Government Response to the Health Committee's Report on the Use of New Medical Technologies within the NHS

Presented to Parliament by
the Secretary of State for Health
by Command of Her Majesty
October 2005

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Introduction

1. The House of Common's Health Committee published its report on the *Use of New Medical Technologies within the NHS* on 12 April 2005. The Government is currently engaged in a series of initiatives to support the introduction of new medical technologies to health and social care services, and therefore welcomes the Committee's interest in this issue at this time. This Command Paper sets out the Government's response to the recommendations and conclusions in the Committee's report.

Increasing the use of new medical technologies in health and social care

2. Access by patients and others to new technologies can bring many benefits – the potential for speedier recovery, shorter hospital stays, localised consultations, diagnostics and treatments. In other words, they can increase users' independence and choice, and enhance their quality of life. A primary aim of the Department of Health's agenda is to empower patients and provide them with the means to take more control over their health. This will drive up the quality of care and as evidenced in the report by Sir Derek Wanless, commissioned by HM Treasury and published in April 2002[1], when patients are 'fully engaged' in their own health care, the cost across the whole system will be lower. So there is a clear business case for adopting this approach, and spreading the use of new medical technologies is an essential part of this overarching policy.

3. However, the introduction of medical innovation, whether through novel products and technologies or through the introduction of new procedures and services, presents considerable challenges to the health and social care system. Sir Derek Wanless identified this in his report. He recognised the value of medical innovation and concluded that the National Health Service (NHS) was a "late and slow adopter of medical technology".

4. His report also noted that new medical technologies are key drivers of increased health expenditure and if costs are to be prevented from spiralling without effective control, their introduction must be based on an assessment of their clinical and cost-effectiveness.

1 *Securing our Future Health: Taking a Long-Term View* – www.hm.treasury.gov.uk

5. The Government accepted that much needed to be done to realise the benefits of new medical technologies for patients and other service users. The NHS Plan[2], and subsequently the NHS Improvement Plan[3] were strategies put in place by the Department of Health to reform and modernise the NHS, including improving the speed of adoption of new medical technologies. In addition, the Government recognised that this country is renowned world-wide for its capacity to produce innovative ideas, and that there were mutual benefits to be gained from working more closely with UK-based manufacturers of medical technologies and devices.

The Healthcare Industries Task Force (HITF)

6. From October 2003 to October 2004 HITF was established as a joint venture between Government and the UK healthcare industries. Established to deliver better access to medical innovation that would benefit users as well as the industry, it was the first strategic collaboration of its kind in this country. It focused primarily on devising practical solutions to this enduring issue.

7. Throughout its deliberations, the Task Force was mindful of the conclusions reached by Sir Derek Wanless in his study of health expenditure. It was aware of the need to encourage the use of new medical technologies to deliver improved outcomes for patients and service users, but also conscious that expenditure needed to be justified and effectively targeted. Better guidance on how technologies perform, and an assessment of their benefits and drawbacks, including financial implications, were considered key to achieving informed decisions. The Task Force sought to address these issues through a range of measures which, taken together, aim to balance the need for effective financial control with the needs of a modern, responsive health and social care system.

8. The Task Force published its final report in November 2004[4] and Government and industry are continuing to work closely on delivering the commitments made by the Task Force. The Government was therefore grateful for the opportunity to give evidence to the Committee and to contribute to the Committee's deliberations on the use of new medical technologies.

HITF outputs and implementation

9. The Task Force identified nine specific outputs in its report. Most of these impact on the uptake of medical innovation and a new high-level group, led jointly by Jane Kennedy (Minister of State for Patient Safety and Quality at the Department of Health) and Sir Christopher O'Donnell (Chief Executive of Smith & Nephew plc) is charged with ensuring delivery of the improvements agreed by the Task Force.

2 *The NHS Plan: A Plan for Investment, a Plan for Reform* – www.dh.gov.uk/publications
3 *The NHS Improvement Plan: Putting People at the Heart of Public Services* – www.dh.gov.uk/publications
4 *Better healthcare through partnership: a programme for action* – www.advisorybodies.dh.gov.uk/hitf

10. The new Strategic Implementation Group (SIG) met for the first time on 29 June 2005 to review progress on implementation. Some six months had elapsed since publication of the HITF report and during that time, Government officials and industry representatives had continued to work closely together to action the HITF outputs. In particular, advances have been made on:

Device Evaluation Service (DES)

10.1 The Task Force saw the development of the existing UK Device Evaluation Service, previously part of the Medicines and Healthcare products Regulatory Agency (MHRA), as essential to more informed procurement decisions and therefore key to speeding up the introduction of beneficial new medical technologies. On 1 April 2005 responsibility for DES management was transferred to the NHS Purchasing and Supply Agency (PASA) where it is linked more closely to procurement policy and processes. From 1 September 2005 the service formally became part of PASA and changed its name to the Centre for Evidence-based Purchasing (CEP) to reflect its new responsibilities. A major consultation had previously been undertaken with stakeholders, including patient groups, to help redesign its functions and outputs to better support its new role. CEP's role will include for the first time an assessment of the benefits of market-ready medical products, as well as how effectively they perform. Building on its well-established network of experts, CEP will develop its service to become a national resource for purchasers at all levels, tailoring its activities to therapeutic priorities whilst also being responsive to industry needs. It will publish independent guidance and disseminate this widely to promote a consistent approach to evaluation and adoption. See also response to recommendation 3.

Procurement

10.2 The need to ensure intelligent and professional procurement is being embedded throughout procurement policy and processes. The NHS Collaborative Procurement Hubs (CPHs) have been designed to ensure that clinicians have an opportunity to provide advice on purchasing decisions from a practitioner's perspective. Suppliers are already being involved in national procurement plans and the need to give full recognition to the benefits of innovative products is being built into procurement processes. Access to CEP advice is also being actively promoted (see 10.1 above).

10.3 *Payment by Results* (PbR) also has a positive contribution to make to procurement and the uptake of new technology. The Task Force recognised the constraints of the budgeting system in relation to hospital commissioning of innovation and emphasised the importance of ensuring that PbR rewards the uptake of new technologies which are cost-effective over a longer term. In accordance with its recommendation, there is now an active dialogue with industry as PbR is being rolled out. Industry has made a number of suggestions with regard to the collection of activity data, coding and their application which directly relate to supporting the introduction of innovation. This communication has proved valuable in helping to iron out some teething problems and will continue as the new scheme is phased in.

National Innovation Centre (NIC)

10.4 A new national innovation centre is under development as part of the NHS Institute for Innovation and Improvement established on 1 July 2005. It will provide a focus for advice for companies with promising new products and ideas, helping them to develop and translate these into successful commercial products. It will also be able to link them directly with relevant parts of the NHS and social care system. In addition, the Institute's central role is to assess the impact of useful innovation on services and support service providers in making any necessary organisational changes. NIC will therefore be able to contribute to and inform the wider agenda of the Institute, helping to create the "pull" for the introduction of innovation from within the system to complement the "push" from industry.

Building R&D capacity

10.5 To support access to the NHS for clinical trials and investigations involving medical products and technologies, the Board of the UK Clinical Research Collaboration (UKCRC)[5] now includes a representative of the healthcare industries. In addition, industry representatives are being engaged in the key workstreams which focus on building up the research infrastructure and workforce in the NHS, streamlining regulatory and governance processes, and developing incentives for research in the NHS. Expansion of UKCRC's activity specifically to encompass new medical technologies will help ensure that these types of products are increasingly developed and tested here, form a regular part of NHS activity and, as a consequence, are more readily taken up by the health and social care system. In addition, proposals to increase funding to the Department's New and Emerging Applications of Technology programme have been announced in the R&D Strategy[6] released in July 2005 for consultation.

Healthcare Technology Co-operatives (HTCs)

10.6 HTCs were a concept of the HITF Working Group exploring R&D issues. The main objective of HTCs is to support clinically-driven, pioneering new technologies by harnessing the best of our national medical expertise in the NHS, academia and industry in collaborative ventures. They will function as drivers for "technology pull" into the NHS on the basis of identified clinical need. This was only loosely defined while the Task Force was in operation and the process for establishing and evaluating the pilot proposed in the Report was not identified. Government and industry have now set up a joint Working Group to define fully HTCs, their outputs and the options for funding. A full report and project plan will be submitted to the second SIG meeting in November 2005 for approval so that work in establishing a pilot can proceed rapidly.

5 The UK Clinical Research Collaboration (UKCRC) was established in September 2004 in light of recommendations from the Research for Patient Benefit Working Party

6 The Department of Health launched its consultation document *Best research for best health: A new National Health Research Strategy – The NHS contribution to health research in England: a consultation on* 29 July 2005 – see www.dh.gov.uk/consultations/liveconsultations

Training and education

10.7 As the four HITF Working Groups were developing their proposals for change during the summer of 2004, the Task Force recognised that additional training and education for professionals was essential to underpin the introduction and widespread use of innovation. In its report, the Task Force therefore charged stakeholders to work together to improve training in this area, building upon plans already underway with such education partners as Skills for Health, the Royal Colleges, the General Medical Council and other professional bodies involved in medical training, whilst also developing new initiatives, to ensure that staff are confident and competent in the safe use of new technologies.

10.8 A multi-disiplinary working group, chaired by Professor Sir Ara Darzi and including the new NHS Institute for Innovation and Improvement, will be responsible for delivery of this HITF output. The group will provide the strategic lead on training and education to underpin the use of innovation, and develop the toolkits for local trainers and staff to use. It will produce a paper outlining a coordinated way forward for the second SIG meeting in November 2005. In addition, the Task Force concluded that training and education needs to be considered as part of the procurement process for all new technological innovations. Plans are in place to ensure that appropriate consideration is given to this aspect in drawing up contracts with suppliers.

10.9 New technologies are also given key prominence in the social care green paper *Independence, Well-being and Choice*[7] and we are assessing the implications of this for education and training. This will involve the wider social care workforce as much as, or perhaps more than, the professional social work workforce, and we will involve Skills for Care in looking at the implications of this for education and training for the social care workforce.

10.10 Further details about social care training plans are given in the response to recommendation 8.

Forward look

11. In accepting the need to promote the wider adoption of new medical technologies for the benefit of patients and service users, the Government recognises that the issue is complex and that there is no single "quick fix" solution. In particular, the Government believes that working in partnership with the main stakeholders, including industry, health and social care professionals, patients and carers, will increasingly have a positive impact on uptake of new technologies, alongside the range of measures being implemented as a result of HITF.

7 Published for the Department of Health by The Stationery Office in March 2005 – www.tso.co.uk/bookshop

12. In addition, the Government is committed to putting people at the heart of services and a key target to reflect this is to reduce waiting times for treatment to 18 weeks by 2008. This involves the greater use of telecare and telemedicine, easier access to local services, including diagnostics, provision of information and giving greater priority to individuals' preferences.

13. Furthermore, the Department of Health's recently released consultation on a new R&D strategy for the NHS (see paragraph 10.5 above) will, if agreed, introduce radical new mechanisms for access to better facilities, more research-orientated staff and faster access to patients for clinical studies and assessments needed for new medical technologies.

14. The Government is also conscious of the changing needs of the population due to demographic factors. As the proportion of people over 60 years of age increases, the demand for health and social care services is changing. We need to plan now to support services to enable more older people to live independently, and to manage chronic conditions themselves where there is good evidence of their effectiveness.

15. The challenges of the future are considerable, not least the need to develop a health economic strategy that will deliver these priorities. The Government is investing heavily in the future health of the nation – over the three years from 2005/6 to 2007/8 NHS expenditure will increase on average by 7.1% a year over and above inflation, a total increase over the period of 23% in real terms. Over three years this will take the total spent on the NHS in England from £70bn in 2004-05 to almost £93bn in 2007/08. This clearly demonstrates the Government's commitment to improving services, now and in the future.

16. However, many of the objectives outlined above cannot be effectively achieved without the deployment of modern technologies in health and social care. Harnessing scientific advances for the benefit of all is a necessity, not a choice. The Government has therefore given considerable impetus to the prioritisation of the workstreams referred to above, their links with existing mechanisms (such as the National Institute for Health and Clinical Excellence (NICE) and the Health Technology Assessment (HTA) programme) and integration with future plans. At the same time, the Government is continuing to support work in other related areas not specifically targeted by HITF (eg in telecare – see response to recommendation 2). We believe that, taken together, these measures will help ensure effective progress across institutional boundaries and the entire health and social care agenda.

The Government's response to the Health Committee's conclusions and recommendations:

1. **We recommend that Trusts be encouraged to identify 'clinical champions' to promote the benefits of telemedicine within the Trust and to ensure that the organisational and staff development requirements to make the system workable are in place. It is crucial to establish policies that enable the lessons of pilot programmes to be used in clinical delivery: at present it is often the case that the organisational requirements of integrating telehealthcare systems into hospital and primary care settings are rarely considered in R&D pilots.**

   The importance of having local leadership is widely recognised as being essential to the delivery of change. Engaging clinicians and NHS management in the National Programme for IT in the NHS continues to be an important priority for NHS Connecting for Health. National clinical champions have been recruited who are clinically credible, experienced people whom the professions trust to communicate between the Programme and the service in both directions.

   The successful implementation of a telemedicine system at the Queen Victoria Hospital (QVH) in East Grinstead (as noted in their Memorandum to the Committee) is an excellent example of this. Its success was in part due to the full engagement of the clinical staff and the recognition that the adoption of technology is only one element of a process of redesigning the way healthcare services are delivered (in trauma management in this instance). However, one of the key features of the QVH implementation is that it is in the context of a regional specialist service working closely with other Trusts over a large geographic area, so that model may not be directly reproducible in specialties. The Department of Health will, nevertheless, take due note of the lessons and examples of QVH in developing the application of telemedicine within the National Programme for IT.

   Long-term conditions and primary care are represented within the second tier of priority programmes for the NHS Institute for Innovation and Improvement. When fully resourced, the Institute will consider how it can best bring its expertise to bear, working with existing parties to develop, amongst other things, the telemedicine programme.

2. **We recommend that when telecare systems are installed in the domiciliary environment, clinicians, technicians, health and social care workers, formal and informal carers and, most importantly, the patients are involved in determining the level of telecare that is suitable and acceptable to each individual recipient. It is essential that a balance between the use of technology and the continuation of human contact is an important element in any such judgement.**

The Government agrees that involvement of individuals is crucial in introducing telecare and the Department of Health has taken steps to ensure that this is recognised. In July 2005, the Department of Health issued policy guidance on developing telecare services and the use of the Preventative Technologies Grant[8] to local authorities and Primary Care Trusts (PCTs). In line with the Social Care Green Paper – *Independence, Well-being and Choice* – the guidance emphasises the importance of placing individuals at the heart of assessment, stressing that assessments should focus on the best outcomes for the individual and that the views of the people using services and their carers should form the starting point of any assessment.

Through the telecare policy guidance we are encouraging all local partners including clinicians, technicians, health and social care workers, housing providers, independent and voluntary sector partners as well as carers and service user representatives, to come together in strategic partnerships when developing and delivering local telecare services. Where such partnerships are already established and working effectively, we are encouraging local development.

The guidance makes clear that telecare needs to become a mainstream option as part of an integrated, person-centred package of care which is balanced between the use of technology and the continuation of human contact. Appropriate response protocols, agreed with the individual is as important – if not more – than the equipment and monitoring itself. Those protocols must consider patient confidentiality and data protection issues. Explicit consent is necessary from each service user to the telecare package and response protocols being provided.

More detailed guidance on developing person-centred telecare services is contained in the Telecare Implementation Guide published by the Care Services Improvement Partnership (CSIP). CSIP will also be re-iterating these messages through regional learning events aimed at implementers of telecare in 2005/6.

Several of the detailed factsheets published by CSIP alongside the *Telecare Implementation Guide* include information and advice on risk management for telecare, including issues to consider around social isolation, liability, reliability of equipment, response protocols, confidentiality, ethics. The *Service Redesign Factsheet* includes a detailed checklist for different types of organisations to consider when developing a telecare service. The guide and factsheets are available from www.icesdoh.org/telecare.

8 The Preventative Technologies Grant – £80M over 2 years, £30M in 2006/7 and £50M in 2007/8, aimed at extending the benefits of community alarm style services (telecare) to help 160,000 older people to live independently at home.

3. **Furthermore, evaluation needs to take account of the qualitative benefits for users and carers over time. There is a need to develop new ways of evaluating the qualitative benefits of new medical technologies in the long-term budgetary cycles. Methodologies are needed that can determine the social and economic benefits of new medical devices that fall outside the direct costs to the NHS.**

   The tools to do this work are well established, widely available and already applied in formal research studies undertaken by the Health Technology Assessment (HTA) programme, which includes economic, social, organisational as well as clinical aspects. Access to data collected by NHS Connecting for Health would greatly increase the speed and efficiency of such research. However, we accept that further attention should be given to longer term quality of life and resource utilisation measurements beyond the initial formal research when the study is planned. The new Response Mode Funding announced in the new Department of Health R&D Strategy, released recently for consultation (see footnote 6), will link into a new national network of R&D Support Units which will support high-quality proposals.

   The development of the former Device Evaluation Service will bring the opportunity to provide a central information point for evaluation methodologies and tool kits to help with the planning of services involving products and equipment. The new organisation, located within the NHS Purchasing and Supply Agency (PASA) from 1 September, has been renamed the Centre for Evidence-based purchasing (CEP). Its remit includes the provision of cost benefit analysis across health and social care, and information about lifetime costs of equipment. This will give decision-makers the information they need to purchase with confidence.

   CEP will therefore be an important component of the overall evaluation "landscape" within the NHS, as its remit and relationships with other players such as NICE, the HTA Programme and the new NHS Institute for Innovation and Improvement is developed. CEP will begin implementation of its new structure and remit from Autumn 2005.

4. **We recommend that the Department should seek to introduce a national system for reviewing and tracking the implementation of new devices over a number of years to ensure patient safety and efficacy issues are closely monitored. Currently there is no clear system for determining safety and efficacy beyond the clinical trials and evidence-based model of the Health Technology Assessment (HTA) programme while there is also a need for developing more sophisticated measures of the utility of systems for patients that reflect more relevant criteria. Much greater patient participation in assessing the utility of telehealthcare is required.**

The Government agrees that safety and efficacy issues are important concerns with the introduction of any new healthcare technology. Existing national systems address numerous aspects of the recommendations in some measure and changes currently underway can augment these eg monitoring of innovations supported by the NHS Institute and adopted into service. However, comprehensive coverage of the recommendations would require considerable co-operation between existing national systems and some additional datasets. We propose a scoping study to consider:

- the extent to which existing national systems already meet the above recommendations
- what constitutes "new" technology, eg unlike black triangle drugs where the product will remain relatively static after introduction of the new product, the safety profile and performance of a device can alter dramatically from one model iteration to the next
- the scope of any gaps
- options to address the identified gaps
- the outline costs and benefits of options
- recommendations for next steps

There will be a number of stakeholders whose work impinges upon these recommendations, including:

Medicines and Healthcare products Regulatory Agency (MHRA)
MHRA operates a national reporting system for safety or quality related problems for all medical devices. This incorporates all types of assistive technology including some telehealthcare systems and devices used "near to the patient" which have a medical purpose, used both in the domiciliary environment and healthcare premises. The reporting system is available to all users including the public, carers, healthcare staff and others. As many of these "near to patient" devices fall within the scope of the Medical Devices Directive it is the manufacturer's responsibility to have in place a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action. The manufacturer is obliged to report any serious adverse incidents to the MHRA occurring within the UK.

All reports are held on one central MHRA database. Individual reports are investigated at levels appropriate to the risks associated with the reported problem. The database is also regularly reviewed to see if there are any emerging trends concerning a particular device or manufacturer, usage information, design or quality. MHRA subsequently arranges for designs or usage information etc to be updated and/or issues guidance or safety warnings where appropriate. MHRA may also carry out enforcement action where there is evidence of a breach of the Medical Devices Regulations.

Adherence to the various reporting requirements, guidance and safety warnings issued by MHRA is a major point in the NHS National Standards. The recommendations are also used by the Healthcare Commission during audit of healthcare systems during their annual health check.

MHRA has recently reviewed its overall approach to assistive technology in use "near to patient" in the community. In view of the increasing use and dependence on such equipment, MHRA has decided to establish a specific centre for assistive technology to ensure all safety and quality aspects are covered by a dedicated workforce. In addition, acknowledging advances in all types of medical device technology, MHRA has created a new post to identify potential regulatory gaps and suggest means of addressing them, together with relevant stakeholders.

MHRA has had considerable experience of setting up, funding, working with and reviewing the outputs of registries for medical devices eg heart-valve, pacemaker, breast implant. This experience will provide valuable input into the proposed feasibility study considering the introduction of a national system for reviewing and tracking new devices.

NHS Purchasing and Supply Agency (PASA)
NHS PASA is developing with the new Collaborative Procurement Hubs tools to track the benefits associated with national and regional contracts negotiated by them, which could include collecting information about patient safety, usability and efficacy.

New Centre for Evidence-based Purchasing (CEP)
The remit of CEP (formerly DES) after September 2005 will include the development of cost benefit analysis across health and social care. The overall costs of technology can be strongly influenced by any adverse effects on patients, particularly if this involves serious adverse incidents and subsequent emergency procedures and follow-up. This can be taken into account when CEP are reviewing telehealthcare technologies. CEP is also committed to the involvement of users in evaluation and will be able to consider how utility measures are developed to incorporate the user's perspective. See also the response to recommendation 4.

National Patient Safety Agency (NPSA)
All NHS organisations in England and Wales have had the opportunity to report patient safety incidents to the NPSA national reporting and learning system since December 2004. Patient safety incidents are any unintended or unexpected incidents that could have or did lead to harm for one or more patients receiving NHS funded care. This could include incidents involving telehealthcare systems and other devices that are "near to patient". This information is currently shared with MHRA.

Other initiatives such as the "Statements of Clinical Need" initiative being managed by the Biomaterial and Tissue Engineering Centre for Industrial Collaboration may well also provide useful partnership exemplars for collecting and collating efficacy and performance data.

5. The Department should ensure that Primary Care Trusts (PCTs) and hospital trusts (and if possible SHAs) should commission new technologies according to nationally approved standards (determined by the new Device Evaluation Service [DES] in conjunction with HTA/National Institute of Clinical Excellence [NICE]). Such standards should provide the basis for the selection of base-line devices and technologies. It is important that the tendency towards technology 'creep' and uneven mix of systems that lack interoperability or require different competences to be used should be avoided. Standardisation on clinical based systems should be undertaken in light of discussion with Social Services, who have a greater responsibility for telecare.

As contracting authorities, NHS Trusts are responsible ultimately for purchasing equipment that they feel best suits their individual needs, with due regard to appropriate core standards set by the Healthcare Commission in respect of patient safety and clinical/cost effectiveness. It would therefore be inappropriate for CEP (formerly DES) to set standards in this area, although it has a definite role to play in providing advice and guidance in line with the national evidence base to NHS CPHs (and, therefore, Trusts), in conjunction with NICE, HTA and the NHS Institute, to inform their procurement activity.

At any given moment, there will be a mix of equipment and technology in use within the clinical environment, due in part to factors such as (but not limited to) clinical preference, product life cycles and development stages, cost/value issues and the freedom of NHS Trusts as statutory authorities to choose the equipment they procure. The Department of Health recognises that, in certain circumstances, there might be the potential for non-interoperability between systems and a need for differing skill sets amongst staff, but does not accept that imposed standardisation is the solution. This could thwart innovation and runs counter to the Government's stated intentions in this respect (the DTI innovation report[9], the HITF report and Sir Derek Wanless' report all point to the underlying need for the NHS to adopt new technologies more rapidly). The Department agrees that the right balance needs to be struck and the work of NICE, HTA and CEP to address what the Committee terms technology 'creep' should focus on issues of compatibility wherever practicable, with the involvement of Social Services on telecare systems.

6. We recommend that, when new medical technologies are introduced, protection of confidentiality and the privacy of the individual are key factors in the decision making process. Privacy and confidentiality policies and protocols should be developed, implemented and audited when new technologies are introduced.

We recognise that some telecare devices generate and store information about individuals. The telecare policy guidance highlights the need to develop protocols on information sharing both at a strategic level, in line with guidelines around confidentiality and information sharing, and also at an individual level during the assessment process. These protocols must ensure that the information is available (with the individual's agreement) to those who need it to facilitate proper care and that it is protected from access by those who do not.

9 *Competing in the Global Economy: The Innovation Challenge* – published in December 2003, accessible at www.dti.gov.uk/innovationreport/index.html

Some telecare equipment gathers information about the lifestyle and activities of users in their own homes. In these cases, the need to obtain the informed, explicit agreement of the individual is stressed in the guidance. The Care Services Improvement Partnership (CSIP) is currently developing a detailed fact sheet to help local authorities in understanding and addressing ethical and confidentiality issues. Ethical issues are one of the topics CSIP is likely to focus on in learning events for implementers of telecare. Local authorities are also being encouraged to empower telecare users and their carers by increasing their knowledge of telecare and how it works through demonstration sites, newsletters, training and education.

7. There is also a need for a system of reporting with regard to the utility and limitations of telehealthcare systems or other devices that are 'near to patient'. It is clear that this will not be the responsibility of the reshaped DES, and there is currently no national 'clearing house' where this information might be lodged. This may well be a function for the Healthcare Commission.

As explained as part of our response to recommendation 4 about monitoring of medical devices, all NHS organisations in England and Wales have had the opportunity to report patient safety incidents to the NPSA national reporting and learning system since December 2004. We also accept the need for local authorities and PCTs to have access to good and timely information about the efficacy of telecare and telehealthcare systems available on the market and are currently exploring options for how best this can be achieved. The Healthcare Commission was set up to promote improvement in NHS care and to regulate independent healthcare provision. It does so primarily by carrying out reviews and investigations of individual service providers or of types of care. While it receives and analyses data in pursuit of these functions, it was not established to create a system for reporting with respect to patient safety generally or in relation to particular devices or classes of device. The Government's response in recommendation 7 proposing a scoping study will seek to address this issue.

8. The Government has proposed some improvements to training, but these will not be sufficient. The Department should ensure that adequate training is in place to enable greater benefits to be derived from new technologies. To encourage greater familiarity with the possibilities and opportunities as well as limitations and risks of telemedicine, training should be modified in those specialist areas that are most likely to be primary users of telehealthcare such as pathology and radiology. Medical schools as well as the professional bodies should develop programmes to ensure effective training is put in place. Training in telecare for health care assistants working for social services and in the community also requires improvement to gain full benefits of new technologies.

The Government believes that the strategies being developed on training and education for NHS staff and those who work in social care will support the progressive use of new medical technologies. Whilst under-graduate and post-graduate education is not the responsibility of the Department of Health, the Government does collaborate with relevant education partners and seeks to influence their priorities to help ensure that they are convergent with the training needs of the health and social care workforce. Some examples which demonstrate the Government's long term commitment to this important aspect are:

- central funding for postgraduate medical and dental education has more than doubled since 1996/97 from £0.53 billion to £1.34 billion in 2004/05
- over the last three years extra funding has been provided to increase numbers of postgraduate medical training opportunities
- we have introduced annual appraisal for NHS doctors which results in an agreed personal development plan which takes account of the needs of the individual doctors and the organisation where they work
- in the longer term the introduction of electronic staff records will help to ensure that records of key skills are transferable as staff move around the NHS
- the number of students on social work courses rose by 33% from 2000 to 2003 (from just over 4000 to 5382) and early indications show this increase continuing in 2004

Undergraduate education
The Department of Health shares a commitment with the General Medical Council, the Council of Heads of Medical Schools, the Council of Deans of Nursing and Allied Health Professions and other relevant bodies to ensure that all health care students have the skills and knowledge to deliver a high quality health service to all groups of the population with whom they deal. This would include use of appropriate medical technology. The Department has regular meetings with the regulatory bodies that enables it to reinforce these issues.

Training for doctors
The content and standard of postgraduate medical training is the responsibility of the UK competent authorities – the Specialist Training Authority for specialist medicine and, for general practice, the Joint Committee on Postgraduate Training for General Practice. Their role is that of custodians of quality standards in postgraduate medical education and practice. They are independent of the Department of Health. In addition, the General Medical Council's Education Committee has the general function of promoting high standards of medical education and co-ordinating all stages of medical education to ensure that students and newly qualified doctors are equipped with the knowledge, skills and behaviours essential for professional practice.

All of these bodies have a vested interest in ensuring that doctors are equipped to deal with the problems they will encounter in practice – including incorporating new medical technologies. Through its contact with these bodies, the Department of Health is able to ask them to take account of specific issues such as this.

Modernising Medical Careers (MMC)
MMC reviews the way we train doctors, the speed and quality with which we do it and the end product of that process. Its proposals include:

- introduction of Foundation Programmes – two year training programmes following graduation (ie replacing the current Pre-Registration House Officer year and first Senior House Officer (SHO) year) as the platform for further training
- specialist and general practice training – in liaison with the key stakeholders we will review specialty by specialty the current training programmes and consider the most appropriate model of training.

Although curricula are already reviewed regularly by the medical Royal Colleges on behalf of the competent authorities, implementation of MMC and the development of new training programmes require corresponding development of new curricula, which will ensure that technological changes have been incorporated.

Training for NHS staff
Work towards improving training and education on medical devices for NHS staff and strengthening linkages between the NHS, its education partners, purchasers, device evaluation staff and industry to support the spread of best practice in the competent and safe use of medical devices can be achieved through the initiatives currently being pursued in postgraduate medical training, the development of the Strategic Learning and Advisory Group and new ways of working in social care.

Consideration of initial and ongoing training and education needs to be part of the procurement process for new technologies. That is to say, all new technological innovations have both capital and revenue elements. The training and development of staff in their use of the innovation needs to be included in the revenue costs at the planning stage. This aspect is being taken forward by NHS PASA as part of the HITF implementation strategy.

Also, in response to HITF, the Department of Health has set in train three key workstreams:

Development of an education programme for individual groups of healthcare professionals who are significant users of medical devices
To date we have:

- set up a programme of day workshops for practice and community nurses to provide this group with education across a broad range of relevant device related issues, identified by them as of particular importance to their day-to-day practice
- discussed with the Royal Pharmaceutical Society a programme of education for pharmacists, predominantly dealing with over-the-counter devices, including proposals for a workshop/seminar to provide information covering the regulations governing these devices, safety issues, how to report adverse events, where to obtain advice as necessary, etc

- set up a device education programme (with input into their examination syllabus) with the Association of Operating Department Practitioners
- set up a device education programme with individual PCTs

Production of a multi-media device education programme for availability on the MHRA website and on CD ROM, etc.
We are proposing to produce a series of programmes (subject to budget), the first to cover general principles, eg purchase, storing, maintenance, training; the basics of the Medical Devices Regulations; principles of good practice and use of medical devices; what users should know and ask before using a medical device; a checklist for patients being discharged from an acute trust with a medical device, etc.

The Medical Device Driving Licence (MDDL)
We are proposing to develop MDDL as a modular-based process similar in concept to the European Computer Driving Licence. All healthcare workers would eventually be required to hold the entry-level modules covering the basics of the safe use of medical devices including storage, servicing, etc. A range of modules would be available, increasing in sophistication and complexity depending on the class of devices covered. Some modules would be valid indefinitely; others would require revalidation on a regular basis as the technology advances. Achievement of competency would eventually form part of the essential requirements for Foundation Years, Higher Professional Exams such as the FRCS, FRCA, FRCR, etc, and Certificate of Completion of Specialist Training. Wherever possible the MDDL would make use of e-learning, recognising that some devices require "hands-on" education and training.

The MDDL would consist of a centrally held electronic record administered via a secure website and accessible via the new NHS National Network (N3)[10] and the World Wide Web. The MDDL would be transferable between employers across all healthcare sectors and across professional boundaries, so facilitating the development of advances such as nurse practitioners, physician and anaesthetic practitioners, etc. There would be a facility for a provisional MDDL, allowing locum healthcare workers to function under appropriate supervision.

Social care
As a follow on from the Green Paper *Independence, Well-being and Choice* (see footnote 7), the Department will be exploring, as part of wider work on developing capacity and expertise how the Sector Skills Council could take forward developmental work around standards and competencies needed across the workforce. Skills for Health has indicated its willingness to support the development of the overarching Assistive Technology Education Framework being developed by a working group of multidisciplinary/inter-agency Assistive Technology Forum. If it does, competencies for telecare may be best placed within that framework.

10 The National Network (N3) is replacing the NHS communications network and underpins delivery of the reforms and new services needed to improve patient care. For more information see www.connectingforhealth.nhs.uk/programmes/n3/

The Department will also explore whether the education and training framework being developed for "Trusted Assessors" (non-professionally qualified personnel) involved in the provision of simple equipment to older and disabled people could be developed to include telecare equipment and services.

The Department acknowledges that a national framework is needed to achieve consistently high standards of knowledge, skill and best practice across the range of assistive technology services generally, and new telecare services specifically. Until that can be achieved, local authorities are being encouraged, through the telecare policy guidance, to develop short term local training strategies to ensure that appropriate staff in social services, housing, health, social alarm services and the voluntary sector have the knowledge and skills needed to ensure the success of their local scheme. Funds from the telecare grant may be used for that purpose.

Further guidance around developing capacity and expertise for telecare is contained in the Telecare Implementation Guide published by CSIP[11]. CSIP has also developed a programme of learning support networks some of which will have a focus on telecare.

Radiology
We accept there is a need to train, recruit and retain more radiologists in the NHS. Working with the Royal College of Radiologists, the Department of Health is developing new radiology academies and a national e-learning environment that will enable us to increase significantly the number of radiologists in training. Increasing the numbers of consultant radiologists trained through these academies and the implementation of e-learning will help ensure that we have a greater, highly qualified, quality workforce for the future.

Pathology
In light of the national shortage of histopathologists, working with the Royal College of Pathologists, the Department of Health has funded since 2002 histopathology training schools for SHOs to ensure that we could meet *The NHS Cancer Plan* commitment to have in place enough staff to provide high quality care to patients. We now have 12 schools in place, plus an Intensive Training and Assessment (ITA) School for exceptional graduates with at least two years' overseas experience in pathology. The schools and the ITA now train 112 SHOs each year to be eligible to apply for Senior Registrar (SpR) posts in histopathology. An independent evaluation also shows that the schools have delivered an 11% efficiency gain in teaching time per trainee and produce trainees who, at the end of Year 1, are deemed equivalent to SpRs Year 2 or 3. The Royal College of Pathologists is aware of the need to develop the schools' curriculum to include new technologies, including molecular diagnostics, and image digitisation.

11 Telecare Implementation Guide available at www.icesdoh.org.uk/telecare

9. The Payment by Results scheme has been said to provide an incentive for new technologies, given its tie-in with the 18 week treatment target for patients (thereby encouraging Trusts to select those technologies and devices that can speed up care to meet the 18 week target). Devices that enable this to happen should be a key priority for the new DES. Given that in some cases the Trust that purchases and invests in new technologies may not necessarily be the beneficiary (or sole beneficiary), we recommend that the Department should build into the PbR tariff an incentive payment to offset these development and on-going costs.

The use of the national tariff is structured so as to provide organisations with a financial incentive to reduce the length of stay of patients in hospital, and will therefore also incentivise the development and adoption of new technology which results in a reduced length of stay. Trusts can fund the development and on-going costs of new technology either from surplus income received under Payment by Results, or the commissioner can agree to fund the costs using a pass through payment. Pass through payments are made on top of the national tariff and are specifically designed to allow the commissioner to cover the development and adoption costs of new technology. See also response to recommendation 12 – transfer of funds.

10. There is a need to differentiate tariffs for specialised devices/technologies and those that relate to basic care provision to ensure that the reimbursement structure properly reflects the level of complexity and pattern of use of new medical technologies.

The Department of Health recognises that the national tariff does not currently reflect the full costs of some specialised services. For this reason a number of services are excluded from the scope of the tariff and specialised services top-ups are provided for others. A full revision of the tariff currency is taking place and will result in a more sophisticated tariff which better reflects levels of complexity of service provision. The new tariff is expected to be in place by 2008/09.

11. We welcome the initiatives already undertaken by the Department in this area. Now it must ensure that it devotes adequate attention and resources to rectifying the currently unstructured adoption of new medical technologies.

The newly formed HITF Strategic Implementation Group, co-chaired by Jane Kennedy, Minister of State for Patient Safety and Quality at the Department of Health, and Sir Christopher O'Donnell, CE of Smith & Nephew plc, has responsibility for ensuring HITF outputs are actioned in accordance with the commitments given in the Task Force's report. Its membership includes senior Government officials accountable for delivery of the agreed measures and counterparts from industry so as to ensure effective implementation. In addition, Government membership includes officials from related policy areas, such as NHS financial reforms, patient safety and quality, and social care, so that there is convergence of priorities across a wider agenda and an integrated approach towards the adoption of new technology.

The Government recognises that co-ordinating the adoption of innovation across the NHS and social care system is difficult to achieve. These comprise a collection of individual and autonomous organisations which are free to take their own decisions in relation to the equipment they buy and use. The Department of Health has a strategic role in advising and guiding policy, and also has a national procurement role in specific areas (eg in purchasing large items of capital equipment such as CT scanners to support national programmes). Therefore, through the implementation of HITF outputs, its policy guidance on telecare, its strategies on social care and the development of patient choice, the Department aims to work towards an integrated, well understood and communicated framework that facilitates consistent decision-making, leading to more rapid adoption of new technologies that improve health and social care in this country.

Different strategies are needed for products which represent incremental technology enhancements, those disruptive technologies which are complex, invasive, specialist and often expensive and may require evidence from randomised controlled trials to support adoption, and for those disruptive technologies, adoption of which would challenge existing delivery infrastructure (eg telecare).

12. We recommend that the Government in addition to its current proposals should address the following issues of concern to the Committee:

- **problems relating to the inability to transfer budgets between holders**
- **lack of clinical engagement and clinical champions**
- **the impact of practice based commissioning on procurement**
- **an NHS preference for short-term savings to be made as opposed to long-term advantages for patients**

The Department considers that there is flexibility in the budget system to allow *transfer of funds between holders*. Under Payment by Results (PbR), PCTs are able to meet development and on-cost funding for specific developments that would benefit patients under the 'pass-through flexibilities'. These flexibilities allow PCTs and Trusts to agree additional payment in respect of new technologies, devices or drugs, or other new developments. The payments are made in addition to the tariff payments available under PbR. Where there are service developments outside hospital that result in a reduced length of stay in hospital, PCTs are able to reduce the tariff to reflect the reduction in length of stay to provide funding for the new service development. Further 'unbundling' of national tariffs will be part of the new version of Healthcare Resource Groups (HRGs) under development and planned for use from 2008/09.

The Department agrees that the *involvement of clinicians in the procurement* decision-making process is key to supporting the uptake of new medical technologies. This was recognised by HITF and increasing clinical engagement formed part of the Department of Health's commitments in modernising procurement processes. This is currently being implemented via the developing NHS Collaborative Procurement Hubs who are identifying health professionals to take on this responsibility.

On 1 July 2005 the new NHS Institute of Innovation and Improvement was established. The role of this new organisation will be to support the NHS in adapting to innovation of all types where these are beneficial. The NHS Institute incorporates the National Innovation Centre, a key HITF output, where it will be well placed to provide the focal point for the global industry, the NHS and other innovators to seek advice on how best to develop their products and technologies to match clinical needs. The NHS Institute for Innovation and Improvement will work directly with *clinical champions* in the development towards adoption of these products and technologies.

In addition, the NHS Institute will develop, via an Education and Training Innovation Hub, research and applications for innovative and best practice training tools and techniques. It is also expected that the NHS Institute will be able to support the adoption of technologies through its specialist learning function, helping to ensure that health and social care staff have the right skills to use new devices and technologies safely.

The Department agrees that is important to gain a clear understanding of the potential *impact on procurement of increased practice-based commissioning*. To address this PCTs are represented on CPHs, which are responsible for satisfying the procurement requirements of their members drawn from the entire local healthcare community.

Ensuring that the *longer term value of a device or technology* is taken into account was major theme of HITF and the need for the NHS to consider value rather than simply lowest cost in its procurement activity was clearly identified. The incorporation of health economics into the redesign of device evaluation will be a new departure, making an assessment of value an integral part of CEP guidance for purchasers. Similarly, the NHS Institute will need to know the impact of new devices and technologies on costs, including longer term benefits, in order to support their introduction into use by the NHS and social care system. In addition, increased clinician involvement in procurement provides the platform for CPHs to develop further the 'intelligent customer' concept agreed by HITF.

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