



Innovation for health: Making a difference

Report of the Strategic Implementation Group (SIG)

March 2007

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**Strategic Implementation Group
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Foreword

By the co-chairs, Lord Hunt and Sir Christopher O'Donnell



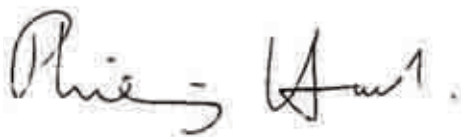
In the last two years' implementation of the recommendations of the Healthcare Industries Task Force (HITF) report, a great deal of progress has been made. A clearer picture has emerged of what the medical devices industry needs in order to prosper. And, just as importantly, it is clear that the NHS also needs to introduce and use innovation more widely for the benefit of patients. The new Centre for Evidence-based Purchasing (CEP) has become operational. The National Innovation Centre, based in the NHS Institute for Innovation and Improvement, has come into being. We shall shortly be identifying the first pilot Healthcare Technology Co-operatives. The modernisation of NHS procurement has begun to make progress. Some first steps have been taken towards developing a meaningful set of metrics for the industry and its competitiveness. The specialist Training Hub is already in operation to support use by the NHS of advanced training tools for key innovative surgical procedures. This will serve to highlight the potential of education and training for maximising the benefit of innovative technology in the NHS.

And this is not all. Through joint working in progressing the original HITF outputs, the relationship between government and industry has been further strengthened. Taken together, this should make a real contribution to more efficient working in the NHS.

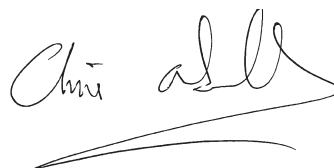
But this tally of achievements is not the end of the HITF story. At the top of the agenda is the development of a central commercial strategy that supports sound procurement decisions and takes account of suppliers' ability to innovate. The facts and figures available to us in identifying the value the industry adds to the UK economy are not yet comprehensive or fit for purpose. The needs of small- and medium-sized enterprises that form such a large part of this industry sector in the UK are not yet clearly understood.

So there is more to do, and this report closes with a number of recommendations, of which perhaps the most important is ensuring that the relationship embodied in HITF and in the Strategic Implementation Group (SIG) continues.

This report sets out the fruits of two years' solid progress. It sums up our achievements in working together and points forward to the potential that such co-operation can have for the future.



Lord Hunt of Kings Heath OBE



Sir Christopher O'Donnell

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1. Executive summary

Introduction

The Foreword to the Healthcare Industries Task Force (HITF) report¹ stated that ‘focusing on this industrial sector reflects the Government’s agenda by stimulating innovation as a means to maintain the UK’s edge as a market leader in science- and technology-intensive markets ... The domestic and global business environment is evolving rapidly, and both government and the industry need to be able to keep pace with new technology advances so that we can provide a modern health service.’

The HITF report identified a range of key outputs for delivery under the implementation programme of the HITF Strategic Implementation Group (SIG). Progress has been made on all of these outputs and, on some of them, SIG can point to significant achievement, in particular on:

- device evaluation to inform procurement decisions
- stimulating more innovation and encouraging a more entrepreneurial culture in industry and the NHS
- building R&D capacity
- the creation of Healthcare Technology Co-operatives (HTC) pilots to pioneer specialist techniques in patient treatments and to inform the future development of such collaborations.

Following its transfer to the NHS Purchasing and Supply Agency (PASA) in September 2005, the Centre for Evidence-based Purchasing (CEP) has been focusing its services to help purchasers make informed choices and has been creating an organisation to contribute to the overall aims of the Innovation Landscape project (see Chapter 3). Its work with the NHS Institute for Innovation and Improvement (NHSI) will help create implementation strategies to support technology adoption becoming part of normal business for NHS and social care.

The National Innovation Centre (NIC) became operational in September 2006, and has established itself as a centre of guidance and expertise on the successful development of new medical technology. Its website² provides a comprehensive resource for companies seeking practical advice. The NIC’s pilot Adoption Hub will make the practical case for adoption on selected projects and work with stakeholders to create the right environment to bring these successfully into practice.

1 Healthcare Industries Task Force, *Better health through partnership: a programme for action*, November 2004, available at: www.advisorybodies.doh.govuk/hitf

2 www.nic.nhs.uk

The HTC pilots initiative has created a model for engagement between the NHS, industry and academia to identify unmet needs for new technologies.

The Government's new health research strategy *Best Research for Best Health*³ includes specific proposals for enhancing the support available for devices research. In addition, the Cooksey Review⁴ recommends that increased funding be made available to support expansion of the NHS Health Technology Assessment (HTA) programme to enhance the evidence base to inform decisions on the effectiveness and cost-effectiveness of technologies.

The agenda has sharpened over the ensuing two-year period covered by SIG's work programme. On the NHS side, there has been no lessening in the need to innovate, as the momentum to improve productivity has mounted. On the industry side, the Government has identified,⁵ across a range of policy areas, the significance of the bioscience industries for UK growth potential. The role of small- and medium-sized enterprises (SMEs) and of inward investment have emerged as important factors in the context of this aspect of government policy. Balancing this with the needs of the NHS has been one of the key themes of the interactions between government and industry over much of the period covered by SIG.

Procurement for innovation and value

Procurement issues lay at the heart of the HITF SIG discussions. There was a recognition of the need to balance the opportunities afforded by new and innovative technologies with the obligations on the NHS to ensure that overall expenditure was managed within budget. A large group of stakeholders from industry, the NHS and the Government met regularly to address the specific challenges and endeavour to create mechanisms that would promote the NHS's adoption of innovation. The group also looked at inefficiencies in the market created by the diversity of procurement practices and processes which characterised the landscape.

While the group developed work plans relating to HITF outputs, the Department of Health continued with roll-out of the Supply Chain Excellence Programme (SCEP). This culminated in the outsourcing of the NHS Logistics Authority, together with some functions of NHS PASA, to create NHS Supply Chain. Collaborative Procurement Hubs were piloted at an earlier stage as part of SCEP.

3 Available at: www.dh.gov.uk/ResearchStrategy, published January 2006.

4 Available at: www.hm-treasury.gov.uk, published December 2006.

5 UK Trade and Investment, *Prosperity in a changing world*, July 2006; Technology Strategy Board, *Developing UK Capability*, April 2006; Office of Science and Innovation's horizon-scanning work, cited in HM Treasury, *Long-term opportunities and challenges for the UK: analysis for the 2007 Comprehensive Spending Review*, November 2006.

This programme of reforms to NHS procurement structures and processes was undertaken as part of wider government initiatives to professionalise public procurement and deliver good value for money for taxpayers. Industry representatives perceived this development largely as an exercise to reduce short-term costs for the health service. They were concerned about the effect of outsourcing of NHS supply chain activity, along with the procurement function for a number of product categories previously handled by NHS PASA, on the uptake of innovation, competition in the market and the interaction of the new organisation with the Collaborative Procurement Hubs (CPHs). Early in 2007, developments on the emerging role of CPHs, in particular a procurement framework for the NHS embracing the HITF output on procurement processes, helped clarify how the commercial landscape should work across the NHS in future. This, together with plans for future stakeholder involvement in the Department of Health's commercial strategy, is expected to meet the challenges set out in Treasury's report *Transforming government procurement*.⁶ Industry welcomed this development cautiously with a view to discussing implementation plans as part of its future engagement with government.

Government and industry will work in partnership on this and on a number of key issues, in particular:

- continued transparency and stakeholder involvement as the Department of Health develops its commercial strategy, which will also take account of the recommendations flowing from Sir David Cooksey's Review
- the need to set in place robust systems to measure performance of the new arrangements against yardsticks for innovation and involvement of SMEs.

Investment and how medical technology companies grow

A key area of work that has emerged under SIG has concerned gaining a better understanding of what helps UK-based medical devices companies prosper. In view of the high proportion of SMEs in this industry and the way in which larger companies expand by acquiring smaller ones (a feature of UK industry more generally but especially so for medical technology), achieving a better understanding of these dynamics is crucial. Further work is envisaged, with a view to directly informing the government's approach to stimulating investment in the sector, including inward investment. In the latter case, this should enable development of a more detailed strategy, which might take a specific approach to encouraging investment in UK-based R&D as compared, for example, with

⁶ HM Treasury, *Transforming government procurement*, January 2007, available at: www.hm-treasury.gov.uk

attracting European headquarters operations. Growth in this sector seems often to be linked to acquisition by foreign companies of much smaller UK companies heavily involved in R&D. It is therefore important to nurture and preferably grow SMEs' commitment to R&D. The SME role in this sector of industry is made more complex by the changes in the NHS procurement landscape. It is recognised that the impact of these changes on innovation needs to be closely monitored, given the potential role of SMEs in innovation and development of value chains in this part of UK industry. Future strategy will need to work towards alignment of procurement and broader commercial strategy with the Cooksey recommendations, the Lisbon Agenda⁷ and other elements of national economic development strategy, to create a balance of interests and issues which is understood by all parties.

Training and education

Like HITF, SIG recognised the scale of the need for medical devices training and education, involving many staff groups in the NHS – registered staff and also those with less advanced qualifications. Beginning to deal with this requires an incremental approach in terms of resources, time and the need to change behaviour. Four key outputs have therefore been developed:

- development of a strategic route map following wide consultation, which SIG has adopted as the blueprint to take forward the training and education component
- a technical and leadership focal point to be established within Skills for Health (SfH) – the Sector Skills Council for the NHS – to take this work forward as part of the Department of Health/SfH service level agreement from April 2007
- adoption of a business programme for SfH through which key HITF training and education deliverables are to be managed in association with a Department of Health programme board, the NHS Institute and the Training Hub (see below)
- a Training Hub for advanced/specialist technologies, based at Chelsea and Westminster Hospital, which was launched in September 2006 by the NIC and is developing innovative learning methods.

⁷ The Lisbon Agenda put in place an overall strategy for the European Union aimed at promoting economic growth, fostering competitiveness and job creation, and advancing structural and regulatory reform, while ensuring social cohesion and environmental sustainability as defined by the Göteborg European Council. Further background information is available at: www.dti.gov.uk/europeandtrade/europe/promoting-economic-reform/lisbon-agenda/page19769.html and www.hm-treasury.gov.uk/media/093/DD/lisbon_jobs131005.pdf

Regulation and international trade

The regulation of medical devices and the promotion of UK companies in overseas markets are ongoing mainstream activities between government and industry. Both have benefited from heightened focus throughout the SIG process as a result of the HITF outputs on these areas. On regulation, there is commitment to continued development of the dialogue between industry and government. This will be important given the increasing complexity of medical products, and potential overlaps between devices and other regulatory fields, for example device/drug combinations and advanced therapy products such as human tissue engineering. In addition, government and industry plan to play an active role as the European Commission's initiative to explore competitiveness issues develops. On international trade, support for companies selling into overseas markets is a key part of the government's strategy, led by UK Trade and Investment (UKTI),⁸ and will be complemented by an increased focus on attracting more investment to the UK from this sector.

Metrics

At the end of 2005, the Department of Trade and Industry (DTI) published the second set of metrics initiated by HITE. Towards the end of the SIG process, it became evident that these needed to be restructured and expanded as changes were being made to the commercial landscape and new processes introduced to support the uptake of innovation. The data have therefore been revised to capture some of the useful information being generated and are published as part of this report (see Annex B). This also led to a recommendation by SIG that development of indicators of key industrial factors and technology adoption should form a fundamental part of our future collaboration. Such data should reveal the domestic industry's strengths and weaknesses, and be aligned with uptake of innovation. This in turn should help shape government strategies on service provision and interaction with suppliers. At its final meeting, SIG endorsed this approach.

Future government/industry dialogue

SIG recognised that implementation of HITF outputs had come a long way, but that a new mechanism needed to be put in place to continue government's dialogue with industry at a higher level. SIG therefore recommended that terms of reference should be developed and agreed for the establishment of a new joint group to take forward the recommendations and consider other issues of strategic importance that may arise.

⁸ UK Trade and Investment, *Prosperity in a changing world*, July 2006, available at: www.uktradeinvest.gov.uk

Summary of recommendations

During the SIG process, a number of issues came to light as HITF implementation progressed which resulted in the development of several recommendations. Full details are in Chapter 6.

1. Procurement of technology and innovation within the NHS

Development and adoption of the procurement framework for collaborative procurement organisations by the NHS to support effective, consistent decision making and the uptake of beneficial innovation in line with the Cooksey Review and HM Treasury's report.⁹

2. SME support

Stocktake of existing support mechanisms and consideration of SMEs' access to finance with a view to publicising these more effectively and reviewing the need for any additional measures.

3. Inward investment and international trade

Development of a UK marketing strategy which addresses both inward investment and trade development, targeted appropriately for the main industry sub-sectors, larger companies and SMEs.

4. Measurement and analysis of the UK healthcare industry environment

Creation of a new set of indicators that focuses on the success factors important for the growth of the UK-based industry related to innovation, trade surplus and inward investment.

5. Europe

Active participation by government and industry in the European Commission's inquiry into the competitiveness of the European medical devices industry and any subsequent action.

6. Future mechanism for government/industry engagement

Development of a mechanism for the future strategic engagement between government and industry.

⁹ HM Treasury, *Transforming government procurement*, January 2007, available at: www.hm-treasury.gov.uk

Highlights of HITF implementation

- Launch of the new Knowledge Transfer Network for medical devices in February 2006
- A highly successful innovation event to mark the NIC coming into operation, the launch of its website and web-based tool to help those with promising new products navigate the Innovation Landscape (September 2006)
- Launch of a new Training Hub to support the use of advanced training tools in key innovative procedures to NHS staff, and development of longer-term education strategy for NHS staff on the use of medical devices (September 2006)
- Development of the model for procurement for the Collaborative Procurement Hubs (February 2007)
- Production of the first outputs of CEP (from November 2006)
- Establishment of a joint strategic group on Payment by Results (December 2005)
- Full proposals for pilot HTCs invited for evaluation (by April 2007)
- Medical devices industry issues fully embedded in UK Clinical Research Collaboration (UKCRC) work programme, increased funding for devices research to be provided via *Best Research for Best Health* and bureaucracy-busting measures agreed to speed up the initiation of clinical studies
- Development of key messages to communicate to health professionals and the public on the regulation and safety profile of medical devices
- Development of established mechanisms between the Medicines and Healthcare products Regulatory Agency (MHRA) and industry for discussion of regulatory matters
- Successful government/industry collaboration on the use of auto-identification technology and launch of best practice guidance, *Coding for success: Simple technology for safer patient care* (February 2007)
- Implementation of country strategies in key overseas markets to promote UK exports of medical devices
- Development of a strategy for embedding training on medical technology within NHS workforce education plans
- HITF metrics expanded and restructured (February 2007)

2. Background

Origins and role of the Strategic Implementation Group (SIG)

The final report of the Healthcare Industries Task Force (HITF)¹⁰ set out nine key outputs and included the first published data sets in a new series of metrics on the UK-based medical technology industry. More importantly, the report launched an action plan to deliver the HITF outputs, involving stakeholders from government and its agencies, industry, the health and social care services in England, patient groups and others. A new joint government/industry collaboration – the Strategic Implementation Group (SIG) – was established in the months that followed publication of the HITF report to oversee implementation and direct the work programme.

The central theme that emerged from the Task Force's deliberations focused on improving the adoption of beneficial new medical technologies by the NHS and social care services; making this happen more quickly and with greater consistency was crucial to achieving the HITF goals. Sir Derek Wanless's¹¹ report to HM Treasury, *Securing our Future Health: Taking a Long-Term View*,¹² resonated strongly with the Task Force's conclusions. The Task Force recognised that although innovative technologies are often more expensive, the benefits – clinical and financial – that occur further downstream needed to be taken into account. A better understanding of the value of innovation would encourage uptake and help counter the NHS tendency towards a short-term approach to procurement. This would in turn stimulate trade and innovation in the industry, create a significantly more competitive domestic market and make beneficial, state-of-the-art treatments more readily available to patients. The NHS should be persuaded to invest now in the right kind of technology to secure benefits for the future.

Health Select Committee report

In April 2005, the House of Commons Health Committee published its report *The Use of New Medical Technologies within the NHS*¹³ following a short inquiry into current levels of innovation uptake, particularly in the area of telecare. The Committee recognised the potential of new medical technologies to facilitate remote monitoring and diagnoses for

10 Healthcare Industries Task Force, *Better health through partnership: a programme for action*, November 2004, available at: www.advisorybodies.doh.gov.uk/hitf and ABHI's website at: www.abhi.org.uk

11 Sir Derek Wanless, *Securing our Future Health: Taking a Long-Term View*, April 2002, available at: www.hm-treasury.gov.uk

12 Available at: www.hm-treasury.gov.uk

13 Available at: www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/398/398i.pdf

patients in community settings. Both the Government and industry gave evidence that the continuing work initiated by HITF was driven by very similar objectives and that action was underway to deal with issues highlighted in the Committee's report.

In its response,¹⁴ the Government agreed that safety and efficacy issues were important concerns with the introduction of any new healthcare technology. The Department of Health subsequently initiated an exercise to identify existing mechanisms for reporting adverse incidents involving medical devices, which resulted in confirmation that the reporting mechanisms already in place were sufficiently robust.

As a further development, in June 2006 the first national framework agreement for procurement of telecare and associated services¹⁵ was launched to facilitate the uptake of these technologies across health and social care services. The framework agreement was developed through a pan-government telecare project management group, sponsored by the Department of Health, led by NHS PASA with the involvement of representatives from a range of organisations, including CEP. Up to the end of December 2006, approximately £5 million had been spent on procuring telecare equipment and services through the NHS PASA framework agreement. In addition, there is clear evidence of growing uptake by local authorities and other non-NHS organisations as more recognise the benefits of telecare equipment and service solutions.

The challenge for SIG

The agenda set by HITF was undoubtedly challenging. SIG's aim was to advance the HITF implementation programme over a period of two years, primarily by developing an integrated framework to support the adoption of innovation, linking together effectively the key areas explored by the Task Force. It was clear that this work would continue for some time to come and needed to evolve to complement developing health priorities and changing delivery structures.

Emulating the successful model set by the Task Force, SIG adopted a collaborative approach and officials worked in unison with industry representatives on each of the nine HITF outputs. A central unifying project – the Innovation Landscape – was developed, combining all the elements of the HITF outputs in a single exercise – to construct a network of organisations working together towards the successful adoption into service of new medical technologies.

¹⁴ Available at: www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4120880&chk=PtJqE5

¹⁵ Further details available at: www.pasa.nhs.uk/telecare/

The changing healthcare environment

SIG was responsible for ensuring that HITF outputs were translated into practical measures that would deliver the improvements envisaged. To achieve this, the changes proposed needed to align with the priorities and structures of the service. At a time when health and social care services were being transformed, this posed a considerable challenge. But SIG also viewed it as a major opportunity to embed HITF goals in the new structures. Although the pace of change was (and remains) challenging, there were clear opportunities for the benefits of new medical technologies to shape and support future service delivery. *Best Research for Best Health*¹⁶ set out the Government's strategy for developing the NHS as a world-class research environment. The changes it is introducing to NHS R&D will be further embedded by the implementation of recommendations in the Cooksey Review,¹⁷ which places increased emphasis on applied research and translation of research into health and economic benefits. The White Paper *Our health, our care, our say*¹⁸ set challenging objectives to bring care closer to patients' homes. Other health priorities, for example, achieving the 18 weeks access target (including diagnostics) by December 2008, require the deployment of technology to speed up the patient pathway. The increasing number of foundation hospitals and the introduction of more independent sector treatment centres (ISTCs) are addressing some of the bottlenecks in patient pathways. They have also begun to forge partnerships between public and private sector providers that in turn help foster a closer relationship between clinicians, manufacturers of medical technologies and patients.

The introduction of Practice Based Commissioning is focusing NHS managers more closely on the relationship between expenditure and clinical outcomes. This strategy is helping improve understanding of the value of medical technology and the extensive benefits it can bring clinically and financially, leading to more investment in efficient new products.

Payment by Results (PbR) was recognised as a key driver of technology adoption by the Task Force. The phasing in of this new financial regime to the NHS continued throughout the SIG process and, as recommended in the HITF report, greater engagement of medical devices industry stakeholders has been achieved by the establishment of a joint strategic group towards the end of 2005. The membership is drawn from the leading UK trade bodies (Association of British Healthcare Industries (ABHI), British Healthcare Trades

16 Department of Health, *Best Research for Best Health*, January 2006, available at: www.nihr.ac.uk

17 The Chancellor of the Exchequer announced the Cooksey Review of UK health research on 31 March 2006: Sir David Cooksey, *A review of UK health research funding*, December 2006, available at: www.hm-treasury.gov.uk/independent_reviews/cooksey_review/cookseyreview_index.cfm

18 Department of Health, *Our health, our care, our say*, January 2006, available at: www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/Modernisation/OurHealthOurCareOurSay

Association (BHTA), British In Vitro Diagnostics Association (BIVDA) and Surgical Dressing Manufacturers Association (SDMA)) and key government officials (the Department of Health's PbR team, Industry Sponsorship team, the NHS Information Centre and Connecting for Health). The group has provided a strong focus for industry engagement on the policy development around PbR, case mix and classifications work, and has enabled an exchange of views on related developments. It continues to meet on a quarterly basis.

While the changing environment should serve to make the services more receptive to the aims of HITF, the ongoing reforms have increased the complexity of SIG's work. Effective communication with and closer involvement of front-line NHS and social care staff – from supporting clinical studies to their role in procurement and introduction of innovative products into service – is crucial to the success of HITF and will continue to play an important part in underpinning implementation. Keeping pace with the emerging structure, the changing market and new initiatives will be essential if HITF implementation is to be 'future proofed'.

Industrial environment

Technology is a central component of modern medicine, and the rate of innovation and technology dependence is accelerating. Often medical applications of technology derive from broader advances generated in other fields, such as the use of digital imaging, high-definition visualisation in surgery and broadband telephony delivering care in the community.

Innovation in medical technologies is continuous, encompassing both incremental and transformational development. Devices such as anaesthesia machines have been evolving for more than 80 years and pacemakers for 30–40 years, while technologies such as vascular stents are comparatively recent arrivals in the last 15 years. Each has been iterating fast and over time has completely transformed the management of patients. Many have the ability to revolutionise management of patient needs and expectations. The development, marketing and distribution of some innovations have involved considerable risk and investment from industry, collaborating clinicians and scientists.

The UK has over 2,000 medical devices companies that interact with clinicians and the science base to bring beneficial technology to market. Very sophisticated devices bringing technologies from other fields and integrating them to deliver the latest capabilities often require high levels of capitalisation, but there are many smaller companies developing extremely innovative products from much more modest investment. In many cases,

these businesses will be absorbed by larger companies, once both technology and market are proven.

A well-aligned research and development environment, coupled with a market structure enabling the NHS to engage creatively with professional procurement specialists, is a prerequisite to achieve the goals of HITF. Competition between suppliers of care (trusts and the independent sector) and a wide range of suppliers capable of providing technologies that drive improvement in care is essential to this vision of a vibrant future.

Conclusion

Although the SIG agenda has been challenging, it is now clear that the timing of the whole HITF initiative was opportune. The health environment has received increased public investment to modernise services and the medical technology industry was keen to secure a stronger footing in the UK market. The continuing collaboration between government and industry under SIG has led to an improved understanding of the drivers for change and new opportunities for close working to deliver mutual benefits. Despite important differences arising during the SIG phase, there has been a large measure of agreement running through both HITF and SIG processes.

SIG's primary focus became the development of the Innovation Landscape project unifying all nine HITF outputs, linking them all to the central aim of promoting and supporting the uptake of new medical technologies which demonstrate the potential to deliver clinically effective outcomes for patients, value for money for the health and social care services, and development of a vibrant market for industry. SIG also recognised the importance of continuing this work.

Implementing HITF goals also highlighted the need to link this work more closely to increasing inward investment. SIG recognised that the improvements being implemented (particularly in relation to support for medical innovation) would also make the UK an attractive location and market for overseas companies. At a time when radical change is taking place in the delivery of our health and social care services, and when medical technology is advancing rapidly, this presents a good opportunity to convey to business globally how the market here is changing and what the improved potential from investment here is.

The following chapters set out SIG's objectives, achievements and proposals for continuing a strategic dialogue between government and industry. Included are summary reports on each HITF output, an update on developments on metrics, and SIG's recommendations.

It is clear that substantial benefits have continued to flow from the collaborative approach adopted during the SIG process, ultimately strengthening the relationship between government and industry. An example of this is the co-operation between the Department of Health and several external stakeholders, including the medical devices industry, on a wide-ranging initiative to communicate the benefits to patient safety and efficiency of using auto-identification on medical and pharmaceutical products. This culminated in the issue in February 2007 of *Coding for success: Simple technology for safer patient care*,¹⁹ best practice guidance that includes an action plan to encourage the NHS and manufacturers to adopt this approach.

As the SIG process drew to a close, all agreed that the dialogue needed to continue. There now needs to be a focus on establishing new joint mechanisms for strategic engagement between government and industry to address the key issues of the future.

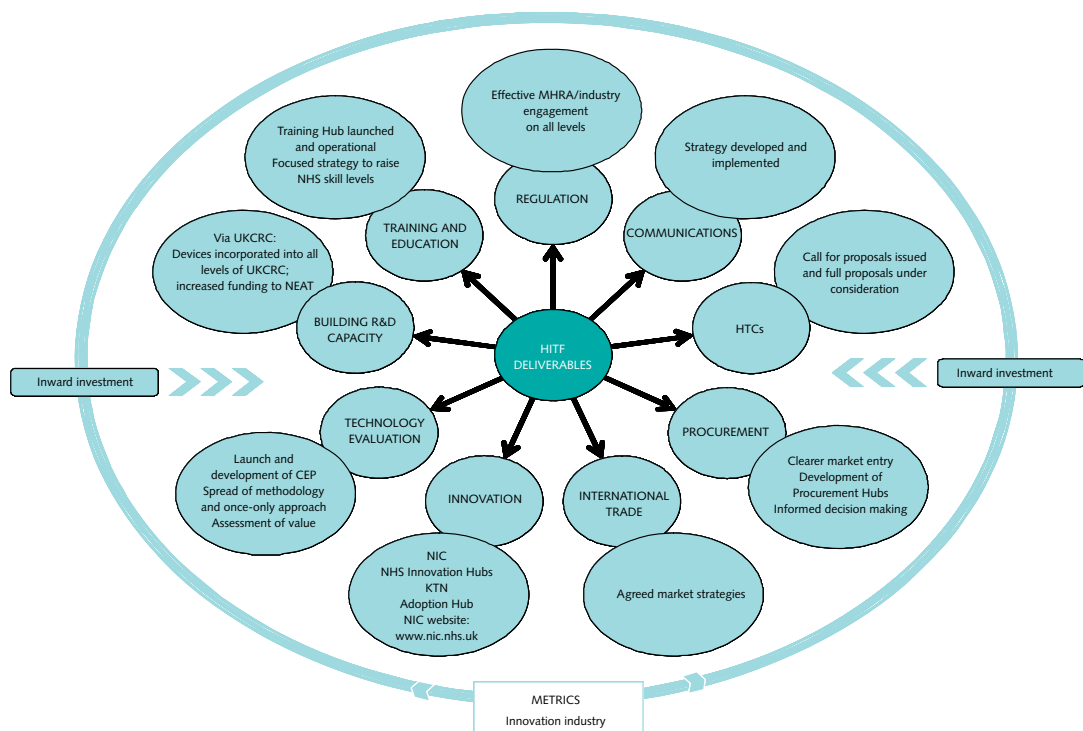


Patient receiving an angiogram

¹⁹ Department of Health, *Coding for success: Simple technology for safer patient care*, February 2007, available at: www.dh.gov.uk/publications

3. The Innovation Landscape – bringing HITF outputs together

Figure 1: The Innovation Landscape – bringing HITF outputs together



Improving uptake of innovation emerged as the key theme from HITF. Progress towards this would contribute to all the HITF outputs, complementing and benefiting all of the workstreams for mutual advantage, eg:

- increasing NHS R&D quality and capacity in relation to medical technology encouraging companies to conduct their trials here, benefiting patients and companies, and developing a more entrepreneurial culture in the health service
- appropriate regulation underpinning product safety and performance
- better, quicker product evaluation supporting earlier adoption of beneficial medical innovation
- more innovation showcased in the NHS leading to more inward investment and potential increases in exports for industry

- better NHS training and education on the use of new medical technologies encouraging safe and competent use of innovation.

The Innovation Landscape project was initiated for these reasons. The aim was to map the processes involved in the successful marketing of products and the various organisations that play a role in facilitating technology adoption.

What quickly became clear in the early stages of the project was that there was no single, linear pathway to market for these products. Because of the diverse nature of this product group, and the typical iterative and relatively rapid process of product development, it was not possible to plot a universal route from concept through to successful uptake, since the cycles that products undergo to reach the market are complex and individual. Gaining a comprehensive understanding of the processes and organisations involved would not only help to develop a clear line of sight to adoption for innovators, but also support integration and delivery of all HITF outputs.

Through the project, however, the key players on the Innovation Landscape were identified and their roles defined. This has resulted in a clearer understanding of the pathways to market and companies are better able to navigate the Innovation Landscape and more prepared at each stage of the process.

SIG recognised that effective communication and co-operation between the organisations on the Innovation Landscape was key to ensuring that there is a more systematic approach to the adoption of new medical technology.

Figure 2: The Innovation Landscape

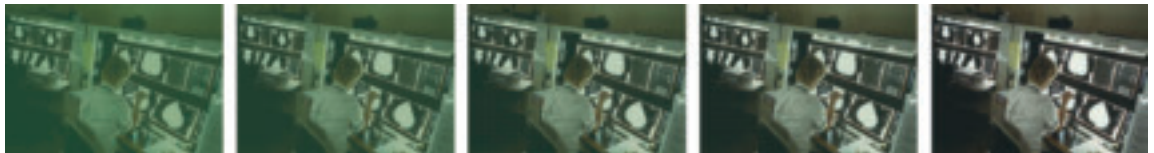


Work continues to help ensure alignment of the objectives of organisations on the Innovation Landscape. Arrangements will be put in place for a mechanism for the heads of the key bodies (eg the NHS Institute, Department of Health Research and Development Directorate, Department of Health Commissioning Directorate, and those directing the new commercial strategy) to oversee the smooth functioning of the Innovation Landscape and resolve any blockages or other strategic issues.

4. Implementing HITF outputs

SIG's responsibility during its period of operation was to progress implementation of the nine key HITF outputs efficiently and effectively. Officials and industry representatives worked together at all levels to develop proposals and measures to deliver the successful outputs.

Significant progress has been made. The challenges, key outputs and forward plans for the continued development of implementation are outlined in more detail in the sections that follow.



Radiographer observing breast scans on a lightboard

CENTRE FOR EVIDENCE-BASED PURCHASING (CEP)

HITF output: Device evaluation

Develop a new device evaluation service to integrate and strengthen horizon scanning, and the assessment of value and effective performance of new and enhanced healthcare technologies, devices and related procedures.

Develop nationally accepted methodologies and toolkits for device evaluation that can be used locally to ensure consistency of approach whilst facilitating decision-making at the appropriate level.

Consider how best to ensure speed of evaluation, a “once only” approach and prompt sharing of outputs with stakeholders throughout the health and social care system and industry.

The Task Force viewed device evaluation as a catalytic mechanism crucial to accelerating uptake of new medical technology. This led to the former Device Evaluation Service (DES) undergoing a major redesign, following comprehensive consultation with all stakeholders, including customers and peer groups. Following its transfer to NHS PASA in September 2005, and its renaming as the Centre for Evidence-based Purchasing, CEP has been creating an organisation to help achieve the overall aims of the Innovation Landscape (see Chapter 3). The rate of progress has been affected by the differing levels of maturity of the Collaborative Procurement Hubs, the creation of the new NHS Supply Chain, and the restructuring of strategic health authorities and primary care trusts. Other wide-reaching developments such as the Cooksey Review of a single fund for health research, the Carter Review of pathology services (www.thecarterreview.com) and the increasing impact of the NHS Institute's work will help CEP deliver greater adoption of innovative technologies via strategic sourcing and supply.

CEP is currently funding four pilot projects that bring together the aspirations of the HITF outputs on both market access and product evaluation. These pilots are being supported by the Centre for Research in Strategic Purchasing and Supply (CRiSPs) at Bath University and the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH). The aim is to create a common understanding of value across a diverse range of technologies. These projects will be completed during 2007 and should offer the opportunity for industry to shape its own studies appropriately at a pre-market stage, making the task of evidence review – and therefore adoption – simpler.

Future plans include development of electronic specification databases for comparing products that are available on the market and buyers' guides for all adopters to understand the challenges involved in adopting new technologies.

CEP will work with the NHS Institute to create implementation strategies to help make technology adoption part of normal business for the NHS and social care. CEP will also seek opportunities to integrate more closely with the business processes of Collaborative Procurement Hubs.

Outputs

- 1 September 2005: CEP launched as part of NHS PASA; funding for development secured for first three years
- March 2006: Prioritisation board for new projects established and operational – 122 proposals received and considered; 71 new projects commissioned, including four pilots to test ways of embedding value into the evidence base across a range of technologies
- Throughout 2006: Key senior staff and economic adviser recruited
- November 2006: First CEP output – see overleaf

Challenges

- Building credibility of CEP products
- Consolidating our partnership with industry to help manage stakeholders' expectations
- Ensuring that the priorities of key stakeholders are met as their roles evolve

Forward plans and timetable

- Continue to build and promote CEP
- Develop corporate and business plan beyond 2009
- Cement stakeholder relationships, ensuring that CEP is well represented and regarded as part of the overall landscape
- Play an active part in the development of the Department of Health's commercial strategy

www.pasa.nhs.uk
email: cep@pasa.nhs.uk



Home test kit for blood sugar levels

Summary of CEP's first published output on use of a silver-coated catheter and hospital-acquired infections (HAIs)

CEP

As a constituent organisation on the Innovation Landscape, CEP's role is to underpin purchasing decisions by providing objective evidence to support the uptake of useful, safe innovative products and related procedures in health and social care. As a key output of HITE, it is refocusing its service to deliver this objective and published its first output in November 2006.

Field of use

Catheter-associated urinary tract infections (CAUTIs) are the most common type of HAI and account for up to 40% of all HAI. Normally the urinary tract is sterile, but catheters disturb the body's natural defences and bacteria can be introduced either intraluminally (along the bore of the catheter) or extraluminally (along the outer wall of the catheter).

There have been many initiatives to reduce this burden of infection, the most promising of which is the use of anti-infective catheters. CEP's review concentrates on studies of one type, the silver alloy-coated hydrogel Foley catheter manufactured by Bard.

Evidence reviewed

We reviewed the clinical and economic evidence on use of the catheter. Most studies indicated a reduction in the rate of CAUTI following introduction of the catheter in question. However, the majority suffered from significant limitations, such as low patient numbers, use of historical baseline data and absence of controls. In addition, there was no standard definition of CAUTI, which could lead to the data being misinterpreted.

CEP's verdict – significant potential

Because of the way the studies were conducted, no firm conclusions can be drawn on the clinical and cost-effectiveness of the product. There is no evidence to suggest that there is any clinical disadvantage associated with the use of the catheter. There is, however, a significant body of evidence, including that available from early adopters in the NHS, which indicates that the product could be effective in reducing CAUTI in short-term catheterised patients.

NATIONAL INNOVATION CENTRE (NIC)

HITF output: Innovation

Stimulate more innovation and encourage a more entrepreneurial culture in industry and the NHS:

- **work towards the development of a new Innovation Centre in an appropriate organisation to promote and support the rapid development, dissemination and commercialisation of a pipeline of innovations coming from the NHS, academia or the global healthcare industry; the role of this centre would be to:**
 - **co-ordinate and develop the activity of the existing network of NHS Innovation Hubs**
 - **improve interactions and promote the exchange of knowledge between the NHS, industry, financiers and other key stakeholders, utilising online knowledge exchange and communication tools**
 - **play a brokerage role between industry, financiers and the NHS, fostering partnership and collaboration opportunities**
 - **promote successes and facilitate innovation uptake in the NHS**
 - **introduce an ‘innovation fund’ to promote the development and exploitation by the NHS of innovative products and procedures**
- **establish collaboration between the Medical Devices Faraday Partnership, other appropriate partners and the new Innovation Centre networks, covering the supply industry, academic departments, business and finance organisations, and NHS and DH bodies, to:**
 - **promote the exchange of knowledge between the networks**
 - **deliver an online ‘integrated routemap’ guiding stakeholders on product development, business planning and manufacturing, regulatory and marketing procedures, through to entry into NHS and world healthcare markets**
 - **when appropriate, promote co-ordination of respective brokerage activities**
 - **work to increase both public and private funding for translational research in developing new products from proof of concept to commercialisation**

The NIC was established to accelerate the development and uptake of technology innovation into the NHS and to manage intellectual property emanating from the NHS via the regional Innovation Hubs. In the first five months or so of its operation, it has achieved a significant amount of progress and has been enthusiastically supported by its key stakeholders. The NIC has played a crucial role within the Innovation Landscape (see Chapter 3) and is developing two new important hubs – on training and on adoption. As the understanding of the value of medical innovation begins to gather force, the NIC will need to stay at the forefront of developments so that it can continue to fulfil its objectives.

Outputs

- Establishment of the NIC within the NHS Institute in July 2005 to manage a broad programme of activities designed to enhance integration of innovation; operational from September 2006 – marked by an inaugural conference at Imperial College, London, and launch of website, including an online self-assessment tool to test the potential of innovative ideas for healthcare products in development, linked to support material such as ‘how to’ guides, case studies and other resources, plus an ‘Innovation Assistant’ tool providing information on taking a potential product from concept to market
- Series of stakeholder workshops to start interaction with the NIC, NHS Innovation Hubs, industry partners, DTI, Treasury, Department of Health and university networks from October 2005 to July 2006
- Training Hub launched in September 2006 and first products released (a Medical Devices Training Guide and patient safety video) – see also Training and education output page 38
- Development of pilot Adoption Hub in Manchester
- Medical Devices Faraday Partnership relaunched in February 2006 as the Health Technologies Knowledge Transfer Network (KTN) to link industry, academia and the NHS, supported by an interactive website at: http://healthtech-globalwatchonline.com/epicentric_portal/site/healthtech/

Challenges

- Developing activities and sustainable business plans to meet the needs of stakeholders

Forward plans and timetable

- Production of structured programme for future engagement with stakeholders.
- Networking meetings on the following topics:
 - leveraging clinical expertise
 - positioning of innovation
 - adoption of new technology and procurement
 - effective sharing of information in the network
- Establishment of innovation fund – target date end of 2007
- Enhancement of website
- Agreeing metrics to measure success

www.nic.nhs.uk

PROCUREMENT

HITF output: Procurement processes

Embed modern approaches to procurement in the NHS to deliver better value for the service of patients through:

- **nationally-agreed/accepted models, including early communication with industry on workplans (eg Supply Chain Excellence Programme) to provide clarity on levels of market access and to ensure capture of innovative solutions**
- **a focus for regional procurement with significant clinician involvement to provide the platform for an informed approach to procurement decision-making**
- **ensuring that the role of procurement in supporting the timely uptake of new technologies identified as providing benefit to patients is embraced**

The above will be incorporated into the redesign of NHS PASA, the proposed model for Collaborative Procurement Hubs under SCEP and the continuing development of Supply Management Confederations.

- **regular dialogue between NHS and industry to encourage input into policy-making generally and specifically (eg National Service Frameworks and Payment by Results initiatives)**

A Steering Group with industry, NHS, Department of Health, National Institute for Health and Clinical Excellence (NICE) and National Patient Safety Agency (NPSA) representation worked to create understanding and define the projects that need to be undertaken to deliver HITF outputs. These are at various stages of planning and implementation. A strong spirit of co-operation and collaboration created the right backdrop in circumstances which might otherwise have hindered commitment to the project.

Outputs

- The Collaborative Procurement Hubs (CPHs) project (part of SCEP) is establishing regional focus for procurement so that by 2008 every trust should have access to a Hub within its region
- The HITF Steering Group for procurement was established to provide an effective communications and decision-making network

Outputs (continued)

- A single procurement process has been developed for the NHS (including CPHs and NHS Supply Chain) to incorporate all the decisions/outputs from the Steering Group comprising an overarching strategic framework and process flow, together with a comprehensive series of tools and methods, eg innovation assessment, clinical and stakeholder engagement and broader benefits realisation
- Value definition/assessment model in development with CEP

Challenges

- Commercial strategies need to be joined up across the Department of Health and the NHS
- Ensuring procurement/commercial inputs more consistently influence and deliver policy
- Strategic relationships with industry
- Direction and support for CPHs which are at different levels of development, maturity and scope/capability
- Engaging and creating widespread understanding about the broader commercial opportunities and longer-term benefits for the NHS in working with CPHs
- Spreading adoption of the procurement model across the NHS

Forward plans and timetable

- Collaborative Procurement Hub project continues to 2008
- New commercial strategy to be developed
- Continuing engagement with a wide range of stakeholders to inform ongoing development of tools and methods and to ensure their adoption
- Findings from the Assessment of Value project (four pilot studies in conjunction with CEP) available in 2007 to inform the future approach to defining and assessing the value of new health-related technologies
- Development of implementation plans for spreading the use of the procurement model across the NHS

BUILDING R&D CAPACITY

HITF output: Building R&D capacity

Through the UK Clinical Research Collaboration (UKCRC) DH will:

- **incorporate devices into the disease hubs/networks starting with five initial disease areas: mental health, diabetes, new medicines for children, stroke, and Alzheimer's)**
- **develop a capacity-building programme, including fellowships**
- **increase commitment to the new and emerging technologies R&D programme (New and Emerging Applications of Technology (NEAT))**

UKCRC will provide a platform for harnessing the quality and expertise of the NHS for all stakeholders by:

- **building up the clinical research infrastructure in the NHS**
- **building up the research workforce (through improved training opportunities and career structures)**
- **developing incentives for research in the UK**
- **streamlining the regulatory and governance processes**
- **co-ordinating funding (through a strategic analysis of current portfolios)**

The Task Force recognised the need to expand NHS capacity to conduct clinical trials, studies and investigations on medical devices. The UKCRC, established in April 2004 during HITF, provided a mechanism to meet this objective and gave the healthcare industries representation in this new partnership. The UKCRC's aims are to establish the position of the UK as a world leader in clinical research and to benefit patients and the public by improving national health and increasing national wealth.

The vision of the Government's new R&D strategy for the NHS in England, *Best Research for Best Health*, published in January 2006, is to ensure that the UK becomes the pre-eminent location in the world for health research, development and innovation. An explicit objective of the strategy is to support research in partnership with and for the industry. Its implementation will be critical to ensuring that the UKCRC objectives, including those relevant to HITF, are delivered successfully. The changes to NHS R&D being implemented will be further embedded by implementation of recommendations in the Cooksey Review, which builds on *Best Research for Best Health*, and places increased emphasis on applied research and translation of research into health and economic benefits.

Outputs

- Healthcare industries represented on key strategic and operational groups – the UKCRC Board, Industry Reference Group and working groups
- The *Invention for Innovation* will bring together the NEAT programme, the Health Technology Devices Programme and the Department of Health's commitment to Healthcare Technology Co-operates funding, with an additional £5 million per annum for a new Challenge Fund for Innovation to promote and accelerate the transfer of knowledge between the National Institute for Health Research (NIHR) and the NHS; funding allocated by the NIHR scheme for the NEAT programme and the Health Technology Devices Programme being doubled from £4 million to £8 million per annum from April 2007 over a three-year period
- Establishment of a UKCRC Industry Road Map Group in May 2005, with representation from the healthcare industry, to identify services that the UKCRC could offer to industry
- The UK Clinical Research Network (UKCRN), comprising a Co-ordinating Centre and six topic-specific research networks, now operational; the Co-ordinating Centre and Local Research Networks for stroke, diabetes, dementias and neurodegenerative disorders and medicines for children, established during 2005 and 2006 via competitive process, have each appointed an industry lead as a specified contact for companies interested in conducting studies in the networks
- Plans to create a Primary Care Research Network and Comprehensive Research Network for England, as announced in *Best Research for Best Health*, to provide the infrastructure to support clinical studies covering the full range of applications relevant to the healthcare industry but not addressed by the topic-specific networks, with implementation commencing from April 2007
- Agreement that the Comprehensive Research Network will play a key role in research management and put in place systems to provide central sign-off for R&D at a national level for multi-centre trials in 2007
- Key UKCRC developments include funding and implementation of new integrated and flexible training pathways for clinical academics; capacity-building strategies under development for nurses and other research professionals

Outputs (continued)

- Implementation of recommendations from the *Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees* to establish committees with special interest and experience in reviewing devices studies; consultation on the draft guidance on medical devices studies published in December 2006
- Establishment in spring 2006 of a UKCRC Connecting for Health Advisory Group, on which industry is represented, to develop capability within the National Programme for IT to support research; pilot research simulations on the research uses of data initiated in October 2006
- Discussions of a model Clinical Investigation Agreement, designed to speed up the initiation of industry-sponsored clinical studies in the NHS, commenced in June 2006
- Healthcare industries stakeholder day held in January 2007 to provide an overview of NIHR activities that are improving the clinical research environment for medical devices, and to gain device-specific input on developments, eg UKCRN and the draft model Clinical Investigation Agreement
- Discussions to explore possible co-funding by government and industry of clinical trials involving SMEs from pharmaceutical, biotech and healthcare sectors initiated in March 2006
- Devices industry participation in an industry stakeholder event in November 2006 to inform development of the NIHR portal and management information systems, which will simplify and support more efficient research administration and approval processes

Challenges

- Effecting a culture change within the NHS at a time of reorganisation
- Growing competition from other countries for clinical trial business
- Clinical research needs specific to the medical devices industry, with its high proportion of SMEs, operating in an environment in which there is often an absence of agreed methodologies and variable understanding of device issues among the clinical and academic communities

Forward plans and timetable

- Implementation of *Best Research for Best Health*, including calls for proposals for funding new research programmes, according to published plans
- Implementation of Cooksey Review recommendations as appropriate
- Launch of the model Clinical Investigation Agreement for relevant studies involving devices in the second quarter of 2007
- The Department of Health's Research and Development Directorate to establish a new working group to complement the activities of the UKCRC Industry Road Map Group, to focus exclusively on the needs of the healthcare industry sector and involve a broader range of stakeholders; the aim is to support the joined-up articulation and delivery of the NHS service proposition to industry
- Implementation of recommendations from the *Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees*, according to published plans

www.nihr.ac.uk, www.ukcrc.org, www.ukcrn.org.uk, www.corec.org.uk



Paramedic checking medical equipment

HEALTHCARE TECHNOLOGY CO-OPERATIVES (HTCS)

HITF output: HTC pilots

Government and industry will work together to develop a suitable academic centre of excellence as a HTC pilot to pioneer specialist techniques in patient treatments in order to inform future developments.

The concept of HTCs evolved from discussions within the HITF working group on R&D and the industrial base. It was agreed that enabling industry, academics and clinicians to interact on an equal footing, sharing ideas that could translate into new products, would be vital to successful innovation in healthcare technologies and the subsequent uptake within the NHS. An HTC working group was convened in September 2005 to refine the concept of an HTC, develop proposals for the pilot activity and explore funding. There was consensus that HTCs should be clinician-led, formal but responsive collaborations between clinicians, patients, academia and industry. They would act as sources of technology-pull into the NHS to deal with areas of unmet clinical need, identified from a front-line service perspective, to deliver solutions on a national basis, and to be distinguished by the emphasis they place on engagement with users or patients. The scope of the HTC pilot activity is restricted to disorders associated with high morbidity, which place a large burden of care on the NHS and its interface with social care but which do not currently attract significant research funding or academic interest. Pilot HTCs represent a novel concept and are expected to come into operation during 2007. The success of this venture will be assessed over the following two years with a view to additional funding being made available to roll out the programme more extensively.

Outputs

- September 2005: Working group formed, defined the scope of an HTC, made proposals for pilots and their evaluation, and confirmed the availability of funding and the relationship with the Devolved Administrations
- May 2006: Briefing event for Regional Development Agencies and Innovation Hubs
- June to July 2006: Publication of the call for outline proposals and briefing event for potential applicants
- October 2006: Closing date for receipt of outline proposals
- November 2006: Full proposals invited
- February 2007: Full proposals submitted

Challenges

- The need for prospective HTC pilots to gain significant financial support to fund day-to-day operations and achieve long-term sustainability
- Ensuring that HTC pilots develop as truly collaborative national ventures, rather than exclusive centres of excellence, and that there is effective engagement with industry
- Ensuring appropriate governance arrangements for HTC pilots so that intellectual property rights (IPR) and shared know-how are managed appropriately, without being overly prescriptive of the organisational structure and framework, and state aid issues addressing where relevant

Forward plans and timetable

- Decisions to be communicated in April 2007
- Pilots to be initiated in 2007
- Reviews of pilots to be carried out in 2007, 2008 and 2009
- Decision on renewing funding and future development to be made in 2009

www.nihr.ac.uk/programmes_research_programmes.aspx
www.advisorybodies.doh.gov.uk/hitf/newsdesk.htm



Patient having her heart scanned via ultrasound

REGULATORY PROFILE

HITF output: UK as the regulatory lead in the EU and internationally

Maximise UK influence in regulatory matters in the EU and other international forums, in consultation with industry, across all relevant issues to:

- **help ensure regulation and enforcement are appropriate**
- **maintain high standards of patient safety**
- **provide a stable legislative framework in the UK**

Engagement between MHRA and industry on regulatory matters is fundamental and continuous. The HITF agenda has elevated the profile of this communication. The main areas of co-operation have focused on the revision of the Medical Devices Directive (MDD) and the draft Regulation on Advanced Therapy Medicinal Products (ATMP) which covers tissue engineering. MHRA and industry have built on their existing excellent working relationship through a variety of stakeholder groups and regular discussions to draw up, agree, promote and secure UK objectives in important EU negotiations. MHRA and industry have also explored ways of improving the MHRA service to SMEs by tailoring communication and advice on the regulatory frameworks to their needs. MHRA no longer participates in the development of international technical standards. However, where these have a direct impact on the Agency's regulatory role, it will maintain an interest.

Outputs

- Joint steering groups set up on MDD and the ATMP Regulation
- Autumn 2006: MHRA improvements to their service for SMEs via MHRA website information, including a simplified map of regulatory processes and contact points tailored to the needs of SMEs

Challenges

- Timelines and outcomes subject to EU processes
- Achieving agreement with a wide range of stakeholders

Forward plans and timetable

- EU revision of MDD and negotiations on ATMP Regulation likely to continue well into 2007
- Ongoing engagement at all levels

INTERNATIONAL TRADE

HITF output: Export strategy

Whilst continuing to service healthcare exporters in all markets, UK Trade and Investment will focus its strategic activities and resources in favour of the USA, Germany, France, Japan and China in relation to the devices industry. A watching brief will be maintained on developments in India. A range of key supporting initiatives promoting export opportunities has been identified.

Industry is working closely with government (the Department of Health and UKTI) to promote healthcare products and services overseas. HITF initiatives have promoted particular benefits in building robust relationships and networks to deliver highly effective overseas support.

Outputs

- 2006: Country strategies have been developed for the identified five key markets, plus India. Main features are as follows:
 - **USA:** Seminars held in the UK on insurance (2005) and market entry (2006), and a report, *Overview of Medical Devices Distribution in the US*, launched (June 2006)
 - **Germany:** Large groups of exhibitors supported by Trade Access Programme (TAP) events, such as Medica and Rehacare; seminars held in the UK on product accreditation and regulatory issues (April 2005)
 - **France:** Scoping missions to homecare and orthopaedics exhibitions in Paris assessed the potential for TAP support (June 2004); seminars held in the UK on regulatory and distribution issues (February 2006)
 - **Japan:** Considered a suitable market for larger companies only, due to problems with market penetration and regulatory issues; industry is in regular contact with local Commercial Officers and assists in the organisation of meetings between UK companies and Japanese companies and other potential business sources
 - **China:** Chinese interest in the NHS is considerable, with over 40 inward missions during 2004–06; healthcare prioritised under the Deputy Prime Minister's China Task Force, and Department of Health International chairs the committee on healthcare

Outputs (continued)

- **India:** Joint Economic Trade Committee (JETCO) set up, together with JETCO officials group to implement agreed activity. Feasibility study into a rural e-health project commissioned. Seminar on doing business in India held in the UK (September 2006)
- 1 April 2006: Programmes to support companies exhibiting at overseas trade fairs (SOLO) and the new TAP implemented – criteria for support tightened to focus on new exporters and new-to-market exporters in emerging markets such as China, India, Brazil, the United Arab Emirates and Russia, and on high-tech events; TAP (including SOLO) continues to be popular with companies and there is a full programme of events for 2006/07
- June 2005: British Healthcare relaunched and, following a joint review by UKTI and ABHI, key functions incorporated into the work of UKTI's Lifesciences Team (from September 2006)
- May 2006: Healthcare Advisory Group set up to provide guidance and input to UKTI's strategy and business planning process
- January 2006: Programme of international non-TAP events (inward and outward missions, seminars, conferences, training and briefing at exhibitions and other trade development and promotion activity) for 2006/07 agreed and funded
- Centres of excellence for inward missions identified as key reference sites for showcasing medical excellence (developed since 2005/06)
- Briefing on positive developments regularly circulated to overseas Commercial Officers
- April 2006: Revised arrangements implemented to improve market intelligence (see www.uktradeinvest.gov.uk)

Challenges

- Ensuring resources are effectively focused on those markets that offer the most potential and directed towards more experienced companies
- Managing the effects of political and economic policy in overseas markets, especially emerging markets, eg intellectual property protection, taxation, company law and non-tariff barriers
- Balancing the HITF strategy with local and regional priorities
- Considering operational and resource implications for the Department of Health as a result of UKTI's new strategy

Forward plans and timetable

- Continue regular meetings and liaison between industry and UKTI
- Develop and implement a new UK international strategy, which brings together trade and inward investment agendas and the marketing of the UK

www.uktradeinvest.gov.uk



Nurse showing a medical student how to use a defibrillator on a dummy patient

COMMUNICATIONS

HITF output: Communication with patients/public to improve understanding of benefits and risks of medical devices

Increase the general understanding and appreciation of the role medical devices and technologies play in public health, by more effective communication to health professionals, social care personnel, patients, service users and the public. Particular emphasis to be placed on the risk:benefit profile and the regulatory system for devices.

Communication on the regulation and safety of medical devices is already part of MHRA's objectives. The HITF output has served to highlight this activity further and ensured a responsibility for industry in conveying to a wider audience the valuable contribution that these products play in healthcare.

Industry and MHRA worked closely on comprehensive and joint consultations with health professionals, patients and consumer groups to identify key issues and general levels of awareness about the benefits and risks of medical devices. Information and insights gained through that process enabled us to develop a number of significant messages about the regulatory environment, the importance and safety of devices, the responsibilities of the manufacturers and the role of MHRA. MHRA and industry continue to work together to develop an implementation strategy to disseminate those messages widely and effectively.

Outputs

- Working group set up to manage this work
- Autumn 2005: Two consultation processes
- Key messages agreed (see overleaf)
- September 2006 onwards: Implementation plan agreed

Forward plans and timetable

- Discussions ongoing with industry to develop implementation plans
- Build into MHRA's broader ongoing communication strategy

www.mhra.gov.uk

Medical devices – Key messages

- Medical devices and technologies range from syringes and wheelchairs to pregnancy test kits, pacemakers and X-ray machines which are critical to the delivery of healthcare to patients and the public.
- New devices are being developed all the time and are regulated under EU legislation to ensure they work for the intended purpose and that the benefits to patients and the public outweigh the risks. The CE mark is the sign that this assessment has been made.
- Manufacturers are required to operate robust quality systems. For all but the most low risk of devices, these have to be independently checked by a European Notified Body. These are auditing bodies which are designated and monitored by the national regulator, which is the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK.
- As well as protecting patients and the public, the regulatory system encourages the timely introduction of innovative treatments and technologies that support life-long health.
- Like any product, medical devices are not risk-free and remain under continuous monitoring. In order to ensure medical devices are as safe as possible, patients, the public and healthcare professionals should report anything that has gone wrong to the MHRA.

TRAINING AND EDUCATION

HITF output: Training and education

Work identified 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.

- **consideration of initial and ongoing training and education needs as part of the procurement process where appropriate, eg for new technologies**
- **exploration with Skills for Health of how to raise the profile of competencies in the use of medical devices and technologies**
- **consideration of the development and use of learning programmes/tools**
- **in the longer term, the introduction of electronic staff records to ensure that records of key skills are transferable as staff move around the NHS**

There is widespread stakeholder acknowledgement that a more standardised, co-ordinated, better organised and funded approach in relation to medical devices education and training would improve technology adoption, patient access and streamlined care pathways, patient safety, productivity, the transferability of skills within the NHS and the economics of education and training programme development. Commissioning medical device performance within the NHS will be possible on a practical basis for the first time to better support key aspects of National Service Frameworks, Public Service Agreements, the 18 weeks access and care closer to home strategies, as well as other NHS front-line operational requirements.

Outputs

- Development of a route map (see Figure 3) through wide consultation with industry and the NHS, which has been adopted by HITF/SIG as the blueprint to take forward the training and education component
- Adoption of a business programme for SfH through which key HITF training and education deliverables are to be managed by the Department of Health and the NHS Institute
- A Training Hub for advanced/specialist technologies, based at Chelsea and Westminster Hospital, which was launched in September 2006 by the NIC and is developing innovative learning methods

Challenges

- The need for more, specific educational support at both higher technological and less specialist ends of the spectrum means that the medical devices training and education agenda would require more resources than are currently available, along with a long-term programme timeline and further buy-in from stakeholders

Forward plans and timetable

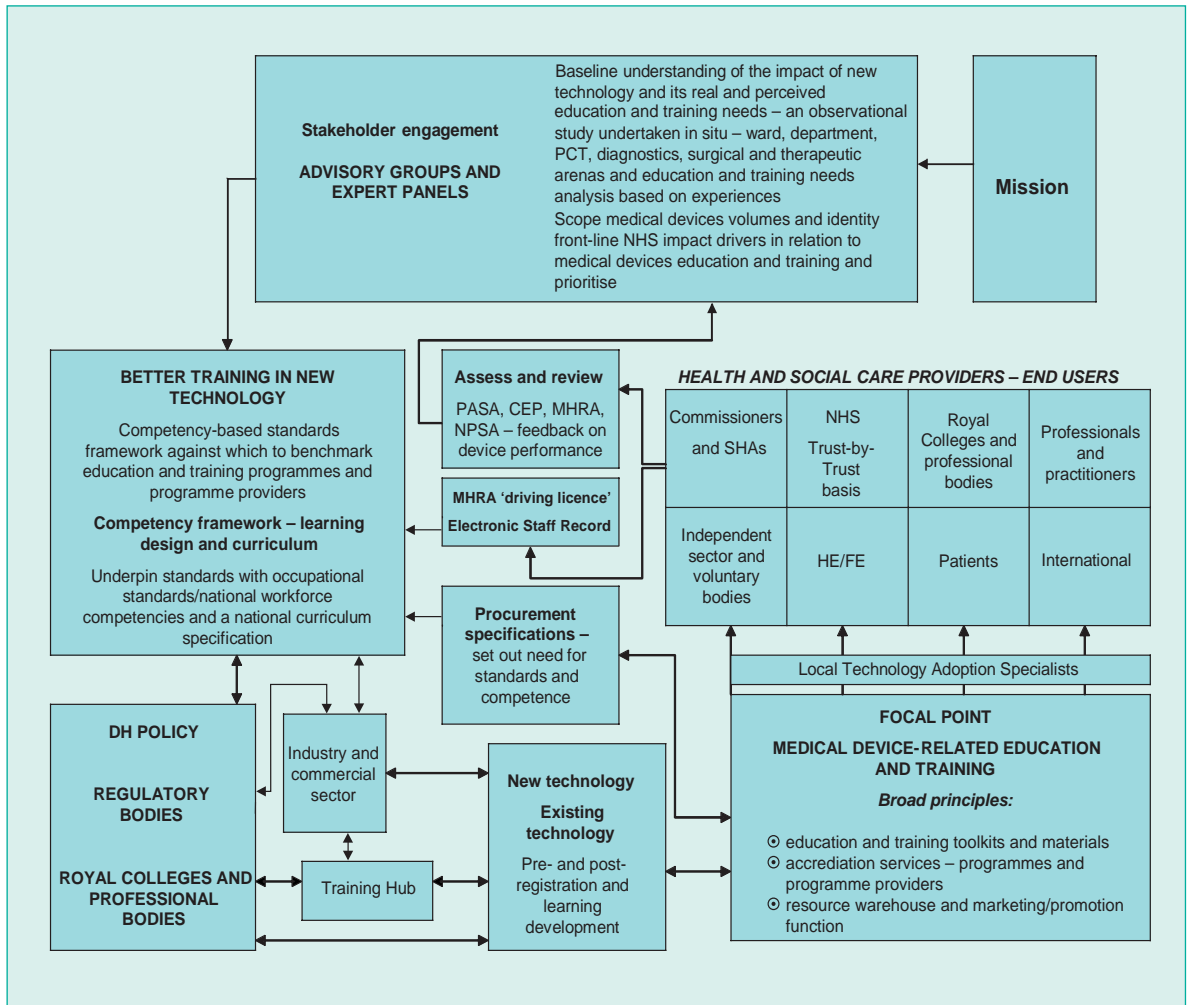
To be taken forward from April 2007 by a new focal point set within SfH and to include a wide range of programme work to sustain and build on progress to date:

- a national stakeholder partnership to identify and consolidate future workstream opportunities, enhance the inclusion of industry partners and develop specific mechanisms to engage with professional organisations, regulatory bodies, etc (summer 2007)
- a partnership arrangement (plans by May 2007) with SHA Workforce to:
 - create a representative framework through which to develop/support cases for specific commissioning of clinical training and education
 - identify where such programmes can add best value at the NHS front line and the extent to which these best support national health priorities
 - identify undergraduate and postgraduate training and education needs in relation to specific medical devices-related clinical pathways
 - map availability with need and engage with educational providers, colleges and professional bodies to promote identified requirements and have them embedded in national learning programmes
- an examination of how implementation of this output can support the 18 weeks access target and care nearer home programmes to ensure that full advantage is being taken of medical devices technology with a view to identifying where there are strong reasons for targeted investment (January 2008)
- the development of an electronic warehouse for best practice, the standards framework and competencies, training programmes/providers and methodologies, along with an options appraisal for the inclusion of these outputs into an e-based clinical pathway router, eg The Map of Medicine (or similar), by the end of 2007

Forward plans and timetable (continued)

- the development and implementation of a communications strategy to manage awareness of this work programme and promote sustainability (for approval summer 2007)
- the development of harmonious medical devices-associated standards between those currently in use by the NHS Litigation Authority and the Healthcare Commission and those developed as a consequence of this HITF output (April 2008)
- an examination of the need and role content for the adoption of Local Technology Adoption Specialists for front-line NHS services (March 2008)
- the development of a national overarching standards framework and underpinning competences for medical devices technologies which define skills and knowledge requirements and provide a vehicle through which to benchmark the content and provision of education and training programmes (March 2008)
- the joint development and funding with industry of a minimum of four e-learning modules in association, linked specifically with the 18 weeks access programme (delivery of first two modules December 2007; complete March 2008)

Figure 3: Training and education



5. Metrics – updating and development (see Annex B)

Background and overview

The Task Force found the lack of reliable data on the healthcare industries a hindrance to understanding the dynamics of the sector and the value of its activities. It was agreed at an early stage that the UK, led by the DTI in liaison with the Department of Health and industry, would compile a set of statistics and key indicators to give a more accurate picture of the domestic industry (eg size, composition, performance) so that trends may be identified and a better assessment made of its position in the market. The commitment to this initiative included a yearly review and making the data publicly available on an annual basis.

Work began on identifying and compiling statistics during 2004 while the Task Force was in operation, and the first set of industry metrics was published as part of the HITF report in November 2004. The second set of tables was published on DTI and Department of Health websites in December 2005 and included two new tables.

During 2006, government and industry reviewed all the indicators and agreed to explore how the current data could be supplemented and the tables restructured in order to provide better clarity and additional statistical information. On the basis of this, and taking into account the significance of this industry sector in the wider economy, SIG recommended a comprehensive review by government and industry to gain a better knowledge of the dynamics of what helps UK-based medical devices companies prosper in UK and global terms and what helps them grow into successful larger companies, with due regard for the high proportion of SMEs in this industry.

This work should be conducted through an econometric analysis of relevant data, which will allow government and industry to assess current and future investment trends and provide a baseline against which to consider the foreseeable implications of future policy proposals. The analysis should concentrate on key elements that contribute to a competitive environment for the medical devices sector, including global perspective, science and skills base, education, employment, capital markets and corporate venturing. A mechanism should be put in place for collection, validation and annual publication of industry performance indicators, which will help formulate policy responses relevant to the role played by this industry in contributing to the health and wealth of the nation. It should take into account the need for a healthy relationship with the NHS as the predominant purchaser, the impact of the development of an inward investment strategy and the need for appropriate support mechanisms for SMEs.

Commentary

The new metrics structure is divided into four categories – supply environment, demand environment, industry productivity and regulatory environment. SIG recognised that, over time, this approach would not only facilitate a better understanding of the industry's performance in the market place, but also begin to provide an indication of the uptake of innovation and quantification of the value of industry's contribution to the economy.

Key points

- The industry's contribution to the UK economy continues to be important, with 47,000 people being directly employed in 2005 and a contribution to national income of £50,400 per employee in 2005 (the most recent data available on gross value added)
- In 2004/05, the number of science graduates with degrees relevant to the medical devices industry in the UK was relatively high with an overall increase of 1.3% compared with 2003/04
- The UK-based medical devices industry spend on R&D fell significantly (by 21%) in 2005/06 compared with 2004/05 (DTI R&D Scoreboard) while FDA positive decisions dropped by 22 in 2005 compared with 2004
- The UK-based medical devices industry was third behind the USA and Germany in patents awarded between 2000 and 2004

Changes

- Figures on the number of UK manufacturers have been collected and included alongside the number of employees within the sector (Indicator 8).
- In addition to recording the export figures, statistics on the number of imports have now been identified so that the trade surplus can be calculated and compared with other major markets (Chart 9a).
- Three new data sets have been added:
 - the number of graduates who receive degrees in subjects and skills relevant to the medical devices industry
 - the amount of venture capital invested in the industry
 - international comparisons.

Where available, figures for 2005/06 have been included.

Forward plans

Because of the importance of metrics in gaining a clear understanding of the dynamics of the market place, SIG considered that a radical review of data should be undertaken. Statistics on key activities, such as industrial R&D activity, production and uptake of innovation, will have a vital role to play in helping to identify the areas of focus for both government and industry, and will help shape the future strategic agenda for both parties.

SIG therefore recommended that a joint exercise be undertaken to explore afresh what data could and should be collected to inform the future engagement between government and industry.

List of tables/charts/graphs

The updated tables are listed below and full details annexed to this report (Annex B). The tables will also be published on the DTI and Department of Health websites, and the ABHI website will include a link to the tables. Government and industry will continue to review the metrics and publish them on their respective websites on an annual basis.

Supply environment:

1. Number of new graduates with degrees relevant to the medical devices industry
2. Venture capital invested in the medical devices industry
3. Value added per employee (UK)
4. Total industry R&D spend and R&D as a percentage of sales

Demand environment:

Value

5. Sales of medical devices
6. Profit from sales of medical devices

Volume

7. Size of UK market

Industry productivity:

8. Number of manufacturers in the UK and employment in the medical devices industry in the UK
- 9a. Medical devices trade surplus
- 9b. Medical devices production
10. Number of patents awarded

Regulatory environment:

11. FDA decisions on applications from UK companies

General observations**Supply and regulatory environment**

The supply of high-quality science graduates available on a regular basis is an important inward investment factor for medical devices companies. **Indicator 1** shows that the UK continues to supply an adequate number of graduates relevant to the medical devices sector. Overall, the UK supply of science graduates with first degrees relevant to the medical devices industry is increasing. In 2004/05, there were 306,665 graduates, 1.3% more than in 2003/04 (302,680).

Indicator 2 shows the venture capital invested in the UK medical devices sector over the past five years. Although investment dropped between 2001 and 2002, there was a recovery over subsequent years to 2005.

The total 2006 investment in the European biotech/devices/healthcare/health IT category as a whole declined by 13%. A possible explanation is that European venture capitalists showed renewed interest in investment in the IT sector in 2006, at the expense of the health-related sectors. However, within the health sector, investment in medical systems/software remained steady. In addition, there was plenty of early stage activity, with more than 40% of the medical devices, healthcare services and medical software funding rounds going to early stage deals.

Indicator 3 shows the contributions of the industry to the national income based on the most recent data available on gross value added. In 2005, the UK value added per employee was £50,400, compared with £42,000 in 2004. Value added as a percentage of production value in medical devices in Europe in 2004 was 45.8 million euros – the highest among other industry sectors.

Indicator 4 shows the total industry R&D expenditure and as a percentage of sales. Although industry spend was broadly stable from 2002/03 to 2004/05 and higher than the spend in 2000/01, it dropped in 2005/06 by 21%. These figures cover only companies included in the DTI R&D Scoreboard. FDA positive decisions also dropped by 22 in 2005 (No=37) compared with 2004 (No=59) (**Indicator 11**).

Demand environment

Indicator 5 shows that between 2000 and 2005, the sales of UK-based medical devices manufacturers rose by just under 25%, with the best performing sub-sector being medical and surgical equipment, with a total increase of sales of around 41%. Over all sub-sectors, 2005 was the year with the greatest increase (8.6%) over the previous year.

Indicator 6 shows that between 2000 and 2005, the profits achieved by UK-based medical devices manufacturers increased by nearly 74%, though this figure is mainly accounted for by a substantial increase in profits in the medical and surgical equipment sub-sector between 2004 and 2005. Profits achieved across all sub-sectors fluctuated over the years, with the lowest profits in 2003.

Indicator 7 presents data on the size of the UK market for the period 2000 to 2004. From the four selected categories, only 'invalid carriages'²⁰ has fallen (marginally) from 2003 to 2004. All others, which include in vitro diagnostic devices (IVDs), dental materials, in vivo diagnostics and medical and surgical equipment, increased significantly from 2003 to 2004.

Industry productivity

There were approximately 2,036 medical devices manufacturers in the UK in 2005, 23 more than in 2004. The 2005 employment figures show that the UK-based medical devices industry employs a significant number of staff (47,000), some 2,000 more than the previous year (**Indicator 8**). In Germany there were an estimated 1,221 medical devices companies in 2004 (a slight increase over 2003 with 1,183 companies), 792 fewer than in the UK; but the workforce employed by the German medical devices companies was almost double the UK figure at approximately 90,000 people, showing a 2.8% increase on the previous year. (Source: Arab health 2006 website: www.arabhealthonline.com)

²⁰ 'Invalid carriages' includes wheelchairs, electric and manually powered invalid carriages and associated equipment.

UK exports have been higher than imports each year, but there are signs of a declining balance. Germany, as the largest producer and importer, has a large positive trade balance. France has overtaken the UK by a small margin to take second place and is now some 2% higher (**Indicator 9**).

The UK is third, following the USA and Germany, in the number of patent awards, with 100 patents in 2004, similar to 2003. Although this represents a significant number of patents awarded to the UK per year, there has been a declining trend since 2000, in contrast to other countries such as the USA and Germany. Canada demonstrates a similar statistical decline as the UK (**Indicator 10**).

6. Recommendations

Review of progress and learning

Two years is a relatively short time to deliver the major work programme set out by HITF. However, although we could not claim to have completed implementation, we have made significant progress. Both government and industry have improved their understanding of their different perspectives on key issues of importance and have come through a steep learning curve. This has benefited the relationship, which has developed and matured. The work begun under HITF and progressed under SIG has been enlightening. This work needs to continue, as does the good relationship built up between government and industry – this is borne out by the commitment of key players to keep up the momentum of HITF and to seal the future engagement between government and industry in the establishment of a new joint group.

Recommendations

At its final meeting in February 2007, SIG reviewed the HITF implementation programme and made the following recommendations in light of progress made to date and in the interests of furthering the impact of HITF in the future.

1. Procurement of technology and innovation within the NHS

The HITF purpose was to embed modern approaches to procurement in the NHS through best practice, supplier involvement and better clarity on levels of market access. Taken together, these would ensure that procurement takes proper account of the deployment of innovation in promoting value for money. This has been further supported both by the Cooksey Review and by *Transforming government procurement*.²¹ Joint work between government and industry has produced a clear agenda that has resulted in the development of a procurement framework for NHS collaborative procurement organisations. SIG recommends that this model should be implemented across the NHS (including the NHS Supply Chain) in a way that involves key stakeholders, including patients and industry, and helps ensure a level playing field for SMEs in the local economy. Collaborative Procurement Hubs should take the lead on accountability for delivery of the range of benefits identified in the procurement framework.

²¹ Published in January 2007 and available at: www.hm-treasury.gov.uk

2. SME support

In recognition of the high proportion of SMEs in this industry, SIG recommends a stocktake of existing support mechanisms at national, regional and European levels with a view to publicising the schemes more effectively to companies in this sector. There is already an effective network of largely publicly funded SME support organisations (the ‘Medilinks’ and their equivalents in the Devolved Administrations), which derive most of their income from the Regional Development Agencies. The increasing funding that these organisations are attracting reflects both the magnitude of opportunity for business growth and the tangible results that have been delivered since these organisations came into being. The regions are already investing heavily in this sector as a growth engine for their local economies. National and regional organisations should work closely together for the benefit of the industry sector. There should also be consideration of any issues affecting healthcare SMEs’ ability to access private finance such as equity or debt finance. Government and industry should review what measures would be needed to address any issues that are identified.

3. Inward investment and trade development

There is much to gain from attracting more overseas investment into the UK health technology market and HITF outputs were designed to create a better environment for the industry, as well as to benefit patients. Linking this activity with support for UK companies exporting to overseas markets would be beneficial, as the UK healthcare environment can often be an important selling point for overseas buyers. We therefore recommend the development of a UK marketing strategy that addresses both inward investment and trade development for the main industry sub-sectors. It should determine the countries and sub-sectors on which the UK should focus its resources. It should cover the core messages about UK strengths and the development of high-quality marketing materials. It should also include clear performance targets and metrics. The strategy will reflect the likelihood that trade activity will be largely focused on SMEs, while inward investment activity will target larger companies.

4. Measurement and analysis of the UK healthcare industry environment

The Government attaches great importance to making the UK a good place to do business by creating and sustaining a stable and dynamic economic environment for UK-based medical devices companies. It agrees with industry that a deeper, shared understanding is required of other factors that support growth of UK-based medical devices companies and encourage inward investment. Government studies (UKTI, Technology Strategy Board, Office of Science and Innovation, HM Treasury’s analysis for the 2007 Comprehensive

Spending Review – *Long-term opportunities and challenges for the UK*²²) have identified the significance of the bioscience industries for UK growth potential. SIG therefore recommends that the set of indicators, identified by the Task Force and further developed by the group, should be expanded to focus on success factors related to innovation, trade surplus and inward investment.

5. Europe

The European Commission is conducting an inquiry into the competitiveness of the European medical devices industry. As the UK has gained valuable experience of these issues through HITF and its implementation at national level, SIG recommends that government and industry should play a leading role in the Commission's initiative with a view to helping to shape a European structure that reflects and complements the actions taking place in the UK as a result of HITF.

6. Future mechanism for government/industry engagement

There was consensus among SIG members on the need to structure a new mechanism to succeed the SIG process and continue the dialogue between the medical technology industry and government at a strategic level. SIG therefore recommended that a small ministerial industry strategy group should be created to include senior representatives from government and industry to consider progress with the recommendations outlined above and other strategic issues that may arise, including consideration of how to take forward the implications of the Cooksey Review as they affect medical technology. The group should have an ongoing remit and could meet twice a year.

²² Published in November 2006 and available at:
www.hm-treasury.gov.uk/spending_review/spend_csr07/spend_csr07_longterm.cfm

Annex A

STRATEGIC IMPLEMENTATION GROUP MEMBERSHIP

Co-chairs

Lord Hunt, Minister of State for Quality, Department of Health (*from January 2007*)

Sir Christopher O'Donnell, Chief Executive of Smith & Nephew plc

Andy Burnham, Minister of State for Delivery and Quality, Department of Health,
(*June 2006 to December 2006*)

Rt Hon Jane Kennedy, Minister of State for Delivery and Quality, Department of Health
(*May 2005 to May 2006*)

Lord Warner, Parliamentary Secretary (Lords), Department of Health (*to April 2005*)

Members

Malcolm Wicks, Minister for Science and Innovation, Department of Trade and Industry
(*from November 2006*)

Lord Sainsbury, Minister for Science and Innovation, Department of Trade and Industry
(*to November 2006*)

Ken Anderson, Commercial Director, Department of Health (*to December 2006*)

Duncan Eaton, Chief Executive, NHS Procurement and Supplies Agency (*to June 2006*)

Professor Sally Davies, Director General, Research and Development, Department
of Health

Professor Kent Woods, Chief Executive, Medicines and Healthcare products
Regulatory Agency

Professor Sir Ara Darzi, Adviser on Surgery to the Department of Health

Liz Eccles, Director of Financial Reform, Department of Health (*from November 2005*)

Bill McCarthy, Director General, Policy and Strategy, Department of Health
(*to October 2005*)

Dr Jane Moore, Director, Healthcare Quality, Department of Health

Harry Cayton, National Director for Patients and the Public, Department of Health

Craig Muir, Director for Older People and Disability Division, Department of Health

Professor Sue Hill, Chief Scientific Officer, Department of Health

Bob Driver, Director, High Technology Sectors, International Sectors Group,
UK Trade & Investment

Dr Felicity Harvey, Head of Medicines, Pharmacy and Industry Division,
Department of Health

Professor Bernard Crump, Chief Executive, NHS Institute for Innovation and Improvement
(from October 2005)

Duncan Selbie, Director General, Commissioning Directorate, Department of Health
(from July 2006)

Dr Kate Barnard, Director of Development, Department of Health *(December 2005 to
June 2006)*

Colin S Morgan, Chairman, Johnson & Johnson Medical Ltd and Managing Director,
Ethicon UK

Geoff Morris, Regional Vice-President, UK and Ireland, Medtronic Ltd

Dr Christopher Hodges, Associate Fellow, University of Oxford and Consultant,
CMS Cameron McKenna

John Jeans, President and General Manager, EMEA, Life Sciences Commercial Operations,
GE Healthcare

Brian Fishwick, President, British In Vitro Diagnostics Association

Ray Hodgkinson, Director General, British Healthcare Trades Association

Joint secretariat

Richard Carter, Head of Industry Sponsorship, Department of Health

Chris Bantock, Section Head, Industry Sponsorship (Medical Devices),
Department of Health

Naseem Mahtey, Industry Liaison Manager, Industry Sponsorship (Medical Devices),
Department of Health

John Wilkinson, Director General, Association of British Healthcare Industries

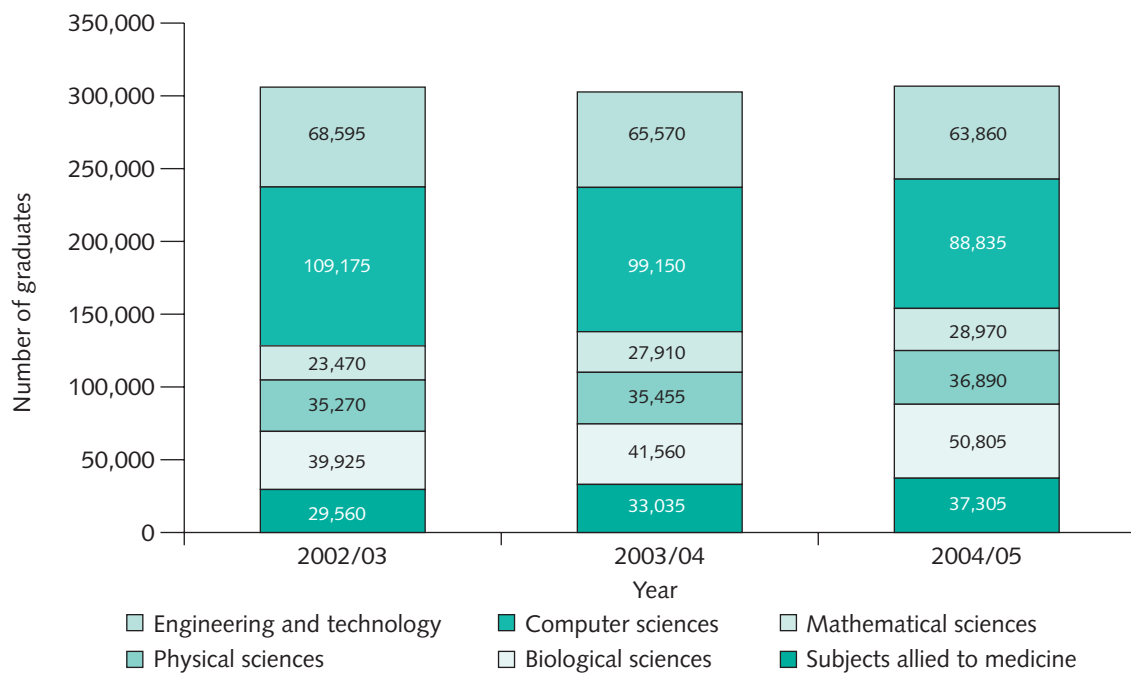
Andy Taylor, Director, Healthcare Policy, Association of British Healthcare Industries
(from November 2006)

Linette Irons, Facilities Manager, Association of British Healthcare Industries

Annex B

METRICS TABLES, CHARTS AND GRAPHS

Indicator 1: Number of people graduating with first degrees relevant to the medical devices industry, 2002–05



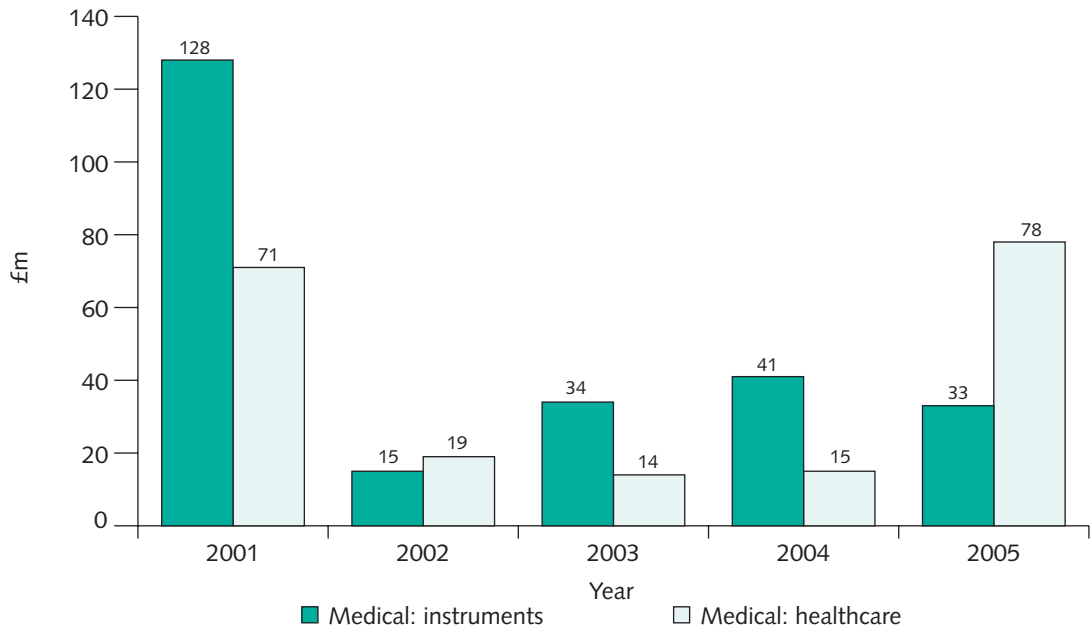
Source: Higher Education Statistical Authority (HESA)

Note: From 2002/03, HESA has moved over to the new JACS subject coding system, which has replaced the HESA subject codes. However, the subject groups have not changed significantly.

The six categories in the chart include the following subjects:

Subjects allied to medicine	Biological sciences	Physical sciences	Mathematical sciences	Computer sciences	Engineering and technology
Anatomy, physiology and pathology	Biology	Chemistry	Mathematics	Computer science	Mechanical engineering
Ophthalmics	Genetics	Materials science	Operational research	Software engineering	Electronic and electrical engineering
Medical technology	Microbiology	Physics	Statistics	Artificial intelligence	Production and manufacturing engineering
	Molecular biology, biophysics and biochemistry				Materials technology not otherwise specified and industrial biotechnology

Indicator 2: Venture capital invested in the medical devices industry, 2001–05



Source: British Venture Capital Association (BVCA), *Report on Investment Activity*

Note: According to BVCA, the reduction of investment between 2001 and 2002 is likely to be a result of the ending of the technology boom, which peaked in 2000 and 2001. In 2002 there was greater investment in biotechnology, possibly at the expense of medical technology.

In 2006, European medical devices companies received €240.38m of venture capital investment, compared with €354.08m in 2005 (source: Dow Jones, Venture One and Ernst & Young).

It is noticeable that the European medical devices industry received less venture capital funding in 2006 than in 2005. This contrasts with a 5% increase in venture capital funding across all sectors. The same trend was observed in biotechnology. A possible explanation is that venture capital investors showed renewed interest in 2006 in investing in IT companies, including medical software and systems. Investment in medical devices mainly took the form of early stage investments in young companies.

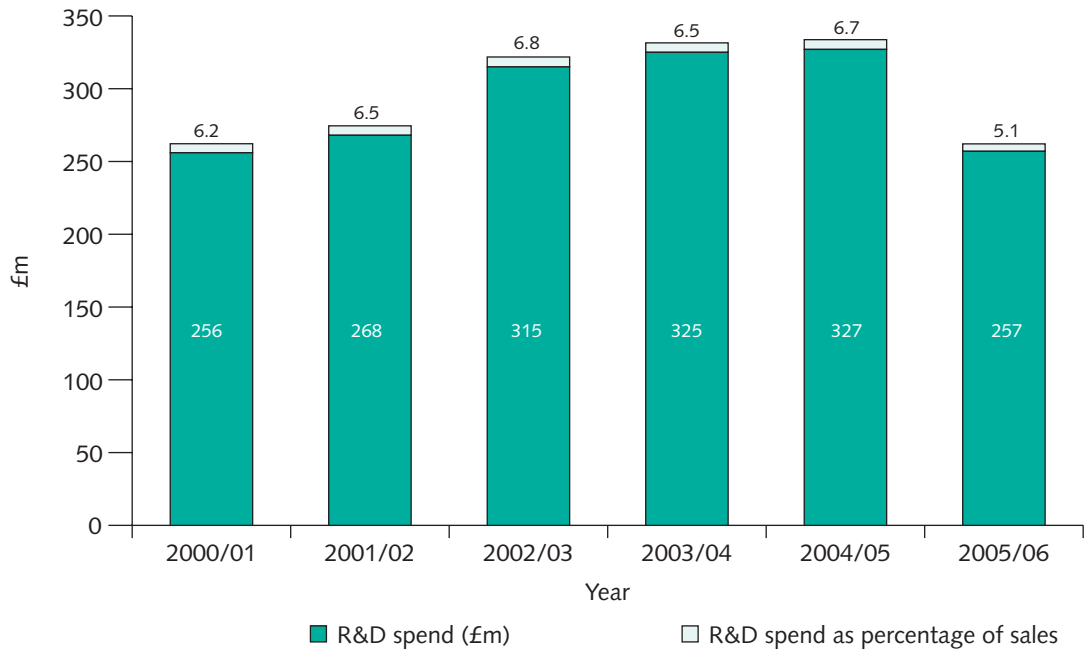
Indicator 3: UK value added per employee, 2000–05

£k	2000	2001	2002	2003	2004	2005
In vitro diagnostics and dental materials (ex SIC 24.66)	60.8	54.6	51.8	52.9	60.7	66.0
In vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc	40.2	33.0	34.4	45.4	32.1	53.9
Invalid carriages (ex SIC 35.43)	43.3	39.6	31.4	31.1	32.4	32.2
Medical and surgical equipment (ex SIC 33.1)	37.3	34.2	41.3	37.2	41.2	48.6
TOTAL (weighted average)	40.3	36.6	41.3	39.6	42.0	50.4

Source: Office for National Statistics (ONS), *Annual Business Inquiry*

Note: The data include importers/service providers. For comparison, equivalent figures in 2005 for some other sectors are: metals – 36.8; food – 47.3; transport – 52.9 (includes the invalid carriages above); and chemicals – 79.2 (includes the diagnostics figures above). ONS data for 2004 and 2005 are provisional and are likely to be revised later in 2007.

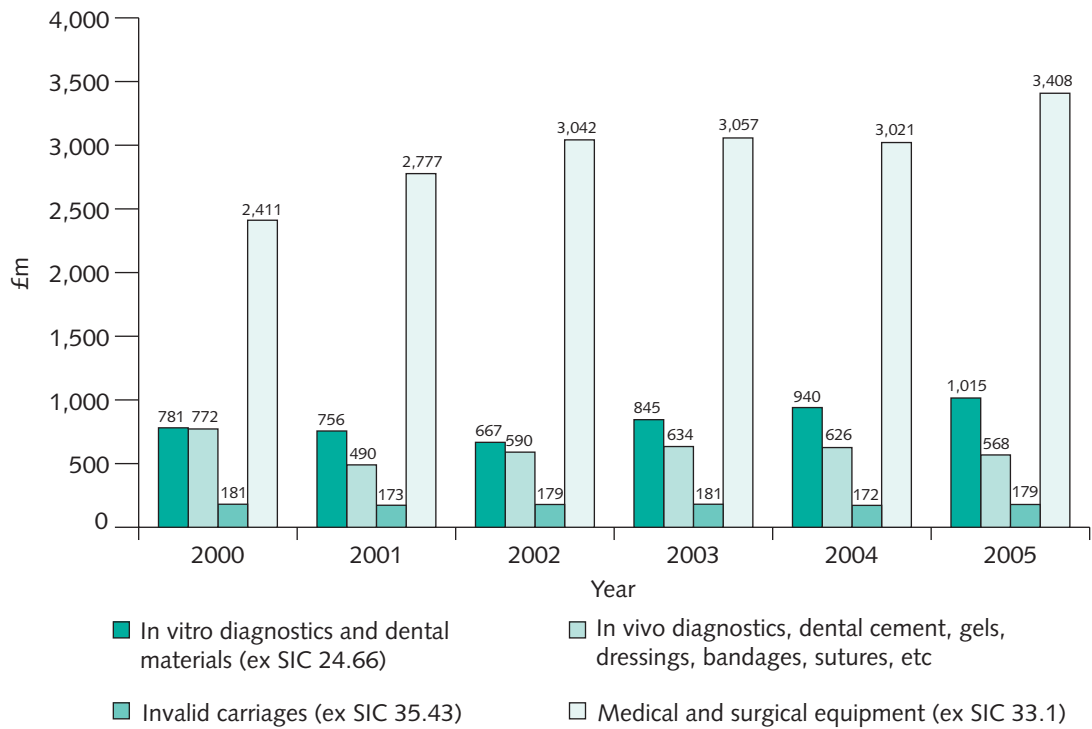
Indicator 4: Total industry R&D spend in £m and as a percentage of sales, 2000–06



Source: R&D Scoreboard

Note: These figures are for the companies included within the 'healthcare' category in the R&D Scoreboard. The Scoreboard excludes companies that spend less than £370,000 on R&D, so some smaller companies are excluded. The Scoreboard also excludes companies that do not identify R&D in their accounts. Some companies included within other categories will also have carried out R&D on healthcare products. These include Axis Shield and Radox, which are included in the 'pharmaceuticals and biotechnology' category (total R&D spend in 2005/06 was £17m for the two companies), and Smiths 'aerospace and defence' category (total £144m R&D expenditure in 2005/06). Data on government spend on medical devices are not currently available. However, based on ONS data, health R&D spend in 2003/04 (the most recent year available) was £1,168m. This compares with a combined Medical Research Council and NHS R&D spend of £963m in that year.

Indicator 5: UK sales of medical devices, 2000–05

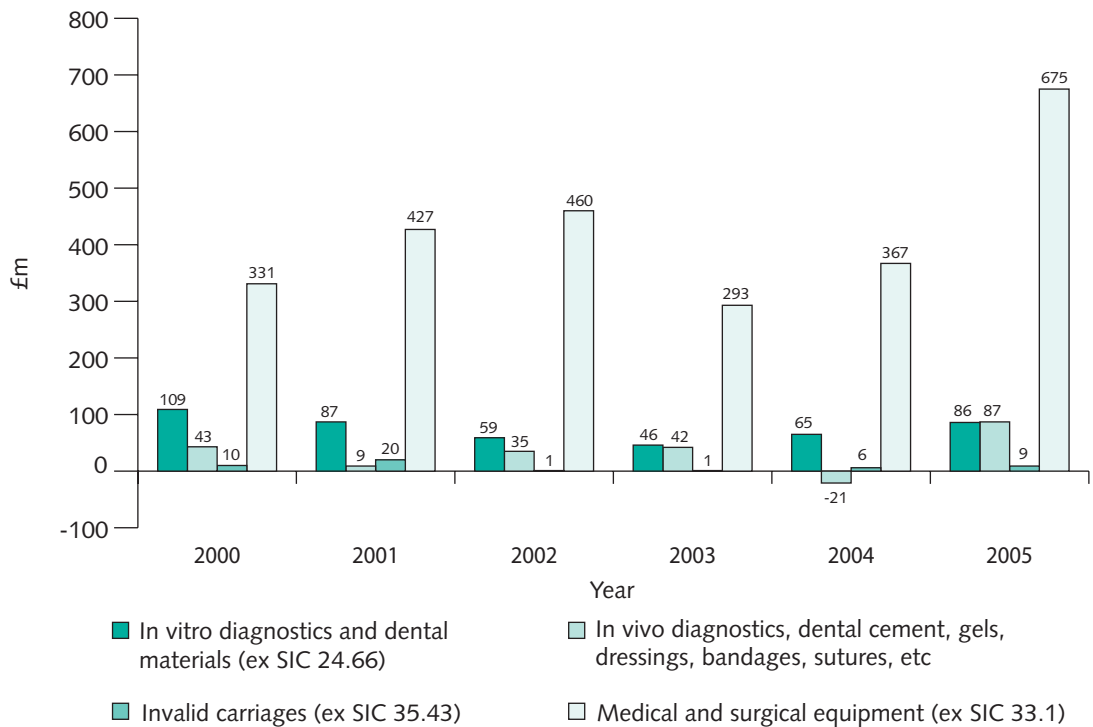


Source: ONS, *Annual Business Inquiry*

Note: ONS data for 2004 and 2005 are provisional and are likely to be revised later in 2007. These data refer to the total turnover, excluding VAT, of UK manufacturers.

In vitro diagnostics and dental materials represent 27.34% of total sales within SIC 24.66. In vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc represent 66.25% of total sales within SIC 24.42/2. UK medical devices sales increased by 8.6% in 2005 compared with 2004.

Indicator 6: Profit from sales of UK-based medical devices, 2000–05

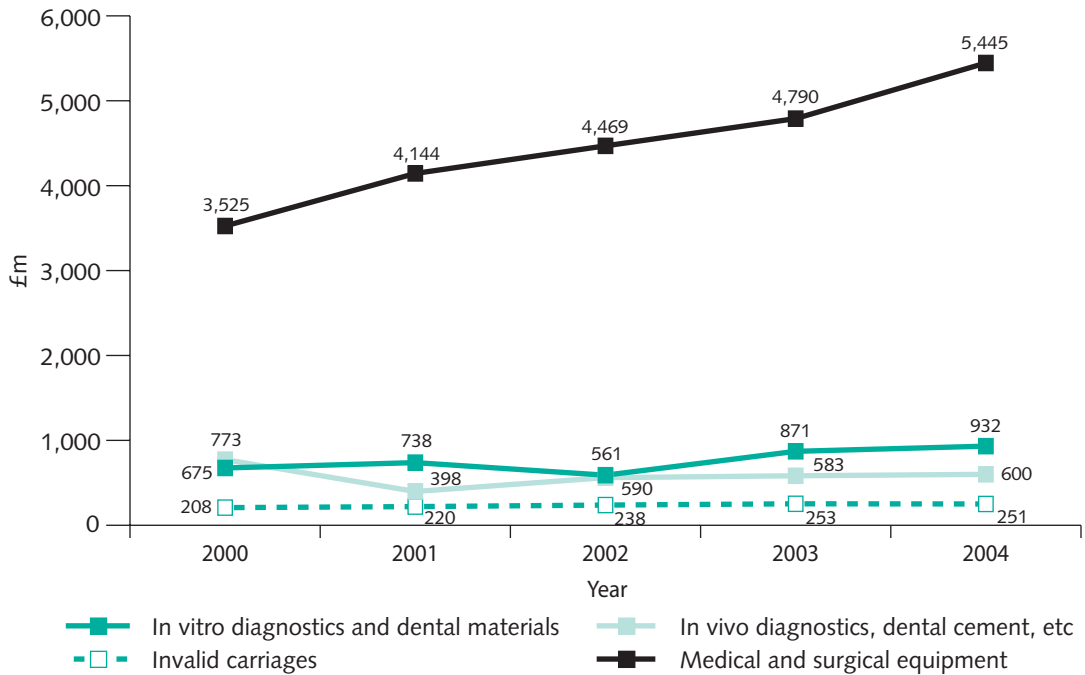


Source: ONS, Annual Business Inquiry

Note: ONS data for 2004 and 2005 are provisional and are likely to be revised later in 2007. This indicator measures the UK sales minus operating costs (cost of purchases of goods, materials and services plus employment costs) minus weighted average cost of capital applied to operating costs. Cost of capital is estimated here to be 8%.

In vitro diagnostics and dental materials are calculated estimating 27.34% of total operating costs within SIC 24.66, while in vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc are calculated estimating 66.25% of total operating costs within SIC 24.42/2.

Indicator 7: Size of UK market, 2000–04



Source: ONS, *Annual Business Inquiry*; ONS, PRODCOM

Note: The size of the UK market equals UK sales plus the net balance of imports over exports. Import figures from trade data are adjusted to take account of sales, general, administrative and service costs in the UK as well as profit. It is estimated that sales, general, administrative and service costs and profit should reach about 40% of the total price of a medical device on the UK market, so basic import figures have been increased by 66.567% before calculating the trade balance.

We estimated that intra-EU exports increased at the same rate as extra-EU exports, as exact figures for intra-EU exports are not available.

Figures for 2005 were not available at the time of publication. EU membership increased in 2004, which affected the market size of some states. ONS data for 2004 are provisional and are likely to be revised later in 2007.

Indicator 8: Number of manufacturers in the UK and employees in the UK-based medical devices industry, 2000–05

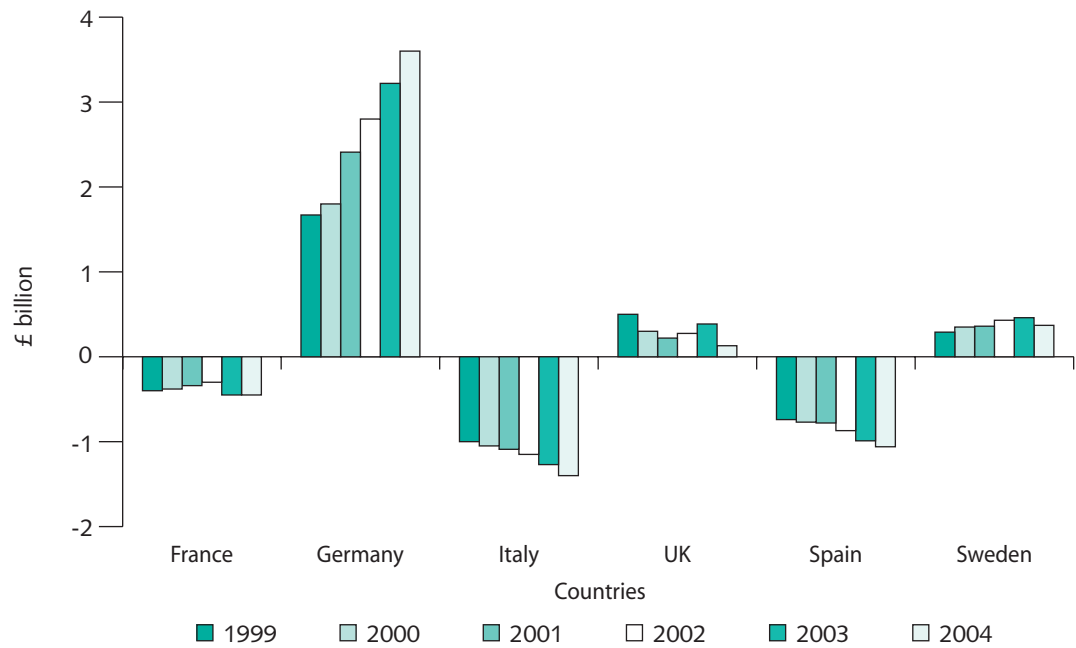
		2000	2001	2002	2003	2004	2005
In vitro diagnostics and dental materials (ex SIC 24.66)	Manufacturers	157	154	148	141	144	150
	Employees	5,000	5,000	4,000	5,000	5,000	5,000
In vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc (ex SIC 24.42/2)	Manufacturers	76	78	81	92	92	95
	Employees	7,000	5,000	6,000	5,000	6,000	5,000
Invalid carriages (ex SIC 35.43)	Manufacturers	37	43	54	54	50	40
	Employees	1,000	2,000	2,000	2,000	2,000	2,000
Medical and surgical equipment (ex SIC 33.10)	Manufacturers	1,742	1,726	1,725	1,701	1,727	1,751
	Employees	31,000	38,000	34,000	35,000	32,000	35,000
TOTAL	Manufacturers	2,012	2,001	2,008	1,988	2,013	2,036
	Employees	44,000	50,000	46,000	47,000	45,000	47,000

Source: ONS, *Annual Business Inquiry*

Note: Employment figures do not include employment in sales, marketing, distribution and service operations of companies not manufacturing in the UK. The number of manufacturers/employees within in vitro diagnostics and dental materials is calculated estimating 27.34% of the total within SIC 24.66, while the number of manufacturers/employees within in vivo diagnostics, dental cement, gels, dressings, bandages, sutures, etc is 66.25% of the total within SIC 24.42/2. ONS data for 2004 and 2005 are provisional and likely to be revised later in 2007.

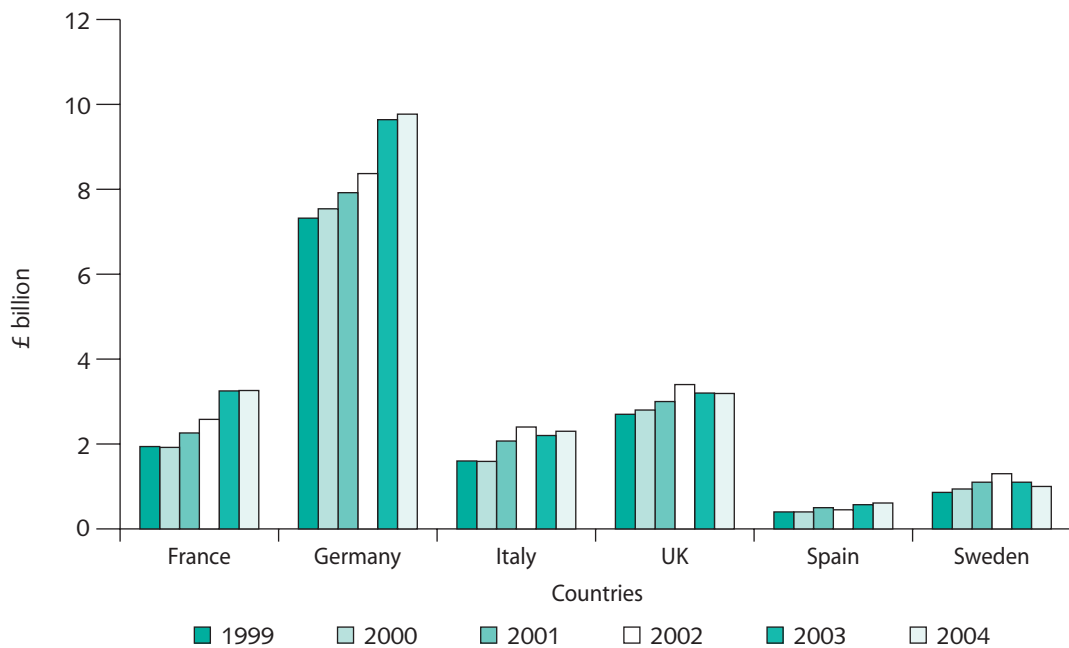
Indicator 9: Medical devices trade balance and production of medical devices, 1999–2004

Chart 9a: Trade balance, 1999–2004



Source: Eurostat, Europroms and ukrtradeinfo

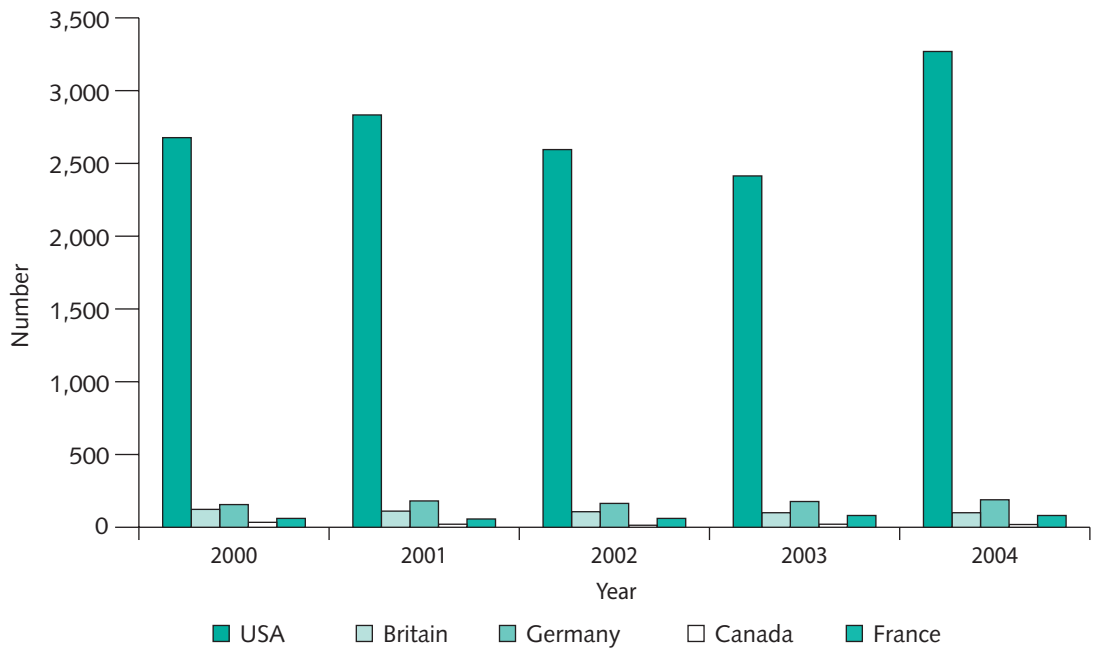
Chart 9b: Production of medical devices, 1999–2004



Source: Eurostat, Europroms, UK PRODCOM, and estimates

Note: Spanish production is low as the level of missing data does not allow reasonable estimates to be made.

Indicator 10: Number of patents awarded, 2000–04



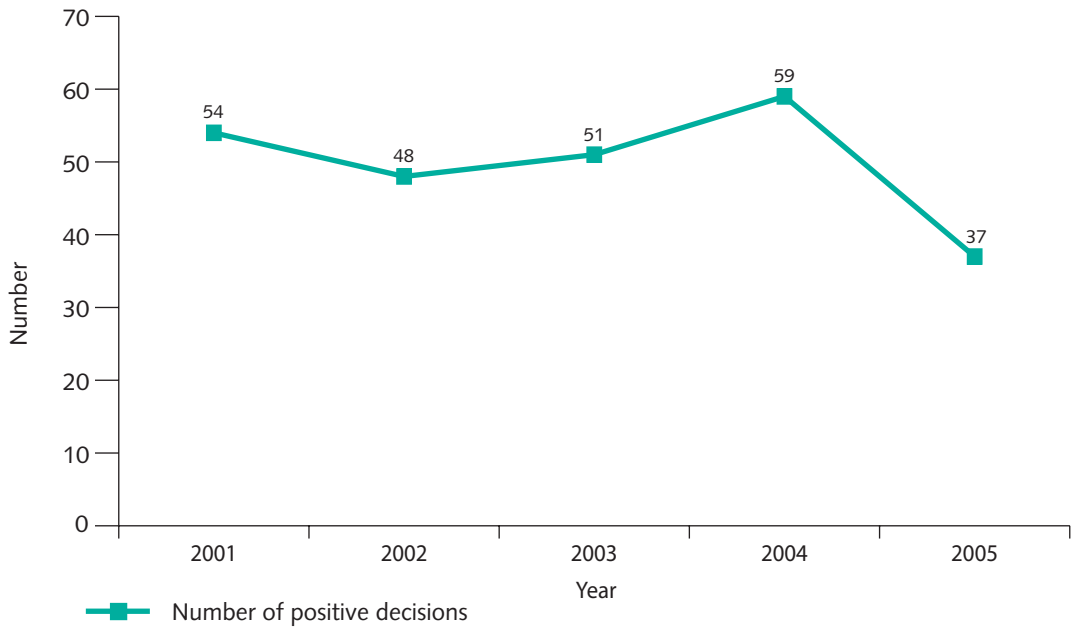
Source: Dialog (Derwent World Patents Index)

Note: The following categories were used for this search – based on the categories used in the Arthur D Little report (*UK Sector Competitiveness: Analysis of six healthcare equipment segments*, published in May 2005 and available at: www.dti.gov.uk/files/file10462.pdf):

- medical imaging and ultrasound equipment and materials
- diagnostic (including pathology) equipment and materials
- electro-medical and respiratory devices
- radiotherapy equipment
- active and passive implantable medical devices and orthopaedics
- tissue engineering and wound-care materials.

The above data show the total numbers of patents granted in priority application countries.

Indicator 11: FDA decisions on applications from UK companies, 2001–05



Source: Databases on FDA website, www.fda.gov

Note: These decisions fall into two categories, as defined by FDA:

- **Premarket Approval** is the scientific review required by FDA to ensure the safety and effectiveness of all devices classified as Class III, ie those with a higher degree of risk.
- **Premarket Notification** or a 510k document must be submitted to FDA by medical devices manufacturers if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. To be legally placed on the market, a device has to be classified by FDA as 'substantially equivalent' to an existing legally marketed device. With the exception of certain exempt low-risk devices, all devices will require a Premarket Approval or 510k. Of the 212 decisions, 203 were for 510k applications. They represent products from a total of 78 companies, all of which had addresses. They do not include applications from UK-based firms that have submitted applications from their US office.

The figures, therefore, do not represent the totality of devices and diagnostics activity carried out in the UK. They do, however, give a fair idea of the activity of small- and medium-sized enterprises.

Annex C

ABBREVIATIONS etc

ABHI	Association of British Healthcare Industries
ATMP	Advanced Therapy Medicinal Product
BHTA	British Healthcare Trades Association
BIVDA	British In Vitro Diagnostics Association
CAUTIs	catheter-associated urinary tract infections
CEP	Centre for Evidence-based Purchasing
CPH	Collaborative Procurement Hub
DES	Device Evaluation Service (now CEP)
DH	Department of Health
DTI	Department of Trade and Industry
EU	European Union
FDA	Food and Drug Administration (USA regulatory authority)
HAIs	hospital-acquired infections
HITF	Healthcare Industries Task Force
HPA	Health Protection Agency
HTCs	Healthcare Technology Co-operatives
HTD	Health Technology Devices
IPR	intellectual property rights
IT	information technology
IVD	in vitro diagnostic devices
JETCO	Joint Economic Trade Committee
KTN	Knowledge Transfer Network
MATCH	Multidisciplinary Assessment of Technology Centre for Healthcare
MDD	Medical Devices Directive
Medica	Annual international trade show held in Dusseldorf and information portal

MHRA	Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
NEAT	New and Emerging Applications of Technology
NHS	National Health Service (in England)
NHS PASA	NHS Purchasing and Supply Agency
NHSC	National Horizon Scanning Centre
NIC	National Innovation Centre
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NHS Institute	NHS Institute for Innovation and Improvement
NPSA	National Patient Safety Agency
PbR	Payment by Results
RDA	Regional Development Agency
RDD	Research and Development Directorate (of the Department of Health)
Rehacare	German trade exhibition of rehabilitation equipment
SCEP	Supply Chain Excellence Programme
SDMA	Surgical Dressings Manufacturers' Association
SHA	strategic health authority
SOLO	UKTI exhibition support scheme
SIG	strategic implementation group
SME	small- or medium-sized enterprise
TAP	Trade Access Programme
UKCRC	UK Clinical Research Collaboration
UKCRN	UK Clinical Research Network
UKTI	UK Trade & Investment

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