improved domiciliary nasal ventilation systems, cardiac defibrillators) or improved screening (DH investment in digital cameras to support diabetic retinal screening).

7.6 Within the clinical engineering and physical science disciplines many scientists have a key role in equipment evaluation prior to procurement. Clinical engineers and physicists play a key role in designing and introducing a range of new technologies not only to support imaging, but rehabilitation, clinical measurement and in radiotherapy. Other scientists working in maxillofacial prosthetics would have a key role in introducing new biomaterials to support reconstructive approaches. Some healthcare scientists are employed in specialist units where they evaluate equipment and software to support, for example, the introduction of advanced imaging technologies into the NHS.

7.6.1 *Supporting education and training*

Part of the training and education requirements to support regulation of practice of healthcare scientists (currently regulated or the aspirant professions where regulation will be extended in 2005–06) includes:

— an understanding of the principles of measurement;

— application within the health sector;

— evaluation, review and implementation of new technologies and techniques based on comparative research methodology (including reviewing the evidence base and ensuring that they measure what they are supposed to measure, to the degree of accuracy and precision etc).

This is reflected to some extent within both undergraduate and postgraduate programmes and in professional body examinations.

The National Occupational Standards Project in Healthcare science has produced a clear set of occupational standards based on competences for introducing new technologies and techniques into the health sector covering all elements of the function at all levels of practice from early evaluation, through to comparative studies, introduction, review, procurement etc. In addition, standards have been developed to define the competent performance for the quality assurance of measurements, calibration of equipment, protocols and procedures for undertaking the measurement which is an integral part of any introduction of new technologies and techniques. These standards define what needs to be demonstrated in terms of skill and knowledge requirements, with assessment criteria to determine competent performance are being built into pre and post registration programmes and into award and qualification frameworks.

The contribution of healthcare scientists to training and education will be included in HITF considerations on how to improve training and education needs, taking into account the services also provided by industry in this area (see paragraph 5.5.9).

Conclusion

7.7 Taken together, all these measures are designed to stimulate appropriate innovation and provide mechanisms for more rapid uptake of beneficial new medical technologies by the NHS. HITF produced its report in November 2004 and work to deliver the outputs has already started. The first milestone will be the transfer of DES from 1 April 2005 to PASA. Other initiatives are already underway eg the creation of NILSI which will manage the new Innovation Centre, improvements to procurement processes, development of UKCRC's programme including medical devices, regular regulatory dialogue between MHRA and industry. Some issues have still to be settled, including more detailed plans and funding arrangements for the new DES, the Innovation Centre within the wider context of NILSI and the development of a pilot HTC. Co-ordinating and supporting the work on improved training and education will also be taken forward. The new strategic group to be led by Lord Warner and Sir Christopher O"Donnell will oversee progress and ensure timely delivery of the HITF outputs.

8. The Effectiveness and Cost Benefit of New Technologies

Development of DES

8.1 HITF addressed the issue of how to assess the effectiveness and cost benefit of new technologies. The Task Force concluded that existing mechanisms, with some re-focusing, would be the best way to provide this information. Development of DES, currently part of MHRA, is at the centre of HITF proposals to help ensure that new technologies are taken up by the NHS. A key component is the provision of authoritative advice to purchasers on performance and value. The current service provided by DES does not take account of costs, but this will become an additional responsibility as the new service is developed under NHS PASA.

8.2 DES has strong links with NICE, particularly in relation to NICE's role in evaluating significant new medical technologies. The new DES will continue to work closely with NICE on areas of common interest.

NICE

8.3 Established in April 1999, NICE plays an important role in advising the NHS on clinical and cost effectiveness of new and existing health technologies, and in promoting uptake where technologies are demonstrated to be clinically and cost effective. NICE develops three forms of guidance: clinical guidelines (management of particular clinical conditions), appraisal guidance (guidance on specific health interventions, including pharmaceuticals), and guidance on the safety and efficacy of interventional procedures.

8.3.1 *Topic selection processes*

The NICE technology appraisal and clinical guideline work programmes are jointly set by the Department of Health and the Welsh Assembly Government. Topics for referral include both new and emerging health technologies and those drugs, devices and procedures currently in use in the NHS where there is variation in practice.

New medical technologies are chosen for referral to NICE by the Department of Health topic selection process. Information on these topics is provided by bodies commissioned by the Department of Health to track the progress of new medical technologies (whether they are drugs, devices or procedures). Information may also be submitted directly to the Department of Health by interested parties.

8.3.2 *Clinical guidelines and technology appraisals*

In its first five years NICE has published 86 technology appraisals giving guidance on 159 pharmaceuticals, 21 procedures, 17 diagnostics, one Health Promotion and 106 devices (as of December 2004).

The first NICE-commissioned guideline, covering the management of schizophrenia, was published in December 2002. Up to December 2004, NICE had published 23 clinical guidelines, six cancer service guidelines and eight inherited guidelines. NICE also has 44 guidelines and 53 technology appraisals in simultaneous preparation, making it the largest programme in any country.

8.3.3 *Interventional procedures*

NICE's Interventional Procedures Programme (IPP) provides guidance about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use. Referrals can be made at any time directly to the Institute itself. Since the launch of the IPP in February 2003, 96 guidance documents have been produced (up to December 2004).

8.3.4 *Implementation of NICE guidance*

There is clear evidence now emerging that, while overall NICE guidance has led to faster uptake of recommended treatments and some narrowing of variations between different parts of England and Wales, there are still significant and unacceptable variations. Ministers announced on 14 June 2004 a broad programme of action to aid faster uptake of NICE guidance. Action to support the implementation of NICE guidance does not fall to any single body. There is a broad partnership to ensure that patients get ready access to the quality of care recommended by NICE.

Conclusion

8.4 DH fully recognises that a major element of improving patients' access to new medical technologies is via evaluation of their effectiveness and benefits, and is already taking steps to address this issue.

Annex A

THE UK-BASED HEALTHCARE INDUSTRIES

The scope of the healthcare industries is extensive and covers a wide range of medical consumables, hospital supplies and equipment, devices used in the community and services. The Healthcare Industries Task Force (HITF) focused attention on healthcare product manufacturers, ie producers of non-pharmaceutical, but specifically medical, equipment, and used the definition of medical devices in the European Medical Devices Directive (MDD).

Definition

The Task Force agreed that the European Medical Devices Directive (Council Directive 93/42 of 1993) contains a useful working definition of the sector for the purposes of collecting performance data. The Directive states in Article 1(2):

"'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process; and

— control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."

The definition does not cover the provision of services.

The Healthcare Industries and the NHS

The NHS approach to innovation has a significant impact on UK industry and economic activity. The NHS is the main purchaser of pharmaceuticals and medical devices and is also an important market for IT equipment and services.

Clearly the prime responsibility of the NHS is to look after people's health and well-being. Consequently all its investments and decisions must be strictly justified on healthcare grounds. Nevertheless there is considerable scope for the NHS to work with business to support its own innovation and to benefit patient care, whilst at the same time encouraging innovation and commercial success in UK industry. Public/private partnership for innovation is in the interests of all.

Industry Metrics and Performance Data

As part of the HITF exercise, Government and industry agreed that it was important to come to have a common understanding of the coverage of the and how to measure its performance in key activities. The Task Force decided to collect relevant data and publish regular performance indicators measuring:

— output and economic profit;
— value added and productivity;
— R&D and innovation; and
— size and quality of market.

An initial set of data for nine of the proposed metrics were published in Annex D of the HITF report. These tables cover:

— UK sales of medical devices;
— exports;
— economic profit from sales of medical devices;
— manufacturers' employment in UK medical devices;
— value added per employee;
— R&D spend; R&D as a percentage of sales;
— patents awarded; and
— size of UK market.

Some initial data on clinical investigations and NHS licensing and spin out agreements will be included at a later stage.

DTI have taken responsibility for updating the data which will be published each December.

Annex B

COMPETITIVENESS ANALYSIS OF SIX KEY SUB-SECTORS OF THE UK MEDICAL DEVICES INDUSTRY: INTERIM FINDINGS

In 2004, the Department of Trade and Industry commissioned a study "UK Sector Competitiveness Analysis of Six Healthcare Equipment Segments". The study was undertaken by Arthur D Little Ltd and examined six different sub-sectors:

— medical imaging/ultrasound equipment and materials;
— diagnostic equipment and materials;
— active and passive implantables/orthopaedics;
— radiotherapy equipment;
— electromedical/respiratory;
— advanced wound management.

These sub-sectors were chosen as being representative of the areas where an innovative technical approach was particularly required to develop new clinical treatments.

The study particularly examined:

— the differences between UK sources of supply and other supplying areas;

— UK strengths and weaknesses and factors creating business success;
— procurement effects on competitiveness of domestic suppliers.

The UK was compared against France, Germany, the US and Canada (particularly Ontario).

At the time of writing, the final report is available awaiting publication.

Success Factors

Among the factors which, according to the study, are important for the development of a successful national sector are:

— the size of the national market, and the ease of market entry;
— procurement systems which evaluate and acknowledge the benefits of innovative products, including those developed by SMEs;
— a strong degree of innovation within the sector, and the ability to commercialise innovation;
— a high quality commercial clinical trials framework;
— investment in skilled labour, scientific knowledge and specialist infrastructure;
— new forms of product differentiation; the ability to introduce a continuous stream of new products;
— good quality management, processes and leadership within companies;
— the involvement of clinicians in the development of new techniques and products.

Market Size

Arthur D Little has estimated that the UK market for the six selected sectors is as follows:

— in-vitro diagnostics ..... $483 million (2.1% of world market)
— orthopaedics ..... $421 million (2.5% of world market)
— imaging ..... $435 million (3% of world market)
— advanced wound management ..... $156 million (13% of world market)
— electromedical/respiraratory ..... $48 million (3.7% of world market)
— radiotherapy ..... $54 million (5.7% of world market)

Eucomed, the European trade association which represents most of the sector, estimates that the world medical devices market is worth 184 billion Euro, of which the UK market is 5.8 billion Euro (around 3.2% of the world market and 10.5% of the European market).

Characteristics of the UK Sector

Based on the findings of the study, and other intelligence collected by DTI and DH, the following conclusions can be drawn about the characteristics of the UK sector:

— The UK sector is diverse and includes companies of all sizes. For example, there are numerous multinational companies, many of which are US or German owned. There is only a handful of multinational companies which are UK owned. There are only two UK-owned medical device companies in the FTSE100 index.
— In contrast, there are many SMEs, mainly UK-owned, with innovative products and technologies offering new clinical benefits.
— Mergers, acquisitions and consolidation are quite common in this sector, which has led to many UK companies being acquired by foreign players. This means that more decisions about the location of future investment are taken outside the UK. On the other hand, several global multinationals have invested heavily in building centres of excellence in different technologies in the UK.
— The variety of companies and technologies mean that there is no single business model, and no cohesive structure across sub-sectors. This supplier structure is similar to other G7 countries.

UK Strengths and Weaknesses

Particular UK strengths lie in the emerging/growth industry sectors, such as advanced wound care, diagnostics and orthopaedics. These sub-sectors lie at the convergence between "traditional" medical device technologies of precision engineering and electronics on the one hand, and advanced bioscience on the other. The UK has strong industrial and academic capabilities in biotechnology and biochemistry, and has the most developed bioscience sector within Europe. It should be able to leverage this advantage to secure investment in cutting-edge technology in the medical device sector, but it must be recognised that the United

States is in an even stronger position. The UK can already claim to be a global leader in advanced wound care, where there are strong supporting industries in technical textiles and speciality chemicals as well as bioscience.

However, in the more mature areas of medical devices, the UK has fewer differentiating strengths, with less prospect of immediate growth.

The UK's industrial R&D in this sector mainly takes place in the emerging/growth industry sectors, particularly IT applications and the bioscience end of the medical device spectrum, for example in advanced wound management, where the highly technical nature of the product means that substantial investment in R&D is required to meet market needs. For example, the study estimates that 20–30% of the biotechnology value chain is accounted for by R&D.

There is some large scale manufacturing in the UK, much of which is there for historical reasons. In some sub-sectors, new large-scale manufacturing facilities are more likely to be placed in countries which can offer lower labour costs or higher incentives. However, outsourcing of high labour cost components and technological advancement are enabling much manufacturing and associated research and development activity to be retained in developed countries and the UK has some high quality centres of manufacturing excellence.

There are numerous sales/marketing/servicing operations in the UK, with some multinational firms maintaining these operations while not locating any R&D or manufacturing in the UK. Servicing costs of complex electronic equipment can form a significant part of the value chain.

The UK medical devices sector is not as strongly clustered as its biotechnology industry, for example, though there are concentrations in particular sub-sectors:

— wound management and orthopaedics in Yorkshire;

— research and manufacturing of magnetic technology in Oxfordshire;

— radiotherapy in Sussex;

— in-vitro diagnostics around Dundee.

Medical device companies involved in biotechnology can link to the major UK biotechnology clusters such as London, Oxford, Cambridge, North West England and Scotland.

The UK does not have clustering on the scale of the US medical device clusters in locations such as Boston, Minneapolis-St Paul and Orange County/San Diego.

The UK has some significant networking organisations, such as the Medical Devices Faraday Partnership, the network of five regional Medilinks, and Diagnox (for the diagnostics industry). All of these networks promote links between industry, academia and the health sector, and encourage the exploitation of UK expertise.

The UK has a skilled workforce and strong technical universities in many areas. However, the decline in the UK electronics industry has led to a skills gap for the medical electronics sector.

The UK has a strong supply chain in areas such as biotechnology, biochemistry, fine chemicals and metals processing. The situation is less good in electronics.

Inward Trade and Investment

The results of the study will be used by the Government to identify potential areas where UK strengths can attract further inward investment from the global medical devices supply market. The Government will continue to work with industry associations to assist UK based firms (particularly SMEs) who want to increase their overseas sales.

Annex C

DH RESEARCH—HEALTH TECHNOLOGY ASSESSMENT (HTA) FINDINGS AND APPLICATIONS

Review of Stents and NICE Guidance

Some HTA outputs feed directly into the development of NICE guidance (see paragraph 2.6.1). For example, a systematic review of stents found that:

> "in sub-acute heart disease (especially stable angina and unstable angina) there is evidence for the effectiveness of elective stents in reducing the need for repeat coronary angioplasty".

This fed directly in to NICE guidance which states:

> "stents should be used routinely where percutaneous coronary intervention is the clinically appropriate procedure for patients with either stable or unstable angina or with acute myocardial infarction".

Virtual Outreach Services and their Incorporation within Healthcare Systems

Other examples of HTA assessing new technologies include an evaluation of virtual outreach or joint teleconferenced medical consultations. This trial found that:

— virtual outreach consultations resulted in significantly higher levels of patient satisfaction than standard outpatient appointments and led to substantial reductions in numbers of tests and investigations. However, they were associated with increased rates of follow-up. Virtual outreach was not cost neutral although changes in costs and technological advances may improve the relative position of virtual consultations in future.

These findings have important implications for the design and implementation of virtual outreach services within healthcare systems and suggest that appropriate patient selection, significant service reorganisation, and provision of logistical support for arranging and conducting consultations will be required if such services are to operate efficiently.

Use and Benefits of New Glucose Monitoring Devices

The HTA programme continues to commission research to evaluate new technologies in healthcare. For example, a randomised trial to compare minimally invasive glucose monitoring devices in the management of insulin treated diabetics is due to report in 2008. The trial will consider reliability and patient acceptability of the new technologies and will include modelling of long-term health benefits and costs and cost effectiveness of the technologies involved.

Annex D

HEALTHCARE INDUSTRIES TASK FORCE (HITF) TERMS OF REFERENCE

The Healthcare Industries Task Force (HITF) will bring together government and industry leaders to identify steps to develop, stimulate the growth and performance of the UK healthcare industry and maximise the benefit to patients from healthcare products, in particular to:

— increase healthcare professionals' and patients' access to appropriate and innovative medical technology across all healthcare services;

— foster and facilitate an improved environment for product research, development, clinical evaluation and related manufacturing investment;

— provide a clear framework of regulation and information that serves patients; and

— promote international trade in products in this sector.

Co-chaired by a Government Minister and a leading Chief Executive, HITF will within a year report and deliver recommendations which should benefit patients, encourage the best use of NHS resources and stimulate science and industry in the UK to improve growth in manufacturing, investment, employment and exports. The Task Force will be assisted by working groups bringing together experts on each area. Four Working Groups are planned, each with co-chairs from government and industry. The Task Force will produce a report and recommendations within a year.

Annex E

EXAMPLES OF TELEMEDICINE AND TELECARE APPLICATIONS

There are a number of examples of telemedicine and telecare in use in the NHS (a more comprehensive list is available from the UK Telemedicine and E-health Information Service—www.teis.nhs.uk).

At St Mary's NHS Trust in Paddington, ComMedica Ltd's web-based telemedicine software has been rolled out to form an electronic image-sharing link between St Mary's Paediatric Accident and Emergency department and the specialist Burns Unit at Chelsea and Westminster NHS Trust. The system is to be used for the instant referral of digital pictures of lacerations and burns. More patients will be treated at St Mary's under expert guidance from Chelsea and Westminster Hospital's burns specialists and plastic surgeons. The software will help Chelsea and Westminster Hospital to determine better which patients need to be transferred for specialist attention. St Mary's NHS Trust has already installed ComMedica's software for an electronic image-sharing link between St Mary's and the National Hospital for Neurology and Neurosurgery near Holborn, which has allowed speedier diagnosis and treatment of critical head injuries since September 2002.

The Royal Cornwall Hospital has a successful project using videoconferencing to treat minor injuries. Eight minor injury units are linked to the county's main accident and emergency centre at the Royal Cornwall Hospital in Truro, via BT videoconferencing. Cornwall Healthcare Trust is expecting to save approximately £100,000 a year through use of the technology which gives patients visiting the hospitals immediate access to fully trained accident and emergency specialists at the Royal Cornwall Hospital. The use of videoconferencing is also improving communications between the hospitals and providing a valuable

new medium for internal training. The experience from the project has also provided valuable input to the work of the National Programme for IT in the NHS—it was one of the precursor "Electronic Record Development and Implementation Programme" projects.

Teledermatology has been a notably successful application area for telemedicine. Working in conjunction with the NHS, a commercial company (tds Telemedicine Ltd) provides a commercial service where specially trained nurses take digital photos which specialist software routes to consultant dermatologists—who may be anywhere in UK, and can work from home—for diagnosis.

The highly successful NHS Direct service (and its counterpart, NHS24 in Scotland) is the biggest telemedicine project in the world. Trained NHS nurses provide confidential advice to telephone enquirers, supported by a clinically-proven decision support system. It is complemented by an online, web-based information service (NHS Direct Online) that provides a health encyclopaedia linked to the national library for health, together with a query service for non-confidential, non-urgent health questions. NHS Direct Online also allows access "Healthspace"—a secure facility to allow patients to record health information of importance to them. In the future it is planned to use Healthspace to support online patient access to the NHS Care Records Service, subject to appropriately robust authentication and security measures being in place. In the longer term these developments could allow patients to track and control their treatment pathway—allowing patients to select and synchronise appointments, order transport, set recalls and reminders with personal diaries and communicators. The NHS Direct portfolio has recently been further extended by the launch of the health information service NHS Direct Interactive on 16 December 2004 on Sky and free-to-view digital satellite. In 2005, it is planned to launch the service on cable and Freeview.

Great Ormond Street Hospital (GOSH) has a sophisticated telemedicine system with facilities in the clinical areas directly linked to the Kennedy Lecture Theatre in the Institute of Child Heath.[18] Regular clinical consultations are undertaken with John Radcliffe Hospital in Oxford. Educational activities are also broadcast to various institutions, conferences and symposiums around the world. A separate Tele-Echo service, established in cooperation with Northampton General Hospital (UK), makes the expertise of the GOSH cardiac team available to other hospitals. Various other areas of the hospital are also involved in telemedicine activities.

Watford and Three Rivers Primary Care Trust's Chorleywood Health Centre uses video-conferencing to bring patient, consultant, nurse and GP together to discuss diagnosis and treatment. Many of the tests patients require can be done at the surgery or in people's homes and the results e-mailed to a hospital consultant, reducing the number of times a patient needs to attend hospital for outpatient appointments. Patients are saved lengthy journeys to see a consultant, and have the support of their own nurse or GP when seen by the consultant. Chorleywood runs its telemedicine programme in collaboration with the John Radcliffe Hospital in Oxford and St Mary's Hospital in London. A treatment room in the practice houses equipment for ECG and exercise testing, facilitating prompt diagnosis and treatment of urgent cases.

The Chorleywood example demonstrates very clearly that the technology needed can be easily bought off-the-shelf, and with proper training readily usable by local staff. However, full cost-effectiveness only comes if it used across several specialties rather than dedicated to a specific disease area. Also crucial is effectively managing the changes in the relationships between healthcare professionals that come about through the greater use of ICT.

A 10-year partnership with Brunel University has seen all of the computers in the health centre connected to a local area network that gives access to a multimedia patient database and through a broadband connection to the secure NHS national network.

The "MIDAS" project based at Cheshire County Social Services is piloting the use of an intelligent telecare system within a social services residential short-stay setting for older people undergoing rehabilitation as part of an intermediate care service. Social Services is funding the cost of the equipment and providing the environment of the community support centre and its staff. The aim of the project is to evaluate the contribution of a prototype "MIDAS" intelligent telecare system and its use as an assessment and monitoring tool. Since January 2000, Cheshire Social Services and Vale Royal Borough Council have been jointly working with a company, Technology in Healthcare, trialling prototype individual social care sensors. These sensors, if successful, then go on to be developed into a marketable product by Tunstall Telecom http://www.teis.nhs.uk/jsp/search/person.jsp?person=.

ICES (Integrating Community Equipment Services) is a DH funded initiative across health and social care to develop community equipment services in England, remove unnecessary barriers for users and modernise services.

[18] In partnership with Great Ormond Street Hospital and as part of University College London, the Institute for Child Health is the leading British academic research institution for child health. It is co-located with Great Ormond Street Hospital.

Supplementary evidence of the Department of Health (MT 1A)

ROLL OUT OF PICTURE ARCHIVING AND COMMUNICATIONS SYSTEMS (PACS)

Three contracts for the implementation of PACS solutions have been agreed for the North West and West Midlands, London and Southern clusters. Contracts for the North East and Eastern clusters are still in negotiation.

The following agreements have been signed between the relevant LSPs and PACS providers to implement PACS in the Clusters stated:

Cluster	*LSP*	*PACS subcontractor*
London	BT (CCA)	Phillips
Southern	Fujitsu	GE
North West and West Midlands	CSC	Kodak & ConMedica

PACS implementation activity at 12 early adopter sites has commenced—five in the Southern, four in the London and three in the North West and West Midland Clusters. These are expected to go-live in late spring/ early summer.

Targets for PACS roll-out, as stated in the LSP contracts, is 80% take up by March 2006 and 100% take up by March 07.

The NHS has significantly invested in modalities in recent years and the National PACS programme is not about replacing existing medical devices. Rather it is about providing IT which enables images to be digitally stored, analysed and shared; first locally, then regionally and eventually nationally.

Where a Trust already has Digital Radiography equipment their existing outputs can be incorporated into the national PACS. Trusts who currently use older Conventional Radiography will benefit from the National PACS programme by using equipment being provided as part of the programme which enables their images to be stored digitally.

March 2005

Witnesses: **Professor Ian Philp,** National Director for Older People's Services, and **Dr Felicity Harvey,** Head of the Medicines, Pharmacy and Industry Group, Department of Health, **Professor Tom Walley,** Director of the Health Technology Assessment Programme, Department of Pharmacology and Therapeutics, University of Liverpool, and Department of Health and **Sir Christopher O'Donnell,** Co-Chairman, Healthcare Industries Task Force, were examined.

Q55 Chairman: May I welcome our second group of witnesses. We have an empty chair at the present time. We understand that Professor Philp is stuck in a traffic jam with a minister—we are not sure which minister he is lucky enough to be stuck with—but he hopes to be here within the next quarter of an hour or 20 minutes. We will make a start because we hope to complete this session in round about an hour. Could I ask our witnesses to introduce themselves to the Committee briefly.

Dr Harvey: I am Dr Felicity Harvey and I am Head of the Medicines, Pharmacy and Industry Group within the Department of Health. Within my remit I cover the sponsorship of the devices industry; indeed, it was my part of the Department that was working very closely with industry in the Healthcare Industries Task Force work over the past year.

Professor Walley: I am Tom Walley. I am Director of the Health Technology Assessment Programme on behalf of the Department of Health. I am also Professor of Clinical Pharmacology at the University of Liverpool and a Consultant Physician at the Royal Liverpool University Hospital.

Sir Christopher O'Donnell: I am Chris O'Donnell. I am the Chief Executive of Smith & Nephew, which is the largest producer of medical devices and technology based in the UK, one of the 10 largest companies in the world, and we contribute particularly to healthcare technology research and innovation as a key part of our activities.

Q56 Chairman: Could I begin by referring to some of the evidence that came out in the earlier session. I am not sure whether you were present and heard the evidence but one of the points that was raised related to the difficulties of services being organised and viewed in silos. One of the issues that particularly concerns me—and you probably heard the example I gave of the effect on the National Health Service of telecare solutions preventing a broken hip—is that the budgetary crossover is not there, so the investment, possibly by social services or, indeed, the individual into those telecare solutions in their own home, does not in a sense relate to the savings that are made in the health service. I wonder, Dr Harvey, how you would respond to that concern, in particular the concern that increasingly the service is devolving decision-making to a local level; and is there any strategy you might favour nationally? It is, in many respects, down to those local people to drive it forward, and it would appear in many instances that they are not driving it forward.

Dr Harvey: Chairman, quite an element of this Professor Philp would be in a very good position to speak to when he arrives. He, as you know, has the brief for older people's care, both from the health and social care perspective. In terms of silo budgeting, from the primary care trust perspective, as you are aware, they now have budgets—they have about 80% of the NHS budget now. That allows

them to develop services, working closely with social care across the health/social care interface, and through the Payment by Results mechanism that we have, which was referred to earlier, with the intention through that to unbundle what we have as the groupings of services within the HRGs that lead to the tariff, this will allow Primary Care Trusts, working with their local authorities, to look more carefully at how they deliver services locally. It is down to local decision as to how they do that but, as you are aware, there is quite a lot of movement now from care that would have been delivered within a secondary or tertiary care setting to looking at delivering that in different ways in a primary care and a primary care/local authority/NHS way. I think there are now more mechanisms, particularly as Payment by Results develops. Also, I think one needs to remember that Primary Care Trusts, although in the past they have had annual budgets, have since 2003–04 been given a three-yearly budget. Some of the concerns that have been raised have been around short-termism, and therefore primary care thinking about just one year. Now we are looking to a longer horizon, to say that Primary Care Trusts, working with their local authorities, should be looking over a longer period of time. Therefore some of these benefits, around the sorts of treatments that they might deliver that would have efficiency/cost-saving benefits or whatever, and, most importantly, benefit patients more, are now far more within the capability of PCTs to deliver in terms of this new mechanism that we have in place.

Q57 Chairman: Why do you feel we are so behind other similar European countries in introducing telehealth and telecare within the UK? I mentioned in the first session that it always strikes me very strongly when we go to other European countries and elsewhere in the world that we frequently see they have made these quite remarkable advances but often using British technology that we do not see in use in our own country.

Dr Harvey: I think there are two issues. One relates to where we got to in the Healthcare Industries Task Force about how we get innovation into the NHS, but the other is possibly a more practical immediate one, and that is that, in terms of telemedicine—telemedicine requires the possibility of transferring data, transferring digital images, etcetera—it needs quite a lot of capability within the system. The National Programme for IT is actually rolling out a broadband based network and service between primary, secondary and tertiary care. This, if you like, gives a platform to allow the telemedicine aspect, which is very much around the clinician and interfaces between the clinician with the patient. If you look at the telecare element, and even telemonitoring, where, as one of the witnesses was suggesting, you could send data down the telephone line—you do not require broadband for that, you can just do that through an ordinary telephone line—there is therefore the possibility for doing telecare—and we have already heard there are some examples of that, although possibly not as many as we would like to see in the future—and also there is a possibility for telemonitoring, of patients transferring data into hospitals. I think the National Programme for Information Technology allows us the platform to develop that further in the telemedicine context. In terms of the telecare context, Professor Philp will be able to say a bit more about what is happening in terms of strategies to move that forward, but I think it is very much supported by the Healthcare Industries Task Force recommendations which are very much around: How do we get new innovation into the National Health Service? We accept the fact that the NHS has not been very good at getting new technology in. I think there were quite a lot of environmental issues, particularly working towards the target within the National Health Service Improvement Plan around a maximum of an 18-week wait for treatment from referral. To deliver that—which means diagnostic services have to fall before that 18-week maximum—we have to move to far more innovative methodologies for both diagnosis and treatment mechanisms. I think that gives us the sort of impetus, along with the mechanisms that we have been trying to set up through HITF—the implementation of which Sir Christopher O'Donnell as well as Lord Warner will be overseeing—to catch up with those other countries, whose innovation and entrepreneurial culture is possibly indicated more in terms of how they deliver services now.

Q58 Dr Naysmith: Are you implying that a lack of "good enough" IT systems in this country up until now has been one of the factors inhibiting the growth of telemedicine?

Dr Harvey: In terms of telemedicine, the fact that you do need more of a broadband based basis—and I am not the expert on this, but we would be delighted to give you further details—does actually mean that for things like, for example, the Picture Archiving and Communications system (PAC's) which are now being introduced and will be introduced by 2008 (for example, for diagnostic radiology and scans), unless you have a networked facility—

Q59 Dr Naysmith: Yes, I understand that, but are you saying that it is because of a lack of the ability to transmit images of sufficient quality that that is inhibiting that? Then the question is: Why did they manage it in the Scandinavian countries 10 years ago?

Dr Harvey: I think it may be the lack of a national capability for doing it. There are various pockets within the country where they can, they have, and they are doing it, but in terms of a national capability to do that, the National Programme for IT gives us the platform from which to think about that nationally, rather than just local investment in local particular areas where they have decided in the past that for them it would be of benefit.

Chairman: Could I go along that tack? I am interested in you calling it a platform because that implies it is just a start and you can jump off it into all sorts of directions.

Chairman: Or fall off it!

Q60 Dr Taylor: Or fall off it, yes. We have had a submission from the Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care—who are not among our witnesses—who are very concerned that, by looking at the new technology, we are in some way disregarding the advances in the routine services, like routine x-rays. They say—which is rather the opposite to what you have said: "Within the current remit of the National Programme for IT, there is no provision for direct digital acquisition of x-ray images despite the fact that the roll-out of IT infrastructure relies heavily upon hospitals being able to acquire images digitally." Do they have that wrong? Did I understand you to say that the Picture Archiving and Communication System is going to be in everywhere by 2008?
Dr Harvey: It is actually being rolled out across the NHS starting this year. We should have 80% coverage using the PAC System by 2006, with full coverage by 2007 in fact.

Q61 Dr Taylor: Eighty per cent by 2006?
Dr Harvey: Eighty per cent PACS coverage is intended by March 2006, with full by March 2007. That is, I think, fairly recently announced.

Q62 Dr Taylor: That is very, very reassuring. Can we hold you to that?
Dr Harvey: We would be very happy to provide more details through the National Programme on that.
Dr Taylor: It would be very helpful if we could have that.

Q63 Chairman: The information you have given us is in contrast to some other information we have received. We would perhaps welcome you writing to us on this, if that is convenient.
Dr Harvey: As you say.

Q64 Dr Naysmith: I would like to ask Sir Christopher a question relating to the Device Evaluation Service. It is said by the Department to be a cornerstone of the Task Force report. Do you think the Department will be ensuring, therefore, that it will be closely linked to procurement? How will this advice tie in with the National Service Frameworks and the new NHS Payment by Results? Are you confident that it is going to work is basically the question.
Sir Christopher O'Donnell: I think there is a very good chance it is going to work. A lot of effort is going into it between industry and government. A fair amount of the discussion has gone on about: "Why have we not in the UK adopted as much innovation in terms of technology as other comparable European countries in particular?" Historically, to be blunt, there are three factors. One is absolute level of spend, which has been lower. The second is the silo budgeting issue. The third is the issue of multiple acceptance points. Professor May pointed out that the NHS is in fact a confederation. Particularly for smaller companies, if every one of the trusts who are thinking about using something decides it wants to do an evaluation, it (a) slows things down and (b) is a diabolical use of overall resources. We see, in terms of the adoption of innovation, really three key roles to this. One is to have a focused Device Evaluation Service—and that is at the point where there is a device; in other words, if a company brings something that is a product in production, appropriately signed off in terms of the quality assurance standards related to the EU Directive and so on, that device can then be evaluated—and evaluated once, not evaluated 246 times or whatever the number happens to be at the available centres. In order to do that and fund it effectively, the proposal is made to move the Device Evaluation Service from being managed by the regulator, which is the MHRA, to the NHS Purchasing and Supply Agency (PASA), and to make it an integral part of that service, so that it gives the service the ability actually not just to make unit-cost based decisions but to look at how value and innovation can be brought to bear. That is not an easy task but the work of doing that is underway. It is my understanding that the transfer of the resource will take place effectively from 1 April, with the administrative follow-up to make that happen constitutionally taking place later. So I think that is going to happen. I think it will be very effective. The second issue is to get cultural change and to work out how this mechanism should work on a once-only basis, and that relates to evaluation methodologies and toolkits, so that people have a broad acceptance of what is going to be done, so that it does not get repetitively done in a wide variety of locations, as unfortunately is the case at this point in time.

Q65 Dr Naysmith: How is it going to be tied in with NICE and NICE evaluations?
Sir Christopher O'Donnell: NICE concentrates, in relation to medical technology as opposed to pharmaceuticals, in terms of interventions, typically surgical or medical interventions, and makes recommendations related to those. For example, is it sensible to do hernias by endoscopic means? It does not really talk about the technology related to endoscopy and how you process the digital images.

Q66 Dr Naysmith: But presumably they have to be aware, when they are doing their evaluations, of what may be in the pipeline and coming along.
Sir Christopher O'Donnell: NICE have a fairly effective way, and there is a horizon-scanning facility which inputs to both, but they do come out with a fairly regular consultation document saying, "We are going to look at this. Does anybody want to make a submission?"

Q67 Dr Naysmith: That is what I am really getting at. You can feed into that.
Sir Christopher O'Donnell: Actually NICE is a reasonably good model. It is relatively light on its feet. It does not spend—and I am talking in the interventional area—enormous amounts of time assessing things, so it does make concrete recommendations. That is the sort of model we would like to see the evaluation centre impose.

Q68 Dr Naysmith: Finally, on this bit, how do you tie in with the National Service Frameworks and when they are being produced?
Sir Christopher O'Donnell: That is something that probably Dr Harvey would be better able to relate to, but the intention is that it would tie in because of the positioning of PASA within the Health Service framework, and they would be looking at how those are integrated.

Q69 Chairman: Do you want to answer that point on NSFs, Dr Harvey?
Dr Harvey: I think in terms of the mechanisms for joining up, we do need very much to make sure that NHS PASA and the Device Evaluation Service are very tightly joined up in terms of the intelligence they get. That also needs to include NICE. Certainly NICE do carry out the interventional procedures. If there is a particularly disruptive technology which is changing delivery of care, they will actually do an appraisal of that as well. That also, I think, needs to link into the new innovation centre. The new innovation centre which will sit within the NHS Institute, which, as you are aware, pulls together the skill sets from the Modernisation Agency, the NHS University and this new innovation centre, is really almost at the forefront of trying to pull all that information together, with horizon scanning as well, to make sure that the right information is informing the Device Evaluation Service, is informing NHS PASA, and, indeed, the collaborative procurement hubs that will work very closely with PASA. In terms of a linkage with industry on the National Service Frameworks, and what is happening in terms of innovation, that will be initially certainly through the strategic group that we will have overseeing HITF, but actually each of the strands of HITF has very close working between government and industry, so that we ensure that in designing the new mechanisms that we have, they actually answer the problems and possibly some of the disjunctures that there are the moment to make sure the right bits talk to the right bits and we have an integrated, strategic approach.

Q70 Chairman: Could I move on to Sir Christopher. You analysed why we are behind other countries and gave a series of three key points. One was general underfunding, you implied—and, as I am sure you will accept, a lot of additional money has gone into the NHS now.
Sir Christopher O'Donnell: Indeed.

Q71 Chairman: Which should make a difference.
Sir Christopher O'Donnell: Sure.

Q72 Chairman: Although, I have to say, if people are short of money I would have thought that was an argument to look at some of the technologies that could save more money. I wondered, in relation to the improvement mechanisms for telehealth/telecare technologies and the new advances that we have talked about this morning, looking at the silos and the dilemma between a national recognition of what can be achieved by some of these new technologies and the decisions to use them being taken by a large number of local bodies such as PCTs, is there a mechanism, if we have a clear assessment of advantages that could be gained by the use of these technologies, whereby you could include an assumption in terms of your national budgeting that: "We are assuming you will be using this technology and therefore we can reduce your money by such and such because you are going to be using it." Do you follow the point? You could incentivise. You have your PCT allocations of budgets two weeks previously and you could incentivise the use of these approaches by centrally budgetary mechanisms. Is that a possibility that you would think is reasonable? Would it be helpful?
Sir Christopher O'Donnell: You are stretching me out into two areas which I know nothing about: one is telemedicine and the second is NHS budgeting.

Q73 Chairman: You gave us three reasons why and that is why I came back to you in particular. I know you are not in the Department, I appreciate that, but I would be interested in what you feel could be a way of moving this forward at a local level.
Sir Christopher O'Donnell: I think the issue is that you say: What is the central role of the National Health Service? Given the fact that the budgeting is a distributed process and that decisions are taken at local level against national targets, the frameworks of the national targets, I think the issue and the thought behind the Device Evaluation Service Route was to try to get a fairly clear idea of what the benefits actually are and what the best way of achieving them is and then to disseminate that information and have intelligent purchasing. It may be purchasing of a device or a piece of capital equipment or it may be buying into a system, but I think that is more likely to be a successful route, looking from the outside in. Certainly, the way of going forward, the National Health Institute to which Dr Harvey referred, it is really going to be important that it actually looks at the adoption of innovation as one of its major driving forces. Telecare/telemedicine may be a very good example for it to pick up on and determine exactly what the best methodologies are, what is likely to work best, and certainly it is in a very good position to disseminate information and best practice.

Q74 Dr Taylor: I really wanted to go on to training. With the arm's length body review, we had the abolition of the NHS University and the Modernisation Agency, which is now called, NHS Institute of Learning, Skills and Innovation. How is this really going to take on the huge new training programmes that are going to be necessary for the use of the new medical technologies? What sort of staff are going to be trained? Is it in medical schools, nursing schools? There are very few schools for medical technologists. How are you going to face that.
Dr Harvey: Firstly, in terms of the Institute itself, it will indeed have a strategic oversight for training and development of staff. But I think one of the issues through the Healthcare Industries Task Force

that we recognised was that the whole area of training and development we had not had sufficient time through the course of the Task Force to really get to the bottom of. We were very clear that it was absolutely fundamental in terms of getting innovation into the NHS. In fact, through the HITF implementation, we have a workstream devoted to training and development which from the Government side will be headed from Professor Sir Ara Darzi and there will be a co-chair from the industry perspective. Because we also have the NHS Institute, which has the innovation bit as well as the modernisation skill sets in it, we will be working with them along with the MHRA and others to see how we move the system from what we have at the moment to something that is better in dealing with the skill sets required. We do already have the MHRA taking forward some work, looking at the development of a medical device driving licence, looking at modules of training that people need for individual devices, and they are about to pilot that with the Royal College of Surgeons. Industry obviously has a big role in this because industry already provides a huge amount of training for clinicians around the use of devices and that is clearly very important. There are issues that concern us, though, about the devices you have in hospitals where people may have been trained or they may have been trained on a different one, and how we ensure, from a patient safety perspective, that everyone has been trained on all of the devices—be they external devices, or, indeed, surgically trained if they are dealing with internal devices. We need to work with the Royal Colleges, with Skills for Health, with the NHS Institute, to pull together all of those strands to have a coherent strategic way forward. Because, as you say, at the moment there is a lot of training and happening in a lot of different places, and we really need to see how that all fits together and whether, indeed, it is coherent or whether there is more that we need to do. I think the MHRA is also developing a multimedia device educational programme as well. We do understand that this is a very important area in which we need to do more. One of the other recommendations that came out of HITF, in terms of procurement and in terms of making sure that we have, as Sir Christopher said, intelligent procurement, is that we need to ensure that in procurement for the future we include a training aspect. That may not necessarily have been what happened in the past. Basically, if we move to intelligent procurement, which means that the specifications that get used, either by NHS PASA or, indeed, by the collaborative procurement hubs, it means we have to have enough information in the specification so that the specification is properly defining what is required, and also it is something that does not dampen down innovation but facilitates more innovation in terms of the way people might meet that specification.

Q75 Dr Taylor: So, despite the fragmentation of the NHS into trusts, procurement for relatively uncommonly used bits of medical technology could be standardised across the country?

Dr Harvey: Indeed—one of the recommendations through HITF, as Sir Christopher and others have said. At the moment in terms of buying something for a primary care trust to use, there are lots and lots different mechanisms for doing that—and I think somebody said you may have to go and see 300 or 400 different people. In terms of having a Device Evaluation Service that comes out with a national standard product that can be used by anyone who purchases, we are moving more to a situation where you will have a reformed national PASA, intelligently procuring, you will then have the development of collaborative procurement hubs, which will be lots of trusts coming together with much more clinical input than has hitherto been the case, and we think that will then move us to a position where the vast majority of purchasing for the NHS takes place either through the collaborative procurement hubs or, indeed, through NHS PASA, all being supported by the information from the Device Evaluation Service, from NICE, with information going to them from the National Innovation Centre within the NHS Institute.

Dr Taylor: I am sorry, what is a collaborative procurement hub? How wide does that stretch?

Chairman: Do you mean you do not know, Richard?

Jim Dowd: Keep up to speed!

Q76 Dr Taylor: Is it a strategic health authority?

Dr Harvey: It could be bigger than that but it could be a strategic health authority. We have at the moment three pilots, one running in Greater Manchester SHA, one in West Mid-South SHA, and one in Shropshire and Staffordshire SHA. There is not any definition as to how many of these there will be. They are developing. At the moment we have Supply Management Confederations up until this point, but we see the movement through to these collaborative procurement hubs being very important in terms of purchasing for the future.

Q77 Dr Taylor: A really basic piece of equipment throughout the hospital service are defibrillators. These are as old as the hills, but is there yet any standardisation? I remember going somewhere where each ward had a different one, so a cardiac arrest team had to know how to drive each one of them. Is there any standardisation in that sort of thing—standardisation yet across not only collaborative procurement hubs but the whole National Health Service?

Dr Harvey: To be honest, I do not know the answer to that because it is not an area of which I have detailed knowledge. I know that in terms of where we are aiming to go in the future, with the HITF recommendations and their implementation—and we have to remember NHS PASA is in transition to the new NHS PASA now, so these bodies are being set up very shortly—the intention is that with a lot of clinical input into each of these collaborative hubs, they will then know what it is that they should be procuring for the clinicians within their patch. That patch might be very large but the clinician is still going to be very important in that, along with

the advice they will get from the Device Evaluation Service, if there has been a NICE review, either a guideline or an appraisal.

Q78 Dr Taylor: There is a fearful paradox, because, although we want national standardisation, that completely removes competition among commercial firms that produce things and obviously raises tremendous implications for different firms that are making different things.

Sir Christopher O'Donnell: If I may comment, I do not think we are specifically looking at national standardisation. We are looking for a clear case for the benefits and obviously the costs of any particular device, but for devices like defibrillators, infusion pumps, and things where a wide number of people come into contact, broadly it is best practice to have one or at most two per facility—hospital or whatever—and then to make decisions after whatever time to replace the whole lot. Because what tends to happen is that something comes out that is better, so you get 10 of those, then something else comes out and you get 20 of those, and you end up with a creeping mix of equipment. In terms of the training and development needs that were specifically identified in the Task Force, they particularly relate to (a) the need for making sure that safe practice is followed and (b) taking advantage of the benefit of equipment. For example, if you do install an MRI imaging suite, then you need to have staff who are able to use it for its full benefit, and it is pretty obvious that there are cases around the country where actually that has not happened—so I am reliably informed—and therefore the considerable installation and maintenance costs are not being fully utilised. So an integrated plan needs to be undertaken in this area. It is quite a task and it is on the agenda of the NHS Institute of Learning, Skills and Innovation.

Q79 Dr Taylor: Yes. We have already heard about other reasons why MRI scanners are not being used. Could I turn to Professor Walley for a moment. With the Health Technology Assessment Programme, did you look at training for the various bits of equipment under that?

Professor Walley: We look at technologies in a very broad sense, which includes not just the individual technology but also how to influence the pathway of patient care. So issues such as training and patient outcomes are key to what we do. Yes, we do look at training issues, and they are usually particularly in consideration of the cost-effectiveness of the therapy—because there is a training cost to be put in there and a question of how that training is renewed and as to the advice that has to be renewed in the future. So, yes, we do address this. On the specific point you raise about defibrillators, this has been a hospital-by-hospital issue, as you are aware. My hospital is finally down to two different devices.

Dr Taylor: Down to two! Thank you.

Q80 Dr Naysmith: I have one or two other questions associated with the Device Evaluation Service and the Task Force before we move on to Professor Philp, now that he has arrived, and a different area. I was going to ask how the Device Evaluation Service is going to decide on its priorities, and, crudely, which it was going to look at first, and I was going to ask Sir Christopher O'Donnell—but maybe, since Professor Walley has not had an awful lot to say, I could ask how he thinks it should decide on its priorities and then I will ask Sir Christopher if that is what they are planning to do.

Professor Walley: I think it is important that the evaluation of the device is proportional to that device. Some devices might be regarded as disruptive technologies that will cause a major shift in how we manage patients in the NHS—and they clearly are the major priority for very detailed evaluation. Other devices might be regarded as an incremental advance: in other words, we are already doing this and this new device may be a slight advantage over the old devices. I am not quite sure what the structure of the DES is going to be. It is going to take time to build up its skills and its abilities; particularly in areas such as health economics, to undertake studies of the long-term cost-effectiveness of devices. My own programme particularly looks at the much more disruptive devices—as, indeed, NICE does—and, depending on the level of evidence available to evaluate that device, we may either commission work on behalf of NICE to review the existing evidence around a device or build a UK-specific economic model around that technology and then NICE might issue guidance on it.

Q81 Dr Naysmith: What is an example of a disruptive technology?

Professor Walley: We have had an example already: for instance, insulin pumps. There is a treatment that has not been available up to now which has a potential benefit for selected patients but it is a completely new way of managing patients. On the other hand, there may be other disruptive technologies where there is currently inadequate evidence available to judge what the benefit for devices is. In that situation, my programme might undertake a full, randomised-control clinical trial. We have heard already from Professor May this morning that there is a conflict here between the time it takes to develop evidence around a new technology like that and perhaps the urge to modernisation. If I might give you an example: one of the trials we are funding at the moment is an evaluation of a graft into the aorta (the major blood vessel through the abdomen) to replace an aneurysm (a swelling of the aorta which can rupture and cause sudden death). Up to the recent pass this has been undertaken by open surgery. We have a new device available which can be inserted by radiologists working through the patient's artery without a need for a laparotomy—so it is a much simpler technology to put in place—but it may have a downside. The downside is that the major operation is a once-for-a-lifetime procedure; we are not entirely clear that the radiological procedure is actually going to last as long. So there is a device that will totally alter the pattern of care. We cannot evaluate it simply in a small study lasting six months,

we need a study that is going to go on for several years, so we have been funding that study. One of the advantages we have had in funding that study is that the access to that technology has only been available through the trial. As a result, we have captured everybody in the country who has had this technology performed and we can follow these patients—obviously with their consent—so we will know ultimately what the benefit of this is and whether we should allow this technology to filter into the NHS more widely.

Q82 Dr Naysmith: Roughly how many people does that involve?
Professor Walley: In the trial so far?

Q83 Dr Naysmith: The ones you have been able to contact.
Professor Walley: We have randomised over 600 patients into each arm; so 600 patients with surgery, 600 patients with the new device. We have 30-day results which show a benefit for the new device but we need to see the follow up over the next five years.

Q84 Dr Naysmith: Will it take you five years to reach a decision?
Professor Walley: I think a decision has to be incremental. There may be a process whereby we may allow it in to a limited degree after one year, but the final decision may need to be taken at five years, because, for instance, although I mentioned that the old technology is a once-for-life procedure, the early evidence is that the new technology requires a new procedure in 1% of the patients every year. If the patient has a life expectancy of 20 years, this new technology might not be very smart. On the other hand, if we can reduce that rate, it will be very valuable. It is another interesting example of how we evaluate individual devices, because it takes a long time to do a trial like this to recruit the patients and follow them up. These devices are changing all the time. In setting up this trial, we did not specify that a single device had to be used; we specified the standards to which any device used must reach. We would hope that over time we will be able to track sufficient numbers of patients on each of the devices that at the end of the day we will be able to compare the different technologies. It is what we call a tracker study, where we are not looking at a static technology. We may observe, for instance, that later results are better than earlier results. With sufficient numbers of patients in the study we should be able to detect that.

Q85 Dr Naysmith: I was going to ask Sir Christopher if that is the way they have gone.
Sir Christopher O'Donnell: If you want me to follow up on that, let me just stick with the insulin pump example, because it is probably a good one as to who is going to do what. If the issue is: Should the NHS be more widely using insulin pumps as a method of treatment? then that is a health technology assessment issue, it is not a Device Evaluation Centre issue. The Device Evaluation Service, as we would see it in the Task Force, would say, "Okay, there are six insulin pumps on the market," and produce a matrix of "Here are their characteristics, this is what you get," effectively producing a *Which Guide* to these. For example if it was an elderly patient who needed larger buttons, for the sake of argument, then this device might be preferable. If it was somebody who was very, very active, weight might be very important. That will actually evaluate the device.

Q86 Dr Naysmith: That is the role of the Device Evaluation Service?
Sir Christopher O'Donnell: Yes.

Q87 Dr Naysmith: Not the bigger question of whether it should be adopted.
Sir Christopher O'Donnell: Not the bigger question, which is somewhere with health technology assessment, typically, and also things like some aspects of innovative service delivery will fall within, I think, the National Health Service Institute. It is pretty evident which patients will benefit from insulin pump treatment, the problem is—just to give you an example of silo budgeting—the diabetic department in the hospital has small budgets and low political clout. We, as a company, are not involved in insulin pumps; we do have bio-engineering products that are suitable in this area. We have not introduced them into the UK because they will not get funded.
Dr Harvey: I think the other incredibly important aspect here is the aspect of patient choice. Because, with Payment by Results and trying to unbundle the sort of different services that are delivered to the primary care trust, which is the GP referring through to secondary care, or maybe not secondary care but maybe a specialist practitioner in primary care, there is the element of patient choice in terms of how they are treated and, I think, as we see that coming more to the fore, this will also have an impact in terms of the types of treatment that people have. That means they have to be properly informed about the different sorts of treatments and there is also an aspect—one of the outputs from the Healthcare Industries Task Force again—about communication with patients and patient information, because patients cannot make informed choices unless they actually have that information. I think, therefore, whereas one might have been concerned more up to now in terms of budgets within NHS trusts, it now comes back more, with Payment by Results, to the treatment that an individual patient with their GP and then their clinician would choose, which then is reimbursed through Payment by Results.

Q88 Chairman: Could I turn to telecare and particularly the care of older people? I presumed Professor Philp was stuck in a snowdrift in God's own county but I gather you were stuck in a traffic jam. We are pleased to see you here. I wanted to reflect on a question that arose from the earlier part of this morning's session, which was how we get away from this silo mentality, with health and social care separated in budgetary terms and in organisational terms. Looking at the advantages of

telecare for the health service, we had the example discussed of technology that exists to quite radically transform the house of an old person or flat to avoid them having falls or problems that would result in some fairly intensive care within the NHS. As that care within the home is a social service responsibility, it is organisationally separate, and separate in terms of budgetary considerations from the NHS. How do you make those two click together in a way that they are not doing at the moment? Because it is such an obvious commonsense thing to do to save funding in the NHS.

Professor Philp: Yes. Thank you, Chairman. First may I record my apology for my delayed arrival. In fact I was returning from a visit to Hertfordshire with Dr Ladyman MP, Parliamentary Under-Secretary of State for Community, where we were announcing £60 million going to councils to help keep older people at home in order to reduce pressure on acute hospital beds—the very point you are making.

Q89 Chairman: That is a pretty good excuse, anyway!

Professor Philp: Thank you. The issue as it stands in terms of the interface between the NHS and social care in policy and practice is that we are dealing with two cectors that are interdependent on each other for their mutual success. The overall thrust of policy for older people has been to invest in community services, usually led by councils and social services departments but with clear agreements with the NHS about both the NHS contribution and the outcome impact on not only the wellbeing, independence and health of older people but better, more efficient use of health services. That is the overall policy direction, accepting that there are separations in these two big sectors that need to come together to deliver the care that older people, in particular, but many of our client groups need in that joint approach. In relation to telecare, we have also announced an £80 million budget to councils to invest in telecare, again with the explicit objective of both keeping older people in their own homes and reducing pressure on acute hospital services.

Q90 Dr Naysmith: That was in the last budgetary announcement?

Professor Philp: Yes.

Q91 Dr Naysmith: Which arose from a Treasury visit to a company where they could see the advantages. We are wondering how we can drive that concept much more radically, because that was just the start, and surely they can save huge amounts of money by that little bit of investment in telecare impacting on the NHS in a massive way.

Professor Philp: Small investments can make a huge difference.

Q92 Chairman: Absolutely.

Professor Philp: For example, £2 will pay for a temperature sensor in an older person's bedroom or living room, and, if connected to a warden scheme and if targeted on vulnerable people, we could detect temperature drops, say, below 16 degrees C, at which point a vulnerable older person is at risk of death due to low temperature. There is a clear correlation. So small investments tied to good organisational practice, in terms of linking the system together can make a huge difference. We know that. The trick, as you rightly say, is: How do we translate that knowledge that we have through our systems into effective practice and deployment of good telecare? The main vehicle that the Government is using to support that is the Policy Collaborative on telecare, which has engaged a large number of stakeholders from industry, from the advocacy sector, from the statutory sector and academia, in order to get a shared understanding of what would make the biggest impact through the investment in telecare. To secure effective deployment of telecare within local communities, there needs to be local ownership as well as national ownership of the agenda and to support that the telecare policy collaborative will be publishing this summer a shared vision of what makes a difference. That is a shared vision of all the stakeholder groups. Then we will be encouraging councils to work with PCTs to that shared vision, owning it, and using the money that government has made available to councils in order to deliver better investment in telecare.

Q93 Chairman: We have been looking at new technology, particularly from a care perspective, and one of the concerns that is expressed by some people is that we are losing the personal touch. People increasingly are being monitored technologically rather than by somebody coming along and saying hello at their door. How do you balance out those concerns in looking at the interests of older people?

Professor Philp: From the older person's point of view, the human factor is the most important. The visit that we made this morning was a handyperson scheme, where the council are working through the Anchor Trust Organisation locally to provide handyperson support to vulnerable older people with simple things, like fixing electric points or if there was a problem in changing a light bulb—not undercutting the local market in terms of major plumbing jobs and so on, but these low-level things. It is that sort of way, in which a care assistant or a handyperson or whoever is in contact with the older person has the knowledge and skill to support the older person in making best use of technologies, some of which can be quite mundane—as I say, temperature sensors—and some which can be much more complicated—extensive home monitoring schemes, for example, for somebody with advanced dementia who wants to stay and their family wants them to stay in their own home; a telecare system of alerts when a door opens, to make people aware that a person might be walking outside; or having reminders and prompts in the house. We can use telecare at a low level or a very high level but it does depend on the level of dependency and need of the

individual, and not to intrude beyond what would be acceptable for them enjoying an independent quality of life and a degree of autonomy.

Q94 Chairman: You described some changes in terms of investment in telecare, which are very welcome. In the dialogue that your Department will have with the Treasury, have you raised with them at all the possibility of somehow through the tax system incentivising older people who may wish themselves to take steps to raise their own telecare in advance of needing it in their own home environment? It strikes me that we have not really helped people to think through. We talk about saving for old age, we talk about the pensions' issue, but equally important is where people will be when they reach the stage of limited ability and of requiring care and support. Some people may take steps to spend their own money on making arrangements for their home to be suitable for their care and supervision when they reach that stage. Have you had any dialogue with the Treasury about how in fiscal terms we might encourage that sort of step being taken by older people? I would argue that society ought to help people with that kind of provision. But, realistically, that may well not happen.
Professor Philp: You are absolutely right to point out the interconnectedness of the work of many government departments if we are looking to improve the independence, wellbeing and quality of life of vulnerable people. In the context of cross-government work in relation to older people, there have been extensive discussions which have been led by the Department of Work and Pensions, with the Treasury, with the Department of Health—in fact with every government department—and there is a cabinet committee on which the Secretary of State for Health, a PS(C) in Health, the Secretary of State for Pensions and the Pensions Minister will sit, as well as there being representatives of every government department, and that committee is considering the interconnectedness of the whole range of government policies for the older population. So discussions are taking place and I hope there will be something coming out in the near future that reflects these discussions. But I do not think I am in a position to talk about the detail of the interaction between the Treasury and DH on the issues that you describe.
Chairman: May I apologise, but I have to leave. I have to speak at Leeds University at four o'clock and I am slightly concerned about the travel arrangements today. Dr Naysmith will take over the chair.
In the absence of the Chairman, Dr Naysmith was called to the Chair

Q95 Dr Naysmith: Professor Philp, the British Geriatrics Society put in a submission in which they argued for "soft technologies" in the care of older people. In particular they asked that new levels of service provision around intermediate care and chronic disease management should be provided, and that intermediate care and chronic disease management should be provided and would require proper needs assessment methodologies as well. Do you agree with them?
Professor Philp: Yes. A lot of the detail of our thinking in this area is likely to be described in the forthcoming Green Paper *Vision for Adult Social Care,* and I think it would be reasonable of me to say that PS(C) Health has already spoken publicly about the direction of travel in this area and the importance of investing in telecare in combination with the development of services in intermediate care and in long-term conditions management, and to integrate these different parts of service improvement.

Q96 Dr Naysmith: One of the things which has been drawn to our attention as well is the fact that there will be an increasing burden of responsibility on informal carers when the telecare system is used for caring for older people. Has the Department considered that?
Professor Philp: Yes, again the Department is not only trying to provide more support for informal carers to recognise the critical role that they play in the care of older people and other groups, but is also recognising that the carer perspective and the carers having power and ownership (and not just respite, if you know what I mean) are genuinely empowered to help find solutions that meet their needs as well as the person's that they care for. Also in that context the need to link the assessment of the older person's needs with an assessment of the carer's needs.

Q97 Dr Naysmith: That is the point, in a way, that we are getting at. It is a new thing for carers to have to do—to act as an intermediary between the Health Service and the person they are caring for. They have got to be absolutely clear that the information is provided to enable them to do this properly and feel comfortable in doing this.
Professor Philp: Absolutely. This is about the social contract between the state, the citizen and the support for the partnership that carers have for their loved ones. If I could go back to what was quite critical in forming my thinking about this. As we were developing the National Service Framework for Older People's Services, two principles came into conflict. One principle was the autonomy of the older person and the concern that professionals sometimes talk over the older person to the family and make decisions when the older person is not fully engaged and involved and is rather patronised and infantilised as a result of that. There were concerns about that. On the other hand, there was the principle about the partnership with carers and fully involving carers in the decision-making process. We got our advisory structures representing older people and carers, including many older people and carers, to debate these issues. It surprised me that unanimously all the advice from older people and carers was that older people saw their family carer as their main guardian and protector within the care system and they wanted as far as possible—except when there were extreme cases of the career not providing love and support or

concern—that the carer would always be involved in the decision-making process and that the carers' needs would be respected. We are trying to reflect that perspective in giving a very strong emphasis on obtaining the carers' viewpoint and offering carers choice to engage and support as much as much as they wish to do but also giving them choice and support to withdraw and help to withdraw when it becomes inappropriate for them to be involved in care that they do not feel able or competent so to do.

Q98 Dr Naysmith: It will be a fairly complicated relationship in some instances, I suspect?
Professor Philp: It is human nature, is it not? It is complicated and I think we should avoid simplistic solutions.

Q99 Dr Taylor: We have talked about cost effectiveness quite a bit so I have only got a couple of questions. Professor Walley, you talked about access to this particular aortic graft being available only through clinical trials. I think we can understand the importance of that but we do get people coming to us to complain about having to wait for a clinical trial before they can get a treatment or a technology and from some of the firms that this is one way that in the UK we are slower at adopting things than elsewhere. What are the answers to these sorts of questions?
Professor Walley: I do not think there is an easy answer to this. I think clinicians are going to demand evidence of the benefit of the new technology before they wish to unleash it on their patients and likewise patients are entitled to have that evidence before they undergo a new technology. Sometimes I have to say this argument that we need further evidence before accepting technology is used as a barrier to the introduction of new technology. I think that is inappropriate. If for instance the technology is not a disruptive one that is going to alter fundamentally patterns of care and is a matter of device evaluation, as Sir Christopher has outlined, then I do not think that is a reasonable argument as to why that technology could not be adopted.

Q100 Dr Taylor: The Chairman did mention incentives for people themselves. Would there be any opportunities for financial incentives for trusts to take on new technologies?
Professor Walley: Within trials, if I can answer in this specific case of the aortic graft, we have had to incentivise trusts to take part in the trial. We have had to fund them specifically for the service costs required in taking part in this trial because it would be quite expensive otherwise and we would have had no up-take whatsoever. For many important trials we do have to provide some kind of support for trusts, PCTs or hospitals to allow them to participate in the research.

Q101 Dr Taylor: Where does that support come from?
Professor Walley: It comes from the NHS R&D support fund.

Q102 Dr Taylor: Not from the firm that is making the technology?
Professor Walley: No, not usually because we are not in the business of evaluating a single device. We are looking at a technology which could involve several different devices. We are not making a market for one company. Having said that, we would often encourage investigators to seek some kind of support from a company providing it was done in such a manner that it would not influence the outcome of the study. I cannot think of an example for a device but there are certain examples in drug trials where the drug has been supplied by the company at no cost to the NHS but the service and research costs related to that trial are supplied by the NHS.
Sir Christopher O'Donnell: It is very frequently the case if you are introducing a new device—even a simple device like a compression bandaging for leg ulcers—if you want to do this and demonstrate your product is better then you have to fund the cost typically of the research associate, nurse, fellow (depending on what level) to actually do the work associated with the trial. It has to be done in the right way and in the right framework.
Dr Harvey: I think there is also, in addition to the incentives that colleagues have spoken of, an incentive in terms ,as we move to a position where we are trying to get a maximum 18-week wait for treatment (which means diagnosis has to happen before that time), there is more of an incentive for NHS trusts to develop services that people will choose because of the patient choice agenda where they do bring technologies in that allow them, for example, to do day case surgery or even interventions in a clinic so you do not have to be an in-patient at all. Those are the sorts of interventions with Payment by Results, whereas before with block contracts there was no benefit to a trust in actually being able to carry out a lot of interventions. Through Payment by Results there is an incentive because you are being reimbursed for each event with a patient, so with the patient choice agenda and with more technologies that allow more rapid, high-quality interventions for patients and with Payment by Results, you do then get some incentives coming into the system that possibly we have not had in the same way of late.
Dr Taylor: Thank you very much.

Q103 Jim Dowd: This is principally I think for Sir Christopher and the officials. I want to look at a few questions on whether we can approach this in a more strategic and co-ordinated fashion. Many submissions we have received have highlighted the lack of co-ordination of the many bodies involved in developing health care technologies and thee fact that it was completely *ad hoc*. It has even been suggested there should be one body, perhaps even a special health authority, charged with co-ordinating across the whole e-health field. What is your response to that?
Sir Christopher O'Donnell: I think it is difficult to do because technology arises from such a wide variety of sources that it may be sensible to have some kind

of evaluation or technology assessment groups, of which those do exist, but in terms of looking at where it comes from, there are some very good ideas originally within the National Health Service but there are an awful lot more that come from outside. It is a case of trying to work out through horizon scanning and technology assessment as to which of those are worth taking forward. Does that answer the question?

Q104 Jim Dowd: Yes I think the answer is no, if that is what you mean? Within the Task Force you recommend the Innovation Centre. Would that not fall into that category?
Sir Christopher O'Donnell: The Innovation Centre is not going to originate the innovations; it is going to look for providing frameworks or pathways for taking them through, depending on what the level of the innovation is, and essentially almost, as a "go to" point in terms of expertise, whether it is somebody in the NHS who has come up with a very good idea and does not know what to do about it because they are not in the business of developing them or whether it is somebody in industry, particularly from the small and medium-sized enterprises to go to the centre and say, "I have got this great idea. It is not quite a product (and if it is a product it needs to go to the Device Evaluation Service) but this is what we think it could do. Can you help me find the right people to work with and the right centres to trial it?" It would be a "go to" mechanism both for inside and outside the Health Service and also then to act as a facilitator to drive innovation forward, which is a secondary role which is very important but which is going to require a combination of leadership skills, training and development, and looking for ways of minimising any disincentives and providing some incentives to the system. We heard the plastic surgeons say that they had to find £85,000 which they have never been formally funded for to put their telemedicine system into place, which is great but it really ought not to be happening that way round. The idea of the Innovation Centre would be to facilitate exactly that kind of development.
Dr Harvey: As a result of that function, one would hope that the Innovation Centre will actually get a lot of intelligence from what is happening out in the market-place, what the developments are out in the market-place that they can then feed into the Device Evaluation Service and indeed NICE, the HTA programme, et cetera. As Sir Christopher says, they will get a lot of information and as a result of that we would hope that our horizon scanning is better. The other thing that we flagged as we were going through the HITF process, one thing that we recognised is the need to strengthen horizon scanning. We have had horizon scanning for a while—horizon scanning for NICE—so we know what the big issues are that are coming over the horizon that should be going into the appraisal process. That may be very good for pharmaceuticals but when you look at the device sector it is probably not as good at picking up all of the innovations that are coming up as it would be helpful for it to be. Therfore one of the other issues that we need to follow up in implementation of HITF is how we improve the horizon scanning so that we have more of a large view of the innovations that are likely to come over the horizon that could be either disruptive and therefore very important in terms of different ways of providing services or indeed important developments on things that we already have. I think the Innovation Centre will have a role in terms of its intelligence and we need to try and build in a better horizon-scanning process that can feed into NICE and indeed the Device Evaluation Service.

Q105 Jim Dowd: Thank you. Many telemedicine and telecare initiatives are developed through a combination of local enthusiasts and supportive environments in local authorities or health authorities but that has led to an *ad hoc* development and uneven pace of development. Is there any way we can approach this more strategically and have a more consistent approach in developing new initiatives?
Sir Christopher O'Donnell: Are you talking about telemedicine or more generally?

Q106 Jim Dowd: Telemedicine.
Sir Christopher O'Donnell: I will pass that down the table because I do not know.
Dr Harvey: I think in a way—

Q107 Jim Dowd: I think the answer is no so let's save time!
Dr Harvey: I think where we are saying the NHS Institute will have a role in terms of technology is if you think of a new type of pacemaker, we would also expect the Institute to be able to pick up new technologies in terms of telemedicine as well so we would hope that it will be able to scan the breadth of new devices, et cetera, that will come up that could have an impact. We do not just mean a surgical device or whatever. It will be very important in terms of informing the NHS of the sorts of things it may wish to invest in. I think it does cover the telemedicine aspect as well and the platform is there on the telemedicine as against the telecare side through the National Programme for IT and we would expect that to build over time.

Q108 Jim Dowd: Finally, what about the criticism about the lack of co-ordination between the UK health technology industry and the Department of Health? Does it exist? If so, what is the effect of it?
Sir Christopher O'Donnell: I think the whole idea behind HITF, which started in discussions in 2002 really, was that over a relatively long period of time the medical technology industry in the UK has grown but it did not have an interface with Government in the same way the pharmaceutical industry has, and I think both industry and certainly Government see this as being a step to say, "Look, there are some needs here, there are some mutual benefits. Let us try and find some practical ways of making this happen." Now I think we have identified some practical ways of going about it and made a commitment on an on-going basis over the next two years to follow up on that in terms of the things that

we have talked about today. There is a high level of commitment from both the Government and the industry to do so and that meeting programme will commence shortly.

Q109 Dr Naysmith: Professor Philp wanted to add something on the previous question. Could I take the opportunity of saying this will be the last chance that any of you have got . So ,if there is anything that you came bursting to the Committee to tell us this morning and you have not had a chance to do so, now is your chance. Professor Philp first.

Professor Philp: I wanted to add a supplementary to your question about the strategic, as I see it, adoption of high-impact technology changes because I have been involved in some of the latest discussions about the new NHS Institute for Learning Skills and Innovation. It is very clear that one of its purposes is to be strategic and to use horizon-scanning techniques to identify where there would be high impact on the NHS and our care system through adoption of new technology which is emerging from whatever source and that part of the process of that is for national clinical directors such as myself to advise on the one or two things that might be happening in our area where there really would be a difference if we could accelerate the pace of movement from invention to adoption within the service and then how we would stimulate that through market mechanisms or whatever. I think there is a mechanism through the NHS Institute to be more strategic in the way that we pick up on new technologies and the potential impact they could have on health.

Dr Naysmith: If there are no takers on my offer, then can I thank you all very much indeed for coming. This is a relatively short inquiry but it has raised a lot of interesting questions.

Memorandum by the Medical Technology Group (MT 44)

Introduction

The Medical Technology Group (MTG) appreciates the opportunity to submit evidence to the Health Select Committee, addressing the critical issue of patient access to medical technology in the United Kingdom. Representing 25 health care organisations, the MTG is a coalition of patient groups, clinicians and industry representatives committed to increasing patient access to medical technologies within the NHS (see Appendix A). As such the MTG welcomes the announcement of the Committee's inquiry.

The MTG has long been concerned that the UK lags behind other industrialised nations in its use of critical, life-saving and enhancing medical technologies. The reasons behind the barriers to patient access of medical technology are numerous and the MTG's submission attempts to outline the nature of these barriers plus make recommendations for reform.

MTG Views on the Inquiry's Terms of Reference

1. *The effectiveness and cost benefit of new technologies*

1.1 Medical device technologies span a very broad range of therapeutic, palliative and preventive modalities, serving patients in innumerable ways. From tissue based implants for reconstructive surgery to neurostimulators for severe movement disorders, to computer-driven drug delivery systems, medical technology plays a role in every facet of health care.

1.2 The uses of medical technology bring enormous benefits to patients, from critical and acute care to rehabilitation, patients depend on medical technologies to continue every day activities and to give new hope for productive, healthier lives. In addition to clinical and other patient benefits, medical technologies also bring significant economic benefits to the NHS and to our society.

1.3 But traditional tools for measuring the benefits of medical technologies often have failed to reach beyond the clinical setting. This broad range of life enhancing products can bring economic and human returns in terms of enhanced quality of life and renewed patient and health care provider productivity.

1.4 Models for assessing the benefit of technology should consider wider benefits to society as a whole. A patient who's quality of life is improved by more effective treatment methods, reduced hospitalisation and fewer return visits to hospital is likely to have a quicker return to pre illness activity. That might be a return to work and income generation, to a vital caring role within the family or just to live independently. All reduce the burden on other community services and/or State support.

1.5 The MTG believes that adequate patient access to medical technology will enable the Government to achieve many targets including those set out in the National Service Frameworks (NSFs) and other Department of Health guidelines.

Improved quality of life for patients

1.6 In addition to providing cost benefits and effective clinical solutions, medical technology has an enormous role to play in raising the quality of life of patients who suffer from a wide range of chronic and acute medical conditions. This manifests itself in a number of different ways:

— Increased life expectancy.

— Reducing further complications for patients.

— Improved standards of living.

— Improved productivity, both for patients and their caregivers.

1.7 In contrast to this, there are significant costs if adequate provision of medical technology is not made. For example, the continued dominance of coronary heart disease patients in UK hospitals is a problem that can be addressed through new technologies for prevention and treatment.

1.8 A questionnaire by SADS UK to families with a member suffering from a cardiac condition that had been addressed by an implantable cardio-defibrillator (ICD), showed that there was not only increased quality of life, but peace of mind for parents and carers:

> "The positive response from those living with an ICD or as a parent of a child with an ICD was quite staggering compared to the more negative response of those purely taking anti-arrhythmic medication".[19]

Personal statements from this survey included:

— "I feel it's a life saver."

— "It gives me freedom from the anxiety of suffering cardiac arrest."

— "It's like having a portable hospital inside me."

— "I can live as normal a life as possible without the worry of dropping dead at any moment."

— "It's a life-saver after losing my other child to the same condition."

1.9 There is evidence that suggests once a condition is detected, and the necessary treatment is given, patients can experience improvements in psychological well-being. In a study of 38 patients (6–18 years) with recurrent arrhythmias who underwent radio frequency catheter ablation of ectopic myocardial foci, psychological functioning was assessed and the patients resembled a normal population without elevations in anxiety or depression. After they had had the ablation, the patients showed reductions in the "fear of their heart problem" and increases in "the things that they enjoy". The findings showed that the patients who underwent a curative ablation had better functioning and that children appear to have the opportunity for an improved quality of life after ablation[20].

Increased Safety

1.10 Improved safety and reduced complications often result from the adoption of new medical technologies. This lessens the anxiety for patients and their families, that results from uncertainty and repeated hospital visits. For example, innovations in phacoemulsification for cataract removal mean that fewer complications will occur, meaning less post-operative visits and increased patient throughput.

1.11 Case Study 1 (below)—Reduction of injuries using safer needle devices, demonstrates clearly that all the stakeholders have worked together to massively reduce the risk from sharps to both healthcare worker and patients (see case study 1 and Figure 1, below). Reducing these complications has led to service improvements:

Case Study 1—Reduction of injuries using safer needle devices

— It is estimated that over 100,000 sharps injuries[i] occur in the NHS every year, and these could cost NHS trusts as much as £500,000 per year[ii].

— But sharps modified with safety devices are now readily available to the NHS (see Fig 1).

[19] Anne Jolly, SADS UK Chair, speech to the Parliamentary launch of the *"Making the Case for Economic Technology"*, June 2004.

[20] DeMaso *et al*, "Psychological Functioning in Children and Adolescents Undergoing Radiofrequency Catheter Ablation", *Psychosomatics* 41: 134–139, 2000; research by Cardiac Risk in the Young.

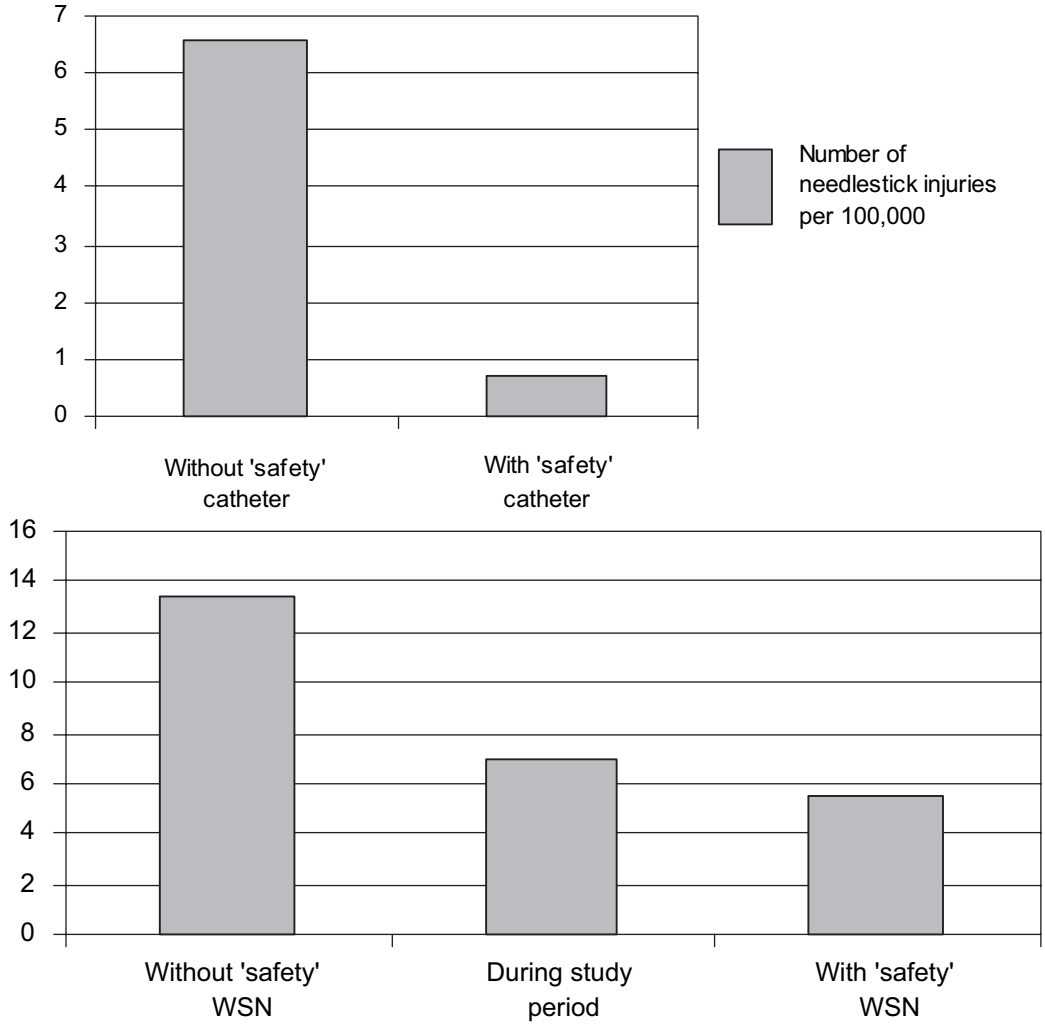
— The Department of Health's "Blue Book" on preventing sharps injuries is expected soon, and will require NHS trusts to take measures to improve data collection, identify training needs and identify where safety technology could be introduced to reduce risks[i].

— MTG supports the Government in this drive and notes that additional funding may be required, in the first instance, for safer technologies to be introduced.

[i] www.saferneedlesnow.net
[ii] National Audit Office, "A Safer Place to Work: Improving the Health and Safety Risk to Staff in NHS Trusts", p 30, 2004.

Figure 1

REDUCTION OF INJURIES USING "SAFETY" CATHETERS AND WINGED STEEL "SAFETY" NEEDLES[21]



Economic benefits

1.12 The use of medical technology plays a large role in helping transform the NHS and increasing patient productivity—a vital element in an economy facing the prospect of an ageing society. According to Government figures, the number of people aged over 65 has doubled in the last 70 years and the number of people over 90 will double in the next 25 years[22]. New technology can increase the throughput of patients, address problems of bed blocking, reduce patient waiting times and improve overall patient access to the NHS (see Case Study 2, overleaf).

[21] Chen *et al*, "Prevention of needlestick injuries in healthcare workers: 27 month experience with a resheathable 'safety' winged steel needle"; Mendelson *et al*, "Evaluation of a safety IV catheter"; both Mount Sinai Med Center, New York, NY, 2000.
[22] Department of Health, *National Service Framework on Older People's Care,* 2001.

— **Hospital productivity**

1.13 The use of medical technologies can bring long-term economic gains by shifting the site of care to less intensive settings, for instance from inpatient hospital to day-surgeries or home care. By reducing hospitalisation, waiting times are often reduced and hospital capacity is freed. For example, women suffering from menorrhagia (heavy menstrual bleeding) can be treated by free fluid thermal endometrial ablation in a day case setting and consequently avoid the need to undergo surgical hysterectomy, which has an average hospital stay of over five days and many weeks recuperation period.

— **Improved patient productivity**

1.14 Increased investment in medical technology leads to an increase in societal productivity. In today's ageing society, this is vital if people are to lead active lives unencumbered by the health and mobility problems associated with old age. For instance, technologies like hip and knee implants are improving the quality of health care and reducing costs by enabling people to return more quickly to active, productive lifestyles. These effects therefore have the potential to assist the UK economy in its drive to maintain a competitive edge—and by reducing dependency on social security and disability benefits.

1.15 Use of technology to improve public health has widespread consequences for the economy. For example, in the US, the societal value of a 1% reduction in heart disease has been found to be worth some $500 billion—twice the size of the public Medicare insurance annual budget[23]. According to David Canning, a health economist whose work is cited in the 2002 Wanless Report, a similar per-ratio figure for the UK is not inconceivable. A new study investigating Patent Foramen Ovale closure for migraine could begin to address the £750 million and 18 million work days lost to the UK economy each year due to migraines[24].

Case study 2—Thyroidectomy by Harmonic Scalpel

— In the UK currently around 9,000 thyroidectomies are performed annually[i]; the procedure takes between one and three hours to perform. The current technique involves careful dissection and tying of the vessels with sutures, which results in blood loss.

— Alternatively, thyroidectomy can be performed using the harmonic scalpel. This reduces blood loss, clinical risk and procedure time by 30 minutes[ii].

— Based on sample resource costs from 11 NHS hospitals, it is estimated that the net saving would be around £740,000 across the UK after taking into account additional capital and consumable costs. This should also free up NHS capacity to treat more than 3,000 additional patients waiting for major surgery.[iii].

— Adoption rates for this technology are limited by annual capital budget constraints at the hospital level and poor financial flexibility on capital finance options.

[i] Hospital Episode Statistic 2003–04 and industry estimates of private activity.
[ii] P Voutilainen *et al.* "Ultrasonically Activated Shears in thyroidectomies", Helsinki University, Finland.
[iii] Estimate by Johnson and Johnson, based on average resource costs of the 11 Trusts taken from reference cost databases.

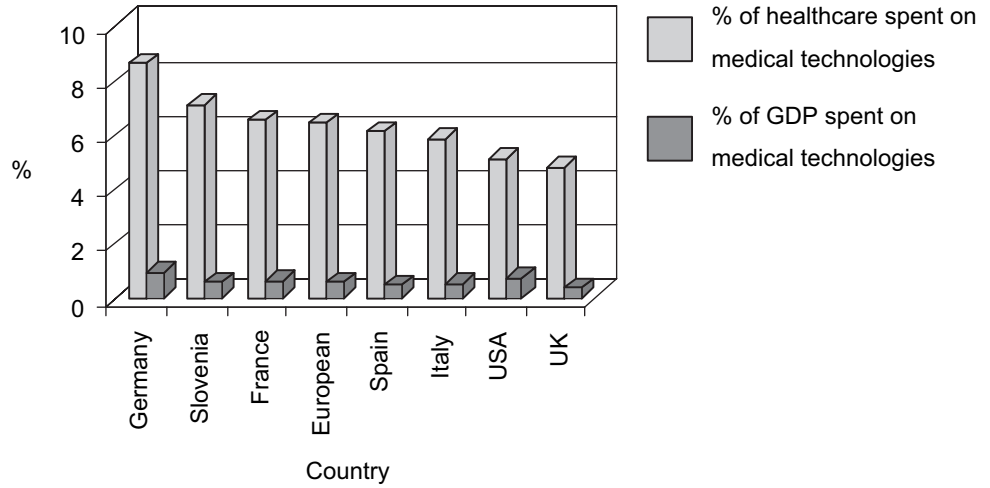
2. *The Speed of and Barriers to, the Introduction of New Technologies*

2.1 Although the UK is a world leader in inventing and developing technologies,[25] this is in stark contrast to its continued failure to exploit this strength in innovation, and utilise the vast investment in research and development. The UK lags far behind other countries in its spending on medical technology, as illustrated in Figure 2:

[23] University of Chicago research by economists Robert Topel and Kevin Murphy.
[24] Migraine Intervention with STARflex technology trial, 2004; see www.migraine-mist.org
[25] Technology in Orthopaedics, Professor John Kenwright, Research Director, Wishbone Trust; Science in Parliament, Vol 60, No 1, Spring 2003.

Figure 2

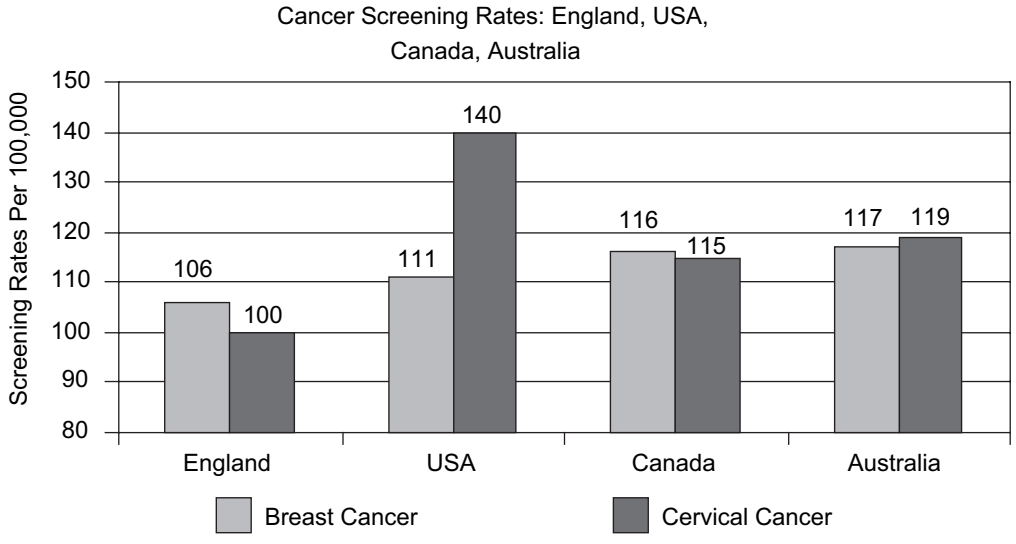
EXPENDITURE ON MEDICAL TECHNOLOGIES BY SELECTED COUNTRIES, AS A PROPORTION OF TOTAL HEALTHCARE EXPENDITURE AND GROSS dOMESTIC PRODUCT[26]



Country	*% of healthcare spent on medical technologies*	*% of GDP spent on medical technologies*
France	6.5	0.62
Germany	8.6	0.92
Italy	5.8	0.5
Slovenia	7.1	0.57
Spain	6.1	0.46
UK	**4.8**	**0.36**
European average	6.4	0.55
USA	5.1	0.71

2.2 Because of these low rates of utilisation, patients in the UK fail to reap the benefits of technologies available to other nations, through shorter recovery times, reduced hospitalisations, and increased quality of life and productivity. Illustrated overleaf is just one example of the UK's technology access gap: modern cancer screening techniques that are used more widely in other countries.

Figure 3



[26] Eucomed Medical Technology Brief 2004.

2.3 Not surprisingly, the same countries listed above with higher screening rates also enjoy higher survival rates for these two types of cancers.[27] Nationwide, the NHS would stand to benefit from increased utilisation rates for many technologies, as capacity and waiting times would improve, as more patients could be treated more effectively with fewer hospital beds, and nurse and physician time.

2.4 Where the Government has attempted to improve particular areas of healthcare, through focussing on recommended solutions in the National Service Frameworks accompanied by significant and sustained investment, technology uptake has been higher and Government targets reached. For example, the National Service Framework on Coronary Heart Disease set a goal of 750 interventions per million population each, for coronary artery bypass grafting and coronary angioplasty; these targets were exceeded in 2003.[28]

2.5 However, where this investment and focus has been less concentrated, so uptake has been less rapid. For example, a low-cost patient monitoring device that assists GPs in the early diagnosis of atrial fibrillation (AF) for stroke prevention and other life-threatening heart rhythm disturbances has been taken up by less than 1% of all GPs since its introduction over four years ago, even though estimates by the current users suggest that over 150 patients' lives have been saved since then.[29]

Barriers to Introduction of New Technologies

2.6 The MTG has identified three potential barriers that we believe will threaten patient access to new technologies. These are outlined below.

(i) Inadequate Tariffs Under Payment by Results.

2.7 The MTG applauds the enormous efforts of the Department of Health (DOH) to design and implement a system of "Payment by Results" to facilitate choice and patient centred care. While Payment By Results promises to bring new efficiency and improved performance over time, the current transition to Heathcare Resource Groups (HRGs) for English hospitals as the central method of achieving payment by results risks the use of tariffs that do not reflect the true costs of patient care for a number of critical technologies.

2.8 HRG tariffs are calculated based on prior two year data submitted by hospitals. Inaccuracy for certain tariffs may reflect routine errors on the part of hospitals in submitting costing data, as many hospitals are challenged in adapting to this complex system. For newer technologies, inadequate tariffs simply reflect the absence of an appropriate code available to collect data two years' previously—so related costs become "lost" in the hospital costing data.

2.9 To address potential shortfalls, the DOH established a "pass-through" payment that allows for primary care trusts (PCTs) to pay for the additional costs of new technologies in a supplemental fashion, for a period of up to two years. The DOH also recently expanded the pass through definition to include certain low volume, existing therapies that may face underpayment.

2.10 The MTG fully supports these measures but remains concerned that PCTs actually have the staff and financial resources to establish pass-throughs for critical technologies. MTG also is concerned that a diverse, local approach to providing pass-through payment will present new challenges once the two-year period has expired for a technology and a tariff amount must be calculated. Finally, MTG wishes to bring attention to a number of existing technologies that likely do not fit the pass through criteria, but are nonetheless facing extremely low payment under the 2005 tariffs (please see Appendix B).

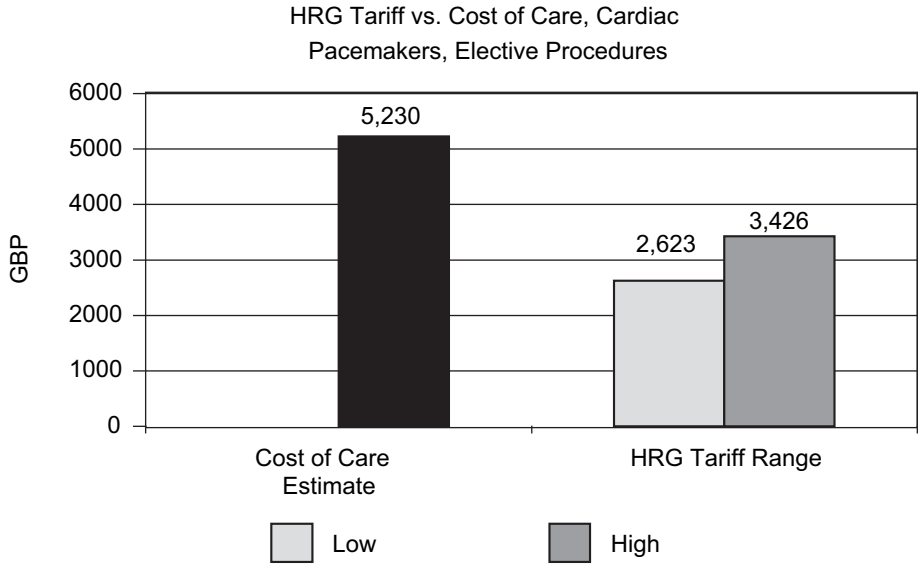
[27] Source: Health Affairs, 23:3, May/June 2004, p 92, Exhibit 1.

[28] BCIS audit return, adult interventional procedures, 2003.

[29] British Journal of Cardiology: (2001: Vol 8–6). "Changes in referral patterns to cardiac out-patient clinics with AECG monitoring in general practice".

Figure 4

CARDIAC PACEMAKERS CONSTITUTE A HIGH VOLUME, EXISTING TECHNOLOGY FACING TARIFF UNDERPAYMENT IN 2005[30]



MTG has written a policy paper on the HRG issues, with recommendations for Government action; this paper is attached as Appendix C.

(ii) Audit Mechanisms in Support of NICE Determinations

2.11 MTG has long supported a fair and transparent product review process by the National Institute for Clinical Excellence (NICE) and has worked to support the adoption and enforcement of NICE recommendations. However, the adoption of technologies covered by NICE recommendations has failed to improve substantially and patients continue to face barriers to access.

2.12 One hindrance to improving adoption of NICE recommendations is the current absence of reliable national measures for technology utilisation, that could be used to gauge progress towards NICE targets for uptake. A recent study by York University published in the British Medical Journal[31] shows that following guidance from NICE, there was no apparent increase in the uptake of several critical device technologies: hearing aids, hip prostheses, implantable cardioverter defibrillators, laparoscopic hernia repair and laparoscopic colorectal cancer surgery. The study also found that NICE guidance has been "less influential in surgical procedures and use of medical devices" than for pharmaceuticals.

2.13 MTG calls on the Government to ensure that NHS bodies—such as the Healthcare Commission—understand the difficulties of auditing devices and recognise the need to do so. The Group is also working to ensure that the Healthcare Commission and its counterparts in the devolved nations have in place appropriate systems to monitor uptake of all NICE-approved technologies. Through monitoring uptake, NHS bodies will be able to commission effectively and plan the provision of healthcare to achieve targets and respond to the needs of local communities. Monitoring uptake will also help NICE to assess its own effectiveness as a reviewing body and its relevance to frontline care providers.

2.14 Ensuring compliance with NICE guidance can be achieved by relating the commissioning arrangements within PCTs to the NICE recommendations. Recent Government activity to this end is a positive sign. For example, the Department of Health's *Standards for Better Health*[32] include the need for healthcare organisations to "ensure they conform to NICE technology appraisals and, where it is available, take into account nationally agreed guidance when planning and delivering treatment and care."

2.15 However, there is certainly more work to do. With inadequate assessment tools, the economic benefits of NICE-approved technologies are often not taken into account, and Trusts could be forced to choose between following NICE recommendations or going over budget. There is also evidence of "seasonal prescribing", whereby patients are denied access to certain technologies at times of the year or month when

[30] Reflects Tariff payment estimates for applicable HRGs, with adjustments for specialised services. Cost of care estimate reflects an average industry-collected data from typical hospital purchasers of pacemakers.

[31] Sheldon *et al*, "*What's the evidence that NICE guidance has been implemented*, BMJ 329:999, October 2004.

[32] Department of Health, "*Standards for Better Health*" July 2004.

budgets are likely to over-run. In the future, budget constraints will be increasingly problematic for technologies facing HRG tariffs that are too low to cover the basic costs of care. Thus, further mechanisms must be put in place to reinforce guidance and ensure and encourage its implementation.

(iii) Procurement mechanisms and their impact on quality of patient care

2.16 The MTG is worried that the methods of purchasing medical technology products are shifting away from the interests of the patients and physicians who depend on them. Procurement systems must ensure the availability of the best treatment options for the full diversity of clinical needs of our population, while still supporting innovation. In 2004, the Commercial Directorate embarked on an ambitious scheme to consolidate suppliers, create rapid financial savings, and apply generic, price-focused purchasing tactics to a broad range of items such as office supplies, food products, office furniture and, in equal measure, to medical technologies.

2.17 This is implemented by PASA whose primary focus has been the use of reverse auctions and internet-based purchasing that disproportionately favour price as a purchasing criterion. PASA has maintained that quality will be addressed through its purchasing process, but the MTG is very concerned that this is simply unachievable under the purchasing methods in use. Unlike office furniture, which is purchased by a diversity of consumers in the UK, health care products are purchased almost exclusively by the NHS—and will easily vanish from the marketplace under adverse purchasing conditions that do not recognise clinical value.

2.18 The MTG remains concerned that the approach of PASA is inappropriate for most medical products and threatens to severely limit the treatment options available to clinicians and patients in the UK. In short, we believe that whilst the NHS is seeking to promote innovation and the use of the latest therapies which are wanted by patients and needed by doctors this approach by the Commercial Directorate is creating barriers to access.

2.19 To illustrate the patient impact of this current PASA activity, a recent PASA procurement action excludes a silver alloy and hydrogel urinary catheter that has been identified by the Health Protection Agency's Rapid Review Panel as having potential value in preventing pervasive MRSA bacterial infections—a leading concern in English hospitals. MRSA infections are resistant to antibiotics and have been linked to numerous excess patient deaths. Some hospitals have been obliged to close because of persistent MRSA patient infections. Silver alloy and hydrogel-coated catheters have been demonstrated with extensive clinical evidence to reduce infections, yet they will be unavailable to English patients because of a PASA process that is focused disproportionately on price.

2.20 While the Rapid Review Panel finding serves as a positive model of Government action to address an urgent healthcare need—PASA's actions for this product example shows that it is out of step with the views of other important public bodies such as NICE and the Rapid Review Panels. MTG proposes that nationally-agreed guidance, guidelines and recommendations from public bodies, such as NICE and Rapid Review Panels, should be given more authority, and that a clear division of responsibility is made, so that where action is recommended by such bodies, it is supported and implemented by other bodies.

3. *Key outputs of the Healthcare Industries Task Force (HITF) Report*

3.1 The MTG is hugely encouraged by the key outputs of the Healthcare Industry Task Force (HITF) and is anxious to see its policies implemented quickly and comprehensively. A coordinated approach by Government Departments was taken on the researching and drafting of HITF and a similar coordinated approach by the Departments for Health, Trade and Industry and HM Treasury is needed for the successful implementation of its agreed policies. Amongst the key outputs of HITF, there are a number of particular interest to MTG, as they will have direct impact on patient access to technology.

3.2 Device Evaluation: The MTG supports measures that ensure patient safety, but within a framework that speeds patient access to important new therapies. A barrier to uptake of new technologies is the duplication of evaluations prior to procurement, causing needless delays in patient access and wasted NHS resources. A principle of "once-only" evaluation should be adopted, and an expanded Device Evaluation Service should be the vehicle for accelerating new technology adoption. To achieve this, the DES will require governance to ensure impartiality and independence from short-term cost-saving initiatives that might be drivers of PASA behaviour.

3.3 Procurement: The MTG strongly supports HITF recommendations for a regional procurement focus and joint commissioning between PCTs and SHAs. MTG recommends that mechanisms be established for discussions between policy-makers, industry and commissioners about how to adopt new technologies, across PCT and SHA borders where necessary. HITF also rightly recognises the pivotal role of clinicians in progressive and effective procurement. The early and active involvement of clinicians with procurement representatives should be built in to the commissioning structure to allow for informed, value-driven commissioning and procurement decisions.

3.4 Communication with patients and the public: The MTG strongly supports the recommendation to improve public understanding of medical devices, their benefits and risks and the nature of the regulatory system. We applaud the proposal that MHRA should lead a project to achieve this, as part of their efforts

to increase communication with the public. We believe that this patient education effort fits squarely within the Government's support of patient choice. MTG would recommend a single source repository of patient information (NHS website or NHS Direct) that contains links to approved sources of information for patients and carers. MTG also recommends the establishment of multiple media channels for the dissemination of this information as Internet penetration has been shown to influence only parts of the patient population, whilst being largely ineffective with hard-to-reach patient populations.

3.5 Training and education: Using technology almost always requires taking on new skills; therefore where training is under-provided, incorrect usage can lead to unsafe practices. Therefore, the MTG welcomes the recommendation on training in the use of devices, and notes that substantial training already undertaken by manufacturers is a valuable part of the use of medical technology products. It is also important to ensure that clinicians are kept updated with developments in diagnosis and recognition of symptoms.

4. *The utilisation of Telemedicine (including Telecare) and its future potential for improving services*

4.1 Telemedicine and other remote care innovations are technology applications that can truly recast the paradigm of health care in the UK. Cutting edge technologies in this area include remote transmitting pacemakers that allow for continuous observation of patient heart functions, to remote monitoring tools that survey patient heart rate and blood glucose levels, and other key indicators from the patient's home. Technologies such as these not only displace the need for in-person care, they provide insight to clinicians that in some instances is far more robust that what can be assessed in a clinical setting.

4.2 Remote technologies, including the broad range of telemedicine applications also provide essential economic benefits by reducing the need for hospital observation and testing, shortening waiting times and leveraging more fully hospital based diagnostic assets.

4.3 The challenges facing telemedicine are potentially greater than those faced by conventional therapies, since the provision of diagnostic and monitoring services and their reimbursement has traditionally been linked to in-person clinical visits. In telemedicine, the site of investment is often disconnected from the site where cost savings occur. Additionally, and because investment and cost benefit are rarely linked and the benefits are accrued in other parts of the system, new, comprehensive ways of measuring total cost effectiveness are needed to truly appraise the value of these important new technologies.

4.4 The inequities across different regions in adoption of related technologies is also a challenge, and many of these technologies require capital investments that are beyond the reach of smaller institutions and physician practices. In addition, there is currently a lack of infrastructure to deal with information that is collected, a problem that may be addressable through the new national framework for IT. MTG recommends investigation into the potential for joint commissioning of telemedicine and across PCTs.

5. *Summary of recommendations to the Committee*

MTG recommends to the Committee the following points for action by the Government:

- Put patient care and access to effective treatment as the guiding factor in all commissioning and purchasing arrangements for Medical Technology.
- Ensure that tariffs under Payment by Results reflect the true cost of patient care for new technologies, and do not prevent the introduction of technologies through inaccurate data.
- Equip Primary Care Trusts with the resources to establish pass-through payments, and to ensure there are payment mechanisms for all new technologies.
- Introduce further mechanisms to reinforce guidance from NICE and other public bodies and ensure and encourage its implementation.
- Review the procurement methods utilised by PASA and the NHS Commercial Directorate, with the objective of identifying if and how they limit the introduction of new technologies.
- Implement the key outputs of HITF quickly and comprehensively.
- Investigate the potential for joint commissioning of telemedicine across PCTs and identify mechanisms to link incentives to provision of patient care.
- Nationally-agreed guidance, guidelines and recommendations from public bodies, such as NICE and Rapid Review Panels, should be given more authority, and a clear division of responsibility made, so that where action is recommended by such bodies, it is supported and implemented by other bodies.

APPENDIX A

MEMBERS OF THE MEDICAL TECHNOLOGY GROUP

British Cardiac Patients' Association
British Vascular Foundation
Cardiac Risk in the Young (CRY)
Arthritis Care
Arrhythmia Alliance
Cardiomyopathy Association
Syncope Trust and Reflex anoxic Seizures (STARS)
National Heart Research Fund
ICD Patient and Family Support Group
INPUT
Extra Life Society
International Alliance of Patient Organisations (IAPO)
National Rheumatoid Arthritis Society (NRAS)
Patients' Association
National Heart Forum
SADS UK
Medtronic
Boston Scientific
Guidant
Error! Hyperlink reference not valid.
Advanced Medical Optics, inc.
Cardionetics
Becton, Dickinson and Company
St Jude Medical
Johnson and Johnson
Association of British Health Care Industries (ABHI)
AdvaMed (Advanced Medical Technology Association)
See www.mtg.org.uk for further information.

APPENDIX B

TECHNOLOGIES FACING INADEQUATE HRG TARIFFS IN 2005

Cardiac Pacing Devices
Electrophysiology Equipment and Disposables
Interventional Cardiology Devices
Coated Stents (Peripheral Indications)
Orthopaedic Hip and Knee Implants
Spinal Fixation Devices
Endoscopic Technologies
Interventional Radiology
Devices for Urinary and GT procedures (stents, drainage catheters)
Hematology and Oncology (Catheters and Ports)
Pulmonary Embolism Treatment (Vena Cava Filter)
Hernia Repair (Synthetic and Biomaterial Meshes)
Biliary Stents
Cardiac Resynchronization Pacemakers
Implantable Cardiac Loop Recorders

Neurostimulators (Including Vagal Nerve Stimulators for numerous indications including epilepsy, Parkinson's Disease, Multiple Sclerosis, incontinence)

Prosthetic Intervertebral Discs

APPENDIX C

MTG POLICY PAPER ON PAYMENT BY RESULTS

Ensuring Appropriate HRG Tariffs—It will be essential to ensure that HRG Tariffs accurately reflect the care actually being provided. Inappropriate payment can discourage hospitals from using highly innovative and effective technologies that can help save lives and improve quality of life. This may jeopardise patient access to such technologies and adversely affect the research and development efforts of manufacturers seeking new and improved breakthrough technologies. Payment rates should also distinguish key therapies within specific payment levels, rather than including clinically and economically dissimilar therapies in the same payment groups. The MTG was supportive of the DoH's consultation with all stakeholders to ensure that consideration of national tariff rates is conducted appropriately under the HRG system. The casemix activity of hospitals needs to be monitored to asses the impact of PbR. It is possible, for example, that the system will discourage complex angioplasty in favour of coronary artery bypass surgery due to the inflexibility of a fixed tariff.

Ensuring Sufficiently Specific HRGs—As the HRG system is phased in over the next few years, it is important that there be sufficiently specific HRGs to capture the breadth and complexity of the vast array of procedures used throughout the NHS.

Generating Robust Hospital Data—Robust data will be critical to the success of the HRG payment system. It is essential that a mechanism is in place for generating valid data and utilising this data as early in the evolution of the HRG payment system. This will aid HRG policymaking and ultimately result in more appropriate payment rates. Hospital understanding and accurate use of codes is essential to ensure the collection of robust data.

Ensuring Rapid Adoption of New Innovations—A consequence of HRG-like payment systems is that they can be slow to react to new and innovative medical technologies, especially those that are substantially different from items already being used in hospitals. This can have a detrimental impact on patient access to medical technology. MTG welcomes the apparent flexibility of the "pass through" system described in the technical guidance, but fears that in practice its use maybe seen as cumbersome and time consuming by PCTs and providers alike. Its use needs to be assessed and technologies having particular problems may need to be supported by specific guidance from the centre.

Making HRG Assignments Regularly and Appropriately—Newly marketed and existing medical technologies should be assigned expeditiously to appropriately paying HRGs from the time of their introduction based on valid data submitted by manufacturers. Clear criteria for determining and correcting the inadequacy of payment of an existing HRG should be developed as part of this process.

Anticipate Transition Costs to Ensure Continuation of Patient Care—As the HRG system is implemented over the next few years, policymakers should realise that even the best planning cannot fully predict the costs and challenges of transitioning an entire health care system to HRGs. While the MTG stands firmly behind the objectives of the PBR effort, efficiencies from this system will not occur immediately and the costs of adoption may be substantial. We call upon the Government to ensure that adequate resources are provided to support the transition to HRG payment.

Changing the method of payment in this way alters the commissioning incentives for Trusts; this should mostly benefit patients, as it should ensure that they are treated on the basis of need. However, the system could create incentives for Trusts to discontinue treatments they would otherwise have used—not on the basis of effectiveness or cost-effectiveness, but because the tariff is inappropriate. For example, there are variations in the calculation of outpatient costs, and this may act as a disincentive to providing treatments in outpatients, especially when the tariff for inpatient care is higher; this could have negative impact on patient throughput and access to less-invasive technologies that could be used in the outpatient setting. It will be a significant challenge to tackle these problems without adding to the complexity of the system.

The system should not introduce new sources of delay because hospitals do not have payment levels that are sufficient for certain therapies. In addition, the impact of HRG payment on hospital waiting times should be carefully monitored and understood. Where hospitals are given a low incentive to use certain technologies because of low payments, waiting times could worsen for key procedures.

APPENDIX D

CASE STUDY ON EFFECTIVENESS AND ECONOMIC BENEFITS OF MEDICAL TECHNOLOGY

Case Study 3—Julie's story' Misdiagnosis, access to treatment and improved quality of life[1]

- Julie Fear suffered blackouts throughout her life. After numerous tests and hospital visits as a child she was diagnosed with temporal lobe epilepsy. This diagnosis affected her quality of life: Julie felt she had no control or choices in her life. Her performance in school deteriorated because of her medication and she suffered from depression.
- While pregnant, Julie was in and out of hospital with uncertainty about the survival of her baby. Although Julie's child, Naomi, was healthy, she also had blackouts. Naomi was diagnosed with REflex Anoxic Seizure (RAS), but Julie did not connect this with her own condition. They learnt of a support group for families of sufferers of RAS.
- Years later, Julie's husband suggested that her diagnosis could be wrong: the support group, Syncope Trust and Reflex anoxic Seizures (STARS) told her there was an adult version of RAS, Reflex Syncope, and that sufferers had been misdiagnosed with epilepsy. But when she visited the GP with this information, she was laughed at, told to put her head between her knees in case of an attack, to avoid stressful situations and to stop her epilepsy medication.
- Following further communication with STARS, Julie was referred to a specialist: after waiting 14 months for a consultation and tests, she was diagnosed with VAso Vagal syncope. Her consultant later suggested seeing a cardiologist; STARS referred her to a specialist in Manchester, but to prevent wasting more time they arranged a private appointment.
- Julie was fitted with a pacemaker the size of a matchbox and was discharged the following day. She has not had an attack since, and she says for the first time she feels truly free.

[1] STARS Newsletter, January 2005.

Supplementary evidence by the Medical Technology Group (MT 44A)

1. *Why is the uptake of medical technologies slow in the UK compared to other countries? (Mr David Hinchliffe)*

Factors include:

- Lower overall national spend on technologies than other European Countries and the US and lower proportion of health budget spent on technologies in the UK.
- No ring-fenced budgets, national strategy for uptake of technology or targets for looking at the systematic uptake of new technology.
- A disconnection between clinicians, review mechanisms and procurement within the current Health Service.
- A significant workforce shortfall. For Example in the UK we have approx 650 cardiologists serving a population of approx 59 million. In France, Germany and Italy, with a similar sized population—each country has in excess of 6000+ cardiologists.
- "Silo" or departmental budgeting. Despite budgets now being devolved to PCT level with a strategic overview, in reality the budgets are further devolved to hospital and departmental level; for example, a specific amount of money is given to the cardiology department, or the renal department to deliver their services and achieve savings. Decisions over whether to use a technology are therefore made, in consideration of that specific departmental budget. This "silo budget" system, fails to recognise any savings, which can be considerable, that a specific device or treatment using technology can realise in other parts of the hospital, the health service, to the wider economy. The impact on the local budget is paramount in the decision making process.
- This issue can be exacerbated by the relative short-term approach to decision making in budgetary terms. The long-term benefits of medical technology for both patients and the NHS often take place over a longer period that the two and more recently three year budgetary cycle ie reduced drugs budget for those that would have remained on medication indefinitely; reduced admission or repeat admission to hospital for treatment that can have been avoided with medical technology; increased quality of life and ability to contribute to society for patients. Therefore the primary consideration for assessing the use of medical technology is the initial outlay of cost and the impact on that specific budget.

2. *Explain the assertion that cost effectiveness is not taken into account when assessing medical technology. (Doug Naysmith)*

One key benefit of medical technology, in addition to improved quality of life and survival for patients, are the cost and resource efficiencies that can be achieved.

— Technology solutions and treatments largely increase the number of patients that can be treated both in primary and secondary care, thus addressing problems of bed blocking; reducing patient waiting times and reducing surgery time. For example, it has been estimated that using the harmonic scalpel for thyroidectomy rather than traditional methods, would provide net savings of £740,000.[33]

— An example was provided to the committee of cost savings offered by telecare solutions and preventative measures in the home for elderly patients. We are attaching a case study which records the massive efficiency gains achieved in Newcastle Royal Victoria Infirmary by Prof Rose Anne Kenny to a similar patient group. The "falls" clinic she established assessed the cause of all unexplained falls in patients presenting at A&E. Many patients who present with problems associated with repeated falling are unexplained in elderly patients or misdiagnosed as epilepsy in younger patients. Often the condition when correctly diagnosed can be treated successfully with pacemakers.[34] The cost of a pacemaker which has a life span of 10 years+ is approx £3,000, anti-convulsants drugs costs £1,900 per year and if the patient is mis-diagnosed they will continue to be a drain on the NHS as they are admitted time and time again for tests and the drugs do not solve their problems. They often are subject to fractures, breaks and trauma leading to greater burden on already stretched orthopaedic and emergency services. A pacemaker, once implanted, only needs checking for most patients once or twice each year, a huge saving to the NHS as well an improved quality of life for the patient and their families. (CASE STUDY SUBMITTED IN PDF)

The MTG does not however assert that cost-effectiveness plays no part in the consideration of medical technologies. It has to be assumed that Trusts normally consider both effectiveness and the direct cost implications in their commissioning. However we do assert in our written evidence, "(Payment by Results) could create incentives for Trusts to discontinue treatments they would otherwise have used—not on the basis of effectiveness or cost-effectiveness, but because the tariff is inappropriate." There is a danger that technologies will appear unaffordable in the short term because of inaccurate data collection and inappropriate calculation of tariffs, and therefore discontinued or not commissioned at all.

3. *Traditional approaches often fail to involve quality of life assessments, how should these be calculated? (Doug Naysmith)*

The improvement in quality of life for patients from medical technology can be enormous. They can provide increased life expectancy, a reduction in further complications for patients, improved standards of living and productivity, not only for patients but also for their carers and the people closest to them.

In addition to the example given by John Wilkinson of children with cardiac arrhythmia, there are a number of other examples the committee may like to consider.

— Medical surveys are available to demonstrate the stress and anxiety caused to families that live with a child with arrhythmia conditions. These can be found on the STARS website: www.stars.org.uk

— We are attaching a personal case-study from patient Julie Fear. Ms Fear, was mis-diagnosed for thirty years or more, requiring an ambulance to be called on a large number of occasions, many consultations with neurologists, psychiatrists and GPs, numerous tests such as EEG, ECG and tilt test and the prescription of anti-convulsants and anti-depressants. Ms Fear has been referred out of her area twice and has finally been fitted with a pacemaker and in six months has only needed one check up and has not lost any time off work. It is essential that these quality of life benefits are taken into account, when considering the use of a medical technology.

There are models for assessing the "value" of additional years for a patient which are used in economic models and assessments made by NICE. NICE should already consider cost effectiveness however we would suggest that the quality of life assessments which put a value on additional years are restricting and do not take into consideration the major impact that minor improvements can make to a patients life.

Patient input in assessing "quality" of life should be given higher priority than is currently the case.

[33] As referenced in the MTG written evidence.

[34] A Zaidi *et el*, Misdiagnosis of Epilepsy: Many Seizure-Like Attacks Have a Cardiovascular Cause, Journal of the American College of Cardiology, Vol 36, No 1, 2000.

4. *Much new technology takes care outside of the clinical setting, does this present risks? What role do patients and user groups have in this regard? (John Austin)*

There may be some risks associated with increasing the number of patients receiving care and treatment outside the clinical setting, as the mechanisms to monitor patients are less immediate in some circumstances. However, the benefits to patients in being able to continue their life as normally as possible and rely less on care in the clinical setting are enormous.

KEY ELEMENTS FOR REDUCING RISK ARE

— Provision for accurate and timely information for patients, carers and medical professionals.
— Involving patient support groups as organisations independent from Government, providing support and advice to patients.
— Ensure the necessary funding is available for systems to support home care including patient support.

Support groups such as my own organisation Arrhythmia Alliance by working with patients, clinicians and industry can ensure that the advice and information provided to patients is accurate and of the highest standard.

5. *Evidence submitted suggests that some HRG tariff payments might not cover the cost of the technology, please expand on this. (Richard Taylor)*

COLLECTION OF DATA

— The tariff for each HRG is calculated based on the data collected from the hospitals for the previous two years. New technologies do not have previous data therefore are not captured in the tariffs. Pass-through payments, are being introduced to address this problem, however these are to be decided on a Trust by Trust basis. The problem resulting from this is that the data collection is likely to differ from place to place, unfamiliar recording systems are adopted and data is therefore patchy leading to potential inaccuracies. An accurate reflection of a national picture simply will not exist to base an accurate tariff upon.

IMPLICATIONS OF HRGS

— The impact of HRG payment on hospital waiting times should be carefully monitored and understood. Where hospitals are given a low incentive to use certain technologies because of low payments, waiting times could actually worsen for key procedures.
— As the HRG system is implemented, policy makers should realise that even the best planning cannot fully predict the costs and challenges of transitioning an entire health care system to HRGs and that some transition costs estimates may be too low while others too high.

6. *Previous investigations have shown, for example, that one patient treated with an implantable defibrillator can cost £30,000, which is the approximate equivalent to funding a nurse for a year. How do we balance the benefit of the technology to one patient versus the benefit to many of an additional nurse? (Mr Jim Dowd)*

While it might initially look as though those are the only two options, the increased use of medical technology can achieve resource gains for the NHS in terms of staffing. In this instance, it is again important to consider the longer-term aspects of medical technology. One of the main aims of medical technology is to decrease reliance on clinical setting treatment, particularly in hospitals. By allowing patients to either return home to a relatively normal life, or continue treatment outside the hospital setting, the amount of nursing and other clinical time, which would have been required to treat these patients is significantly reduced. Some technologies also reduce the likelihood of re-admission to hospital, and therefore again reduce the care burden for the NHS.

7. *Expand on the claim that there is slippage between NICE guidance, NSF targets and procurement processes. (John Austin)*

While MTG supports the role that NICE has played in supporting the adoption of medical technologies through product review processes, and published guidance, there are problems with the extent to which that guidance in relation to devices is implemented. Clear data exists to show that the uptake of pharmaceuticals given positive guidance by NICE is implemented quickly. Pharmaceuticals are easily monitored via prescriptions and hospital recording systems, however devices are utilised at the discretion of the clinician and not necessarily centrally recorded.

The result of this is:

— It is more difficult to effectively monitor if NICE guidance is being implemented for devices.

— Variation in uptake across the country and we have evidence of seasonal prescribing, where guidance is implemented at certain times, but less so at times of the month or the year when budgets are likely to over-run.

— Budgetary problems such as this could become more evident and problematic for technologies where the national tariff does not cover the basic cost of care.

However NICE guidance is not the only guidance issued to the NHS and funding and procurement processes can have an effect not only on its implementation, but also for technologies that fall outside these assessments.

Examples from the MTG submission include:

— Where focus had been targeted through solutions in National Service Frameworks coupled with sustained investment, technology uptake has been higher allowing Government targets to be reached. However, when the focus has been less concentrated, technologies that could save lives and reduce the secondary care burden on the NHS, have seen significantly less uptake.

— A recent guidance on a urinary catheter from the Health Protection Agency's Rapid Review Panel, which considers treatments that may help in the fight against hospital acquired infections. Despite being identified by the Panel as having a beneficial effect on the reduction in hospital acquired infections, recent procurement decisions by the Purchasing and Supply Agency, mean that this technology will not be available for patients. Clinicians, patients, advisory bodies such as NICE and the Rapid Review Panel must be connected directly to the procurement process.

A study commissioned by the Department of Health and referenced in our written evidence (footnote) found that funding and clinical support were both important factors in NICE implementation. It stated that the impact of NICE guidance "is likely to be greater if more effort is devoted to . . . adequate funding provision [and] getting professional support".[35]

March 2005

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[35] Sheldon *et al*, "*What's the evidence that NICE guidance has been implemented*", British Medical Journal 329:999, October 2004.

Written evidence

APPENDIX 1

Memorandum by the Royal College of Radiologists (MT06)

1. The Royal College of Radiologists is an organisation whose object is to advance the science and practice of Clinical Radiology and Clinical Oncology. The Royal College of Radiologist would be willing to speak to the issues raised in this memorandum. It is pleased to supply information to this inquiry which covers several areas integral to the practice of these specialties.

2. The remit falls into four main headings which are listed below A–D.

   A. The utilization of Telemedicine (including telecare) and its future potential for improving services

   B. The recommendations of the Healthcare Industries Task Force (HITF) Report, published 17 November 2004.

   C. The speed of, and barriers to, the introduction of new technologies.

   D. The effectiveness and cost benefit of new technologies.

3. Items A, C and D are of great interest to the RCR and comments are included as follows:

A. The Utilisation of Telemedicine (Including Telecare)

Our evidence relates to teleradiology a major component of telemedicine:

Teleradiology

- Teleradiology is the electronic transmission of radiological images from one geographical location to another for the purposes of interpretation and consultation.
- Advantages include:
  - locality of service—transfer of images from a remote area to a major centre;
  - direct patient care—transfer for expert opinion;
  - out of hours imaging—transfer to home or abroad to an alternative time zone; and
  - out-sourcing from the NHS to cope with workload, back logs etc.

There are, however, many issues of risk and potential problems associated with teleradiology which are enumerated. These can be considered under a number of headings.

A1. *Professional Registration*

The Radiologist must be licensed to practice within the UK, have liability insurance and be subject to the same controls as UK Radiologists, such as annual appraisal and five yearly revalidation.

A2. *Radiation Protection*

All examinations must be subject to the same controls demanded by the Euratom Directive and the Ionising Radiation (Medical Exposure) Regulations in order to optimise radiation safety.

A3. *Communication*

- The legal record of an imaging examination is the radiological report. There must be sufficient linguistic capability to ensure that the report is accurate and that nuances of the language are recognised. In particular variations of normality must be properly recorded and not ascribed to disease. Abbreviations used in the report should be commonly recognised by both the reporting Radiologist and the Clinician.
- Although the written report is the legal record there must be the opportunity for direct discussion between the reporting Radiologist and the referring Clinician.
- The opportunity to discuss the findings with the patient may be lost by processes of teleradiology.

A4. *Consent*

There must be clear and explicit consent by the patient for transmission of images out with the referring hospital. There must be sufficient security for the transfer of demographic personal data.

A5. *Team Working*

Much of clinical care now occurs on multi-disciplinary teams. The role of the Radiologist in informing clinical management in this environment could be lost through teleradiology.

A6. *Quality of Care*

Transfer of images may compromise access to previous investigations and reports and access to full clinical information. Commercial viability may depend on high reporting rates. There is evidence that reporting accuracy deteriorates with sustained high workload.

- Continuity of care and out-of-hours services. Several investigations and procedures require a "hands on" approach. It is important that teleradiology does not compromise the delivery of these services.
- Disease prevalence may be different in different countries and therefore differential diagnoses inaccurately reported for the country of origin.
- Deskilling of local staff may compromise local service delivery.

A7. *Education and Training*

Transfer of images from training departments, either for whole subspecialties or "simple investigations" may compromise the exposure of home trainees for this case material.

A8. Downstream Costs

Teleradiology may generate significant downstream costs:

- Additional investigations consequent upon inexperience, insecurity, incomplete information or different imaging practices.
- Clinicians responding to reports of normal variance or pseudo lesions.
- Requirement for review of images by home radiologists in uncertain reports.
- Perverse commercial incentives for teleradiologists to suggest further imaging.
- Fear of litigation. Defensive medicine is potentially more likely if the Radiologist is removed from the clinical environment.

A9. *Teamwork*

The provision of Imaging Services relies heavily on teamwork (radiographers, radiologists, oncologists, physicists, etc). It is recommended that where teleradiology is used it should be undertaken with the close involvement of the local department of Clinical Radiology and staff thereof. The service must enjoy their confidence and enhance their ability to deliver clinical care.

A10. *Practical Example: Fast Track Magnetic Resonance Imaging (MRI) Service*

The Department of Health has recently commissioned a Fast Track Magnetic Resonance Imaging (MRI) Service with the Independent Sector. The MR images are obtained in mobile units supplied by Alliance Medical and the images are sent to other European Centres for reporting.

A summary of the service as experienced in radiological centres around the country is attached as an Appendix. A full audit of the project is now under way which is being undertaken jointly by the RCR and Department of Health.

This project has led to numerous enquiries and critical comments from patients, clinicians and the press. In response the Royal College of Radiologists issued the following statement:

> *"The Royal College of Radiologists welcomes any new initiative to improve patient care and will do all it can to make sure such ventures are a success. Any new initiative to improve patient care will present challenges and, whilst much can be achieved, it is inevitable that there will be teething problems. The RCR has been in discussion with the National Patient Safety Agency to ensure patient safety is paramount while working closely with the Department of Health to monitor the progress of the project and improve the service through continuous appraisal as it develops."*

C. The Speed of, and Barriers to, the Introduction of New Technologies

C1. *The Pace of Change*

It is debatable whether any area within medicine is changing so quickly as diagnostic radiology and radiotherapy. The newer scanning techniques are evolving so rapidly that machines rapidly become outdated. Tumours are better defined and sophisticated radiotherapeutic techniques allow the tumour to be treated to a higher dose with less morbidity. Furthermore, the newer machines have a much greater repertoire; this means that they need to handle an increasing number of patients per annum.

C2. *Barriers*

The finance for new machines can be difficult to come by. Although there has been a welcome expenditure by the NHS for capital purchase, this has not been matched with adequate revenue to run the systems at anything like full capacity.

One new technique, Positron Emission Tomography (PET scanning) has been largely overlooked in this country, compared with the mainland Europe and the USA. Indeed in the last couple of years it is clear that there are several advantages on combining PET with Computed Tomography (PET/CT). It is hoped that there will soon be full funding (capital and revenue) to disseminate this important technique throughout the UK.

D. The Effectiveness and Cost Benefit of New Technologies

D1. *Cost-Effectiveness Studies*

Although the NHS Health Technology Assessment (HTA) Programme often considers studies concerning imaging, few such studies get funded often because the technology changes so fast (see point C1 above) or because the capacity to perform the necessary research is not available. A case in point is PET (see point C2 above). Many enquiries were made as to why there was so little PET in the UK. The HTA committees asked for evidence—but there were virtually no machines from which to obtain the evidence. Thus no progress is made.

D2. *Cost Benefit*

Numerous research studies have shown that the use of high technology imaging often provides increased confidence about the clinical diagnosis and leads to faster throughput of patients in expensive hospital beds. What is not so often assessed is the obvious benefit to the patient in terms of morbidity—reduced need for surgery, invasive investigations replaced by non-invasive outpatient procedures, etc.

Annex

MRI Procurement Outside the NHS

SUMMARY OF COMMENTS RECEIVED AS AT 22 DECEMBER 2004

Background

The following summarises the experiences of clinical radiology departments in Trusts around the UK who were asked by the RCR President to comment on the health service initiative involving Alliance Medical providing on a national contract to NHS Trusts mobile radiological scanning and reporting to reduce waiting lists.

Comments were received from 18 individuals representing NHS Trusts in England. Comments were also received from Northern Ireland, although apparently Northern Ireland is not actually participating in the initiative. However, Northern Ireland's experience with private-public partnerships for the provision of MRI has been rather positive, although it has been of short duration and has involved private providers other than Alliance Medical.

The Initiative in Principle

It was recognised that MRI scanning is firmly established among the general public as a powerful, non-invasive diagnostic tool with no biological effects at current field strengths. The major problem is the ever-increasing demand, with capacity always trying to catch up. It was felt that the "results" of catch-up exercises such as the initiative involving Alliance could have only short-lived impact on waiting lists, at best.

Moreover, the procurement of MRI services in this way was seen as a waste of money by most departments, as it was recognised that there were MRI scanners within the NHS that do not run to full capacity due to lack of funding and lack of radiography staff to operate extended days and weekend scanning.

It appeared from the comments received that some departments did not oppose the initiative in principle, and one department hastened to point out that to do so would be to suggest that clinical radiology departments were "opposed to increased throughput". Most emphasised their own departmental efforts to achieve just that, increased throughput and a reduction of waiting times, through such activities as:

- commissioning of additional MRI scanners;
- expanding existing public/private initiatives;
- initiatives self-funded through private patient activity;
- more efficient use of scanning time;
- modification of scanning protocols;
- more critical acceptance of requests for MRI scans; and
- consultant clinician-only requesting.

What was fairly unanimously criticised by individuals responding to the request for comment was the lack of consultation with clinical radiology departments to be involved in the initiative, the quality of service being provided by Alliance Medical and its effect on issues relating to clinical governance, process delays, additional workload for in-house NHS radiologists and other staff, loss of radiographer staff to the private sector, and "value-for-money" considerations.

Issues concerning the initiative that were widely raised by departments included:

- the contract for service from Alliance Medical putting a significant extra workload on local radiologists who have to sort referral lists, re-scan patients and provide second opinions, and on the clerical staff working in the hospital waiting areas used for these patients -answering patient queries, re-directing patients, etc.
- the mobile Alliance scanners being very selective about the patients and clinical problems they could and would handle.
- the standard or quality of the scans and reports being provided. It was widely noted that Alliance employed "generalist" radiologists, with no subspecialty training and with relatively limited generalist skill. Requests for complex scans were usually rejected, often at very short notice, or inaccurately done. This put extra pressure on departments to re-book patients. Additionally, the radiologists employed by Alliance were often non-native English speakers, and there was concern that they might not be able use English concisely and accurately.
- existing radiologist–clinician dialogue is disrupted by the employment of an external scan provider. Scans reported by an unknown provider necessitate additional consultation. The MR sequences used might not always be the ones that the local radiologist would have chosen and not answer the clinical question, as the local radiologist understands it.
- clinical colleagues wishing to review at MDT meetings unusual reports and reports that did not concur with clinical findings. This would not be possible with radiologists who reported from Belgium/Barcelona. Second opinions from local radiologists would become the norm.
- Alliance Medical being outside the clinical governance of the Trusts they served. Misleading and inaccurate reports could lead to unnecessary or inappropriate surgery with medico-legal implications for the Trusts.

While the comments received were, by and large, critical of the initiative involving Alliance Medical, a set of positive comments was received from Heatherwood Hospital, Ascot, who reported that the Alliance initiative provided:

- an efficient scanning service;
- benefit to local patients;
- a lessening of workload for local radiologists;
- very pleasant and helpful staff;
- shorter waiting time for patients' MRI scans, as appropriate;
- clear and professional reports which assisted transcription onto the Trust RIS; and
- good service despite a lack of legible information on some of the imaging request forms.

Although these positive comments were made, a raft of criticisms from Heatherwood immediately countered them. These related to delays in reporting and unavailability of scans and reports at follow-up appointments, poor registration and administration, skewing of workload within the department, the addition of extra work for clerical staff, concern about Alliance's deficiency in subspecialist radiology, and so forth. These comments are incorporated below.

Additionally, comments have been received illustrating the serious nature of errors involved in Alliance's work and the concern with which this has been greeted by departmental radiologists. In particular, reports have been received where incorrect diagnoses have been made, where incorrect interpretation has been given relating to the clinical information and where inadequate or incorrect reporting has resulted in the clinical information not being taken into account.

Comments by Category

The Alliance Contract and delays

Although the contract appears to be for a national procurement of service, the reporting times appeared to vary from region to region—between 48 hours and five days. In no case had Alliance Medical yet been able to deliver to those times.

In the case of *Worcestershire*, where the contract specified reports within 48 hours, the earliest reports came back three weeks after the patients were scanned and most after seven weeks. 10% had not been done after nearly two months. The Trust had no idea if the patients had been scanned or not. Alliance had supplied no information about the actual number of examinations carried out.

Of the patients referred by *Worcestershire* (510), 50% of initial referrals were returned without scans being done, with explanations of little significance or no explanation at all. In total, it would appear that Alliance carried out examinations on only 40% of patients referred to them by the Trust.

Concern was also expressed that it appeared that Alliance was being paid for the number of scans it "promised" to undertake and not just for those it did do. No one is asking the department for figures on the number of scans actually done. Further, if was felt that Alliance was also likely being paid for scans whose reports were received outside of the contracted 48-hour reporting period.

At *Blackpool Victoria Hospital*, although the first scans had been done 20 days ago, no reports had been returned. With only a few days left of the initial scan episode, Alliance was 30% under-target.

United Bristol Hospitals Trust and *Royal Cornwall Hospital* report that patients had expressed concern about the 5-week wait between scan and return of films/reports. Alliance had also been unwilling to send images to the UBHT image store, so images remained "out of system".

Royal Cornwall Hospital, Truro had no images/reports returned in two weeks, despite Alliance's agreed five-day agreed turn-around time. It was, therefore, impossible for Truro to comment on the general quality of the scans and reports from Alliance, as they had seen so few In one case, the department was alerted to a patients who had "urgent and important" findings seven days after the patient had been scanned, but still could not obtain a report of the film for a further two days.

Heatherwood Hospital, Ascot reported that since 13 September, 185 patients had been referred to Alliance, 165 scans done but only 95 reported. There had been complaints about patients going to follow-up appointments without scans or reports.

Nottingham and *Derby* reported that though the contract stipulated a 96-hour turn-around for scans and reports, this had not been achieved. Centres reported hundreds of reports as still outstanding, though Alliance claimed only 46 were. Alliance was rectifying the situation and claimed all would be put right by 22 November. Alliance claimed that the DH had held them up by saying that reports had to be generated in Europe (and not South Africa and Australia). There were also technical problems reading disks, etc.

Nottingham, Leicester and *Derby* reported that on many days only three or four patients would be seen by Alliance and on a good day possibly 30, but reports were yet to be received on any of these patients.

Additional Workload for Department/Others and Failure of Administrative Processes

Blackpool Victoria Hospital expected the contract to result in substantial additional workload for radiologists in the department who would have to re-report scans at clinical meetings, in addition to their normal (and increasingly complex) workload.

They reported that the initiative had many administrative procedural problems, amongst which were: insufficient patient triage; patients receiving very short notice of their appointments for scans; already protocolised scan requests needing to be re-assessed to determine if they were suitable for transfer to the mobile scanner lists; lack of paper documentation for patients giving reason for appointment, direction to mobile unit, etc. Additionally Alliance had requested a substantial number of additional referrals and then declined to take them four days later.

Princess Alexandra Hospital, Harlow reported that at the start of their Alliance contract it was clear that patients had not been contacted by Alliance to fix their appointments. On the first day, only four patients arrived. Letters to patients had not been posted out and patients in large numbers began ringing the department for information. Alliance supplied no explanation, other than that they were very busy.

The hospital was spending time dealing with the fallout from Alliance's failure properly to arrange appointments for patients in a clear and timely fashion. There was also much concern in the department that the scans and reports undertaken by Alliance would require second reports from local radiologists.

United Bristol Hospitals Trust, Royal Cornwall Hospital and other hospitals in the region expected the frequency with which second reports would be required to rise as more reports were received. Likewise, the cost associated with the transcribing of reports and entering them on the host RIS system would increase. They also found that patients were not being given clear instructions to the mobile site; departmental staff were having to re-direct patients.

Milton Keynes General Hospital anticipated that local referrers would not wish to base surgical decisions or opinions on Alliance radiologists whom they do not know and, therefore, most scans undertaken by Alliance would require a second reading by local radiologists.

Rob Jones Agnes Hunt Hospital, Oswestry noted logistical problems in amalgamating records, particularly EPR and RIS. Additional work would be required. Also, as Welsh patients were excluded from the initiative, the department had to run two waiting lists—one for English patients and one for Welsh (40 to 50% of patients are Welsh). Concern was also expressed that the conversion rate to surgery was predicted to be approximately 50%—higher than the national average of 25%—due to the department's orthopaedic specialty. This would lead to pressure on surgery at a later stage.

Nottingham, Leicester and *Derby* questioned who should be providing second expert reports. Additional work was generated through transcription problems, of which there were many, and links to PACS, RIS and HIS which were also very difficult. They reported that complaints back to Alliance regarding errors and organisational issues were not being dealt with by Alliance. The triage centre did not respond.

In *Worcestershire*, because Alliance had been slow to supply reports, patients had been ringing the Trust to demand results and arrange follow-up appointments, but the Trust was unable to take any action. Blackpool Victoria Hospital anticipated a similar situation arising shortly.

Heatherwood Hospital, Ascot found that the patient registration forms for Alliance were difficult to read, and that patients referred to Alliance were always turning up in the x-ray department, causing lots of extra clerical work in dealing with patient and clinician enquiries. Clinicians were not being given sufficient information about the identity of patients referred to Alliance. Patient information requested from Alliance triage centre had not been received by the department despite several requests

Norfolk and Norwich University Hospital questioned what the department's position should be when called upon to re-report scans provided by Alliance Medical or other external provider. Although these scans are NHS work, they have been provided by a profit-making business that has benefited to the detriment of NHS providers. The department suggests that it does not seem appropriate, therefore, for radiologists in the department to offer free opinion on these images when they subsequently appear in one of their hospitals, often at an MDT meeting. Should the department be making a charge (and doing the work in addition to their job plan) and, if so, who should be invoiced? The department suspects that the problem will become much more frequent if the Government's plans for out-sourcing more elective work, including diagnostics, proceed over the next few years along side the "Chose and Book" agenda.

Alternative Arrangements

Worcestershire had planned for a static MRI to serve three sites, but the Trust had been struggling to find funding for this. The project had now been put on hold as the Trust had entered into the Alliance initiative.

Birmingham Children's Hospital reported that they were about to commence an Alliance arrangement. They had also been in the process of installing static MRI purchased through central funding, but PCTs were refusing to fund the revenue costs.

National Hospital, Queen's Square reported that they were given funding by DH to commission a new MRI scanner which was installed in March 2004. They were later informed that no revenue would be available to fund it until April 2005, so the Trust continued to operate with just a single scanner and the new extra capacity was lost to the department. Instead, the Trust was about to enter into a contract with Alliance to provide mobile scanning near the site of the new non-funded static MRI machine.

Royal Berkshire and Battle Hospital expressed a preference to have funding directed to improving the local radiology resource for the long-term good of the department by recruiting more NHS staff (radiographers, helpers, radiologists) rather than taking part in the arrangement with Alliance.

Loss of Staff

Blackpool Victoria Hospital reported that as a result of the Alliance Medical initiative it had lost radiographic staff, resulting in under-utilisation of NHS scanners and difficulties in performing complex cases due to loss of MR expertise. Although Alliance's contract did not allow it to recruit existing NHS staff for its contract with the NHS, Alliance had nevertheless advertised in the UK and begun recruiting existing NHS staff radiographers to its other private work and transferring staff from other private contracts onto the NHS project. Alliance was also actively recruiting in Canada.

United Bristol Hospitals Trust, Royal Cornwall Hospital and other hospitals in the region reported losing MR-trained radiographers to the private sector (including Alliance) in the past six months, and had therefore not been able to make full use of existing centrally-funded MR-machines.

Stringent Restrictions on Types of Referrals

Blackpool Victoria Hospitals reported that the guidelines used by Alliance for the acceptance of referrals excluded: patients under 18 or over 70 years of age; patients who were not physically able to climb upon the table (as the vertical hydraulics did not function); and patients who had received general anaesthetic within the previous three months, irrespective of the actual procedure.

Princess Alexandra Hospital, Harlow reported that Alliance's contract disclaimed all liability for checking the suitability of patients to go in the scanner. All safety checks remained with the Trust. Additionally, the Trust had to be very selective in the type of case referred to Alliance. No patients who might need gadolinium had been referred as the Trust had been told by Alliance that it would charge extra for this (additional cost unknown). Moreover, Alliance stated that a radiologist must be present when contrast is given. It was not possible for their own remote radiologists to undertake this and hardly helpful if it meant Trust radiologists doing it.

United Bristol Hospitals Trust and *Royal Cornwall Hospital* reported that some patients had been rejected by Alliance on odd grounds, eg, inadequate clinical information when the department thought it was fine. Additionally, Alliance would not do contrast studies unless the NHS department covered them with a crash team.

Rob Jones Agnes Hunt Hospital, Oswestry reported that images would not be reported by Alliance using subspecialty radiologists; therefore, paediatric and spinal injury patients were excluded from the contract. It therefore seemed likely that the situation would result in clinical priority being ignored in favour of "suitability" within the tight parameters which Alliance provided, ie, routine adults waiting shorter times than routine paediatrics.

Nottingham, Leicester and *Derby* reported many patients were excluded from Alliance imaging. *Nottingham*, in particular, found that very few of its patients fit the bill for Alliance referral. c30% were not being referred for a DGH-type opinion. *Leicester* indicated that it would not agree to use Alliance again. There was a general feeling that Alliance capacity might be better used at the primary/secondary care interface, rather than at the secondary/tertiary.

Guy's and *St Thomas' NHS Foundation Hospital* reported that requests for Alliance scans were rejected by Alliance because the request forms were not signed by a consultant. The forms were not signed because they were electronic requests printed only to send to Alliance. The arrangement will therefore not fit in with NPfIT CRS network.

Skewing the Departments' Workload

Blackpool Victoria Hospital reported that Alliance's presence had markedly altered the case mix of the department resulting in lack of simple examinations (eg, knee MRI) and affected the teaching of five registrars. This was seen as detrimental to the work of the department; all of the simpler procedures had been referred to Alliance.

St George's Hospital also noted that Alliance was only taking the simplest cases, which required the least radiological expertise. *Heatherwood Hospital, Ascot* took a similar view.

Nottingham, Leicester and *Derby* reported cherry-picking by Alliance.

Limited Expertise of Contract Service

Heatherwood Hospital, Ascot expressed serious concern that the radiologists supplied under the Alliance contract were Belgians, 1 to 2 years from accreditation with no specific neuroradiology training.

ORH, Oxford reported that it had been asked to refer patients to Alliance, but had not yet done so, as the department was aware that the scans and reports would be done by staff with no neuroradiological experience. To refer patients under such conditions would be to select a group of patients to be disadvantaged, Oxford stated.

Nottingham, Leicester and *Derby* indicated that 30% of studies undertaken by Alliiance had been sub-optimal for a variety of reasons, and the three centres questioned who should pay for repeat scans. Very few patients on teaching hospital waiting lists were suitable for referral to Alliance as the patients needed IV, or had previous MRIs scans. Likewise, there had been apparent major problems with one machine giving artefacts on fast T2 weighting for IAMs. This occurred to such an extent that Alliance reports began with "Interpretation guarded because of artefacts . . ." It was some time before the machine was withdrawn from service. There were sequence problems. Most centres do a quick T2 of the whole brain as well as IAMs. Alliance wanted to count this as two examinations. At *Nottingham* the experience with Alliance put into

serious question the reporting skills of the Alliance radiologists: normal variants were called abnormal; pseudolesions were called infarcts; pseudolesions were called tumours. Nearly all of *Nottingham's* waiting list contains secondary/tertiary referrals.

Uncosted Aspects of Contract

Blackpool Victoria Hospital noted that any images received from Alliance would need to be loaded onto the department's PACS system, and this would add additional costs of roughly £7,000 to the process.

St Georges Hospital reported a lack of provision for clerical and administrative matters relating to the contract with Alliance, such as writing to all the patients and handling the questions about their Alliance appointments. Additionally, the scanning of images into the PACS system was not being funded.

ORH, Oxford had no costed provision for getting Alliance reports into the local RMS system.

PACS Unavailable

Princess Alexandra Hospital, Harlow did not have PACS and there was concern that reporting radiologists would not have ready access to old images or patient notes.

Patient Identification

United Bristol Hospitals Trust found that the scans from Alliance included the patients' names but no hospital number. Additionally, Alliance appeared to think that the site of their mobile unit at Frenchay Hospital was the site from which all of the patients were referred from. The consequence was that all images were returned to Frenchay Hospital and not to the patients' own hospitals.

Non use of Referring Hospital Protocols

Blackpool Victoria Hospital reported that Alliance's contract required them to follow the referring hospital's protocols, but this was not being done. Alliance followed markedly shortened protocols. This would clearly result in clinical colleagues asking departmental radiologists to do second reading of these scans.

Conflicting Private/Public Partnership

West Brimingham & Sandwell reported that they had an existing private/public partnership provider with a static MRI which was not fully utilised due to insufficient funding. The private partner claimed an exclusive contract and would not allow the Alliance mobile MRI scanner to scan Trust patients on the site.

Milton Keynes General Hospital reported that it had an existing managed-care arrangement with Lister In-Health which included an exclusion clause preventing other MRI providers from competing on the site. The Trust estimated that the set-up costs for an Alliance mobile contract would be c £80K. The department preferred buying extra capacity from its existing private provider instead of taking on a contract with Alliance.

Untapped Existing Spare MRI Capacity

Blackpool Victoria Hospital found it odd that the Government was funding the initiative with Alliance when there were MRI scanners in the country that were not working to expected daily capacity due to under-funding (eg, in Bolton and Blackpool). *National Queen's Square* was yet another example where a scanner existed that could be put to work, but there was no revenue to fund its operation.

Kingston Hospital had expressed concern that they had an existing contract with Loadstone which was capped at 3,000 scans. Capacity could have been increased but this was not allowed. Additional scans had to be bought from Alliance. There was capacity available but no funds to release it.

United Bristol Hospitals Trust, Royal Cornwall Hospital and other hospitals in the region reported spare capacity that could not be released because of lack of revenue funding.

Addenbrooke's Hospital reported that though their contract with Alliance had not yet started, they were not keen to proceed, as they felt that they would have an insufficient number of patients to refer to Alliance to make the contract viable on the site. Initially, the department had offered to use its extra capacity on its own systems and bid for an extra 400 cases to add to its own self-funded waiting list initiative. The DH rejected this proposal. The department's own self-funded initiative, funded through private practice activity, could have expanded to handle an extra 1,000 cases. Additionally, Addenbrooke's had a new scanner installed in 2004, bringing the total to three, but PCTs could not afford to run it to full capacity in the first year and were paying for the Alliance contract instead. Addenbrooke's felt the Alliance contract did not appear to present "value for money".

Warrington District General Hospital in December 2004 reported that they were in the process of setting up this service with Alliance.

The mobile scanner would be coming for two weeks in February 2005, and promised to do 260 scans/week (virtually all Warrington's waiting list).

However, Warrington reported that if they had direct funding themselves for evening and weekend work, they could have done these "in house" for approximately £50 per scan, instead of the £135 or so that Alliance would be charging. Obviously, too, Warrington would have complete control over the protocols and reporting.

They see the arrangement with Alliance as a "typical complete waste of money".

Not Needed, but Forced to Take Alliance Contract

Royal Berkshire and Battle Hospital decided that it did not need extra MRI scans and this seemed to be accepted by the DH and the Trust. But then the department was told to review it provision and that it "should" be doing 40 scans per 1,000 population, and if it wasn't doing so it would have to take some Alliance scans in the "second round". The department does about 20 scans per 1,000 population and has only a 6–8 week waiting list. It is unsure where these additional patients are going to come from. It is unlikely that GPs will refer even a fraction of this number, even if they are given open access. The department finds itself in a ridiculous situation. It is, as yet, unclear if the scans and the contract are going to be imposed on the department.

Errors and Near Misses

1. *Queen's Medical Centre (QMC), Nottingham* reported that out of 30 patients only 22 were scanned and seven of these immediately prompted a request for second opinions (including an opinion of the errors).

The first case in Nottingham requiring a second opinion or resolution of error related to a patient with possible sensory-neural hearing loss. The patient was reported as "showing no enhancing mass" when, in fact, no contrast had been given. A "VR" space was described as a "porencephalic cyst". The flocculus was identified and called a "CPA pseudo-mass possibly contacting the eighth nerve". The referring ENT surgeon did not understand the implication of the report. The department wrote a letter of concern to Alliance, who responded admitting that there were problems with language weakness among its radiology staff, which were being addressed, but denying that any significant interpretative errors had been made by its staff. CVs provided by Alliance were of variable quality with none of the radiologists employed on the Nottingham contract describing significant current neuroradiology commitment.

The second case concerned a patient presenting with possible vascular ischaemia. The report on this patient did not address the clinical question, but excluded MS. Low signal changes on the T2* images were reported as evidence of haemorrhage, but were, in fact, partial volume artefact. The neurologist was concerned that the scan had been interpreted without understanding the details on the request card.

The third case involved a patient with epilepsy. The report described "asymmetry of the hippocamal structures", but overlooked the other features of mesial temporal sclerosis and concluded that there were "no arguments for MTS". The neurologist was unsure what that meant.

The fourth case involved a post-trauma patient. The neurologist could not understand the language of the report. A second reading of the scan at QMC reported evidence of frontal contusions.

The fifth case was a non urgent neurology referral. The neurologist was surprised that his request had been exported and complained about the format of the report. The section for clinical information in the report had been filled in with question marks, no information was provided about the site of the MRI scanner or the sequences used. There was no contact address, other than e-mail and a non-UK telephone number. The report was thought to be straight-forward, but the radiologist was unknown to the neurologist.

The sixth case concerned a patient presenting with a possible brainstem lesion. The report received said that hyperintense lesion in mid brain on T2-W and FLAIR could be compatible with ischaemia and stated that "DWI would give better differentiation with a possible artefact". The lesion described was the decusation of the superior cerebellar peduncle and further imaging with DWI was not warranted.

The seventh case concerned a patient, with cerebellar signs and paraesthesia, possible MS. The report received identified a high signal in the cerebellar peduncles and internal capsules on T2-W and FLAIR imaging. It reported the image as "very suggestive of ALS" (amyotrophic lateral sclerosis). The neurologist felt that the conclusion did not correlate with the clinical features and was inappropriate and QMC agreed.

Following these cases, QMC, Nottingham has become increasingly alarmed by the prospect of the workload it will face processing complaints and requests for second opinion if hundreds of patients go through the Alliance system. From QMC's experience, it is clear that cases scanned by Alliance to date have had scans of variable quality performed by radiographers with limited experience and reported by radiologists remotely. Communication has been poor, return of reports has been delayed, and those that do get through are of mixed quality with some, such as those detailed above, containing significant interpretive

errors. The reports have caused confusion and concern amongst clinicians and addressing this issue has consumed NHS time. At worst the factual errors and misinterpretations described could have hindered patient care and may require further imaging for clarification.

QMC argues that from the perspective of risk management and clinical efficiency, scans reported by Alliance in December 2004 should be reported by QMC departmental radiologists. For this purpose, QMS will be discussing a "structured secondment" with the DoH and Alliance.

2. In the first case at *Blackpool Victoria Hospital* (BVH), a patient was referred to Alliance for MR for ENT malignancy, but was wrongly scanned for cervical spine. The referring clinician contacted the Alliance unit and was given no explanation of how the mistake occurred, but simply told that the patient had been scanned incorrectly.

In a second case, an orthopaedic patient was referred with the clinical question "has there been a labial tear?". When the images were reviewed at a medical meeting, it became apparent that specific protocolling had not been performed to exclude a labial tear. The patient has needed to be rebooked for further imaging.

In a third case also involving orthopaedics, scans done on 2 October have (as of late November) not been reported or returned. The patient had been very upset, having been called to a follow-up clinic with no report available.

In a fourth case, departmental radiologists were asked to review scans of a patient who had been booked in with Alliance for a post contrast Gadolinium series in view of the fact that the patient had collapsed four times with no warning and had suffered an abrupt loss of consciousness with no recollection of events and no signs on examination. The clinical diagnosis was that of a probable epileptiform complex. Alliance's conclusion stated that "solitary high signal focus in periventricular deep white matter left frontal lobe, likely to represent an isolated ischaemic focus in this 59-year old female patient but given history warrants post Gadolinium series to exclude a more significant lesion". Departmental radiologists reviewed the scans. The axial scans were actually performed obliquely making interpretation of symmetry difficult, particularly in the region of the skull base on brain imaging. A probable small area of increased signal within the left frontal lobe mentioned in the report almost certainly represented a minor ischaemic focus. The departmental radiologists did not feel that Gadolinium was required in this examination, but believed strongly that from a medical legal point of view it was necessary to recall the patient for further imaging at the risk of increasing the patient's anxiety.

3. *Worcester Acute NHS Trust* stated that they had experienced at least three incidents involving Alliance Medical. Two reports, with different conclusions, were received for the same examination. They have received reports with such significant typographical errors that the reports were confusing and reports where body parts have been incorrectly labelled.

4. *Derriford Hospital, Plymouth* stated that the first report they got back from Alliance Medical was for a 57-year old male patient with suspected acoustic neuroma. The scan was done on 7 October 2004 but not reported until 9 November. The scan was Ax T2w sequence whole brain and single axial T2 FSE IAMs. The report from Alliance stated, "the 7th–8th cranial nerve complex are well seen bilaterally in posterior fossa with no evidence of acoustic neuroma or CP angle abnormalities" etc.

When the images were presented to a departmental neroradiologist at Derriford Hospital for inspection two weeks later, clear evidence of intracanalicular left schwannoma was seen. The patient was immediately recalled for a contrast study and confirmed.

The departmental neuroradiologist attempted to contact the Allliance radiologist, but was informed that the radiologist in question was on a short-term contract and no longer available for comment.

The Derriford department now seriously questions whether it is not vital that all Alliance scans be double-reported.

5. *St George's Hospital, London.* This Trust reports that while they have not had factual inaccuracies in the reports, they have been "puzzled by some of the terminology" used. This has caused "considerable consternation amongst referring clinicians, at least one of whom is making a formal complaint." For one examination, the department received "two copies of one sequence and no copies of the images in which the abnormalities had been reported." The radiographic and clerical staff have spent hours dealing with queries and disgruntled patients.

20% of the requests, which the department carefully vetted and sent to Alliance were rejected and returned. It appears to the department that " a lot of work has been generated for little apparent gain."

6. *The Middlesex Hospital, London.* This Trusts experience with the private sector has not been good. They find that the private sector is happy to perform CT and MRI for NHS Trusts, but their performance of the scans is invariably poor, as is the quality of reporting. Inevitably the scans must be re-reported for Trust MDT meetings, having had no control over the process or the protocol.

This Trust's greatest need has been with plain film reporting, as it is completely on top of CT, MRI and US. If the Trust's waiting lists are too long it is simply because not enough resource has been made in radiographer staffing. It appears that it has become preferable to outsource any backlog to the private sector.

This department firmly believes that complex radiology, such as CT and MRI, needs to be totally integrated into the clinical process within each Trust or the quality of patient care will suffer.

7. Conclusion

The Royal College is working with the DOH and an audit of five clusters is being implemented. This will compare service delivery from Alliance Medical with NHS service in both the teaching hospital environment and the District General Hospital environment. The results of this audit will inform future management of procured services.

APPENDIX 2

Memorandum by BUPA (MT08)

SUMMARY

BUPA welcomes the Committee's Inquiry; notes the slow uptake of technology such as remote monitoring, and outlines how a telecare network could help meet government health targets. We point out the benefits of such a network and endorse the conclusions of the HITF. We recommend clearer central responsibility for improving telecare within the NHS and suggest how the independent sector could help the NHS to develop new technologies in telecare.

Introduction

1. BUPA is a global health and care organisation with eight million members and over 40,000 employees in 192 countries. We are a provident association, which means that any profit we make is re-invested in better health and care services. BUPA's interests include health insurance, hospitals, nursing and care homes, health assessments, occupational health and recruitment services.

2. BUPA's subsidiary—Outcome Technologies http://www.outcometechnologies.com/aboutus.html is a dedicated outcomes service provider providing software and services for the collection and management of outcomes data, information and knowledge. Outcome Technologies (OT) is closely connected with new medical technology developments within the NHS.

BUPA is submitting this evidence on behalf of OT and other companies within the Group.

The Utilisation of Telemedicine (Including Telecare) and its Future Potential for Improving Services

3. The NHS Improvement Plan said that "evidence indicates that telecare can bring substantial benefits in providing people with greater choice over their care, assisting people to remain in their own homes, reducing inappropriate admissions, facilitating discharge from hospital, and providing advance warning of deterioration in a patient's condition 7.2." However, the Interim Wanless Report[1] also said that "the UK has historically been slow to adopt and diffuse technology, leaving it lagging well behind many other major countries".

4. BUPA is clear that faster adoption of a range of telemedicine technologies could greatly improve health services in the UK. To exploit this potential, a network of related services will be required. NHS and independent sector organisations can contribute to this network, which would consist of:

4.1 *Remote monitoring*

Patients with long-term conditions such as heart disease can be monitored at home using new technology such as implantable defibrillators, or monitoring systems which will record data such as their weight, blood pressure, and blood oxygen.

4.2 *Telephone advice*

Trained nurses and operators can remotely monitor the condition of large numbers of patients and either give advice to them directly, or refer them to other professionals for further treatment.

4.3 *Data analysis*

The data about individual patients' conditions can then be shared, yielding evidence about effective treatments and so providing the basis of valuable research. These findings will help health services to focus in future on improving outcomes, rather than just the process of care.

4.4 *Chronic disease management*

The network of remote monitoring, telephone advice and data analysis will contribute to better chronic disease management. This in turn will help to empower patients, providing them with greater choice and control. It may also reduce the burden on the system by cutting down unnecessary admissions to hospital and facilitating early discharge.

[1] *Securing our Future Health: Taking a Long-Term View*—Interim Report November 2001 HM Treasury.

5. The Department of Health's recent paper *Supporting People with Long-Term Conditions* recommends this approach. It calls for the NHS and social care organisations to identify all the long term conditions patients in each health community, stratify them to match care to their different needs, and "over time, develop a system of identifying prospective very high intensity users of services." The paper highlights the need to use data to drive planning and use technology to establish registers of patients with long term conditions. Specifically, it suggests a need for "more systematic tools and processes for extracting data and enhanced data management skills." These are all areas in which independent sector organisations could work closely with the NHS.

6. Telecare—defined as the network of monitoring, advice and analysis we have outlined—could play a major role in implementing government policy on long term conditions. The major benefits would be:

— Greater choice and empowerment for patients, who may be enabled to become experts in their own care.

— Potential reductions in expensive and unnecessary hospital admissions, which are already stretching hospital budgets.

— Helping to reduce the impact of known trends towards higher levels of long term conditions and towards greater co-morbidity.

— Integrating parts of the health and social care services more closely.

— Better planning and swifter implementation of improved services, based on accurate data and research.

The Recommendations of the Healthcare Industry Task Force

7. BUPA also noted the conclusions of the Healthcare Industry Task Force with interest. The key areas which need to be underlined and turned into effective policy are:

— *Improving device evaluation*

The proposed new Device Evaluation Service is welcome but evaluation should not be restricted to specific devices—it should extend to researching what works best in providing services for people with long term conditions.

— *More support for innovation*

Currently, organisations have to make all the initial investment in innovative IT and service designs themselves. The Department of Health's proposals for long term conditions need seedcorn funding to ensure that innovation takes place.

— *Improving procurement processes through regional focus and significant clinician involvement*

While steps have been made to improve procurement processes, a national approach could yield dividends. The independent hospital industry has benefited from the new national approach to procuring services such as Independent Sector Treatment Centres and so a similar national drive for telecare—possibly headed by the DH Commercial Directorate—would also be welcome.

— *Building R&D capacity*

BUPA and other organisations already have a strong R&D base but further investment in providing evidence of the effectiveness of telecare technology is required.

— *Developing a pilot for Healthcare Technology Co-operatives based on existing centres of excellence within the NHS*

BUPA would be interested in collaborating in a virtual Centre of Excellence to prove the model for long term care outlined above.

The Speed of, and Barriers to, the Introduction of New Technologies

8. BUPA has identified a number of obstacles to the faster uptake of new technology within the NHS. These include the continuing strain on PCT finances; the fact that there is no one agency with clear responsibility for ensuring swift uptake of telecare technology in England, and the need to improve the links between the NHS and independent organisations.

9. While central funding for innovation would be welcome, perhaps the main policy recommendation for the Committee to discuss is locating clear responsibility for improving telecare within the NHS. The NHS Improvement Plan said that the Department "will monitor the development of telecare and will ensure that the benefits are realised in the NHS when cost-effective approaches have been identified." Unpacking this statement, the first step would be for the Department to take a lead on identifying the most cost-effective technologies. Rather than just passively monitoring the development of telecare, a more active encouragement of innovation would be welcome. This requires a dedicated lead within the Department of Health. At national level, this lead should actively facilitate links between industry and SHAs.

THE EFFECTIVENESS AND COST BENEFIT OF NEW TECHNOLOGIES

10. New technologies in telecare need to produce evidence that they are cost-effective and above all that they produce better outcomes for patients. BUPA and its partner organisations can help to produce this outcomes data, analyse it and so demonstrate effectiveness.

11. The process of data analysis we have described is already being used to support research in trials of new drugs. The technology linking patients to the research database already exists and is well proven. It now needs to be applied to service development and greater patient empowerment.

APPENDIX 3

Memorandum by Michael Tremblay (MT 15)

INTRODUCTION

1. New health technologies raise a variety of challenges for health care systems, ranging from identifying what technologies are likely to be most effective, what cost-benefit models will reveal true benefits against true costs, and indeed whether these technologies achieve improvements in patient care and health outcomes.

2. The challenge is "finding the e-health winners". The history of technology should, if nothing, tell us that people have generally underestimated or mis-stated the benefits of technology and been generally poor at technological forecasting. For example:[2]

> *"We have a computer here in Cambridge; there is one in Manchester and one at the National Physical Laboratory. I suppose there ought to be one in Scotland, but that's about all." Douglas Hartree, Physicist, 1951.*
>
> *"The Americans have need of the telephone, but we do not. We have plenty of messenger boys." The Economist: Sir William Preece, chief engineer of Britain's General Post Office, 1876.*
>
> *Satellite TV in Britain "will be a flop." Sunday Times (London) 1 December, 1988. Michael Tracey, head of the Broadcast Research Unit.*

3. My focus is e-health[3] (taken to be the widest possible use of information and telecommunications technologies). I will not comment specifically on technologies themselves, but on ways to enable the development of e-health services.

4. New technologies are often viewed as "disruptive" of existing practices. This suggests that ways are needed to incentivise organisational changes that will lead to the development of needed services. It is noted in the literature that research findings from pilots generally are suboptimally translated into practice because of the failure to understand real-world requirements and work patterns. Clearly, this precludes prescriptive organisational advice as it will incompletely specifiy design—practitioners and patients will ultimately need to decide what works.

5. I would advocate in the first instance a "technology neutral e-health policy". We are unlikely to be able to predict what e-health technologies will be winners without developing mainstream e-health services; pilots will not be sufficient. Adoption will demand a more nuanced understanding of technological innovation in health service delivery. It is worth reflecting on the creative process in this respect. To some extent it is "violent"—creative and innovative thinking challenges the status quo, it energises dissent and drives change. Efforts to tame this are as likely to frustrate the creative individuals involved, as ossify organisational change.

6. We will also need to pay attention to what economic incentives are appropriate to pay for e-health services that patients will value. This will entail thinking about ways to encourage the development of an e-health service industry to achieve this.

7. I would also advocate the innovative development of e-health services be left to the market to achieve, in partnership with the NHS.

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[2] All from http://www.hfac.uh.edu/MediaFutures/.

[3] I will use the term e-health to capture the full spectrum of capabilities from telemedicine (interprofessional), e-health (professional/patient), telecare (self-management).

2. Utilisation of Telemedicine, its Future Potential and Introduction into the NHS

8. The historical record across Europe shows over a decade of funding of e-health pilots, yet there are no economically sustained, patient-oriented, regular e-health services operating of any scale within mainstream health service delivery.[4] Pilots have come and gone, but there is little to show for it from a health service and patient-centred perspective. Though the literature is increasingly full of technical articles on the benefits and rarely on the costs, there are no e-health services of scale, so real benefits to patients remain largely unknown.

9. The facts of this matter and the need to move outside of laboratory have been acknowledged by the European Commission, and the Council of Ministers, to the extent that under the Irish Presidency, the first steps were taken to creating the European e-Health Area, with reporting on e-health roadmaps under the UK presidency, later this year.[5]

10. European Commission funded research by the Institute for Prospective Technological Studies, Spain, has produced a roadmapping of healthcare technologies to the year 2020.[6] Through such research, we are better able to understand what technologies are emergent, or imminent; the weakness, as always, lies in adoption of innovation. This does not help us understand services, though.

11. Greenhalgh and colleagues[7] have recently reported on the various barriers to diffusion of innovations, which has served to widen our appreciation of the complexity and uncertainty of adoption of innovations in healthcare; but also the difficulty in predicting in advance whether any particular innovation will be adopted or successful.

12. A whole-system approach to health care systems development to address both public, private and voluntary sector interests and capabilities is needed. This will be a challenge for the NHS until a true plurality of provision is established as a norm. As the health system becomes more plural, jurisdictional (public/private) considerations will cease to drive policy, instead, the patient point of contact will matter. The vast majority of opportunities to utilise e-health technologies lie outside formal institutional settings, anyway, within the home, the workplace and in the schools, reflecting the opportunity to deliver location-independent and real-time health services. A priority on the more narrowly defined telemedicine technologies limits our understanding of the wider e-health potential, by focusing only on professional and institutional applications. It would be far more beneficial to all patients that e-health innovation encompass any setting in which any sort of health or social care is provided and where such technologies can offer benefits. Patients will not understand or appreciate jurisdictional boundaries which create barriers to their continuum of care, or which artificially demarcate where they can and cannot benefit from such services.

13. In research on how accurate forecast use of the telephone would be, between 1876 and 1940, it was found that the individuals responsible for the initial development of the telephone were more accurate in forecasting its future use than outsiders. Pool, *et al*.[8] concluded that pioneers had "a vision of how the inventions could be used, and they controlled the business that implemented those visions". David Donnelly, a specialist in social and cultural impact of technology, has observed that,[9] "[we may] surmise that because the early telephone pioneers were both inventors and capitalists, they understood both the technical components as well as the economic and market conditions."

14. Donnelly also notes a preponderance on the reliance on the features of the technology to predict likely use, rather than on market, social and other forces. We can conclude, as did Pool and Donnelly, that in successful technological forecasts and assessments, "market and technical analyses must be brought to bear simultaneously. Alone either of them fails; together they can produce some very prescient forecasts". But technology assessments and forecasts rarely make use of market analysis. Clearly, we need both a more nuanced understanding of how to assess future potential of new health technologies, but also that that understanding cannot be separated from either those who best understand the potential of new technologies, and the market conditions that make a fertile bed for its use by people.[10]

15. How can the benefits be achieved? The best policy objectives to consider would be those that will incentivise the development and introduction of e-health services (not technologies) into the UK, whether as a service directly to the NHS, purchased by PCTs, or directly to patients. A simple and incentivizing

[4] Commission of the European Communities, e-health, making healthcare better for European citizens: an action plan for a European e-Health Area. Com (2004)356. Page 12.

[5] Commission of the European Communities, e-health, making healthcare better for European citizens: an action plan for a European e-Health Area. Com (2004)356.

[6] Braun, A., Boden, M., Zappacosta, M., (eds), Healthcare Technologies Roadmap, The Effective Delivery of Healthcare in the Context of an Ageing Society, Working Document, 2003. Document available at http://esto.jrc.es/docs/HealthcareTechnologiesRoadmapping.pdf.

[7] Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., Kriakidou, O., Diffusion of Innovations in Service Organisations: Systematic Review and Recommendations, *The Milbank Quarterly*, 82(4-2004)581-629. This team has published additional material on this subject relating to this Department of Health commissioned work.

[8] Pool, I., *et. al.* (1977). Forecasting and hindsight: The case of the telephone. In I. Pool (Ed.) The social impact of the telephone (pp. 127-159). Cambridge, MA: The MIT Press.

[9] http://www.hfac.uh.edu/MediaFutures/assessment.html, referenced 12 January 2005.

[10] In my work on the social implications of electronic prescribing for the Department of Health, a variety of factors were identified to do with the impact the technology itself would have on patterns of behaviour by clinicians, patients and pharmacists, which were implied by the technology. The Social Implications of Electronic Prescribing, available at www.policyinsider.com.

strategy would be to develop a fee schedule which would price e-health services. Leading countries in e-health such as Canada, USA, Australia and Norway have established reimbursement fee schedules to pay for e-health services.

16. A fee schedule would signal not only that there was interest in e-health service provision by the NHS, but encourage service delivery organisations to broaden their health service offerings to include e-health capabilities. Purchasing organisations could then frame contracts with e-health providers to encourage and offer appropriate e-health services. It would be important to avoid pricing e-health in such a way to make it uncompetitive against traditional (non-e-health) service delivery, and thus discourage the uptake of e-health services.

17. The historical record on technological innovation would suggest that governments would not be advised to seek to establish a monopoly position on the introduction or access to novel e-health technologies or services. It would be best that public policy continue to encourage the emergence of a plurality of providers of e-health services, and thus encourage a widening spectrum of innovation and patient responsiveness across public, private and voluntary organisations, working together in the public interest. Having said that, well-developed policy will be needed, especially to ensure compatibility with European Union developments, in the context of cross-border care, and development of the European e-Health Area. This is an issue that is of course applicable to the UK's devolved health administrations as well.

18. Nevertheless, it will also be important to create opportunities for NHS bodies and staff to organise themselves with suitable support, to create their own e-health services. This would create a powerful signal to people in the NHS that they can pursue innovative service development in an entrepreneurial manner without necessarily sacrificing their commitment to a public service ethos or values. Provisions to enable this exist within existing legislation and should be explored for this potential. Indeed, it may be appropriate to consider establishing an "NHS Entrepreneurs Fund", to partner with appropriate private capital, to fund innovation more generally, but importantly, it could fund the startup of new e-health services. I would, however, stress that the focus should be on service development, not just development or procurement of technologies or devices; in this respect, the HITF[11] report does not go far enough in addressing the development of services.

19. I encourage the Committee to be imaginative in its appreciation of the potential benefits that e-health services can bring to patients by thinking beyond the technology.

3. Background on Michael Tremblay PhD

Dr Tremblay runs Tremblay Consulting, a specialist health policy consultancy established in 1997. Dr Tremblay has undertaken policy research work for the Department of Health on the social implications of electronic prescribing, the development of digital interaction television in health, legal and organisational aspects of e-health and is currently conducting policy research on the use of predictive modelling in health care. He has been an expert advisor on e-health to the work of the Council of Europe, based in Strasbourg, on patient use of new media such as the internet to access health information. He has also spoken at conferences on the implications of wider use of e-health technologies on health systems and citizen empowerment.

APPENDIX 4

Memorandum by Smith & Nephew (MT 18)

Introduction

Smith & Nephew welcomes the Select Committee's inquiry and are pleased to have the opportunity to participate in this very important debate.

Smith & Nephew—the company

1. Smith & Nephew plc is a global medical technology business, specialising in Orthopaedics, Endoscopy and Advanced Wound Management products. The Company ranks as the global leader in arthroscopy, is one of the world's leaders in advanced wound management and is one of the fastest growing orthopaedics companies in the world.

2. Smith & Nephew has more than 1,700 employees in the UK and a total of 8,000 worldwide. The Company operates in 32 countries around the globe, generating sales of £100 million in the UK and £1.2 billion worldwide. Smith & Nephew is one of the few medical device companies in the world with its group research focus firmly based in and led from the UK.

[11] Health Care Industries Taskforce, 2004.

3. The Research Centre spearheads the innovation stream for Smith & Nephew. The multidisciplinary team is responsible for the development of radical new healthcare products in all of our three of our business areas. Innovations are driven by discoveries in new materials, biological therapies, treatment modalities and tissue engineering. In 2003 the Company invested a total of £67 million in research and development.

4. Smith & Nephew is dedicated to helping improve people's lives through the development of innovative, cost-effective products and techniques that deliver significant advantages to clinicians and patients. Radical new treatment and surgical techniques are being developed that will deliver new products up to 15 years from now.

5. Smith & Nephew is committed to providing education programmes to surgeons, doctors and nurses to help improve treatments and outcomes. The Company trained 200,000 nurses worldwide in 2004. The Smith & Nephew Foundation is the single largest supporter of nursing research in the UK, providing funding of £300,000 per year.

6. The Company's solutions are driven by health economic benefits. The broader benefits of returning people to their working lives should not be underestimated. Healthcare economic considerations are integrated into the product development process. This ensures that the benefits of the Company's new and existing products not only seek to improve patient outcomes and provide better treatment and procedures for both clinician and patient, but also contribute to more cost effective solutions for healthcare services.

7. Each one of Smith & Nephew's three businesses helps meet the ever-increasing healthcare demands fuelled by the aging population in developed countries, increased incidence of obesity and diabetes, higher numbers of sports and other activity related injuries, and patients' high expectations of quality and scope of treatment, through such benefits as:

— faster and improved healing to reduce hospital stays and rehabilitation time;

— reduced number of products required for effective treatment, ie fewer dressing changes for chronic wounds; and

— less clinician time through improved procedures and treatment regimes.

8. Smith & Nephew help people regain their lives by repairing and healing the human body.

Company representatives

9. The following Smith & Nephew directors are available to appear before the Select Committee to discuss any of the enclosed recommendations in more detail.

Sir Christopher O'Donnell
Chief Executive

10. A chartered mechanical engineer; graduate of Imperial College and London Business School; Sir Christopher has 25 years experience in medical engineering and devices with UK/US companies. Joined Smith & Nephew in February 1988 as Managing Director of Smith & Nephew's Medical Division, appointed main board Director in 1992, and Chief Executive in July 1997. Sir Christopher is a non-executive director of BOC Group and was awarded a knighthood in the Queen's Birthday Honours List in June 2003 for services to the medical devices industry.

Liz Hewitt
Group Director of Corporate Affairs

11. Liz Hewitt joined Smith & Nephew as Group Director of Corporate Affairs in May 2004. Formerly Director of Corporate Affairs for 3i Group, Liz is a Chartered Accountant with wide experience of industry, having worked as a venture capitalist, and has Board experience in the public sector and the private sector including risk and audit committees, corporate social responsibility, and corporate governance. Liz also has experience as international corporate communications director for two FTSE100 companies with businesses in the UK, USA, continental Europe and Japan.

John Posnett
Global Head of Health Economics

12. John Posnett joined Smith & Nephew in February 2000. He is a Professor of health economics at the University of York. Before joining the Company, John spent six years as Director of a specialist health economics consultancy within the University. During this time, he worked with individual trusts and health authorities, the NHS Executive and the Department of Health, and with a number of pharmaceutical and healthcare companies. John has advised health ministries in Mexico and Central America on health sector reform. For five years he was Director of the postgraduate programme in health economics at the University of York.

THE UTILISATION OF TELEMEDICINE

13. Smith & Nephew supports and understands the role that telemedicine has to play in providing effective healthcare, even though the vast majority of their products require professional application by trained clinicians rather than indirect contact with the patient.

14. The Company recognises the increasing demand for consumer information and sponsors various consumer led educational initiatives in our key product areas. However, the Company's main focus is to ensure that healthcare professionals are aware of and understand the range of products available to them and the contribution to quality of healthcare that these can bring now and in the future.

THE RECOMMENDATIONS OF THE HEALTHCARE INDUSTRIES TASK FORCE

15. The Healthcare Industries Task Force report "Better health through partnership: a programme for action" is both timely and necessary.

16. The Company welcomes and endorses the key outputs of the report. In response to the New Enquiry (Press Notice of 7 December 2004: "The Use of New Medical Technologies within the NHS") Smith & Nephew would like to make the following observations on some of the report's key outputs.

Device evaluation—key output 1

17. Smith & Nephew are aware of the importance of accurate, objective device evaluation if the resources of the NHS are to be used optimally.

18. The repositioning of the Device Evaluation Service (DES) offers a good opportunity for the Government to foster an effective collaborative approach with healthcare industry businesses.

19. Some surgical techniques, especially minimally invasive or keyhole surgery, deliver financial benefits at a different location within a hospital trust, and the benefits in terms of health economics encompass more than the simple cost of the surgery.

20. This is particularly true of endoscopic techniques, which in many cases have replaced traditional open surgery. These new technologically advanced and enabling medical devices may add initial costs within the operating theatre department, but they help to reduce trauma to the body and pain to the patient, reduce hospital stays and potentially provide better outcomes for surgeons. In particular, endoscopic surgery results in two or three stitches at the end of a procedure as opposed to a substantially larger wound from open surgery.

21. From a continuum of care perspective, the entire patient episode may prove less expensive to a Trust and the NHS, despite potentially higher initial investment costs for surgical instrumentation.

22. National guideline cost data for the NHS could be published to make this information more freely available to industry.

23. This data has the potential to increase the speed and reduce the complexity of producing healthcare economic outcome studies for new technologies by medical devices manufacturers. This information would include such costs as average patient bed day costs by procedure group and would provide a platform from which overall cost savings to the NHS could be demonstrated.

24. It is unclear how strong the link is between evaluation and procurement at a clinical level within the NHS and the wider potential benefits to the UK economy (such as return to work times). Endoscopic techniques for example, may offer return to work times that are significantly less than those for open surgery.

25. A clearer and faster pathway, through a new or established assessment body, would be helpful in assessment of economic benefits that may fall outside direct costs to the NHS.

Innovation—key output 2

26. Smith & Nephew welcomes the work of the Innovation Hubs, especially their pragmatic approach to intellectual property management.

27. Legislative changes, such as the implementation of the In Vitro Diagnostics Directive from 6 December 2003, have altered the requirements for the manufacture of some devices that were previously part of the so-called "home-brew" development of diagnostics for clinical use.

28. This emphasis on conformity to pan-European manufacturing standards places a new challenge for device innovation from within the NHS and it will be important to ensure that translational arrangements, to move concepts into small-volume manufacture, are put in place.

Procurement processes—key output 3

29. The Company's main observation regarding procurement is that the emphasis on device pricing should not obscure the true cost of a choice of therapy. This theme is explored fully under the section "The Effectiveness and Cost Benefit of New Technologies" detailed below in this document.

30. Smith & Nephew recommends a more effective dialogue be set up between organisations wishing to develop and market medical devices and NICE. The aim of this dialogue should be to ensure the data package demonstrates product safety and efficacy to NICE standards, while remaining as concise as possible so as not to add to the upstream development costs of the product.

31. Smith & Nephew would also like to see a more effective link between the NICE approval on device evaluation and actual product take-up in clinics. At present, the Company's experience leads us to conclude that while a negative report from NICE can be most effective in preventing device usage by a surgeon, the reverse is not true. A positive report may fail to achieve a change in favour of new, more effective and economical therapies.

UK as the regulatory lead in the EU and internationally—key output 6

32. Regulatory categorisation of medical devices can prove to be an impediment to innovation. This is apparent in two ways: in tissue engineering and the categorisation of new technologies as "devices" or "medicines".

33. For tissue engineering, the absence of an EU regulatory framework is not necessarily a road block for access to the UK market, although the situation is difficult. With uncertainty regarding the categorisation of new products ("device" versus "medicine") a piecemeal approach to the introduction of newly engineered tissue products becomes necessary.

34. The resultant risk regarding uncertainty about the size and nature of the submission for a product license, therefore, is not an attractive one for businesses. Similarly, the lack of a formal regulatory framework means that product reimbursement is very difficult. Taken together these features will continue to impede the introduction of advanced tissue products.

35. The industry needs the establishment of a firm definition and class of medical product to encompass this technology. The expectations relating to product license data packages will need to be specified according to the product type. For example, the replacement of a metabolic organ (eg pancreatic function) would require a different level of demonstration of safety, quality and efficacy from that of a replacement of structural connective tissue.

Training and education—key output 9

36. Smith & Nephew welcomes the proposed enhancement of training and education. Without adequate awareness of the principles upon which new device technologies are based, it is unlikely that full benefits will be gained from their introduction. With regard to this issue it is worth remembering that nurses, including Tissue Viability Nurses, usually have to take holiday and pay for attendance at wound conferences. This practice must surely limit the sharing of information and training.

THE SPEED OF, AND BARRIERS TO, THE INTRODUCTION OF NEW TECHNOLOGIES

37. The effects of the Human Tissue Bill continue to impede the progress of the Company's research and development programmes.

38. There has been widespread criticism of the Bill amongst researchers and commercial organisations reliant upon the supply of human tissue for their research and development activities.

39. In April 2003, the Department of Health issued guidelines on the procurement and importation of human tissue. Smith & Nephew has experienced frustration and uncertainty as a result of the lack of guideline clarity, resulting in delayed projects and considerable research time spent sourcing tissue.

40. In particular, the lack of clarity over the circumstances under which patient consent can legitimately be obtained and the resultant anxiety over interpretation of the Bill, has resulted in the supply of tissue from clinicians and the NHS drying up.

41. Within the UK, the Peterborough Tissue Bank is now our only source. The Company recognises the importance of avoiding the tragedy of Alder Hay and the Bristol Royal Infirmary, but believes the wide-ranging influence of the Bill extends beyond the understandable concern over, for example, the removal of whole body organs, into areas such as the relatively uncontentious subject of the use of tissue discards from surgery for research purposes.

42. Smith & Nephew recommends that NHS Trusts develop a strategy and process to encourage tissue donation and a clear distinction be made between living and dead donors. More stringent regulations should be reserved for any request involving the removal of cadaveric tissue.

43. Anonymised discard tissue (ie tissue removed from a patient during routine, non-life threatening surgery) should be treated as cleared for any research purpose under a general consent. It will be important to align UK regulations with both US and European positions to avoid penalising research in the UK.

44. The adoption of a potentially beneficial new medical technology can be slow moving due to NICE's Interventional Procedure or Technology Appraisals evidence requirements. These include unspecified patient volumes, published clinical studies, and patient outcome data.

45. Some outcome studies may require many years to build a sufficient study population to show efficacy under the current systems, causing a time-lag whereby adoption may be one or two generations behind the current level of technology.

46. Clearer guidelines and consideration should be given with respect to the level of published clinical studies and patient outcome data that is achievable in relation to the area of use of particular medical devices.

47. These guidelines could consider what benchmarks of patient outcome volume would be realistic within a set timeframe of evaluation (for example, 18 months from the availability of a new technology). This would be helpful in distinguishing between pharmaceutical interventions, high volume medical devices (such as hip replacements), and lower volume devices and technologies.

The Effectiveness and Cost Benefit of New Technologies

48. The report of the Healthcare Industries Task Force (HITF) highlights the need to promote the timely adoption of worthwhile new technologies into the NHS as an enabler for improved performance. Safe, cost-effective and innovative interventions can provide benefit to patients and improve efficiency in the NHS.

49. Cost-effective new technologies are often more expensive, although because of superior performance, the total cost of treatment is lower overall. Increasing emphasis in the NHS on cost containment, as opposed to long-term value for money, is one of the key barriers to the adoption of new technology. Product cost is usually a very small part of the total cost of treating a patient, and focusing on minimising the costs of procurement, irrespective of product performance, may simply lead to inefficiency and to higher costs overall.

50. This section highlights the vital distinction between product price and the true cost of treating a patient, and illustrates some of the ways in which medical devices can enhance efficiency in the healthcare sector.

Surgical debridement of wounds

51. It is generally agreed that wound debridement, (the cleaning and preparation of the bed of the wound), helps to create a wound environment that is more conducive to healing. Surgical debridement is quick and effective: sharp instruments such as scalpel, scissors or curette are used to remove devitalised tissue and bacterial contamination from the wound. Surgical debridement is normally carried out in an operating theatre under general anaesthetic.

52. A new Smith & Nephew technology (Versajet) has recently been approved in the UK and US for the surgical debridement of wounds. It uses a fluid jet under high pressure (up to 15,000 pounds per square inch) to cut and evacuate necrotic tissue. The new technology is safer and more selective than conventional instruments and offers greater precision. Compared with a scalpel, the fluid jet more completely removes devitalised tissue and at the same time spares healthy tissue. The benefit to the patient is that the wound is expected to close more quickly and the amount of scarring is reduced.

53. The price of the new instrument is significantly higher than the price of conventional instruments, as the price of a disposable Versajet handpiece is nearly 40 times the price of a scalpel blade. However, the greater precision of the instrument means that it is possible to prepare a wound for closure with fewer debridement procedures. In a recent US evaluation, the median number of surgical debridements required was reduced from two per wound with conventional instruments to one with Versajet.

54. In the US evaluation, the total cost of debridement was $2,100 per patient with Versajet compared with $2,800 with conventional instruments. Despite the fact that the new technology costs more initially, because it saves operating theatre, nurse and surgeon time, the overall cost of treatment was reduced by approximately $700 per patient.

55. Not all of this saving will be in cash, although there will be some cash saving from reduced expenditure on saline, pulse lavage and surgical instruments. Most of the saving will be in the form of nursing, surgeon and operating theatre time. All of these resources have alternative uses, and releasing nursing and surgeon time enables the NHS to treat more patients with the same capacity.

Multi-layer high compression therapy for venous leg ulcers

56. A venous leg ulcer is a chronic wound which, if not treated appropriately, can endure for years. The wound can be painful and will often restrict physical and social mobility significantly. In the UK, patients are typically treated by a community nurse at home or in a specialist clinic. There are more than 200,000 new venous leg ulcers annually in the UK.

57. It is well accepted that treatment with multi-layer high compression improves healing compared with no compression or low compression bandaging.(1) The superior performance of high compression compared with traditional dressings has two positive impacts on efficiency:

— The use of high compression, when appropriate, leads to shorter healing times and lower treatment costs overall.

— Due to the greater durability of high compression bandages compared with traditional products, wear time is longer and costs are reduced by the lower frequency of dressing changes.

58. These benefits have been demonstrated in a number of studies. One study(2) compared clinical outcomes for patients with a venous leg ulcer treated with multi-layer high compression to the usual care provided by community nurses in a typical health authority in England. Usual care involved many different treatments, including traditional non-compression dressings. In this study, after 24 weeks of treatment, 40% more patients were healed with high compression than with usual care. In the high compression group, nurses visited on average just over once a week to change dressings. With the cheaper products in the usual care regime, nurses visited more than twice a week.

59. Modern high compression bandages (such as Profore) may cost up to four times more than traditional dressings. Despite this higher initial cost, the cost per week of treatment was 45% lower in the high compression group due to the lower frequency of dressing changes. Total cost per patient was 50% lower in the high compression group because of the lower cost per week and the shorter healing time.

60. This example illustrates the importance of the distinction between product price and the true cost of patient care. Minimising procurement costs by buying the cheapest product leads in this case to a significant negative impact on patients and doubles the overall cost of treatment. Most of this additional cost is in the form of community nursing time.

61. This example also illustrates the importance of reimbursement through the Drug Tariff for products used in the community. Without reimbursement, patients would be forced to buy their own dressings. There is no guarantee that patients would appreciate the impact on nursing time of buying inefficient therapies simply on the basis of price. It is essential for the reimbursement mechanism to recognise the additional value associated with more advanced therapies.

Primary total hip replacement

62. Implantable medical devices, such as hip replacements, are designed to function for the natural life of the patient. Device failure can be catastrophic. At best, failure involves pain and loss of function leading to the need for revision surgery. At worst, there is a higher risk of death associated with revision, particularly in elderly patients.

63. The cost-effectiveness of implantable devices is heavily dependent on the expected life of the device. One of the key impacts of new technology in this area is to extend expected life and to reduce the probability of failure. As with most new technology, the advanced materials and design embodied in new hip prostheses may make them more expensive than existing products.

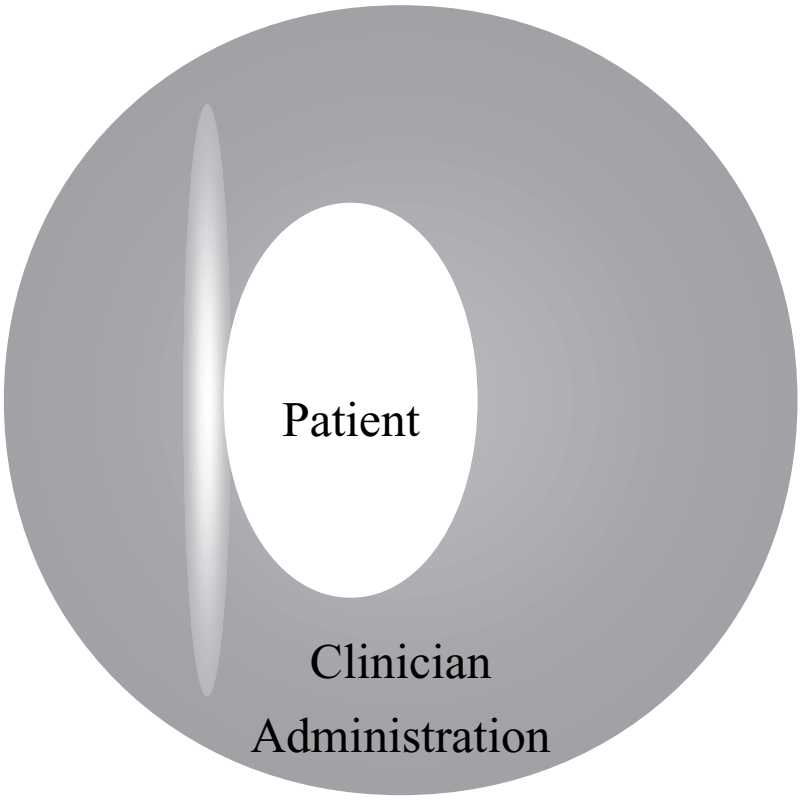
64. In April 2000, NICE undertook a review of prostheses for primary total hip replacement. The resulting guidance(3) noted that "THR [total hip replacement] is considered to be one of the most effective orthopaedic procedures at the present time" (para 2.1). The guidance also suggested that the expected rate of revision at 10 years is a key parameter in the choice of competing prostheses. In our submission to NICE, we demonstrated the long-term cost savings associated with the Spectron (all poly) hip compared with lower priced alternatives. The long-term cost advantage of the Spectron followed from the lower probability of revision associated with its more advanced design.

65. At the time of our submission to NICE, Spectron was approximately 50% more expensive than the hip which was most commonly used in the NHS, known as the Charnley hip. However, based on data from the Swedish National Hip Arthroplasty Register, the mean nine-year revision rate for Charnley hips was 5.3%. The comparable rate for Spectron was 0.8%. Allowing for the likelihood of a patient requiring revision surgery because of failure of the prosthesis, the expected lifetime cost per patient using the Charnley hip was £4,400 compared with £3,800 using Spectron.

66. Although the expected cost per patient is lower, using the Spectron hip would increase annual costs of THR in the initial years because the prosthesis is more expensive. However, because the cost of the prosthesis is a relatively small part of the total cost of the procedure, this increase amounts to a maximum of 5.2%. Within nine years, total annual costs to the NHS would be lower because of the lower number of revision operations.

SMITH & NEPHEW DEVELOPMENT PHILOSOPHY

— Extend the life of the implant.
— Easy to use implants/instruments.
— Enable less-invasive procedures.
— Restore patient function: "Helping people regain their lives by repairing and healing the human body."



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APPENDIX 5

Memorandum by British Geriatrics Society (MT 20)

THE BRITISH GERIATRICS SOCIETY

The British Geriatrics Society (BGS) is the only professional association, in the United Kingdom, for doctors practising geriatric medicine. The 2,200 members worldwide are consultants in geriatric medicine, the psychiatry of old age, public health medicine, general practitioners, and scientists engaged in the research of age-related disease.

BGS work is based on the belief that older people have contributed to society in their earlier lives and continue to do so. Many older people form a vulnerable section of the population whose voice is frequently not heard, and whose views are frequently presented by well meaning members of society who do not recognise that what they are presenting is their interpretation of what the they believe are the desires and beliefs of older people, and not the actual views of the older people themselves.

1. Geriatric Medicine

Geriatric Medicine (Geriatrics) "is that branch of general medicine concerned with the clinical, preventive, remedial and social aspects of illness in older people. Their high morbidity rates, different patterns of disease presentation, slower response to treatment and requirements for social support call for special medical skills". The purpose is to restore an ill and disabled person to a level of maximum ability and wherever possible return the person to an independent life at home.

The Society welcomes the opportunity to contribute to this debate and would comment as follows:

Introduction

Technology broadly defined, includes processes, systems, models and simulations, hardware, and software. Literally, "the study of methods"; equally, the study of skills, new technologies include not only new electronic, assistive and adaptive devices but also methods of implementation of specific types of service configuration or techniques.

Current interest is primarily in new hard technology such as developments in assistive devices, electronic alarms, tele-medicine etc. However, the importance of recognising soft technologies is critically important to understanding the contributions they can make. Failure to recognise a soft technology as a technology can lead to failures in development and implementation and a failure to realise its benefits.

Hard technologies used in the medical care of older people includes new electronic, assistive and adaptive devices (also called), such as electronic alarms, tele-medicine etc.

Soft technologies include methods of implementation of specific types of service and service delivery models.

Factors related to the introduction of new technologies for the benefit of older people are frequently overlooked and on occasion:

- Older people are specifically excluded from new technological and pharmaceutical developments on the basis of cost or mistaken belief that they would not benefit.
- New technologies are introduced with insufficient consideration of matters particular to older people.
- New technologies are applied with insufficiently rigorous evaluation of appropriateness and cost effectiveness prior to and after implementation.

The UK is seen in Europe as a leader in the care of older people. Addressing the importance of soft technologies in particular will make a significant contribution to recognising that these are technologies and that the associated disciplines of specification, implementation and evaluation that this implies are critically important.

The submission will address both types of technologies.

2. Speed of and Barriers to the Introduction of New Technologies in the NHS—the Case of Soft Technologies in the Care of Older People

Provision of health and social care services for older people is a rapidly growing pressure on resources. New models of service provision such as intermediate care and chronic disease management services require underlying sound needs assessment in order to be effective, to be seen to be effective and to generate the evidence required for informed policy, planning and performance management. For the care of older people their development and implementation raises important issues.

Assessment

2.1.1 Comprehensive Geriatric Assessment (CGA) is a term which has become associated with a set of approaches to service provision in the care of older people. The models can be used in a variety of settings, including hospital inpatients(1)(2), ambulatory care and nursing home care.(3–5) The majority of the evaluative literature on the topic comes from the USA, although the approaches are recognisably derived from the multidisciplinary models of assessment and rehabilitation first described in the UK.(6–8) In CGA programmes the multidisciplinary, multidimensional nature of the assessment of health, rehabilitation and social care needs is formalised, often using standardised assessment instruments. The results of these formal assessments are then either used to inform or prompt treatment and management recommendations which may be carried out in dedicated inpatient units, provided as recommendations to the referring physician or team, or delivered in the patient's home or other ambulatory care setting such as the day hospital or outpatient clinic.

2.1.2 Assessment tools or instruments used as a component of CGA are the technology which is the foundation of care of older people and people with chronic and disabling diseases. Based on validated measurement scales, assessment tools can record very accurate information about the health status and the care needs of an older person, irrespective of who uses them for assessment.

2.1.3 New developments in assessment technology have created assessment tools that generate information that can also be used to feed into a more general evaluation of effectiveness and quality of treatment/service provision, feed into cost analysis, can be used for care planning and for policy making purposes. The characteristics and benefits of these new assessment tools are frequently not recognised.

2.1.4 The National Service Framework for Older People introduced the concept of the Single Assessment Process (SAP) as part of standard 2, person centred care. The goal was to introduce the uniform use of evidence-based, reliable and valid assessment instruments across all care settings with the aim of improving care and enabling transfer of information between settings without duplication of assessment effort: to introduce new assessment technology across all settings. A number of assessment tools were accredited by the Department of Health as suitable for "off the shelf" use in the SAP.(9)

2.1.5 The development of the SAP in England has in the view of the Society failed to meet the expectations of the NSF for Older People. Valid reliable assessment instruments have been overlooked in many localities. Locally developed assessment processes and procedures have been introduced which are not based on reliable and tested scales and items, are often superficial and can lead to inaccuracies, bias and errors.

Speed of and barriers to the introduction of the Single Assessment Process

2.1.6 Assessment is the basis of care for older people but there is very little formal training in the characteristics of assessment tools and the role of assessment although there are many textbooks on assessment that could be used as a component of training programmes for care professionals. As a result senior managers, service directors and care professionals do not understand the characteristics of high quality assessment that characterise the technology.

2.1.7 The consequence has been that the introduction of the SAP has tended to be led by care professionals who have little knowledge of the components of good assessment—validity, reliability, comparability and the potential uses of aggregated assessment data. Delays in introduction of the SAP have been caused by protracted discussions and meetings that have often resulted in the development and/or use of locally developed or older assessment tools that do not include the benefits of the new assessment technologies.

2.1.8 Significant problems that are now emerging as a consequence include no utility of assessment data for performance monitoring and incompatibility of assessment information between adjacent service providers.

The effectiveness and cost benefits of new assessment technology

2.1.9 New assessment tools provide high quality information for many purposes beyond recording the immediate needs of the person being assessed. These include:

- Care planning protocols to support care planning for needs, risks and potential to benefit such as rehabilitation potential.
- Indicators of quality of care that can be used for service monitoring and benchmarking.
- Indicators of outcome of care that can be used for service monitoring and benchmarking.
- The development of eligibility criteria for specific services and benefits.
- Resource use case mix measures that can be used for purposes of re-imbursement and evaluation of cost-effectiveness.
- Supporting education and training of care professionals.
- Immediate incorporation into the National Programme for Information Technology.

2.1.10 The report of the Health Ombudsman on funding for long term care published on 16 December 2004(10) based on 4,000 complaints relating to assessment for eligibility for NHS funded long term care, identifies the lack of links between eligibility criteria for NHS long term care and the SAP. Assessment tools that would meet these requirements exist and have been accredited by the DoH but are not widely implemented.

2.1.11 There are also many complaints about assessment for the re-imbursement of the Registered Nurse Contribution to Care (RNCC) of people admitted to long term residential and nursing home care. These arise as a result of subjective decisions that are not based on transparent reliable assessment information. Assessment tools that would overcome these problems exist and have been accredited by the DoH but are not widely implemented.

2.1.12 The NHS Information Authority is currently developing version 4 HRGs that will be the basis of Payment by Results. This includes a programme that has demonstrated that components of accredited assessment tools will improve the performance of HRG's in care of people with Chronic Disabling Disease within acute hospital care and support the extension of payment by results to the community and long term care settings.

2.1.13 Other countries have addressed assessment technology more systematically. The Minimum Dataset Resident Assessment Instrument was introduced into all US Nursing Homes in the early 1990s. An equivalent assessment instrument for community care was developed in the mid 1990s. There has been a rapid spread and introduction of this second generation of sophisticated research based assessments into many countries around the world (www.interrai.org).

2.1.14 In Canada, seven provinces and territories require or recommend the interrai assessment instruments for community and chronic care settings for older people. The data generated from the assessments are used not only to plan the care for individuals, but also for monitoring costs, outcomes and quality of care. Chronic care hospitals in Ontario are re-imbursed on the basis of report cards that include data from the assessments. A decision to invest $600 Canadian into rehabilitation and improved mental health input long term care settings was based on evidence from assessment data in Canada compared with other countries where this approach to assessment had been introduced.

2.1.15 It is the view of the Society that delays and problems with the development of the Single Assessment Process mitigates against equity of access and provision of care for older people, leads to inefficient unfair use of resources and discriminates against the most vulnerable members of the population.

2.1.16 The technology of assessment has been thoroughly developed to very high standards by several groups of researchers and practitioners. It is essential that this technology is recognised as a technology in the same way that surgical implants, diagnostic equipment and pharmaceuticals are recognised. Evidence from other countries where this has been recognised and the technology systematically implemented shows that the benefits for individuals, care providers and policy makers is considerable.

Intermediate care

2.1.17 Intermediate Care was introduced in the NHS plan(11) with the specific requirements that it should be:

- Targeted at people who would otherwise face unnecessarily prolonged hospital stays or inappropriate admission to acute in-patient care, long term residential care, or continuing NHS in-patient care.
- Provided on the basis of a comprehensive assessment, resulting in a structured individual care plan that involves active therapy, treatment or opportunity for recovery.
- Have a planned outcome of maximising independence and typically enabling patient/users to resume living at home.
- Time-limited, normally no longer than six weeks and frequently as little as one to two weeks or less.
- Involve cross-professional working, with a single assessment framework, single professional records and shared protocols.

2.1.18 Intermediate Care was introduced with high expectations, specific objectives and an investment of £900 million. There have been concerns with respect to the likelihood of achieving the objectives and the presence of appropriate structures and techniques for on ongoing evaluation.(12)

2.1.19 The British Geriatrics Society has published a report on Intermediate Care in 2003.(13)

2.1.20 There are two major Department of Health funded evaluations of Intermediate Care nearing completion.

Speed of and barriers to the introduction, and cost effectiveness of Intermediate Care

2.1.21 The intermediate care initiative was received with enthusiasm. The DoH published a report on progress with intermediate care that recognised progress but also identified the importance of a limited evidence base and confusion about configuration, delivery and monitoring of new intermediate care services. This report also addressed the need for mental health and housing to be included in the development of intermediate care.(14)

2.1.22 There have also been concerns that development of the evidence base for effectiveness is complex and requires high quality research using research techniques that are appropriate for the complex requirements of developing the evidence base.(12)

2.1.23 It is our view that with evolution of Intermediate Care, mechanisms for on-going evaluation and development are required. Linkage to implementation of the technology of the Single Assessment Process(15) linked to performance measures are an essential component of ensuring its targeting, effectiveness and value for money.

Chronic disease management

2.1.24 The Evercare programme for chronic disease management has been developed in the UK from a model initiated in the USA by the Evercare Corporation where advanced primary care nurses proactively manage a caseload of very vulnerable adults with primary care physicians. Specific goals are to manage drug therapy, identify any deterioration in physical condition, rapidly diagnose and treat the cause of deterioration with the specific aim of preventing hospital admission and reducing length of stay in hospital should it become necessary. End of life planning is also a key component of the programme.

2.1.25 Kaiser Permanente offers a complete healthcare package to their patients with chronic diseases. Medical staffing levels are far higher than in the UK but strong medical leadership of the programme together with strong and very close working relationships between primary, secondary and intermediate care offer a much more seamless system of healthcare provision than currently exists in the UK.

Speed of and barriers to the introduction, and cost effectiveness of services for Chronic Disease Management

2.1.26 The Evercare model being piloted in nine UK Primary Care Trusts has been modified from that in the USA as most patients are resident in the community rather than in nursing homes. Evaluation of the American model showed reduced hospital admissions but could be criticised in respect of patient selection, lack of randomisation, large numbers of patients with dementia and the effect and influence of supporting sick patients in Evercare owned nursing homes.

2.1.27 The evaluation built into the UK model includes a qualitative assessment by Evercare, of the impact on patients, carers and clinical staff in primary care which include satisfaction and quality of life reports.

2.1.28 The programme is evaluated in the UK by the National Primary Care Research and Development Centre. This evaluation addresses: the ability to improve service co-ordination, reduce NHS workload and the quality of care provided for older people; the way in which healthcare innovations spread from one country to another; and how the NHS can more systematically discover such innovations, modify and apply them for British conditions. This element of the evaluation will be completed in 2006.

2.1.29 Practitioners working within the Evercare pilot sites are impressed by the improved quality of care being delivered to patients in the programme but it's cost effectiveness compared with the initial US models is being questioned.

2.1.30 In the UK a number of PCTs have been involved in developing models of care based on the Kaiser Permanente experience. These include use of highly trained nurses in intermediate care, more focused homecare services and the use of care pathways for long term patient management. There remain concerns that transfer of a model from the United States may not meet the expectations for the programme for the same reasons as outlined for Evercare.

Discharging older people from inpatient hospital care

2.1.31 The NHS R&D Health Technology Assessment Programme commissioned a review of discharge arrangements for older people which was published as a Health technology Assessment report in 2002.(16) This review showed that, although the evidence is patchy in places, randomised controlled trial results consistently suggest that coordinated discharge by primary and secondary care facilities, acting together reduces hospital re-admission by about 17%.

2.1.32 This implies that policy makers need to provide incentives for effective joint working between hospital and community services and between health and social care. The nature of these incentives depends on the structure and organisation of local health and social care arrangements.

2.1.33 Policy initiatives in England have emphasised joined-up working between health and social care.(17) Primary care organisations are encouraged to partner with social services. Joint working between health care and local government organisations is encouraged and supported by financial flexibilities introduced in the Health Act 1999. In some areas, this has led to the formation of Care Trusts, which manage both health and social care services in a locality.

2.1.34 The National Service Framework for older people identifies the range of community-based services (collectively known as intermediate care, see above) that should be used to prevent hospital admission where possible and to provide active rehabilitation in the community following discharge from hospital.

2.1.35 These policy objectives have been reinforced with incentives. For example, time spent in the accident and emergency department is now a performance indicator in the National Health Service and a target of no more than four hours has been set. The Community Care (delayed discharges, etc) Act introduced a system of reimbursement for delayed transfers of care, to encourage coordination between acute health and community social care and so to reduce delayed transfers of care from hospital into the community.

2.1.36 Such incentives can, however, have perverse consequences. For example, if community services are unable to support early discharge from the accident and emergency department, then unnecessary hospital admission may be arranged to avoid a "breach" of the four-hour limit. Introducing financial incentives to reduce delayed discharges can also place health and social care organisations in conflict over those resources and local mechanisms for triggering payment.

3. Speed of and Barriers to the Introduction of New Technologies in the NHS—the Case of Hard Technologies

The Health Industries Task Force (HITF) Report

3.1.1 The HITF report of 17 November 2004 specifically addresses devices which are hard technologies. The recommendations with respect to evaluation, innovation, procurement processes, building R&D capacity, communication with patients/public to improve understanding of benefits and risks, and training and education should be applied to the soft technologies that are of particular benefit to older people.

The utilisation of tele-medicine and tele-care

3.1.2 The potential applications of tele-medicine to the health care of older people create possibilities that are particular to their needs. In some countries (eg Hong Kong), tele-medicine links have been established between acute care and nursing home care settings enabling remote specialist consultation. While nursing homes in Hong Kong differ significantly from those in the UK, we recommend the exploration of the potential for tele-medicine in this environment.

The speed of, and barriers to, the introduction on and cost effectiveness of Hard Technologies

3.1.3 Numerous electronic aids and devices have become available in the care of older people which can improve patients' safety, security and ability to cope. Systems using advanced technology to support people at home could benefit both the patient and the care providers. These technological innovations need to be introduced in partnership with the existing care system in order to fulfil their potential. They require significant organisational arrangements to support their use and ensure safety and responsiveness, as most are methods for distance monitoring and identification of important events that require an immediate response.

3.1.4 *Fit for purpose*: Many devices designed for purposes other than health care have adapted to healthcare. For example, prisoner tagging systems have been adapted to be used with patients with dementia. Clearly, extensive evaluation of such technologies for the use with older people needs to be conducted to ensure that these technologies deliver in the context of healthcare.

3.1.5 *Infrastructure*: Technologies are likely to fail if the appropriate infrastructure has not been developed prior to or alongside implementation. The most successful method of introducing equipment systems is to build them onto an existing platform of service provision. For example, the Community Alarm System (CAS) underpins the use of alarm cords/necklaces/installed in older people's homes. As the monitoring and response arm of the system, CAS works with a sophisticated infrastructure of communications, data-bases, control centres and response networks that is trusted by older people and professionals As such, CAS would provide a ready made framework for bolting on recent developments in electronic and telecommunication technology. Future generations of the Community Alarm System are likely to form part of an integrated telecare system. The BGS would recommend that any technological innovation should where possible be linked to already existing infrastructures.

3.1.6 *Ethical Acceptability*: Research on Electronic Tracking and Tagging of older people with dementia has identified a considerable barrier with respect to ethical or moral objections to the use of equipment by patient interest groups. These groups see the increasing use of technology as a substitute for high quality personal care. It is the view of the British Geriatrics Society is that technology is an additional safety feature which must utilised alongside high quality care organisation and delivery.

3.1.7 *Cost-effectiveness*: There is little formal evaluation of cost-effectiveness in relation to the introduction and implementation of new technologies. There are several reasons: New technologies are frequently heavily marketed by private sector organisations; they tend to be introduced by enthusiasts who have not fully considered cost-effectiveness; there are few organisations or individuals conducting proper systematic evaluations when equipment is introduced; the contribution of health economists, who are in short supply, is not always available

3.1.8 Aids and devices currently being evaluated include:

— *Video-monitoring system*. This system allows people to see each other on their television at the same time as they speak on the telephone. It is useful where parents and offspring live some distance apart. For example, it allows a daughter in Kent to make a "virtual home visit" each day to her mother in Fulham which would be impossible by commuting.

— *Electronic tagging*. Alerts a carer when a person with dementia wanders outside a pre-defined area eg a house. They can wander freely within the area. It allows the carer to perform the housework and only if the person tries to leave the house are they alerted.

— *Electronic tracking*. Locates a person with dementia who has wandered off provided the person is carrying a GPS enabled mobile phone. This system can locate people anywhere in the country with an accuracy of five metres. It allows people with dementia to go out shopping and if they have not returned within an expected period we can locate them.

— *Computerised Fall Detection Systems*. A camera attached to a computer continuously monitors the older person's living area. The computer uses pattern recognition analysis software to detect events such as falls and intruders. Any untoward event generates an alert at the Community Alarm Centre.

— *Bed monitors*. Electronic devices which fit under the mattress and alert a carer or nurse when a patient vacates their bed. These devices can prevent falls and accidents at night.

— *Chair monitors*. Electronic devices which fit under the cushion and alert a carer or nurse when a patient vacates their chair. These devices can prevent falls and accidents during the day.

— *Health monitors*. Electronic devices which are worn on the wrist and alert a carer when the wearer has a fall, collapse or faint.

— *Fall detectors*. Small pager sized devices that fit to the belt and contain a mixture of accelerometers, impact meters or tilt meters to detect falls.

3.1.9 Some devices have shown substantial benefits in the care of older people while others have been less successful. Further evaluation is required to maximise the benefit of these new devices and technologies in care of older people.

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APPENDIX 6

Memorandum by Alasdair MacDonald (MT 21)

The following report, which is a personal submission, was written by Alasdair MacDonald and circulated to a number of colleagues, who are active in the field of e-health, for their comments and contributions. The document is based on real experience and understanding of the sector, its component parts, problems and restrictions. New technologies need new ideas on how to implement and use them, which in turn demands changes not just to how we do things, but how we think about how we do things.

Alasdair originally trained as a fast jet pilot in the Royal Air Force before becoming one of the first IBM authorised PC dealers in the UK. He is an experienced computer programmer and systems analyst and has been an innovator in the telemedicine field for the last 12 years. He is Chief Executive of TeleMedic Systems Ltd and e-Health Consultants Ltd. A promoter of low bandwidth real time solutions, Alasdair designed and built the first remote mobile medical vital signs monitor to send real time ECG, SpO2, Blood Pressure and Temperature from a commercial aircraft in flight to a doctor on the ground. With strong, practical, experience of telemedicine in the most difficult and austere environments, Alasdair has presented a number of papers at international conferences and has worked with the WHO and ITU as well as many other individuals and organisations, including the US special forces.

Executive Summary of Report in response to the UK Government Select Committee on Health Inquiry into—The Use of New Medical Technologies within the NHS

The following report looks at the use of new medical technologies from an e-health perspective. e-health, as with e-commerce and e-government, relates to all aspects of health that utilise electronic processing, communication, storage etc. Given the prevalence of such matters in all walks of life, one would think that this would be a principle concern of any initiative concerned with new technology. Unfortunately, e-health seems to be almost an afterthought, as such, new technologies, even now, are being looked at in isolation, instead as part of an integrated and interoperable solution.

The report begins with some recommendations in order to focus the reader with regard to the relevance of the text that follows. The report then follows with a simplistic overview, in an attempt to ensure that, as far as this report is concerned, everyone has at least the same basic information and can, hopefully, therefore, realise the reasons for the concerns expressed and recommendations given. The ultimate objective should be the smoother delivery of, and ubiquitous access to, healthcare through the use of e-health and new technology.

The report then looks at the four areas specifically identified.

There is a general lack of understanding of telemedicine and telecare, both key components of e-health. The report attempts to explain why there has not been greater success and uptake in this area and how important it is to establish, not only an "Innovation Centre", but a real life working centre of excellence where people can view at first hand what telemedicine is and how it is an integral part of modern, conventional, medicine.

A key recommendation is the establishment of an "accreditation body" for e-health, which will not only accredit a specific device as being fit for purpose, but will look at all the people processes, standard operating procedures and integration issues so that potential users are clear on exactly how and where something can and should be used and for what purpose.

While the scope of the Healthcare Industries Task Force (HITF) report goes far beyond e-health related matters, the content and recommendations are almost exactly those that the author and a number of colleagues have been trying to draw the Government's attention to for several years. This report looks at the key outputs of the HITF report with specific recommendations of how these need to be modified to elevate e-health to a more prominent and contributory position.

The key concern relating to the speed of, and barriers to, the introduction of new technologies is the fragmentation of the health service in terms of its decision processes. If the health service were responsible for food, we would never have cakes because flour is a distinct division, which does not talk to eggs, sugar etc. In real terms, if an initiative is devised within primary care that would only really show benefits further down the line, it is impossible to obtain funding. Primary care cannot show a benefit and secondary/tertiary care will not fund something outside their own direct control!

The primary concern with the effectiveness and cost benefits is one of measurement. How do we measure if something is a success or not? This section gives a specific example of an initiative that the participants thought was a great success, however, an external auditor deemed a failure.

The following report has been prepared as information for the UK Government Select Committee for Health for its inquiry into the use of new medical technologies within the NHS. The report offers useful information towards the understanding of Telemedicine and e-Health, what it means and some pertinent issues around the subject. The ultimate objective should be the smoother delivery of, and ubiquitous access to, healthcare through the use of e-health and new technology. We will begin with our recommendations in order that the information that follows can be read with these in mind, which we hope will bring about a greater relevance and understanding.

Recommendations

Our most important recommendation is that the Government establish a single body to coordinate all e-health activities across any and all boundaries. This body needs to be completely autonomous reporting directly to the Department of Health, it could, perhaps, be a special health authority.

For new ideas, technologies, systems and services to be tested effectively, they must work in a real environment and integrate and interoperate with existing processes. There must, therefore, be an active medical centre using these new systems and services on a day to day basis. In this way, the clinicians with first hand experience of e-health systems would be able to evaluate and appraise new technologies based on experience and their relative value as part of a wider, overall, solution. Other clinicians would be able to come and see for themselves how things work and the benefits that can be gained.

Systems also need proper technical evaluation and accreditation. There is, therefore, a need for high quality medical technicians and IT specialists, to evaluate the technical capabilities of new technologies and systems. That they have passed regulatory approval and are safe does not mean that they will be useful, they need to be appraised against existing systems for compatibility and interoperability. Clear and practical information needs to be produced on the capabilities and limitations of each system in different environments, how and where they could be used, possible interference with other systems and so on.

e-health solutions also need to be regulated by some form of standardisation agency. There needs to be a separate team to look at the people and process aspects. Technologies need to be assessed in terms of their role and the manner in which they should be used. Because not all elements of an e-health solution will be under the control of any one given body, all participants in any specific area of e-health must operate to clear and specific "standard operating procedures". These standards are not those already defined and managed by any other body or agency, these are the people processes and best practice procedures that must be undertaken to ensure the seamless integration and interoperation of a specific device, system or service, irrespective of its place of use or place of service delivery.

Finally, there is the need to inform and instruct everyone as to the relevance and value of e-health services as well as training those who will train people within their own organisation.

We recommend that all these functions be put together in a single centre, which we have called an "Incubation Centre". This is a place where, once started, initiatives are developed and matured before fully defining, standardising and releasing into the wider healthcare market as fully developed and replicable systems and services.

The standardisation group, although acting independently, will work within this centre with both clinicians and technicians to establish how they each see a particular device, system or service working. They will then look at appropriate models of best practice, medical efficacy and any other regulatory aspect before presenting a prospective blue print back to the clinicians and technicians. After any fine tuning, the result will be a clearly documented definition of how this specific device, system or service should be implemented.

Furthermore, by having a clear reference document to work to, not only can other health facilities easily implement their own instance of this system or service, they also have a measure against which to be assessed for accreditation purposes. This standards group will also, therefore, have a role in the accreditation of e-health systems and services. Any accredited system or service should be able to integrate and interoperate with any other accredited system or service anywhere else in the country.

Finally, the centre would be able to train those people responsible for training within their own organisations. Training is, after all just another service and would be subject to the same accreditation as any other service. This means that the training is consistent, irrespective of location.

A full description of the Incubation Centre and its various functions and responsibilities is available on request.

Before reading this report further, we would like to offer readers a common understanding of a number of key issues. In particular, where we are today and what certain expressions and phrases actually mean. In this instance, jargon is not the biggest inhibitor, however, there is such a range of understanding about different aspects that without a short overview it would be no better than trying to explain a "Stealth Fighter" to the Wright brothers. Indeed, for those "within" telemedicine circles, the term "telemedicine" has been dropped in favour of the term "e-health". People seem to be more able to relate to the "e" aspect and its broad scope while "telemedicine" is often only seen as having very limited application, usually being limited to a particular example that an individual has been exposed to in some way, such as Teleradiology.

New technology within medicine is a subject as old as medicine itself and as in any walk of life, is always looked on with scepticism and introduced with reservation. The stethoscope being a particularly good example. It is, however, in the area of computerisation that the biggest problems arise. This is best understood by looking at the history of computers in health. Initially computers delivered little or no clinical benefit but did increase the workload on clinicians and were a long way from being "user friendly". The advent of the PC and more specifically, the Windows operating system, helped dramatically by being more useable and offering easier access to information. However, a whole plethora of dissimilar competing systems popped up with individual clinicians having personal preferences for this or that system. They did not (and still don't) integrate or interoperate with one another and they do not necessarily collect the same data. While much of this is the responsibility of the National Program for IT (NPfIT) there are important aspects that are not covered and it is these that we will look at now.

Most measurements of physiological data by clinicians, such as blood pressure, are done manually or by stand-alone devices. Transcribing this information into a patient's record is also done manually, even when using a computerised electronic patient record system. These electronic devices are obviously more prevalent in hospitals and ambulances. Some even have a data port, which will allow them to connect to another electronic device or link them into a larger, proprietary system. There are two significant problems with this, firstly, they are designed as stand alone systems not as components of an integrated information system and secondly, there is much confusion about what they can or cannot do.

Let us consider an illustration. The Government has recently made money available to ambulance services to purchase "telemedicine" enabled 12 lead Electrocardiograph (ECG) units (An ECG unit is a device for producing a graph of the electrical activity of the heart. The term "lead" refers to a view of the heart through a particular axis, not as most of us would think, the number of wires connected to the patient). Now, let us start by asking, what is a 12 lead ECG? Do we really need a 12 lead or would a three lead do? (A 12 lead is used routinely in hospital because (1) it is available and (2) it usually gives diagnostic details without the need for a cardiologist.) If we do need a 12 lead, do we need all 12 leads simultaneously or one at a time? If one at a time should they all be of the same time interval, sent sequentially, or a representation of the time interval over which they are being sent? How are we going to send it? Who is going to receive it and what will happen to it then? While the reader may not know what is or is not the right answer, they should at least realise that there are quite a few questions that need asking and a simple "that's how it has always been done" is insufficient.

As we will discuss later, devices themselves are not a solution, in fact most devices on their own have little diagnostic value, there are other components necessary to ensure that they work as part of a solution that at least allows access to an appropriately qualified person to use/interpret the data received.

It is also important to realise that because a 12 lead ECG unit has a data port and is "communications enabled" that does not make it a telemedicine unit. Telemedicine requires appropriate data communication and trained personnel. And what does "communications enabled" mean? Often it means that it can communicate with a computer, this is also potentially very misleading. Those with PC experience you will know that even if everything works correctly now, if you try and install a new program or device, while it may or may not work, other applications and systems that were previously working may now not work! This is not an acceptable outcome for a medical device! There is a serious lack of understanding, outside the regulatory bodies, about the use of computers in the medical field and about what is and what is not a medical device and where responsibility for failure lies.

This brings us back to the first point, companies that produce these devices, sometimes also produce a range of other devices that link together to make a total "solution". While this negates the point that the device is entirely stand-alone, it does create an additional problem that you have to use their components, their terminals, their software etc. This is how the computer market was before the advent of the IBM Personal Computer (PC) 25 years ago. To fully appreciate what this means think about your PC. It doesn't matter what make it is, it has the same look and feel (through the assumed operating system, Microsoft Windows) as every other PC. You can buy any PC software and it will run, any hardware and it will connect. You can take data off your PC and run it on someone elses!

We take this interconnectivity for granted, businesses have grown up that only make certain bits of computer hardware. Perhaps less well known but more technically interesting, is the fact that specialist programmers write pieces of code which are used by other programmers to incorporate into their own offerings. Before the "PC" this did not happen, it could not be done. Not only could you not take a floppy disk from one computer and run it on another, the disk probably wouldn't even fit. Programmers not only had to write programs for your specific computer but they had to know or restrict you to a set of known printers and other peripherals.

Just as the PC market changed, so too must the medical market. For the PC this was brought about by an open hardware platform (the IBM Personal Computer or "PC") and a common operating system or user interface. The medical market must change in a similar way but with one important additional item, the adoption of common practices and standard clinical procedures on a national basis. This is nothing to do with clinical or regulatory standards, which are already well catered for, but a clear set of "Standard Operating Procedures" to ensure different people in separate locations know what is going on, where in a process things are and what comes next.

Most professions have clearly defined rules and procedures, as circumstances change then the rules change. Medicine is practised by highly qualified professionals but, and this is really serious, they practice medicine in their own particular way. Imagine if this was how air traffic control was handled. With the advent of e-health, many clinical interventions will be done out of the physical presence of a clinician, or by a less qualified clinician remotely supported, for this to work smoothly there need to be clearly defined operational procedures and processes. As already stated, we are not referring to aspects already adequately covered by existing standards bodies and agencies but the specific elements that pertain to remote use and the interaction and interoperability of people and systems when connected electronically.

Given the global economy in which we now live, these procedures and processes must be International. For example, most airlines now use a company called MedAire in Phoenix, Arizona to handle medical emergencies in the air. As new technologies, such as remote medical monitors, allow the MedAire physicians to obtain qualitative information on the patient's physiological parameters, clear international standards and procedures need to be in place to allow, or deny as appropriate, access to patient information and the forwarding of this to the next people in the process chain

The Utilisation of Telemedicine (including Telecare) and its Future Potential for Improving Services

As has already been mentioned, the term "Telemedicine" now comes under the broader banner of e-health, along with Telecare. However, the intended use for this inquiry is presumed to be the use of e-health systems and services to deliver remote medical interventions (telemedicine) and ongoing remote care at home or other non-medical facilities (telecare). The key word here is "remote", which simply means that one or more elements of the solution are not at the same locality as the patient. Remote can, therefore, be as diverse as the care of an airline passenger by a doctor on the ground or a patient receiving care at home from a community nurse with remote access to patient records, hospital booking systems etc. Large distances are NOT a prerequisite!

At the moment, instances of telemedicine and telecare tend to be looked at in isolation, a bit like looking at flour, eggs, sugar etc as the end product without looking to see how these things can be put together to make something that is more than the sum of the parts! Indeed, very little consideration is given to telemedicine despite the huge cost being incurred in building NPfIT, which will enable telemedicine and turn it into a major form of medical intervention. This could be likened to the use of aircraft by the military at the outbreak of World War One, the powers that be saw them as little more than observation platforms, by the end of the war they had their own service and now "air supremacy" is seen as a pre-requisite of any land or sea intervention!

NHS Direct is telemedicine, the initial activity is telephone based, however, despite doing a reasonable job for many, it does a less than adequate job for most long term or repeat illness patients. In these cases the call centre operative deals with them in exactly the same way as someone who calls in with a stomach ache, these people need an enhanced system where they reach a clinician with direct access to their notes and, in the case of longer term illness, perhaps even real time medical parameters, blood pressure, ECG etc. It is not that the capability does not exist; it is that there is no high level support for such initiatives.

Instances of telemedicine and telecare are currently run as local "pilots" where there is a clinical lead that is willing to support the initiative. Often funding for such "pilots" dries up or the clinical lead moves on. This lack of high-level support means that the same initiatives are piloted again and again all over the country, the outcomes of previous pilots being completely unknown to anyone other than those intimately involved in the project. This lack of understanding also means that people with little or no experience of telemedicine are able to pass themselves off as experts, if you are ignorant of something, someone who knows a little is, in your eyes, an expert!

There is also a sense that telemedicine systems, because they connect to computer systems, which are getting cheaper and cheaper, should also be significantly cheaper than hospital systems. An over the counter blood pressure unit from Boots can cost you less than a hundred pounds, a hospital unit often costs ten times this. The answer is clearly one of quality, but as more and more of these systems are produced their unit cost will reduce. What we shouldn't do, but is happening, is to compare telemedicine systems based on low quality components, with the equivalent high quality hospital based system.

Once we make this change of attitude, the potential for telemedicine far exceeds our imagination. Care homes are, by their very nature, places that tend to have a greater need for home visits and out of hours care. By putting telemedicine equipment into these locations and connecting them to a "virtual GP" system, much of this need could be addressed remotely. Community nurses should also be equipped with appropriate systems both in terms of monitoring and remote access to electronic patient records, decision support tools and so on. Once established, with the staff and patients both conversant with the systems, it will be possible for regular, routine monitoring to take place, not just knee jerk emergency intervention. Regular monitoring combined with other pieces of relevant information can be used for early intervention and ultimately prevention.

As has already been mentioned, however, telemedicine is not simply about technology, it requires the adoption of common practices and processes. This cannot be achieved by individual "pilots" run by local enthusiasts, this must be done, first in a specific area (where it is evaluated and problems ironed out) and then systematically on a wider and wider basis until adopted nationwide. This requires support at the highest level within government and, on an international basis, through cooperation and mutual development with other countries.

Telemedicine will also enable a strong interaction between the private sector and NHS. There is a diving company, based in Aberdeen, which provides telemedicine support for their divers, even while still in hyperbaric chambers. A doctor, also in Aberdeen, is able to monitor a diver, under pressure in a hyperbaric chamber, on board the company's diving vessels, wherever they may be, anywhere in the world. Under the NPfIT, these divers will all have an electronic patient record; the private doctor in Aberdeen should be allowed appropriate access to this record to be able to properly manage the current medical situation. Likewise, on returning to shore, the diver's GP should be able to see what action was taken by the doctor in Aberdeen and by any medic on the ship. This is just one example of how companies and even individuals will pay for medical services, the outcome of which is available to NHS doctors, thereby simplifying and streamlining the interventions and care given and ultimately reducing costs through cutting out duplication of tests etc.

Ultimately, people will be able to receive hospital grade monitoring in their workplace, at the gym, on board an aircraft on holiday and so on. These cease to be isolated incidents but part of the complete picture of a person's long-term health.

The Recommendations of the Healthcare Industries Task Force (HITF) Report, published 17 November 2004

The main recommendations of the HITF report were contained in nine key outputs; however, these are primarily concerned with medicine as we know it, not e-health, which is seen as a new technology in itself. It is our belief that, within a very short time frame, all aspects of health will, in some way, integrate with a wider "e" component, even if they are not themselves part of an overall e-health solution. To that end, this report emphasises the additional aspects needed for this to happen.

The HITF report seeks to "inform procurement decisions and encourage the support and uptake of useful, safe, innovative products and procedures". For this to happen, there must be some system of evaluation and assessment that has also been proven in real life scenarios. Unfortunately, unless these recommendations are followed through, nothing changes. There is also the need to "train the trainers" with regard to the wider benefits of e-health. While the outputs of the HITF are being considered and the follow-on actions devised, e-health implications must be built in. Otherwise technology will only be an add-on to existing practices, not an integral part of healthcare delivery, the folly of which has been well illustrated in earlier examples.

The report also seeks to "Stimulate more innovation and encourage a more entrepreneurial culture in industry and the NHS". The only part of this that needs serious action is that part involving the NHS and even here it is not a lack of desire on the part of those involved, simply those in decision making positions. The UK leads the world in the development of innovative medical technology; the problem is not one of innovation but one of innovative leadership. The author and a number of colleagues have been trying to bring a number of things to the attention of the "powers that be" for, in some cases, almost 10 years.

The HITF report calls for a new Innovation Centre, while this is a good idea in principle, what we really need is an "Incubation Centre" (as recommended at the beginning of this report) where innovations are used and tested in real, working situations. Within such a centre the relevance to and capabilities of integration and interoperation with other systems can be evaluated and an appropriate blue print of how they should be used in other real world situations defined. The "Incubation Centre" would not be just a showcase but a model of how innovative technologies can be used. Nurses need to see other nurses working with something to understand the true potential and value; the same is true of all professionals, not just in healthcare. Such a centre would also fulfil a large number of other recommendations of the HITF report, with the exception of introducing an "innovation fund". However, the output of the "Incubation Centre" will do this and the need therefore is not for a "fund" but to fund the "Incubation Centre".

One aspect looked at in the HITF report is procurement. It is not for us to make recommendations outside our sphere of expertise. However, common sense would suggest that if an "Incubation Centre" is established and it delivers clear guidelines on not only how to use a specific piece of technology for a particular function, but defines best practice procedures and processes, then healthcare agencies within the NHS should, subject to their own budgetary constraints, be able to purchase said technology for use in this manner. Those involved in the procurement process should actively work with the "Incubation Centre" to ensure that "cost effectiveness" is a major consideration and provide details of how this is evaluated.

e-health also has a serious role to play in providing the evidence base in support of R&D activities. Regular monitoring of everyone, by using e-health tools as part of an overall e-health programme, will provide a greater understanding of factors leading to ill health. At the moment people only really enter an

evidence-based program once they are already sick. e-health offers the first real chance of monitoring people, both well and sick, from before birth until death and should, therefore, be embraced as a common thread to any R&D programme.

The author is aware of a number of initiatives involving different academic centres of excellence, which are looking to be "the recognised academic body" within a specific area or aspect of health. The problem here is one of status, rather than have one official academic centre, which will not stop other centres from trying to out-do them to show that they should have been the "official centre", the academics should work with the "Incubation Centre", as outlined above, to ensure that all are working to the same goals.

The establishment of an "Incubation Centre" would also provide a platform from which to address communications with and between patients/the public and clinical bodies/government agencies in all aspects relating to e-health. A working centre that is open to public scrutiny and which would actively encourage the participation of patient and healthcare groups, including Royal Colleges, Unions and other interested parties, would provide an open forum that would actively encourage communication. This, in turn leads to education and training.

"Knowledge dispels fear" is an apt phrase because the converse is also true. People are afraid of what they do not understand. When PCs were first introduced, people from all walks of life became concerned about their jobs and a myriad of other completely unrelated things. Training and education removes this barrier of fear and people move on.

The HITF report suggests "Maximising UK influence in regulatory matters in the EU and other international forums". We agree with this wholeheartedly, the UK already leads the world in many aspects of e-health and to apply best practice and standard operating procedures to this at a time when they simply do not exist would be to secure our long-term influence. This is also a major cost factor as, if other standards are adopted in preference to ours, then in order to operate on an international basis, our systems will have to be changed or adapted to meet these different standards.

The Speed of, and Barriers to, the Introduction on New Technologies

It is fair to say that most e-health "pilots" have not moved beyond the initial "pilot" stage. The reasons for this have been well documented above, principally they have been driven by a single, local, sponsor with no ongoing funding and no "place" for a full blown service within the current healthcare structure.

Healthcare is broken up into very distinct compartments and if an initiative crosses boundaries, or worse if the benefits of an initiative are seen in a different segment, there is no funding. Sources of funding also change, and even when funding has been obtained, it is not unknown for this to be used somewhere else within an organisation, not for or even by the department that applied.

There is little to no long term planning, with short-term goals taking precedence over long term objectives that bring accumulating benefits.

There is a lack of trust by clinicians in IT systems, which have, in the past, been purely administrative tools. There needs to be a place where people from all sectors of healthcare can go and see new technology being used in real situations by ordinary people.

The Effectiveness and Cost Benefit of New Technologies

As new technologies, practices and processes are adopted, there will be the initial benefits for which they were intended, but there will then come additional benefits, many of which will remain unknown until they actually happen. What we have to be wary of, however, is a simplified comparison against some arbitrary factor.

There was a dermatology pilot conducted between GPs in rural practices and a remote consultant dermatologist. When the GPs were faced with a skin problem they could not identify, an appointment would be made for the patient to return to the practice at a time when the doctor could have a live link to the remote dermatologist. The skin would be photographed using an appropriate digital camera and the image sent to the dermatologist. He would discuss this with the patient in the presence of the GP.

At the end of the project it was reported to be a failure, not by the doctors, patients or dermatologist but by a third party auditor. The reason for the failure, after an initial period of regular use, the system was used less and less. On questioning the doctors, they deemed it a huge success. Why the drop in usage? Each time they referred a patient, they were, in effect, receiving ongoing training. Once a condition had been seen on a number of occasions, the doctors no longer needed to refer the patient but were able to deal with the situation themselves!

Healthcare will never cost less, however, it will be possible to do more for the same amount. As new technologies emerge, when a patient is screened for one particular aspect, it will probably be possible to simultaneously screen for many other things at the same time. Medicine will start to move from only dealing

with people once they are sick, to managing them while they are well and intervening at the fist sign of "preconditions" to act in a preventative manner. Once this happens, healthcare in the UK will move to a truly National HEALTH Service.

APPENDIX 7

Memorandum by Attendo Systems Ltd (MT 26)

Corporate Overview

Attendo Systems is one of three main business areas operating within the Attendo Senior Care group, a major Swedish organisation employing approximately 4,000 people across Europe. Countries throughout Europe where Attendo have continuing operations are detailed below.

Group turnover during 2001 was £80 million; representing a 25% increase on 2000, and in 2002 was c £95 million. Group market share is approximately 40% of Europe, whilst Attendo Systems currently has a 20% market share in the UK. Following, a recent acquisition Group turnover is expected to reach £300 million in 2005 making Attendo SeniorCare the fifth largest specialist care provider across Europe.

Since it was established in 1955, the company has grown both organically and through acquisitions, including Cass Electronics and Davis Communications.

The main areas of Group business activity are:

Attendo Systems

— Care phones
— Internal systems
— Door Entry systems
— Nurse Call systems
— Monitoring systems
— Fall detector systems
— Activity validation systems
— Installation, maintenance

Attendo Response

— Alarm Monitoring
— Response services

Attendo Care

— Domicilliary care
— Sheltered housing
— Nursing homes

Attendo Response and Attendo Care are primarily concerned with provision of care services to the elderly and infirm. Attendo Care are a specialist care provider operating a large number of Scandinavian nursing homes providing care services on behalf of local government organisations.

Attendo Response has established monitoring centres in a number of European countries (Figure 1) that provide monitoring and response services in support of the elderly and infirm.

Attendo Systems work with a number of technology partners to develop innovative technical solutions and products for care and security markets. In addition, support of a range of systems is offered by way of responsive and routine service and maintenance solutions.

A common aspect of all Attendo business activities is a partnership approach that aims to provide outstanding levels of service and value on behalf of our customers. A key feature being a willingness to "work with" our customers to ensure ongoing improvement and development of services offered in line with customer need.

Attendo Within the UK

Attendo Response (UK) support a number of Housing Association and Local Authority customers across the UK. In addition, an established partnership with Help the Aged sees Attendo Response as sole provider of care-phones to Help the Aged customers, installing phones on Help the Aged behalf and monitoring calls received from these customers initiating the most appropriate response to the call via key-holders, the emergency services etc.

Attendo Systems are able to provide a full range of products and services to meet the demand for Social Alarm and Telecare systems and products across the UK and Europe. Our product range extends across: Dispersed Alarms and associated sensors and peripheral devices, Warden Call systems, Control Centre systems and software, Nurse call systems and Door Entry systems.

Our service, maintenance and Telecare support agreements are designed to support this range of systems and products to support customers in a varied and flexible way that takes into account changing demands on telecare systems.

1. Summary

This memorandum attempts to make the case that technologies are readily available to meet many of the Health and Social Care policy objectives that have emerged over recent times. Whether these objectives relate to more cost-effective use of resources or less tangible ideals relating to identifying new models of care that will extend the scope for older people to live independently they can be assisted by systems that can already be provided in a useable form.

The limitation on uptake of these systems being explained by an ongoing lack of involvement amongst Health and Social Care staff in the management and development of Community Alarm networks and an inability on the part of Health and Care professionals to understand and recognise the potential of these systems.

We also contend that academic review of the different elements of Telecare and Telehealth systems have tended to view them as disparate solutions rather than complimentary components that enable care to be delivered directly to the persons domestic property. This approach has tended to encourage the review and supply of the systems to be considered along functional lines with Community Alarm staff responsible for provision of Telecare solutions and Telehealth being directed toward Health practitioners.

An integrated approach will provide the greatest potential to develop and enhance community based services and we have identified a number of steps to be followed before services based around these technologies develop into mainstream care provision.

2. Why Telecare and Telehealth?—Choice and Independence

2.1. *Personal aspirations*

2.1.1. "The aspirations of older or disabled people are similar to everyone elses. They want to be seen as individuals with a range of friendships and relationships; 80% of older people want to live in their own homes; they want to be independent and to be as healthy as possible; and most of all they want to be in control of their lives. They do not want others to define their limitations. AT can support these aspirations by allowing people to maintain or regain their autonomy, and it can provide them with the choice of staying in their own homes rather than having to move into residential care." (Audit Commission—Assistive Technology—Independence and well being 2, Why Assistive Technology Matters, Users aspirations, p.7)

2.1.2. Extract from Audit Commission, Older Person—independance and well-being the challenge for public services:

> "5. We need a fundamental shift in the way we think about older people, from dependency and deficit towards independence and well-being. When they are asked, older people are clear about what independence means for them and what factors help them to maintain it. Older people value having choice and control over how they live their lives. Interdependence is a central component of older people's well-being; to contribute to the life of the community and for that contribution to be valued and recognised. They require comfortable, secure homes, safe neighbourhoods, friendships and opportunities for learning and leisure, the ability to get out and about, an adequate income, good, relevant information and the ability to keep active and healthy."

2.2. *National policies impacting Telecare*

2.2.1. The National Services Framework for Older People, Standard 2 calls for:

> "NHS and social care services to treat older people as individuals and enable them to make choices about their own care. This is achieved through the single assessment process, integrated commissioning arrangements and integrated provision of services."

2.2.2. Whilst Section 3 of the NSF suggests that:

> "Older people will have access to a new range of intermediate care services at home or in designated care settings, to promote their independence by providing enhanced services from the NHS and councils to prevent unnecessary hospital admission and effective rehabilitation services to enable early discharge from hospital and to prevent premature or unnecessary admission to long-term residential care."

2.2.3. Preparing Older Peoples Strategies:

> Linking Housing to Health, Social Care and other Local Strategies urges "Social Care and health services to focus on interventions that will promote independence and provide care and support close to home rather than through institutional based services. The change requires flexible and integrated service solutions across health, social care and housing."

2.2.4. This same document questions the role of community alarm services and new technology asking:

> "are they meshed in as part of the wider service system? For example, do they complement a health or social care rapid response service? Is there an integrated 'out of hours' service linking night nursing, rapid response and mobile warden services using the community alarm service as the emergency contact point?"

3. Current Situation

3.1. It is our contention that technology to support these objectives is currently available and well proven in the form of Community Alarm systems and Telehealth systems. It is our believe that the missing link lies in the need for tighter integration between cross functional agencies to ensure medical/nursing involvement to complement Community Alarm and mobile response services.

3.2. This would take the form of knowledge based support to enable health monitoring in the home coupled with introduction of a new perspective to recognise the potential to introduce more advanced services to broaden the choice and scope for independence for older people. To date a clear distinction has been drawn between Telecare systems and Telehealth systems we believe this to be counter productive and believe that more needs to be done to ensure these are simply two components in a package of solutions to enhance community based health and social care services for older people.

4. Technology Availability

4.1. Technical solutions are available in the form of:

4.1.1. Community Alarms to allow the management of risk for people living independently by providing a response network to deal with alarms raised by the user or alarms raised via sensors connected to the system designed to alert responders to: falls, smoke detection, gas leak, low temperature, a lack of activity within the property and many other potential risks.

4.1.2. Telehealth systems that allow the remote monitoring of vital signs to provide ongoing assessment of the users health and well being. These systems also promote greater patient involvement within the care process.

4.2. Both of these technologies have been proven over a number of years with the Community Alarms network well established within the UK and Telehealth systems proven to be effective through a number of American research studies.

4.3. These systems have, to date, been considered as separate solutions with the result that the infrastructures necessary to fully utilise the available technologies have not yet been established. It is our contention that remotely monitored care pathways can be designed to support independence for increasing numbers of the elderly population by utilising these technologies to support the care of older people in the community coupled with investment in the support infrastructure to provide nursing/medical support to existing response and care teams.

5. The Technology

5.1.1. Simple explanation of the technologies are provided in the following extract from Audit Commission, Older Person—Independence and well-being the challenge for public services:

Telecare

> Telecare is provided when a variety of functions are controlled with various technologies that provide communications with the outside world. Once telecare systems, electronic ATs and environmental controls are integrated, the term "smart housing" is sometimes used to describe the resulting accommodation. Telecare systems alllow people with a range of needs to retain their independence through:
>
> — reducing hospital stays, by supporting earlier discharge;
>
> — virtual visiting, for example, by monitoring the safety of older people with dementia who live alone;
>
> — reminder systems, such as reminding older people to take their medication; and
>
> — home security and social alarm systems, by providing smoke and heat detectors, alarm systems and crime surveillance, as well as monitors that pick up any unexpected changes to an older person's routine (refs 21, 22 and 23).

Telehealth

Telehealth (or clinical home monitoring enables a clinical process to be conducted remotely. It enables routine monitoring of vital signs to be carried out by people at home. For example, a chronic disease management service run by the West Yorkshire Ambulance Service can remotely measures people's blood pressure, pulse rate and ECG, breathing rate, breathing amptitude, blood oxygen saturation levels and temperature. People are taught how to apply the sensors and take readings. Data is automatically sent to a control centre, where a clinician is alerted to any variations in the expected readings.

Increasingly, telehealth not only overcomes the inconvenience of distance, but also provides people with greater choice and control over the time and the place for monitoring their condition, increasing convenience and making their conditions more managable. At the same time, it also reduces some of the pressures on clinics and actute hospitals. In the USA, for example, the use of video technology in the home has been found to provide clinical care for patients with certain condictions of an equal quality to hospital care and at a reduced cost (ref 24). Telehealth could make a significant contribution to the management of a number of chronic conditions, including COPD, heart failure, hypertension, asthma and diabetes.

5.2. These technologies provide the potential to provide for safety and security of the older person by monitoring risks to the well being of the older person. This followed by instigation of an appropriate response to an alarm condition by mobile responders, a carer, relative or the emergency services. A number of risk factors can be identified and monitored by the use of a range of sensors that can be linked to a social alarm dependant upon the individuals' personal situation and identifiable as part of the assessment of the needs of the older person.

5.3. The monitoring of these alarm conditions can be carried out via existing community alarm networks with first line response by existing mobile warden services. Preventative aspects of these Telecare systems include a channel of communication from the older person to the outside world to help offset potential feelings of social isolation.

5.4. Having provided as secure and safe an environment as practical and desirable for the individual concerned to raise the possibility of independence. These services can then be complemented, where required, by remote monitoring of the older persons state of health and well being utilising telehealth equipment. This allows health professionals to receive feedback on the persons state of health via measurement of key data on the patients vital signs such as: heart rate, blood pressure, glucose levels, weight etc.

5.5. This allows early indication of deteriorating health, early warning of an adverse reaction to medication and treatment and directly involves the patient in the management of their care provision.

5.6. Alarms to warn of measurements outside pre-set thresholds provide for a responsive aspect to Telehealth systems in addition to the preventative care management benefits.

5.7. In order to broaden the scope for a choice of independent living for a greater proportion of the older population it is essential to consider both modes as part of an integrated solution in order to provide for people with complex or changing care needs. Telecare systems become essential to provide a secure environment from which to introduce more complex preventative care services.

5.8. Telecare can be used to support a range of different patient groups as described in Table 1.

Table 1

THE ROLE OF TELECARE IN SUPPORTING DIFFERENT PATIENT GROUPS

Patient group	*Role of telecare*
Chronic disease	Provide facilities to self-manage care at home but allow patients to stay in contact with carers
Increasing frailty	Provides facilities to allow people to remain at home for longer
Disabled people	Increases home safety and security, share risk of independent living
People with learning difficulties	Increases home safety and security, share risk of independent living
Palliative care	Provides facilities to manage end-of-life debility at home

Extracted from Audit Commission, Implementing Telecare, 2004.

5.9. It is also important for Care providers to understand the potential of these systems to provide a broad range of potential solutions in the development of care services delivered to the patients door. The active involvement of the patient in the monitoring process also encourages patients to take responsibility for their own care and subsequently encourages greater consideration of factors affecting their health and well being.

6. Services Development

6.1. A multi-stage development process is envisaged that includes the following key stages:

6.1.1 Familiarisation and Awareness -Care professionals and decision makers need to understand what is available and how this can be utilised to obtain service delivery improvements and cost savings.

6.1.2 Local networks of care—ensure systems can be developed that enable effective care planning delivered by cross-functional teams of social care and nursing specialists supported by suppliers.

6.1.3 Semi-integrated Telecare and Telehealth systems—Suppliers will find it difficult to justify investment in full-blown integration in the absence of (1 and 2 above). This is described schematically in Figure 1. With health information made available to key people within the support structure via web access to a secure server that sits behind the NHS firewall.

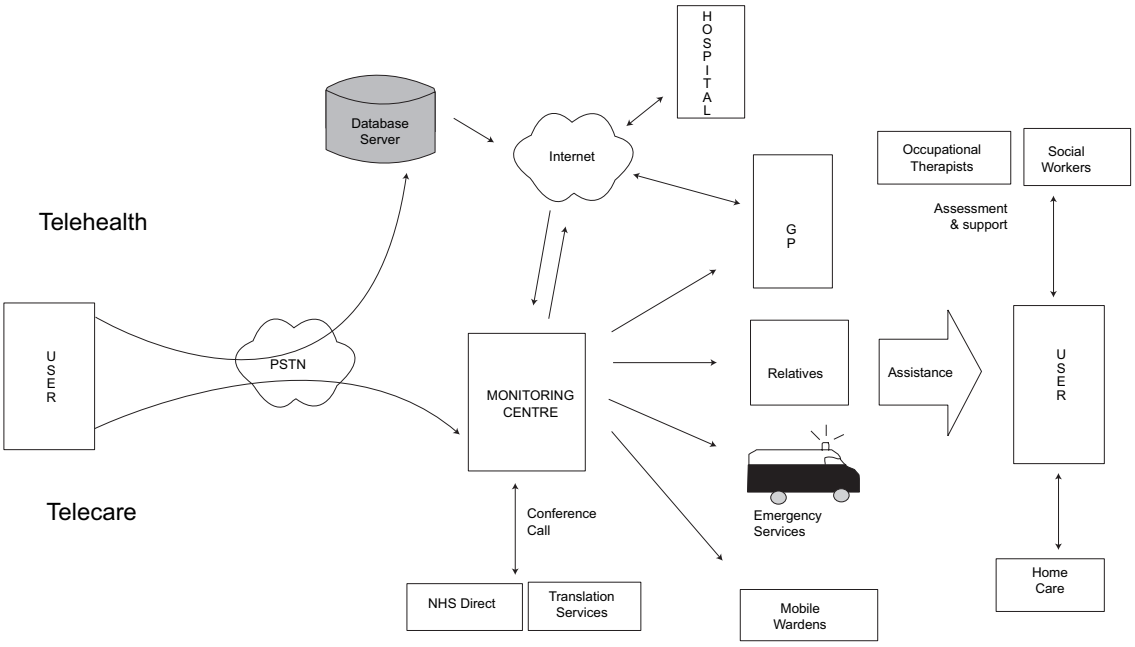
6.1.4 Consultation -Identification of system improvements and refinements.

6.1.5 Full integration—Merging of Telecare and Telehealth solutions to ensure they are able to sit on a common platform in a manner that supports integration of cross-functional teams.

7.

FIGURE 1

SEMI-INTEGRATED SERVICE MODEL



8. Current UK User Base

8.1. There are to date 1.6 million users of community alarm equipment within the UK the vast majority of which are "simple" pendant alarm systems. The vast majority of these systems provided to support older people.

8.2. The UK user base for Telehealth systems remains very small. However, these systems are used more extensively across North America where they have proved invaluable in managing care in a pro-active manner within the users' home.

8.3. The community alarms user base includes older people that are:

8.3.1 Living with long-term conditions.

8.3.2 Developing long-term conditions.

8.3.3 Becoming increasingly frail and increasingly prone to falls and domestic accidents.

8.3.4 Increasingly likely to need extended support and care.

8.3.5 Familiar with the use of technology and the response network to support them. As such they are more likely to recognise the benefits of using technology to maintain their independence.

8.4 The majority of providing agencies have no systems in place to review and enhance systems provided to these users in line with the changing circumstances of users of the systems. Prohibiting factors are believed to be:

8.4.1 Increased complexity of telecare systems—requiring greater installation to ensure correct siting and configuration of sensors and equipment etc places this outside the scope of non-technical staff currently employed to install "simple" systems. This can be overcome by using supplier and technical service organisations in holding stocks and providing rapid response teams to respond to requests for installation of systems against agreed response times.

8.4.2 Support arrangements are not in place to go beyond response mode to preventative mode.

8.5 As such, decisions are supply rather than needs led which:

8.5.1 Inhibits the extension of use of these systems to provide users with an independent living choice for longer.

8.5.2 Inhibits development of preventative approaches and risk management, rather than crisis management.

8.5.3 Promotes short-term decisions on equipment supply for this group with purchases generally price-led with little or no regard to the functionality and scalability of systems. This by-passes opportunities.

8.5.3.1 To provide solutions that are directly matched to initial user needs.

8.5.3.2 To allow solutions to adapt to changing user needs.

8.5.4 Misses the opportunity to set the precedent for providing for a broader range of older peoples developing care requirements within their home.

9. National Targets Relevant to Telecare

9.1. The Department of Health (DH) report Delivering 21st Century IT support for the NHS outlines targets for telecare to be available in all homes that need it by December 2010.

9.2. A further DH report National Standards, Local Action—Health and Social Care Standards and Planning Framework, 2005–06 to 2007–08 establishes a National Target to: "improve health outcomes for people with long term conditions by offering a personalised care plan for vulnerable people most at risk; and to reduce emergency bed days by 5% by 2008 (from the expected 2003–04 baseline) through improved care in primary care and community settings for people with long term conditions."

9.3. This same report also established National Targets to: "improve the quality of life and independence of vulnerable older people by supporting them to live in their own homes where possible by:

9.4. Increasing the proportion of older people being supported to live in their own home by 1% annually in 2007 and 2008; and

9.5. Increasing by 2008 the proportion of those supported intensively to live at home to 34% of the total of those being supported at home or in residential care."

10. Benefits

10.1. The Audit Commission report "Implementing Telecare" concludes that the case for a move beyond pilots and trial telecare projects is compelling. It also agrees with our view that the basic technology is robust and much less of a risk than the challenge of getting public services to work across organisational boundaries. Overcoming this challenge will:

10.1.1. Make independent living a realistic choice for a greater number of people supporting DH objectives to increase the number of people supported to live in their own home by 1% in 2007 and 2008 and the DH objective to provide Telecare in all homes that need it by December 2010.

10.1.2. Promote joint working and integrated care delivery plans to support DH objectives to increase by 2008 the proportion of those supported intensively to live at home to 34% of the total of those being supported at home or in residential care'.

10.1.3. Reduce cost of care by reducing number of beds occupied by older people both in acute hospitals and long-term residential care facilities. Supporting DH objectives to "improve health outcomes for people with long term conditions by offering a personalised care plan for vulnerable people most at risk; and to reduce emergency bed days by 5% by 2008 (from the expected 2003–04 baseline) through improved care in primary care and community settings for people with long term conditions."

10.1.4. Improve management of care by identifying a deteriorating condition before a crisis point is breached enabling treatment to be refined and shaped through timely and accurate health information. Further supporting DH objectives outlined in 1 and 2 above.

APPENDIX 8

Memorandum by Medtronic Ltd. (MT 30)

1. Summary

Medtronic welcomes the opportunity to submit evidence to the Health Select Committee, addressing the important issue of the utilisation of telemedicine, and its future potential for improving services within the NHS. Medtronic provides advanced, implantable medical devices for patients in the United Kingdom. Our most recent innovations in the area of telemedicine have the potential to significantly advance not only the quality of care for chronic disease patients, but also improve the efficiency of overall health care delivery within the NHS. The purpose of this submission is to provide the Committee with evidence of some of the benefits of telemedicine in chronic disease management, and to highlight some of the barriers to adoption.

2. We would like to offer the following evidence, appropriate to the Committee's terms of reference. The evidence reflects our experience in the use of telemedicine applications throughout the world.

3. The utilisation of telemedicine and its future potential for improving services.

3.1 Telemedicine is broadly defined as the use of electronic information and communications technologies, to provide and support health care when distance separates the participants.[12] The applications of telemedicine are increasingly important in the context of chronic disease management. Medtronic is advancing such applications for the remote monitoring of patients with cardiac rhythm management devices (implantable pacemakers and defibrillators), diabetes patients using insulin pumps and in patient data reporting for its emergency response systems (external defibrillators and ambulance based monitors). Remote monitoring allows medical professionals to access clinical information from devices without the patient having to be present in the surgery or clinic. This submission will focus on evidence concerning the remote monitoring of implanted cardiac rhythm management devices.

3.2 Cardiac arrhythmias, where the hearts beats abnormally slowly, quickly or in an irregular manner, are a chronic condition affecting millions of people in the UK, including the 110,000 who die from sudden cardiac death each year. Many of these patients can be effectively treated with implantable medical devices such as cardiac pacemakers for bradycardia (slow heart rates), implantable defibrillators for tachycardias (fast heart rates), and cardiac resynchronisation therapy for heart failure. It is estimated, that in the U.K. there are currently more than 200,000 patients with implantable cardiac rhythm management devices[13] and approximately 40,000 new implants are performed every year[14]. The U.K. is well behind other developed nations in its level of device therapy utilisation, a fact being addressed by the Cardiology community, and additional increases in the number of new implants are expected in order to meet the recommendations from various technology appraisals and clinical guidelines, either published or in preparation by the National Institute for Clinical Excellence (NICE)[15]. All device patients are required to have periodic follow-ups, to review their condition, device parameters and to adjust the therapy if appropriate. Each such visit lasts about 30 minutes and is a considerable inconvenience for patients, as it requires travel to and from the hospital, usually during normal working hours and, in many cases individuals require an escort. Additionally, the periodic routine checks create significant demand for hospital resources (physicians, cardiac technicians and facilities). As many follow-up checks are routine and no action is required, more efficient patient screening would enable the shifting of resources to other activities. This might be focusing on patients who require more attention, or the redeployment of highly qualified clinical staff to other functions within the cardiology department, making better use of their skills and. It is widely acknowledged that there is an acute shortage of trained technicians in the NHS. Any reduction in the number of, and attendees at follow-up clinics also has obvious benefits from a capacity perspective.

3.3 In 2002 Medtronic introduced a remote device monitoring solution called Carelink Network, a telemedicine application enabling data stored in the memory of implanted devices to be retrieved by medical professionals in locations removed from those individuals with the devices . This system allows patients to download the information from their device to a secure server, making it available to clinicians for review almost instantaneously. Remote monitoring of implantable pacemakers and defibrillators provides benefits in three key areas.

[12] M. Field, J, Grigsby "Telemedicine and Remote Patient Monitoring", JAMA, 2002 Vol 288 No 4.

[13] Source: Dr. David Cunningham, Central Cardiac Audit Database.

[14] Estimate, Medtronic Ltd.

[15] National Institute for Clinical Excellence, Technology Appraisals on Implanatable Cardioverter Defibrillators (2000 and currently in review), Dual Chamber Pacemakers (expected Jan 2005) and Cardiac Resynchronisation Therapy (expected March 2007). Clinical Guidelines on Chronic Heart Failure (July 2003) and Myocardial Infarction—Secondary Prevention (tbc).

3.4 Quality of care—better patient outcomes and improved quality of service delivery. CareLink Network service was assessed in a multi-center study[16] as a practical tool for routine device management, which may also allow timely identification of clinically important issues. Clinicians involved in this study found the quality of this service comparable to a device interrogation carried out in a clinic.

3.5 Efficiency in clinics—resource utilisation and workflow efficiency. Remote device monitoring allows for a reduction in the number of hospital visits and better access to device data. The implications of these improvements are a reduction in waiting time in clinics, a streamlined device follow-up process and the ability to free up resources used in clinics for other activities[17].

3.6 Additional reassurance for patients. Patients using remote follow-up technologies have the additional reassurance of being able to rapidly send data for investigation in times of concern. The discharge of a potentially life saving shock from an implantable defibrillator can be an alarming experience for an individual. Yet the overwhelming majority of shocks are entirely appropriate, the defibrillator merely having done its job. The ability of a patient in this situation to quickly and easily verify that the shock was necessary, and that the device needs no alteration, has obvious advantages for that individual. Additionally, patients have to make fewer trips to clinics, and, with many device patients being elderly, this has a major impact on the transport requirements for ambulance services, family and friends, as well as being more convenient for the individual themselves. Finally, remote monitors are portable and allow patients to travel freely.

3.7 Note: Carelink Network does not carry a CE mark and is not currently available in the UK.

4. The Speed of, and Barriers to, the Introduction of New Technologies

4.1 Whilst the benefits of telemedicine applications such as CareLink have been well recognised and documented during the two years of successful use in the USA, the introduction of this type of technology is not straightforward in the United Kingdom. There are three principal obstacles to adoption.

4.2 Funding. Current funding methods do not adequately recognise the value of telemedicine. Whilst Medtronic is encouraged by the attempts of the Payment by Results team to capture appropriate tariffs for telemedicine, there must be clear methodologies described to collect data in a meaningful way to create appropriate HRG labels, and realistic tariffs attached to them subsequently. Both the NHS and industry need to have proper incentives to develop productivity-enhancing technology.

4.3 Guidance. There are presently no guidelines advocating the use of telemedicine applications within the NHS. The development of, for example, NICE guidelines in this area would be welcome, and it will also be important to follow any such recommendations with an adequate set of measures to properly track their implementation.

4.4 Value recognition. Due to nature of their delivery, telemedicine applications provide benefits to various stakeholders. Whilst such benefits undoubtedly occur, they are not always recognised in their entirety, and as such the value of the technology may be underestimated. For example, travel costs and inconvenience incurred by patients are largely not recognised in hospitals, or, indeed, the wider NHS, but their societal impact is significant.

5. The Effectiveness and Cost Benefit of New Technologies

5.1 Remote patient management technologies improve the quality of care. Telemedicine applications provide clinicians with timely access to information about acute events, which require immediate attention. Remote patient management may also provides savings for patients by reducing the burden and cost of travelling to a clinic and spending time away from work.

5.2 The use of telemedicine is an important way of modernising services in clinics. The expected growth in the device patient population could either require extensive investment in resources and clinic capacity, or the additional resource requirement could be minimised through the application of technologies such as CareLink.

6. Recommendations

6.1 Telemedicine has the potential to improve the quality of patient care. Clinical and practical benefits of applications should be considered by NICE and appropriate guidance issued, and measures should be in place to track implementation.

6.2 The use of telemedicine within the NHS should, through favourable tariffs and other appropriate mechanisms, be incentivised, thus focusing efforts on ensuring rapid adoption.

[16] M Schoenfeld *et al* "Remote Monitoring of Implantable Cardioverter Defibrillators: A Prospective Analysis", PACE June 2004.

[17] R Owen "Pacer/Arrhythmia Clinic Improves Patient Satisfaction" EP Lab Digest, October 2003, Vol 3, No 8.

6.3 Introduction of telemedicine technologies can help the NHS to achieve waiting list reductions and other goals set in the National Service Frameworks, NHS Plan and other guidance documents. Investments aimed at achieving current NHS goals should include monies targeted for advanced telemedicine applications.

6.4 The cost of introducing telemedicine technologies can be rapidly offset through the reconfiguration of services across the health economy, and non-healthcare impacts on individuals. It is important to capture the true benefits of such technologies. A wider societal perspective, as well as the costs to the NHS should be considered when assessing the benefits of telemedicine.

6.6 Telemedicine is a rapidly developing field. A clear pathway for the introduction of telemedicine into the NHS should be defined, such that the potential these technologies have is fully realised.

7. Company Overview

7.1 Medtronic provides lifelong solutions for people with chronic disease. During the past year alone, Medtronic technologies treated more than five million patients throughout the world. Products include those for bradycardia pacing, tachyarrhythmia management, heart failure, atrial fibrillation, coronary and peripheral vascular disease, heart valve replacement, extra corporeal cardiac support, minimally invasive cardiac surgery, malignant and non-malignant pain, diabetes, gastroenterological ailments, urological disorders, movement disorders, spinal disorders, hydrocephalus, and ear, nose and throat (ENT) surgery. Founded in 1949, the company's world headquarters is in Minneapolis, USA, with research, manufacturing, education and sales premises in more than 120 countries. Medtronic employs approximately 31,000 people worldwide.[18]

7.2 Medtronic has been present in the UK for over 15 years, and all its businesses have sales, marketing, customer services and distribution operations here. Now employing over 200 people, Medtronic Ltd. is based in Watford, where there is also one of the company's Bakken Education Centres, a facility used by employees, medical professionals and patient groups. Medtronic's Clinical, Technical and Education groups have strong links with the programmes of numerous professional bodies, including the British Cardiac Society, providing, amongst other things, tuition for technicians taking professional exams. The Medtronic Foundation has supported the work of various Patient Advocacy Groups in the UK.

APPENDIX 9

Memorandum by the NHS Confederation (MT40)

Introduction

1. The NHS Confederation welcomes the Committee's inquiry into the use of medical technologies within the NHS and welcomes the opportunity to present evidence.

2. The NHS Confederation is a membership body that represents over 93% of all statutory NHS organisations across the UK. Our role is to provide a voice for the management of the NHS and represent the interests of NHS organisations. We are independent of the UK Government although we work closely with the Department of Health and the devolved administrations.

3. This evidence has been put together with The Future Healthcare Network (FHN). The FHN is made up of organisations that are at the leading edge of thinking about the future development of health services in the UK. FHN is part of the NHS Confederation, but with its own board of management and dedicated staff.

4. Overall the NHS Confederation supports the use of technology to maximise care outside hospital and maintain the independence of people for as long as is possible. Below we detail our response to the Committee's Terms of Reference.

The Utilization of Telemedicine (including Telecare) and its Future Potential for Improving Services

5. The aging UK population means that fewer people in the healthcare workforce and fewer carers are having / will be available to look after a larger number of older people. It is clear that the prevalence of longer term conditions eg diabetes is increasing and this will also have an impact.

6. At the same time, there is readily available technology available that can:

— maximise the care available in the home by guarding against falls, flood, fire through movement and hazard detectors connected to a community alarm service. Specialist expertise can also be made available in the home through internet and digital TV. Assimilation of technology in the

[18] Medtronic, Inc. Annual Report 2004.

home, together with successful partnerships between PCTs, Councils and equipment providers has increased choice for the elderly and those with long-term conditions. Many projects have been undertaken to evaluate how technology can enhance independent living and also assess what level of technology package should be offered.

— substitute technology for people where there is a shortage of skilled staff, for example, miniaturisation, robotics, IT interfaces and digital imaging will all impact on the location of services and the present workforce.

— empower people to take charge of their own healthcare management supported by professionals where appropriate, by allowing people to manage their own health monitoring, eg weight, lung function, blood and urine and blood pressure. Studies show that self-management in general leads to better outcomes in asthma, chronic obstructive pulmonary disease (COPD) and diabetes. Technology currently being used in the home can be further applied to the monitoring of chronic conditions, for example tele-medicine monitors to track the vital signs of COPD sufferers in the home.

— increase the safety of healthcare systems by improving tracking and identification of individuals using Radio Frequency Identity (RFID).

The Recommendations of the Healthcare Industries Task Force (HITF) Report, Published 17 November 2004

7. The NHS Confederation contributed to the HITF report and is supportive of its recommendations. In particular we would like to emphasise our support for the following recommendations:

— the development of device evaluation methodologies and the sharing of evaluation results throughout the NHS (refs 1–3)

— nationally agreed/accepted best practice models being developed for procurement processes (ref 5)

— the creation of an innovation network and funding to fast-track selected innovations and the establishment of a National NHS Innovation Centre (refs 11,13 and 30)

— that the Department of Health works with the Modernisation Agency and other stakeholders to ensure that best practice in commissioning specialised services can be shared across the NHS (ref 27)

— the strengthening of horizon scanning to identify systematically useful new and emerging technologies (ref 36)

— considering how to support the developing market for 'over the counter' medical devices and in vitro diagnostics (ref 43)

— improving the awareness of manufacturers of the importance of good design and exploring ways of feeding back information to them on design issues identified on products and systems in use (ref 44).

The Speed of, and Barriers to, the Introduction of New Technologies

8. There are a number of reasons for slow adoption of new technologies, particularly those which change the pattern of care delivery:

— Plague of pilots: There has been a plague of small pilots which have not established where and how the new technologies are most cost effectively employed. However the evidence around what to do next is not very clear.

— Funding: There is a lack of funding for new types of care both from Social Services and Health. New models of care often need to be introduced in parallel with existing services. Unfortunately the financial regime under which health and social care operate does not allow for the creation of reserves or borrowing to finance new services. This means that it is necessary to disinvest or use growth money. Unfortunately, the former is often difficult and contentious and the latter has many competing claims made upon it.

— Payment by results: The adoption of the payment by results system in the NHS could prevent a further obstacle as the tariff used to pay providers is based on existing technology. Therefore any change that increases the cost and quality or undertakes procedure in a very different way will tend to be under rewarded by the payment system. There is a mechanism to allow commissioners to recognise new technology where the tariff has not caught up with new practice but this is, as yet, untested.

— Attitude to risk: The feeling remains prevalent that whilst the rhetoric supports innovation and risk taking many of the accountability systems in public services are intolerant of risks that do not pay off. It is not possible to have risk free innovation and there will be inevitable failures. A different response to these events is required if the public sector is to become as open to technological innovation as other parts of the economy.

— Change management: Very often the purchase of new technology is the least of the problems in its adoption and implementation. Many truly innovative technologies require professional staff to adopt completely new working practices and systems may need to be substantially redesigned. The change management process required to persuade professional staff to make substantial alterations to their practice is very considerable. There may be similar issues about expectations and inertia when it comes to persuading carers and patients that care that they might have expected to have been provided in one way will now be delivered in a complete different way using new technologies.

— Professional boundaries: Clarity about the boundaries and handover between the professional, carer and personal roles may mean that there may be professional resistance to change. This is also related to the issue of risk. Clinicians may be reluctant to hand over responsibility for care to their patients.

9. One of the most significant potential barriers to implementation is the extent to which new technologies fit with existing systems. For example, it will be harder to adopt devices with an IT interface that are not designed to link with NHS IT systems to form part of an IT record as is often the case at present.

The Effectiveness and Cost Benefit of New Technologies

10. There is still a tendency to ask questions about the cost-effectiveness of new technologies without a similarly rigorous approach being taken to the evaluation of existing technologies. This makes it much harder to disinvest to create financial headroom for investment in new technologies. There is a particular hazard in evaluating new technologies in terms of an arbitrarily selected cost-effectiveness threshold, such as a minimum cost per quality of life year. The danger is that technologies approved in this way may be favoured over existing solutions which are more cost-effective but have not been evaluated.

APPENDIX 10

Memorandum by The Technical Solutions Implementation Group of the UK e-Health Association (MT 41)

UK e-Health Association

The UK e-Health Association is a membership body representing those organisations and individuals interested in promoting e-health in the United Kingdom. It is a non-profit making company limited by guarantee governed by a Board of Trustees. It counts among its members organisations and individuals from both private and public sectors. Further information about UKeHA may be found on its website (www.ukeha.org.uk).

This evidence has been prepared by members of the UKeHA Technical Solutions Implementation Group (TSIG) and approved by the UKeHA Board.

The UKeHA and TSIG would be pleased to submit oral evidence, if required.

Recommendations

1. The Department of Health should provide active top level leadership for the development of e-health services and should more effectively coordinate existing and new e-health activities across the health sector; and to this end should designate an "e-health leader" at the most senior level (outwith the National Programme for IT).

2. There is a need for a showcase for new technologies, systems and services, in use on a day to day basis, designed to allow evaluation and appraisal of new developments based on experience and their relative value as part of a wider, overall solution.

3. Such evaluation should also cover the technical capabilities of new technologies and systems, with support from appropriately qualified medical technicians and IT specialists. Clear information should be produced on the capabilities and limitations of the systems in different environments, how and where they could be used, and interface with other systems.

4. Such evaluation should also cover the people and process aspects of new technologies, to develop "standard operating procedures" to ensure the seamless integration and interoperation of the specific device, system or service, irrespective of its place of use or the place of service delivery.

5. e-health systems and services subject to such evaluation should be accredited such that any accredited system or service should be able to integrate and interoperate with any other accredited system or service anywhere else in the country.

6. Recommendations 2–5 above could be achieved within the context of an "Incubation Centre" where innovations are used and tested in real working situations. Within such a centre the relevance to and capabilities of integration and interoperation with other systems could be evaluated and an appropriate blue print of how they should be used in other real world situations defined. The "Incubation Centre" would not be just a showcase but a model of how innovative technologies could be used.

Introduction

1. This report looks at the use of new medical technologies from an e-health perspective. e-health, as with e-commerce and e-government, relates to all aspects of health that utilise electronic processing, communication, storage etc. Given the prevalence of such matters in all walks of life, one would think that this would be a principle concern of any initiative concerned with improving health or developing healthcare services. Unfortunately, e-health is usually an afterthought, and new technologies are more usually developed in isolation, instead as part of an integrated and interoperating network of care services.

e-health and NPfIT

2. We understand that the Health Committee's Inquiry does not extend to the National Programme for Information Technology (NPfIT). It is however important to understand that e-health extends much wider than NPfIT—indeed NPfIT can be regarded as a relatively narrow programme of infrastructure development, which in due course may well enable much wider e-health development. In the short term there is a danger that the very significant investment in NPfIT and the consequent prominence given to it in the management and funding of the NHS will overshadow and suppress the need for wider e-health development. There is a real danger of missed opportunity through the lack of clear leadership from the centre on e-health development and the coordination of existing e-health activity.

3. This is why our first recommendation is concerned with the need for much more active top-level leadership by the Department of Health on the development of e-health.

The Utilisation of Telemedicine (including Telecare) and its Future Potential for Improving Services

4. New technology within medicine is a subject as old as medicine itself and as in any walk of life, is always looked on with scepticism and introduced with reservation. The stethoscope is a particularly good example of such initial scepticism. It is, however, in the area of computerisation that the biggest problems arise. This is best understood by looking at the history of computers in health. Initially computers delivered little or no clinical benefit but did increase the workload on clinicians and were a long way from being "user friendly". The advent of the PC and more specifically, sophisticated operating systems such as Windows, helped dramatically by being more useable and offering easier access to information. However, a whole plethora of dissimilar competing systems were developed with individual clinicians exercising personal preferences for this or that system. They did not (and still do not) integrate or interoperate with one another and they do not necessarily collect the same data. While much of this is the responsibility of NPfIT (and therefore outside the scope of this Inquiry) there are important aspects that are not covered and it is these that we now examine.

5. Most measurements of physiological data by clinicians, such as blood pressure, are done manually or by stand-alone devices. Transcribing this information into a patient's record is also done manually, even when using a computerised electronic patient record system. These electronic devices are obviously more prevalent in hospitals and ambulances. Some even have a data port, which will allow them to connect to another electronic device or link them into a larger, proprietary system. There are two significant problems with this, firstly, they are designed as stand alone systems not as components of an integrated information system and secondly, there is much confusion about what they can or cannot do.

6. An illustration may help. The government has recently made money available to ambulance services to purchase "telemedicine" enabled 12 lead Electrocardiograph (ECG) units (An ECG unit is a device for producing a graph of the electrical activity of the heart. The term "lead" refers to a view of the heart through a particular axis). What is a 12 lead ECG? Do we really need a 12 lead or would a 3 lead do? (A 12 lead is used routinely in hospital both because it is available and because it usually gives diagnostic details without the need for a cardiologist). If we do need a 12 lead, do we need all 12 leads simultaneously or one at a time? If one at a time should they all be of the same time interval, sent sequentially, or a representation of the time interval over which they are being sent? How are we going to send it? Who is going to receive it and what will happen to it then?

7. These questions serve to remind us that devices themselves are not a solution, in fact most devices on their own have little diagnostic value, and there are other components necessary to ensure that they work as part of a solution that at least allows access to an appropriately qualified person to use/interpret the data received.

8. It is also important to realise that the fact that a 12 lead ECG unit has a data port and is "communications enabled" does not make it a telemedicine unit. Telemedicine requires appropriate data communication and trained personnel. And what does "communications enabled" mean? Often it means that it can communicate with a computer, which is also potentially very misleading. Those with PC experience you will know that even if everything works correctly now, if you try and install a new program or device, while it may or may not work, other applications and systems that were previously working may now not work! This is not an acceptable outcome for a medical device. There is a serious lack of understanding, outside the regulatory bodies, about the use of computers in the medical field and about what is and what is not a medical device and where responsibility for failure lies.

9. Companies that produce these devices sometimes also produce a range of other devices that link together to make a total "solution". While this overcomes the problem of a "stand-alone" device, it does create an additional problem that you have to use their components, their terminals, their software etc. This is how the computer market was before the advent of the IBM Personal Computer (PC) 25 years ago. Nowadays you can buy any PC software and it will run, any hardware and it will connect. You can take data off your PC and run it on someone else's.

10. We take this interconnectivity for granted, and businesses have grown up that only make certain bits of computer hardware. Perhaps less well known is the fact that specialist programmers write pieces of code which are used by other programmers to incorporate into their own offerings. Before the "PC" this could not be done. Not only could you not take a floppy disk from one computer and run it on another, the disk probably wouldn't even fit. Programmers not only had to write programs for specific makes of computer but they might also have to restrict users to a set of known printers and other peripherals.

11. Just as the PC market changed, so too must the medical market. For the PC this was brought about by an open hardware platform (the IBM Personal Computer or "PC") and a common operating system or user interface. The medical market must change in a similar way but with one important additional item, the adoption of common practices and standard clinical procedures on a national basis. This is nothing to do with clinical or regulatory standards, which are already well catered for, but a clear set of "Standard Operating Procedures" to ensure different people in separate locations know what is going on, where in a process things are and what comes next.

12. Most professions have clearly defined rules and procedures, and as circumstances change then the rules change. Medicine is practised by highly qualified professionals but (and this is really serious) they practice medicine in their own particular way. Imagine if this was how air traffic control was handled. With the advent of e-health, many clinical interventions will be done without the physical presence of a clinician, or by a less qualified clinician remotely supported. For this to work smoothly there need to be clearly defined operational procedures and processes. We are not referring to aspects already adequately covered by existing standards bodies and agencies but the specific elements that pertain to remote use and the interaction and interoperability of people and systems when connected electronically.

13. As has already been mentioned, the term "Telemedicine" now comes under the broader banner of e-health, along with Telecare. However, the intended focus of this Inquiry is presumed to be the use of e-health systems and services to deliver remote medical interventions (telemedicine) and ongoing remote care at home or other non-medical facilities (telecare). The key word here is "remote", which simply means that one or more elements of the solution are not at the same locality as the patient. Remote can, therefore, be as diverse as the care of an airline passenger by a doctor on the ground or a patient receiving care at home from a community nurse with remote access to patient records, hospital booking systems etc. Large distances are NOT a prerequisite!

14. At the moment, instances of telemedicine and telecare tend to be looked at in isolation, a bit like looking at flour, eggs, sugar etc as the end product without looking to see how these things can be put together to make something that is more than the sum of the parts. Indeed, very little consideration is given to telemedicine despite the huge cost being incurred in building NPfIT, which will enable telemedicine and turn it into a major form of medical intervention.

15. NHS Direct is telemedicine, in the sense that the initial activity is telephone based (and therefore remote). Despite doing a reasonable job for many, it does a less than adequate job for most long term or repeat illness patients, who need an enhanced system where they reach a clinician with direct access to their notes and, in the case of longer term illness, perhaps even real time medical parameters, blood pressure, ECG etc. It is not that the capability does not exist to provide such enhanced service; it is just that there is no high level support for such initiatives.

16. Instances of telemedicine and telecare are currently run as local "pilots" where there is a clinical lead that is willing to support the initiative. Often funding for such "pilots" dries up or the clinical lead moves on. This lack of high-level support means that the same initiatives are piloted again and again all over the country, the outcomes of previous pilots being completely unknown to anyone other than those intimately involved in the project.

17. There is also a sense that telemedicine systems, because they connect to computer systems, which are getting cheaper and cheaper, should also be significantly cheaper than hospital systems. An over the counter blood pressure unit from Boots can cost you less than a hundred pounds, while a hospital unit often costs

10 times this. The answer is clearly one of quality, but as more and more of these systems are produced their unit cost will reduce. What we shouldn't do, but is happening, is to compare telemedicine systems based on low quality components, with the equivalent high quality hospital based system.

18. Once we make this change of attitude, the potential for telemedicine far exceeds our imagination. Care homes are, by their very nature, places that tend to have a greater need for home visits and out of hours care. By putting telemedicine equipment into these locations and connecting them to a "virtual GP" system, much of this need could be addressed remotely. Community nurses should also be equipped with appropriate systems both in terms of monitoring and remote access to electronic patient records, decision support tools and so on. Once established, with the staff and patients both conversant with the systems, it will be possible for regular, routine monitoring to take place, not just knee jerk emergency intervention. Regular monitoring combined with other pieces of relevant information can be used for early intervention and ultimately prevention.

19. Telemedicine is not simply about technology, it requires the adoption of common practices and processes. This cannot be achieved by individual "pilots" run by local enthusiasts; this must be done, first in a specific area (where it is evaluated and problems ironed out) and then systematically on a wider and wider basis until adopted nationwide. This requires support at the highest level within government and, on an International basis, through cooperation and mutual development with other countries.

20. Telemedicine will also enable a strong interaction between the private sector and NHS. There is a diving company, based in Aberdeen, which provides telemedicine support for their divers, even while still in hyperbaric chambers. A doctor, also in Aberdeen, is able to monitor a diver, under pressure in a hyperbaric chamber, on board the company's diving vessels, wherever they may be, anywhere in the world. Under the NPfIT, these divers will all have an electronic patient record; the private doctor in Aberdeen should be allowed appropriate access to this record to be able to properly manage the current medical situation. Likewise, on returning to shore, the diver's GP should be able to see what action was taken by the doctor in Aberdeen and by any medic on the ship. This is just one example of how companies and even individuals will pay for medical services, the outcome of which is available to NHS doctors, thereby simplifying and streamlining the interventions and care given and ultimately reducing costs through cutting out duplication of tests etc.

21. Ultimately, people will be able to receive hospital grade monitoring in their workplace, at the gym, on board an aircraft on holiday and so on. These cease to be isolated incidents but part of the complete picture of a person's long-term health.

The Recommendations of the Healthcare Industries Task Force (HITF) Report, Published 17 November 2004

22. The main recommendations of the HITF report were contained in nine key outputs; however, these are primarily concerned with medicine as we know it, not e-health, which is seen as a new technology in itself. It is our belief that, within a very short time frame, all aspects of health will, in some way, integrate with a wider "e" component, even if they are not themselves part of an overall e-health solution. To that end, this report emphasises the additional aspects needed for this to happen.

23. The HITF report seeks to "inform procurement decisions and encourage the support and uptake of useful, safe, innovative products and procedures". For this to happen, there must be some system of evaluation and assessment that has also been proven in real life scenarios. The UKeHA TSIG has already produced various documents on how this should be done and welcomes the recommendations of the report. Unfortunately, unless these recommendations are followed through, nothing changes. There is also the need to "train the trainers" with regard to the wider benefits of e-health. While the outputs of the HITF are being considered and the follow-on actions devised, e-health implications must be built in. Otherwise technology will only be an add-on to existing practices, not an integral part of healthcare delivery.

24. The report also seeks to "Stimulate more innovation and encourage a more entrepreneurial culture in industry and the NHS". The only part of this that needs serious action is that part involving the NHS and even here it is not a lack of desire on the part of those involved, simply those in decision making positions. The UK leads the world in the development of innovative medical technology; the problem is not one of innovation but one of innovative leadership.

25. The HITF report calls for a new Innovation Centre, and while this is a good idea in principle, what we really need is an "Incubation Centre" (see our Recommendations) where innovations are used and tested in real, working situations. Within such a centre the relevance to and capabilities of integration and interoperation with other systems can be evaluated and an appropriate blue print of how they should be used in other real world situations defined. The "Incubation Centre" would not be just a showcase but a model of how innovative technologies can be used. Nurses need to see other nurses working with something to understand the true potential and value; the same is true of all professionals, not just in healthcare. Such a centre would also fulfil a large number of other recommendations of the HITF report, with the exception of introducing an "innovation fund". However, the output of the "Incubation Centre" will do this and the need therefore is not for a "fund" but to fund the "Incubation Centre".

26. One aspect looked at in the HITF report is procurement. It is not for us to make recommendations outside our sphere of expertise. However, common sense would suggest that if an "Incubation Centre" is established and it delivers clear guidelines on not only how to use a specific piece of technology for a particular function, but defines best practice procedures and processes, then healthcare agencies within the NHS should, subject to their own budgetary constraints, be able to purchase said technology for use in this manner. Those involved in the procurement process should actively work with the "Incubation Centre" to ensure that "cost effectiveness" is a major consideration and provide details of how this is evaluated.

27. e-health also has a serious role to play in providing the evidence base in support of R&D activities. Regular monitoring of everyone, by using e-health tools as part of an overall e-health programme, will provide a greater understanding of factors leading to ill health. At the moment people only really enter an evidence-based program once they are already sick. e-health offers the first real chance of monitoring people, both well and sick, from before birth until death and should, therefore, be embraced as a common thread to any R&D programme.

28. The UKeHA is aware of a number of initiatives involving different academic centres of excellence, which are looking to be "the recognised academic body" within a specific area or aspect of health. The UKeHA and its TSIG would be happy to work with any academic institute to this end and already has strong representation from a number of academic bodies as members. The key would be for the academics to work with the "Incubation Centre", as outlined above, to ensure that all are working to the same goals.

29. The establishment of an "Incubator Centre" would also provide a platform from which to address communications with and between patients/the public and clinical bodies/government agencies in all aspects relating to e-health. A working centre that is open to public scrutiny and which would actively encourage the participation of patient and healthcare groups, including Royal Colleges, Unions and other interested parties, would provide an open forum that would actively encourage communication. This, in turn leads to education and training.

30. "Knowledge dispels fear" is an apt phrase because the converse is also true. People are afraid of what they do not understand. When PCs were first introduced, people from all walks of life became concerned about their jobs and a myriad of other completely unrelated things. Training and education removes this barrier of fear and people move on.

31. The HITF report suggests "Maximising UK influence in regulatory matters in the EU and other international forums". We agree with this wholeheartedly, the UK already leads the world in many aspects of e-health and to apply best practice and standard operating procedures to this at a time when they simply do not exist would be to secure our long-term influence. This is also a major cost factor as, if other standards are adopted in preference to ours, then in order to operate on an international basis, our systems will have to be changed or adapted to meet these different standards.

The Speed of, and Barriers to, the Introduction of New Technologies

32. It is fair to say that most e-health "pilots" have not moved beyond the initial "pilot" stage. The reasons for this have been well documented: principally they have been driven by a single, local, sponsor with no ongoing funding and no "place" for a full blown service within the current healthcare structure.

33. Healthcare is broken up into very distinct compartments and if an initiative crosses boundaries, or worse if the benefits of an initiative are seen in a different sectors, there is no funding. Sources of funding also change, and even when funding has been obtained, it is not unknown for this to be used somewhere else or for a different purpose within an organisation.

34. There is little to no long term planning, with short-term goals taking precedence over long term objectives that could otherwise bring accumulating benefits.

35. There is a lack of trust by clinicians in IT systems, which have, in the past, been purely administrative tools. There needs to be a place where people from all sectors of healthcare can go and see new technology being used in real situations by ordinary people.

The Effectiveness and Cost Benefit of New Technologies

36. As new technologies, practices and processes are adopted, there will be the initial benefits for which they were intended, but there will then come additional benefits, many of which will remain unknown until they actually happen. What we have to be wary of, however, is a simplified comparison against some arbitrary factor.

37. By way of illustration, there was a dermatology pilot conducted between GPs in rural practices and a remote consultant dermatologist. When the GPs were faced with a skin problem they could not identify, an appointment would be made for the patient to return to the practice at a time when the doctor could have a live link to the remote dermatologist. The skin would be photographed using an appropriate digital camera and the image sent to the dermatologist. He would discuss this with the patient in the presence of the GP.

38. At the end of the project it was reported to be a failure, not by the doctors, patients or dermatologist but by a third party auditor. The reason for the failure was that, after an initial period of regular use, the system was used less and less. On questioning the doctors, they deemed it a huge success. Why the drop in usage? Each time they referred a patient, they were, in effect, receiving ongoing training. Once a condition had been seen on a number of occasions, the doctors no longer needed to refer the patient but were able to deal with the situation themselves!

39. Healthcare will never cost less, but, it will be possible to do more for the same amount. As new technologies emerge, when a patient is screened for one particular aspect, it will probably be possible to simultaneously screen for many other things at the same time. If e-health is taken seriously and the right sort of leadership provided, medicine will start to move from only dealing with people once they are sick, to managing them while they are well and intervening at the fist sign of "preconditions" to act in a preventative manner. Healthcare in the UK will move to a truly National HEALTH Service.

APPENDIX 11

Memorandum by KCI Medical Ltd (MT 43)

Introduction

Founded by an emergency room physician in 1976, Kinetic Concepts Incorporated (KCI) is a global corporation providing leading edge innovation in wound care, pulmonary care, bariatric care, and circulatory improvement in all care settings. KCI manufactures, delivers and services one of the largest offerings of speciality beds and related medical devices. The company is dedicated in taking an active role in the healing process, helping to save a patient's life, helping to improve the quality of a patient's life, and reducing the cost of healthcare along the way.

KCI Therapies have been clinically proven and/or financially justified in, collectively, more than 110 articles published in peer-reviewed clinical journals. Through research-based protocols and a clinically trained support team, KCI helps ensure that the right patient receives the right therapy for the right length of time.

KCI welcomes the Health Select Committee's inquiry into the use of medical technology in the NHS and the opportunity to submit evidence.

KCI's Views on the Inquiry's Terms of Reference

1. *Recommendations of the Healthcare Industries Task Force (HITF) report*

1.1 As an active member of the Healthcare Industries Task Force, KCI hopes the Government will ensure that the recommendations of the report are implemented as quickly as possible. KCI welcomed the opportunity to work with the Department of Health on this important project and presses the Government to ensure that the good work that has been started by this process continues.

1.2 The recommendations from the HITF report pertaining to device evaluation and procurement are of particular interest to KCI. It is essential for the uptake of new technologies that the purchase of medical devices is best aligned with the relevant NHS providers to ensure the quickest possible benefit to patients. This is especially true where the use of a medical device will cross the boundary between secondary and primary care. KCI's concerns regarding this issue are outlined further in the section on barriers to uptake of new technology (paragraph 2.2).

1.3 The Device Evaluation Service (DES) as outlined in the HITF report should go some way to providing a single point of reference for NHS bodies and individuals relating to new medical devices. KCI therefore recommends that the legislative process to enable the move of this body from the Medicines and Healthcare Products Regulatory Agency (MHRA) to the Purchasing and Supply Agency (PASA) commence as soon as possible. However, due to the fast paced introduction of both new and evolving medical technology, it will be essential that the DES has the capability to handle the constant updating and diverse nature of these products. In the first instance, it is not clear whether consideration has been given to how technology will be prioritised in terms of assessment by the DES, as all technologies will not be able to be assessed at once. If it will, for example, be based on clinical and/or financial importance, then it is essential that Industry is made aware of this or any other process as soon as possible.

1.4 Training and Education of NHS staff for new medical devices is an essential element of patient access to this technology. Of particular concern is the prevention of the use of new devices, which improve patient outcomes and quality of life, due to a lack of understanding or awareness of a technology. KCI would encourage the implementation of the recommendations in the HITF report on Training and Education, but also recommend that further attention and consideration (particularly in relation to funding decisions for new technology) be paid to the value that medical device companies can offer for the direct training of NHS

staff. It is also essential that healthcare professionals are given the time to train appropriately, not only on the use of new technologies, but also the updated newest technologies, otherwise the patient benefits of these can be lost.

2. *The speed of, and barriers to, the introduction of new technologies*

2.1 Medical technology is often purchased, or not purchased as the case may be, on the basis of the initial, short-term cost of the equipment. Factors such as the ability to shorten hospital stay, reduce waiting lists and hospital admissions are often not taken into account. The long-term social and economic benefits of medical technology must be evaluated when making procurement decisions. For example, KCI is a world leader in the development of therapeutic medical devices that help promote wound healing in acute care settings, such as trauma and surgically created wounds, amputations, burns, serious pressure ulcers and skin grafts. In 1994, KCI introduced V.A.C.® Therapy™ which is effective in treating the most challenging trauma and abdominal wounds, by applying a vacuum force across a sealed wound using a reticulated foam interface. The vacuum effect and the mechanical forces generated at the interface of the foam positively influence the healing process allowing patients who have to be hospitalised for wound management to be healed and discharged home earlier, thus shortening the length of stay in the hospital and freeing up the bed space for another patient. In addition, V.A.C.® Therapy™ dressings are changed every two days rather than multiple times in one day, which, again, must be taken into consideration.

2.2 Funding in the community also presents a barrier to the introduction to new technologies. KCI has recently launched a variation of the above therapy which allows for the continued treatment in the community. The V.A.C.® Freedom™ has recently won an Independent Living Award for its ability to enable the disabled and debilitated more freedom, mobility and choice:

> "*With the new VAC Freedom I feel that civilisation has returned and I can unobtrusively rejoin society*[19]"

However, present procurement mechanisms prevent PCTs paying for the device through FPI0. This means that although the therapy is often clinically recommended, patients are denied access to the treatment in their own home and remain in hospital to continue treatment. KCI cannot understand why primary and secondary care providers will not work together to formulate specific commissioning arrangements for technologies that cut across PCT and Trust boundaries. The use of such technologies not only benefits patients, but they can also result in financial savings for both providers. It is unacceptable that a patient, although well enough to continue their care at home, should be denied such treatment when a medical professional has made such a recommendation.

2.3 The Drug Tariff is presenting a further barrier to the introduction of new technologies. As more and more devices fail to be funded through the Drug Tariff, manufacturers are creating products that will ensure inclusion in the Tariff, rather than developing innovative products for the benefit of patients. KCI believes that a complete review of the Drug Tariff in relation to medical devices is needed to ensure that patients are not being denied the latest products because of commissioning concerns.

2.4 A lack of clear guidance from the National Institute of Clinical Excellence (NICE) presents a barrier to the introduction of new technology. For example, in the area of woundcare, NICE is focusing on creating clinical guidelines for particular areas of wound management rather than undertaking individual technology appraisals. This is unfortunate as lack of specific guidance from NICE can lead to a variation in service and therefore patient choice and treatment. KCI would recommend that all products receive technology appraisals and that the uptake of products following such recommendations is monitored.

3. *The effectiveness and cost benefit of new technologies*

3.1 New technologies, such as those produced by KCI, bring benefits to the patient, the NHS and society as a whole. As previously mentioned, they are effective by helping to reduce waiting lists, shortening the length of stay in hospital, relieving bed-blocking, enabling patients to be cared for in their own home and, most importantly, improving the quality of life of patients.

3.2 The cost benefit of medical technology must be considered in the long rather than short-term. For the patient, a shorter stay in hospital and care in the community, coupled with significantly reduced risk in readmission can only have positive consequences. Medical technology like the V.A.C.® Freedom™ has allowed patients to return to their lives more quickly and, in most cases, return to work. This has implications not just for the patient who can continue to earn a living and perhaps provide for a family, but society as a whole as it reduces reliance on social security and other State benefits.

3.3 The effectiveness and cost benefit to the NHS is considerable in terms of bed days saved and helping to achieve waiting targets. For example, a recent case study (October 2004) by Claire Campbell, Macmillan Gynaecology Oncology Clinical Nurse Specialist at Northampton General Hospital, demonstrated that for the treatment of women with wounds, as a result of vulval surgery, that have broken down, using VAC machines reduced length of stay in hospital by 7–14 days.

[19] John Hume, *Nursing Times—"The VAC Freedom portable would healing system"*, Nov/Dec 2004.

3.4 However, medical technology is also effective in helping to reduce the risk of hospital-acquired infection and the costs associated with bacterial infection such as MRSA. The Rapid Review Panel set up by the Department of Health and the Health Protection Agency is currently considering technologies which will help prevent hospital-acquired infections. Again, products such as V.A.C.® Therapy™ (which is about to be considered by the Panel), can make a contribution to the problem; while at the same time produce considerable cost benefits to the NHS as a whole.

4. *Key recommendations*

- That the Device Evaluation Service, once transferred to the Purchasing and Supply Agency, is provided with the capability and resources to carry out its role across the diverse and rapidly changing medical technology field to ensure that patients receive the best possible treatment in a timely fashion. That a review of the scope for assessment of technology by the DES takes place and that industry is provided with both this process and the process for prioritising technology assessments as soon as possible.
- That prior to the commencement of any major purchasing initiative involving medical technology, a survey of stakeholders takes place to ensure that any changes will not impact on the viability of NHS services.
- That long-term social and economic benefits of medical technology for both patients and the NHS are considered when making procurement decisions.
- That a complete review of the Drug Tariff in relation to Medical Technology is needed to ensure that patients are not being denied the latest treatments, in the most appropriate setting.
- That there is a permanent mechanism for the rapid review and uptake of technologies that will have a major impact on achieving Government priorities and targets for NHS patients.

APPENDIX 12

Memorandum by QinetiQ (MT 52)

Introduction

1. QinetiQ, its predecessor the Defence Evaluation and Research Agency and the research establishments from which it grew, has a record of almost a century of innovation for Britain's armed forces and defence industries, formerly under the Ministry of Defence and now in the marketplace. Many technologies it has pioneered have actual or potential applications in medicine and healthcare.

2. QinetiQ is involved in collaborative R&D projects with the MoD—its principal customer—the Department of Health, the NHS and its components, Abbot Diagnostics, GlaxoSmithKline, Rentokil Initial, Merlin Biosciences and internationally renowned hospitals and pharmaceutical and medical device companies. It has also over the last five years conducted more than £10 million worth of research in conjunction with the NHS and the UK health industry.

3. As a niche player in the field of healthcare technology, QinetiQ welcomes the Committee's inquiry. It believes much more can be done to harness new technologies to achieve better care and more effective service delivery, and to promote innovation.

The Strategic Use of New Technology in Health

4. Within the Department of Health there is great enthusiasm for new technologies that could revolutionise patient care and service delivery. Yet there is also a realisation that the NHS is failing to adopt them; indeed QinetiQ was recently advised within the DoH that the best chance of getting some of the most promising technologies adopted was to secure the support of the Prime Minister. This raises questions about the ability of current structures in health service governance to achieve results.

5. The DoH needs to adopt a more strategic approach to the development of technology over the long term. Its R&D budget seems to be spent without strategic direction or objectives. Numerous good ideas are supported with widely dispersed funds that in isolation are inadequate to realise scale or implementation.

6. The new NHS innovation hubs are beginning to identify, protect and develop NHS intellectual property; this is welcomed. Strong interaction between these hubs, the DTI and UK industry should be encouraged to see real pull through of selected, meaningful technologies. We would encourage the hubs' work to be set against a sound and long-term strategic view of NHS needs. If the NHS leverages its IP assets properly, it should see the benefit of returned revenue (from royalties) that can contribute to the costs of the NHS.

Harnessing Procurement as an Engine for Innovation and the Need for "First Adopters"

7. QinetiQ participated in the Health Industry Task Force, and strongly supports its recommendations. In particular, we commend its call for more support for innovation; across government there tends to be a lack of backing for the process of getting products and systems out of the laboratory and into the market place. There is no shortage of good science or ingenious inventions in this country, but there remains a chronic and urgent need to bridge this gap, and as it is bridged the NHS will be one of the principal beneficiaries.

8. There is much the DoH and the NHS can do to assist this process. Industry is reluctant to take on a new innovation without market pull, and in health the NHS is that market. The strongest possible engine for innovation is procurement, and procurement on the immense scale required for the NHS is not yet serving as that engine. For it to do so, more joined-up thinking and a greater awareness of strategic procurement and its potential in all sectors of the NHS—whether or not items are centrally procured—will be necessary. Without it, new technologies will too often fail to feed through to patient care.

9. QinetiQ's experience throughout government procurement is that innovation is often stifled through the absence of a first adopter, and this is unquestionably so with health. There are many initiatives put forward to improve care delivery, but often no champion or owner of the problem (with a budget) at Department level to see it delivered. For example the London Heart Project has the backing of strategic health authorities, primary care, industry and many health professionals, yet is languishing due to a lack of committed funds to get it underway because no-one centrally will take ownership of it.

10. To give another example, QinetiQ, when still DERA, received £10.8 million from HM Treasury via the MoD for a number of innovative Health R&D projects packaged as "The Virtual Hospital". This resulted in foetal ECG monitoring systems, a breast cancer grading system and 12 other projects. QinetiQ has since found it very difficult to get the NHS or industry to leverage the output of this research, despite several of the projects being rated as world-class by healthcare professionals.

11. In another instance, QinetiQ has, working with clinicians, proved the ability of simple decision support tools to dramatically reduce the time taken yet improve the accuracy of clinical decisions in intensive care. The potential for significant cash savings through the reduction in bed stay is very high. Despite this, this system has not been taken up because trusts either do not have the necessary IT infrastructure or do not recognise this as a priority.

The Need for Central Evaluation and Published Standards

12. There is no centre of innovation, test and evaluation for healthcare products and processes in the UK. There is a dispersed body of expertise in some universities and NICE produces guidance in the areas of technology appraisal, clinical guidelines and interventional procedures, but the lack of such a centre to reinforce and inform NICE and cover those fields where its writ does not run is sorely felt. The NHS innovation hubs could go some way to close this gap, but no such intention has been indicated.

13. Spain and the US have developed centres where medical devices, new products and new approaches to healthcare delivery can be tested in a near to life simulated environment. Although a few NHS trusts (eg Queen Alexandra, Portsmouth) have developed training suites for surgeons and trauma care using manikins, uptake of use and effectively marketing the use of such a facility is limited. QinetiQ has experience of operating centres of this kind across the range of technology, such as its Centre for Human Sciences at Farnborough.

14. QinetiQ believes that such a centre in the UK in the field of healthcare would be highly beneficial, whether created from the network of NHS innovation hubs or separately. It would test the boundaries of new health technology, add value to training and simulation and test systems for their fitness for purpose, proper design, safety and applicability. This would assist the NHS, the UK health industry and patient safety by bringing through products and systems that would improve healthcare, and which the industry could sell profitably and to the right standard. It would also benefit the UK economy because better products could be exported.

15. The National Programme for Information Technology is underway to address the gross infrastructure and software needs of the NHS but, there are as yet no national standards for connectivity, qualification or accreditation of new systems to be used within it. In Denmark, in contrast, published interoperability standards for information systems have allowed the country's health IT industry to develop innovative products and retain competition and choice in the market place.

The Slow Adoption of Telemedicine

16. Telemedicine—the delivery of care facilitated by communications technology—is not new, but modern multi-media technology facilitates its delivery on an unprecedented scale and in more ways than ever before. It is one of several aspects of eHealth that pull together different information technology applications across the spectrum of medical services, decision support systems and pervasive computing.

17. People like telemedicine. It delivers care at the point of need more efficiently, provides good support to care givers and professionals and reduces the burden on the NHS. A good example of its use with demonstrable benefits is the minor injuries nurse-led assessment programme in Cornwall that has led to a reduction in referrals to hospital, better patient engagement and satisfaction and improved nurse education.

18. While numerous telemedicine projects have been mooted and even trialled in the UK in recent years, very few have yet resulted in ongoing clinical service delivery. The UK telemedicine industry has been left to struggle against a lack of NHS uptake. This is in sharp contrast to the experience and performance of the industry in the United States, which is booming as the use of new technologies and communications is embraced.

19. Many projects in this field have technological merit but lack the care delivery model and health economic assessment needed to support their translation into the world of practical patient care. They also need continuing support and nurture from the NHS, which frequently appears too balkanised to provide it.

20. For example, QinetiQ facilitated between NHS trusts, primary care and NHS Direct a project for supporting chronic pulmonary disease patients in their own home. Great difficulty was experienced in getting the different segments of the NHS to agree how to work together and whose budget such care would come from. Despite a successful project (funded by HM Treasury) that was eventually handed over to NHS Direct, no further implementation has occurred, to the frustration of patients and professionals who were involved.

The Scope for New Technologies Outside Secondary Healthcare

21. A greater emphasis is now being placed on supporting patients outwith secondary care trusts. Yet the balance of investment is not changing; more than 80% of routine healthcare takes place in primary care yet the largest infrastructure spend is in secondary care.

22. The smart use of new technology can support primary care with better facilities, technology and resources, keeping more people out of hospital. Building a new hospital may replace crumbling Victorian buildings, but it does not slow down the stream of patients. Nor does it reduce by much the secondary care costs of treating chronic disease, or help to maintain a healthier working population.

23. Technologies exist to enable the NHS to put major efforts into home and community care, and use High Street facilities to provide day-to-day primary care and health education. For example pharmacies and retail stores can be linked into networks and eHealth systems to provide convenient healthcare and wellbeing. There is scope here for the adoption of point of care diagnostics and software tools to support disease management such as diabetes, congenital heart disease and patients on anti-coagulant therapy. We must also consider how the records of such support are incorporated in the NPfIT.

24. More imaginative use of available communications technologies could also reconnect to the NHS a large number of healthcare professionals who have left its full-time service, but who would be able to work from home or the High Street. For instance, dormant radiologists could review digital X-Rays via broadband links outside a hospital environment.

— QinetiQ is Europe's largest integrated R&D organisation, with nearly 10,000 employees, over 7,000 of them scientists, throughout Britain. Now in the market under a PPP, QinetiQ is increasingly putting its pioneering defence-originated technologies to use in the civilian world.

APPENDIX 13

Memorandum by National Institute for Clinical Excellence (MT 55)

THE NHS

1. Introduction

1.1 The National Institute for Clinical Excellence (NICE) is part of the NHS. It is the independent organisation responsible for providing national guidance on treatments and care for people using the NHS in England and Wales.

1.2 The purpose of this memorandum is to set out the role that NICE plays in managing the appropriate introduction of new technologies into the NHS, encouraging innovation in new technologies that will benefit patients, and assessing the effectiveness and cost benefit of new technologies.

1.3 This memorandum does not address the issue of telemedicine. Although it is possible in theory that NICE could be asked to develop technology appraisal guidance or a clinical guideline on telemedicine in future, this topic has not been referred to the Institute by the Department of Health or Welsh Assembly Government.

2. The Institute

2.1 NICE was established as a special health authority in 1999. Our role is to provide advice to the NHS in England and Wales on the clinical and cost effectiveness of drugs and other treatments. Our advice is for people who rely on the NHS for their care and for health professionals. Further information about the work of the Institute can be found at www.nice.org.uk.

2.2 A summary of the four main types of NICE guidance is set out below:

2.2.1 *Technology appraisals*: recommendations on the use of new and existing medicines and other treatments (devices, surgical and other procedures, diagnostic techniques and health promotion methods).

2.2.2 *Clinical guidelines*: recommendations on the appropriate treatment and care of patients with specific diseases and conditions, such as diabetes and schizophrenia.

2.2.3 *Cancer service guidance*: recommendations on arrangements for the organisation and delivery of services for people with cancer.

2.2.4 *Interventional procedures*: guidance about whether interventional procedures used for diagnosis and treatment are safe enough and work well enough for routine use. An interventional procedure is one used for diagnosis or treatment that involves making a cut or hole in the body, entry into a body cavity or using electromagnetic radiation (including X-rays or lasers) and ultrasound.

2.3 We publish around 25 technology appraisals, 12 clinical guidelines and 60 pieces of interventional procedures guidance each year.

2.4 NICE guidance is a key component of the national standards to which the NHS is now expected to work. Technology appraisals and interventional procedures guidance are "core" standards, which require immediate implementation, and clinical guidelines are regarded as "developmental" standards, the implementation of which will take place over a longer period.

2.5 The Institute is based in offices in central London. It has a budget of nearly £20 million, which is largely provided by the Department of Health but also includes a contribution from the Welsh Assembly Government, to which the Institute is jointly accountable. The Institute directly employs around 100 people.

3. Recommendations of the Healthcare Industries Task Force (HITF) Report

3.1 NICE Chief Executive Andrew Dillon represented the views of the Institute during the development of the HITF report. The HITF report states that the Task Force debated value and cost effectiveness extensively (4.28.8). It states that "the development of a more transparent collaborative approach between NICE, Health Technology Assessment (HTA) and the new Device Evaluation Service will enhance the flow of information along a continuum of evaluation from clinical guidelines through technology assessment to expert evaluation of individual products by users. The new service will inform NHS procurement and help ensure that value for money considerations are at the heart of purchasing decisions."

3.2 Andrew Dillon has met the Chief Executive of the PASA and has agreed to provide support to the team designing the new device evaluation service, particularly in the area of economic evaluation.

4. The Speed of, and Barriers to, the Introduction of New Technologies

4.1 NICE guidance explicitly encourages the managed introduction of new technologies to the NHS. Although the information set out below focuses on the technology appraisal and interventional procedures work programmes, this is a common theme across all the Institute's work programmes. For example, the Institute's clinical guideline on familial breast cancer recommended the targeted use of BRCA1 and BRCA2 tests to identify women at high susceptibility of breast (and ovarian) cancers. A list of technology appraisals that include recommendations about the introduction of new technologies can be found at Appendix A.

Technology Appraisals

4.2 One of the Institute's responsibilities is to provide guidance to the NHS on the use of selected new and established health technologies. In addition to pharmaceuticals, the types of technology referred include:

4.2.1 Medical devices

4.2.2 Diagnostic techniques

4.2.3 Surgical procedures

4.2.4 Other therapeutic technologies

4.2.5 Health promotion activities.

4.3 Topics for appraisal are referred to the Institute by the Secretary of State for Health and the Welsh Assembly Government. An appraisal considers the evidence of the health benefits and costs of a health technology. Evidence is considered by the Institute's independent Appraisal Committee which reaches a judgement as to whether, on balance, the technology can be recommended as a cost-effective use of NHS resources in general, or whether it can be recommended for specific indications or subgroups of patients, if this is more appropriate.

4.4 In reaching this decision, the Institute and the Appraisal Committee take into account the factors listed in the directions of the Secretary of State for Health and the Welsh Assembly Government, namely:

4.4.1 The broad clinical priorities of the Secretary of State for Health and the Welsh Assembly Government (for example, as set out in *National Priorities and Planning Framework 2003–06* and in National Service Frameworks, or any specific guidance on individual referrals).

4.4.2 The degree of clinical need of the patients with the condition under consideration.

4.4.3 The broad balance of benefits and costs.

4.4.4 Any guidance from the Secretary of State for Health and Welsh Assembly Government on the resources likely to be available on other such matters as they think fit.

4.4.5 The effective use of available resources.

4.5 The Institute also takes into account the longer-term interests of the NHS in encouraging innovation in technologies that will benefit patients.

4.6 Since January 2002, the NHS has been obliged to provide funding and resources for medicines and treatments recommended by NICE through its technology appraisals work programme. The NHS normally has three months from the date of publication of each technology appraisal guidance to provide funding and resources. Treatment will only be provided if a doctor or nurse, after discussing the options with the patient, thinks that this is the right choice for that patient.

Interventional Procedures

4.7 NICE makes recommendations about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use. An interventional procedure is a procedure used for diagnosis or treatment that involves one of the following:

4.7.1 Making a cut or a hole to gain access to the inside of a patient's body—for example, when carrying out an operation or inserting a tube into a blood vessel.

4.7.2 Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body—for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth.

4.7.3 Using electromagnetic energy (which includes X-rays, lasers, gamma-rays and ultraviolet light) or ultrasound—for example, using a laser to treat eye problems.

4.8 Although procedures are most commonly notified by clinicians and other healthcare professionals, any individual or organisation may notify NICE of procedures that are being performed or are likely to be performed within the NHS. Evidence is considered by the independent Interventional Procedures Advisory Committee. NICE issues guidance on interventional procedures to ensure that:

4.8.1 Patients and carers are reassured that new interventional procedures are being monitored and reviewed to protect their safety, and have access to public information about notified procedures.

4.8.2 Clinicians, healthcare organisations and the NHS as a whole will be supported in the process of introducing new procedures.

4.8.3 The Institute can foster innovation by facilitating data collection and analysis, conducting rapid reviews and providing advice on the safety and efficacy of new procedures.

4.9 The programme looks at procedures and not the devices (or drugs) used during the performance of the procedure. Performing an established procedure using a new device would not usually fall within the remit of the programme unless the use of the new device appeared to alter the safety and efficacy profile of the procedure. For the purposes of the programme, NICE considers an interventional procedure to be "new" if a fully trained clinician is considering the use of the procedure/technique for the first time in the NHS outside of a Research Ethics Committee approved protocol.

4.10 The Department of Health has issued a Health Service Circular to the NHS in England explaining what should be considered a new procedure and what process the NHS should follow if a clinician wishes to perform a new procedure. The Welsh Assembly Government and the Scottish Executive have issued similar circulars to the NHS in Wales and Scotland. All three circulars can be found at http://www.nice.org.uk/page.aspx?o=201822.

5 The Effectiveness and Cost Benefit of New Technologies

5.1 NICE technology appraisals and clinical guidelines are based on a review of clinical and economic evidence. Clinical evidence measures how well a treatment works and economic evidence, put simply, is a measure of how well a treatment works in relation to how much it costs—does it represent good value for money.

5.2 Standard methodologies are used by the Institute when assessing clinical and cost effectiveness. The Institute has to make decisions across different technologies and disease areas and it is important that analyses of clinical and cost effectiveness undertaken to inform decision-making adopt a consistent approach. These methodologies are set out in detail in the following documents which can be found on the NICE website at www.nice.org.uk:

5.2.1 *Guide to the Methods of Technology Appraisal.*

5.2.2 *Guideline Development Methods: Information for National Collaborating Centres and Guideline Developers.*

5.3 The Institute's technology appraisal process is the primary route for determining the cost effectiveness of technologies. The Insitute defines cost effectiveness as an economic evaluation of the benefits of the technology to the patient and the NHS/PSS costs needed to provide that technology. For costs, evidence requirements include quantifying the effect of the technologies on resource use in terms of physical units (for example, days in hospital, visits to a GP) and valuing those effects in monetary terms using appropriate prices and unit costs. The benefits include the quantification of the effect of the technologies under consideration on the course of the relevant disease. These benefits are to be preferentially expressed in terms of utilities related to the overall impact of the technology on the patients' health related quality of life leading and the valuation of those impacts to reflect the preferences of the general population. This leads to an estimate of the cost per Quality Adjusted Life Year (QALY) gained in the use of the technology and enables comparisons with other treatments currently available in the NHS.

5.4 The Institute's clinical guidelines cover broad aspects of clinical care and the clinical management of overall decisions. Clinicians already take resources and value for money into account in clinical decisions, and the incorporation of good-quality health-economic evidence into clinical guidelines can help make this less arbitrary and more consistent.

5.5 The Institute's interventional procedures work programme considers safety and efficacy. This programme does not assess the cost effectiveness of procedures.

6. Supplemental Evidence

6.1 A list of technology appraisals that include recommendations about the introduction of new technologies is attached at Annex A for information.

7. Conclusion

7.1 NICE develops high quality, credible guidance that supports healthcare professionals and patients and their carers in making decisions the introduction of new technologies to the NHS in England and Wales.

7.2 The Institute plays a key role in appropriately managing the introduction of new technologies into the NHS, encouraging innovation in new technologies that will benefit patients, and assessing the effectiveness and cost benefit of new technologies.

7.3 From 1 April 2005 the Institute will take on the functions of the Health Development Agency to become the National Institute for Health and Clinical Excellence, an independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. The new organisation will continue to support the use of new technologies within the NHS.

National Institute for Clinical Excellence

January 2005

Annex A

TECHNOLOGY APPRAISALS THAT INCLUDE RECOMMENDATIONS ABOUT THE INTRODUCTION OF NEW TECHNOLOGIES

Title	*Wave*	*Completed*	*Review*
Completed appraisals			
Ischaemic heart disease—coronary artery stents (No 4)—obsolete, replaced by No 71	1	May 2000	April 2003
Cervical cancer—liquid based cytology (No 5)—obsolete, replaced by No 69	1	June 2000	May 2003

Title	*Wave*	*Completed*	*Review*
Arrhythmias—implantable cardioverter defibrillators (ICDs) (No 11)	2	September 2000	September 2003
Knee joints (defective)—autologous cartilage transplantation (No 16)	2	December 2000	November 2003
Asthma (older children)—inhaler devices (No 38)	4	April 2002	April 2005
Hip disease—metal on metal hip resurfacing (No 44)	5	June 2002	February 2005
Obesity (morbid)—surgery (No 46)	5	July 2002	June 2005
Central venous catheters—ultrasound locating devices (No 49)	5	September 2002	August 2005
Stress incontinence—tension-free vaginal tape (No 56)	6	February 2003	February 2006
Diabetes (type 1)—insulin pump therapy (No 57)	6	February 2003	February 2006
Diabetes (types 1 and 2)—patient education models (No 60)	6	April 2003	February 2006
Macular degeneration (age related)—photodynamic therapy (No 68)	5	September 2003	September 2006
Ischaemic heart disease—coronary artery stents (No 71)	7	October 2003	November 2004
Angina and myocardial infarction—myocardial perfusion scintigraphy (No 73)	7	November 2003	November 2006
Menstrual bleeding—fluid-filled thermal balloon and microwave endometrial ablation (No 78)	6	April 2004	April 2007
Ongoing appraisals		*Anticipated date*	
Depression and anxiety—computerised cognitive behaviour therapy (CCBT) (review)	R	September 2005	
Diabetes (type 1 and 2)—inhaled insulin	10	September 2006	
Glioblastoma multiforme—carmustine implants and temozolomide	10	March 2006	
Heart failure—biventricular pacing (cardiac resynchronisation)	10	March 2007	
Ischaemic heart disease—coronary artery stents (review)	R	May 2006	
Tooth decay—HealOzone	9	August 2005	

Please note that a full list of clinical guidelines and interventional procedures guidance can be found on the NICE website at www.nice.org.uk.

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