

ABHI submission of comments to Cooksey Consultation¹

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ABHI is the lead Trade Association for the Health Technologies industry and has recently played a leading role in the establishment, development and implementation of the Healthcare Technologies Task Force (HITF). The Healthcare R&D funding proposals are highly relevant to this work. However, research and the translation of its outputs into products and economic benefits is inexorably linked to an effective NHS market and the approach of the NHS to innovation.

With a globally ageing population, a major challenge is find ways to “compress morbidity” and enable people to contribute to society throughout a longer, healthier life. Health technologies are crucial to meeting this challenge.

ABHI is concerned that UK publicly funded R&D support for the engineering-based “health technology” sector is disproportionately low given its relative size and impact on healthcare delivery.

Key Themes

ABHI strongly welcomes the new focus on realising economic benefit from healthcare R&D and this underpins our views in response to the consultation questions.

ABHI has identified four major themes in response to the proposal to improve the effectiveness of funding of Healthcare Research and Development:

- ❖ **Visioning Research;**
- ❖ **One overall commissioning body** informing and co-ordinating the diversity of research councils and other groups funding healthcare R&D;
- ❖ **Research pipeline funding;**
- ❖ **Research into the slow adoption of new health technologies.**

We feel that there is a strong case for ‘**Visioning**’ research which would support a shared view of what technologies and knowledge development will be at the heart of the future UK

¹ This response has been compiled by ABHI with inputs from all sectors of the health technology industry, including members of other Trade Associations.

health services, and will be underpinned by an understanding of **how to measure economic benefit of innovative health technologies** measured on a basis of the benefit arising to the whole economy, and not just to local NHS departments or Trusts, or even just to the NHS itself.

Health Technologies are notable for the range of products and the diversity of science and technology involved. ABHI believes strongly in the essential need for a diversity of approaches to funding of research and development. We believe that a single funding body would find it difficult to sponsor such diversity. Our aspiration is for funding to be managed by different groups with varying remits (as at present), all of which are informed and co-ordinated through **one overall commissioning body** which owns the ‘Visioning’ research outputs, and which would be accountable for the realisation of economic benefit as well as its health and science objectives.

ABHI also recognises the complexity of the development process from research concept to development of a target technology, and recommends that a new form of **‘research pipeline’ funding** should be implemented. This would be able to recognise and support the continuing development of a promising technology continuously through to its adoption. While public funding may not be appropriate for the entire pathway, there are numerous stages in the current process where public funding is vital, but the long-winded and risky process of re-application for follow-on funding lengthens the overall development process to a level where UK-based development of research ideas is internationally uncompetitive.

The Wanless report identified NHS as a slow adopter of innovative health technologies². We feel that **research into the causes of slow technology adoption**, and into the most effective ways to overcome such problems would be one of the most beneficial outcomes of a change in R&D organisation in terms of increasing economic benefit and welfare as a result of this review.

Response to Review Questions

Review Question 1

1. What are the strengths and weaknesses of the MRC and NHS R&D programmes at present? How do each of these support the research and training needs of the NHS, social care, industry and academia? Does more need to be done?

The MRC is recognised for its world excellence in Molecular Biology, and its strength in promoting excellent science through its competitive processes; and NHS R&D has shown its ability to co-ordinate disparate research activities into coherent and high quality research programmes, a process which will be significantly enhanced following the new R&D Strategy.

Research relevant to health technology is also funded to a significant degree by EPSRC, DTI and to a slightly lesser extent, by BBSRC and PPARC. It is unclear to ABHI whether these funders are intended to be within the remit of this report. Our view is that it would be helpful for them to be informed by the same visioning research.

While the MRC is strong in funding science with a view to the long-term, DH is generally seen as more reactive to shorter-term priorities. In addition, the Service Delivery & Organisation programme has almost no visibility within the industrial sector although its remit should be highly relevant.

Both the MRC and NHS R&D programmes are perceived as being primarily directed towards scientific excellence with almost no focus in terms of their selection criteria on the potential

² This is true even when it relates to the take up of new technology which has been recommended by NICE guidance.

economic impact of the research they fund.³ In addition, the MRC tends to ignore most of the science and technology relevant to health which lies beyond its traditional arena of cell biology and biochemistry. A major concern in the past has been the high proportion of DH R&D money which has remained undirected through the ‘Support for Science’ stream. We welcome strongly the new DH R&D strategy which is beginning to address this historic anomaly.

While the scientific excellence of the MRC centres is high, there is limited evidence of their ability to engage with established (as opposed to spin-out) health technology SME businesses, as opposed to other research Councils which have a strong record of such collaborations.

ABHI is aware of the considerable success attributed to the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) funding mechanisms in the USA. On the other hand the DTI sponsored **SBRI** initiative⁴, designed to help SMEs, does not seem to give grants in its own right but to only provide an alert and sign posting activity to small businesses. ABHI feel that the DTI should build a case for a similar approach to that adopted by US in making SBRI a direct funding body for this sector in UK.

Review Question 2

2. What do you believe are the key scientific and organisational challenges facing health research, and underpinning training, in the UK over the next decade? How might the UK Government best help address those challenges? What do you believe should be the Government’s objectives for health research, and why?

UK Health research is typically funded from many small funding pots by organisations which do not have ‘business processes’ in place to deliver the Vision outlined in the budget statement. There is limited visibility of the total health related research activity being undertaken: DH National Research Registry covers only DH funded research, and omits all that funded by MRC, DTI and the other research councils.

Many of the funding bodies (and their committees) have a tendency to develop institutional inertia which can make it difficult to respond quickly to new technological opportunities.

There is a need to find ways to bridge these gaps and establish ‘research pipelines’ which can take a concept through from basic science through concept and system research, design and validation. In particular, there is a need to find ways to fund ‘development’ of important health technologies. Finally, there is limited operational research into NHS processes (e.g. support for guideline development, research into risk management, and support for service delivery change⁵), all of which could have an impact on realising benefits of good new technologies more quickly.

One of the major issues identified in the HITF process was the need to find reliable ways to establish the value of new health technologies, both prospectively, at the time of their introduction and as they continue to develop and improve. One of the main groups working on this is the MATCH IMRC⁶: this is funded primarily by EPSRC (through their Innovative Manufacturing Programme) and by its industry collaborators.

³ The Health Technology Devices programme within NHS R&D is a notable exception.

⁴ [<http://www.sbri.org.uk/>], managed by the Small Business Service (SBS)

⁵ This may be supported to a limited extent by the newly established National Innovation Centre Adoption Hub.

⁶ <http://www.match.ac.uk/>

Review Questions 3 and 4

3. What should be the Government's priorities for health research? Is there anything it should stop doing or funding? What is it not doing or funding that it should do, and, in the absence of further sources of support, what can it lower in order to release the necessary funds?

4. How should decisions be taken on the balance between the long-term economic and social benefits of a high quality biomedical research base; and the needs for research to improve healthcare and other public services? What is the appropriate balance between public funding for investigator-led and priorities led research? How do we balance funding for basic science, translational science and applied science? Is this something that should vary over time? What mechanisms should be used to make judgements about this balance?

As an industry organisation, our tendency is to see the need for more translational research. However, we recognise the need for a balance, and feel that this should be informed by **'Visioning' research work** (see Appendix 1).

Emerging health technologies are increasingly dependent on a convergence of technologies into a therapeutic system (e.g. coatings, biologics, sensors, telecare, etc). Many companies do not have the skill sets or resources to develop these on their own, and measures are needed to accommodate smaller companies and provide intermediate technology platforms from which to diversify into the new technology areas, through collaboration in public funded research and development.

We feel that there should be a shift towards a priority driven approach to research funding whilst still maintaining a capacity to look at innovative ideas and emerging areas. The combined MRC /NHS R&D funds need to support more applied research whilst still funding some investigator-led exploratory research. The current approach to public health research funding is viewed as fragmented and lacking coordination.

Research commissioned in line with defined public health priority areas affords more opportunities for shaping the research community and influencing how the research is to be disseminated. The ability to plan dissemination and uptake as an integral part of research commissioning is vital to realising its value to public health.

The tendency of commissioned work to drive focus on to short-term objectives and possibly lower quality needs to be guarded against when introducing a new funding model. The need to enhance research into cost effectiveness in public health should also be addressed.

We also feel that the quality of major research programmes would be greatly assisted if there were funding for small studies to develop higher quality proposals. This would be particularly valuable if there were also 'research pipeline' funding opportunities for successful bids

The process of identifying gaps in research was generally viewed as needing to be transparent and robust. As indicated earlier in this document research, commissioning decisions should be led by a top-level commissioning body informed by the Visioning research. This should ensure that policy makers, researchers, practitioners and consumers (including patients) are all involved.

There is no doubt that a revised MRC should be engaged in funding cutting edge or innovative research in emerging areas or areas that may become relevant to public-health. However, this exploratory or high-risk work should be funded in stages (not initially large amounts of money) and in partnership with other relevant research councils or charities to spread the risk and release resource for translational activity.

Review Question 5

5. In your experience, how have the results of publicly-funded health research in the UK been used, both in the development of new treatments and to influence / change wider policy and healthcare

practices? What lessons can usefully be learned to improve the uptake of advances in science and medicine?

There is some relevant experience from the three DH R&D programmes related to health technology research.

- MedLINK Programme (1997-2001): the MedLINK Exploitation project final report of June 2005 identified the following 6 projects which were classified as commercialised on the market or in phase III clinical trials:
 - M43 - Surgical Implants Using Embroidery Techniques (through the Aorfix graft stent)
 - M174 - Covalent Bonded Coatings in Tissue Engineered Applications (through the LeMaitre heparin coated vascular access graft)
 - M177 - New Generation Robot Manipulator for Laparoscopy (through the Endoassist/Nerolap robot)
 - M181 - Impulse - Improved Mobility Through Implanted Functional Electrical Stimulation (through Finetech Medical)
 - M182 - A Clinical Technique for Measuring Macular Pigment Optical Density (through Tinsley Precision Instruments)
 - M999 - Millennium Homes project
 - 6 other projects were undergoing clinical trials with the potential to be on the market by 2007.
- Health Technology Devices Programme (2002 – continuing): at present, only one project has been commercialised:
 - HTD 076 Phoneme factory (through the Speech and Language Therapy Research Unit, Bristol).
- New and Emerging Applications of Technology (NEAT): the programmes managers (QuoTec) are not aware of any products as yet commercialised. However, this is a programme directed primarily towards basic science and technology developments.
- EPSRC is an important funder of research into the science and technologies which ultimately emerge as health technologies: in 2003, they were funding approximately 537 grants that are directly relevant to the healthcare sector, with a total value of £194M7. Most of the Programmes within EPSRC fund healthcare related research, and EPSRC has a healthcare sector team which co-ordinates the understanding of healthcare and its related science and technology. EPSRC also has a multi-disciplinary responsive mode Healthcare Panel. The remit of this Healthcare panel includes research directly underpinning the Healthcare and Medical Devices Sector but excludes research underpinning the Pharmaceutical Sector. EPSRC does not routinely collect information on the ultimate commercial impact of its healthcare projects.
- The DTI also plays an important role in funding healthcare related R&D work through its Technology Programme. It currently does this through two routes: its Collaborative Research & Development competitions, and its Knowledge Transfer Networks (KTNs).
The Technology Programme R&D competitions have been running since April 2004, and encompass pure research, applied research and experimental development. There are calls for two competitions per year, most of which have at least one healthcare related theme. These competitions have not been running long enough for any of the technologies to have yet reached the market.

⁷ ‘EPSRC Healthcare Sector Brief June 2003’

<http://www.advisorybodies.doh.gov.uk/hitf/epsrchealthcaresectorbrief2003.pdf>

- More recently, DTI has implemented a framework of KTNs to facilitate the uptake of new technologies. This uses some mechanisms that have relevance to the subject of this paper. The Health Technologies KTN has been closely involved with industry and the HITF process, and has played a vital role in the development of the National Innovation Centre's new Innovation Assistant which is designed to support the more effective commercialisation of new health technologies.

Importantly, it recognises the need for more Foresighting to inform the key demand driven technology developments, supported by a series of methods to find the technologies, the appropriate researchers/partners, the funding mechanisms and the personnel to encourage translation of the research into adoption.

Developing such new networks, building on existing healthcare networks such as UKCRC and the NHS Institutes/Innovation Hubs, and having the funds to provide more translational research will encourage the uptake of scientific advances in health technologies and biosciences.

- BTG plc has considerable experience of commercialising health technology related IP, much of which has come from publicly funded research⁸. The key lessons from these were the need to have close co-operation of a UK company with the inventive team. In addition the intellectual property for the devices was independently protected by BTG who were able to negotiate license terms acceptable to the industry, ensuring that income was fed back to the inventive source. Given the global character of the health technology industry, it may not always be possible to have close collaboration with a UK company. As a result it is crucial there is an emphasis on capturing the intellectual property, so the innovation is not lost to third parties. This capture, and the budget to allow it, needs to be a priority, as the focus of organisations like BTG have now changed to more project specific activities. This highlights the important role of organisations such as the NHS Innovations hubs in realising economic benefit from UK health R&D spending.

All these funding schemes represent an important source of diversity which is of real value in being able to respond to the wide variety of health technology related opportunities arising. However, unless they use the networks to understand which of these are most relevant and accessible to them, SMEs can find the funding landscape confusing. It would also be helpful if the various funding groups were all informed (but not directed) by a co-ordinated understanding of a common vision of the direction of healthcare technologies; and of the directions which are most likely to result in economic benefit arising to UK.

Review Question 6

6. How might better links be forged between 'basic', translational and applied researchers, working across the whole field of health research, from the laboratory bench to the front line of the NHS? How might better links be forged across disciplines, e.g. with engineers, physicists, and social scientists?

ABHI supports the LINK model of funding as a way of supporting networks of collaborating companies and research groups. In support of this, there is a need to promote funding panel preference for multi-disciplinary research groups. ABHI also supports the use of networks (e.g. UKCRC, DTI funded Knowledge Transfer Networks) as a means of connecting the right people together at the various stages of the research pipeline.

We feel that our **concept of a 'research pipeline'** (as above and Appendix) would be useful in improving links. Such an approach would recognise the need for changing collaborations,

⁸ Examples of these are included in the Appendices.

research focus and funding models throughout the process, but would eliminate many of the discontinuities which currently exist.

There is a significant mismatch between the way Government sponsored research and industry research is managed. As concepts move from basic research to exploitation, the value of projects could be improved by implementing more industrial type stage gating of research programmes to identify and eliminate failure as early as possible, rather than the current approach where fixed term (e.g. 3 year) grants may encounter a failed stage gate relatively early but the project continues anyway.

Promotion of greater flexibility of project resourcing would be highly valuable, especially in longer and more complicated projects. This would recognise the changing skill needs throughout a project, rather than having RAs dedicated to a project throughout its duration. This could be realised either by funding larger research centres, or promoting greater flexibility in funding collaborations between complementary groups, including ways to increase the direct involvement of clinical staff in research programmes.

Review Question 7

7. How can the Government encourage translation, entrepreneurship and innovation in health research to improve public services in the UK?

ABHI believes strongly that this is best achieved by **ensuring that the NHS is a responsive healthcare technology market that is able to recognise the value of innovative products**. Ways in which this could be realised were part of the HITF recommendations⁹: it is highly frustrating that short-term cash saving measures continue to be allowed to make the NHS market even less responsive than it has been historically.

The development of creative and innovative commissioning of healthcare will play a central role in the creation of such a market. There needs to be recognition of where and when value arises from new technologies (e.g. Longer term benefit, which may be in increased tax yield but will cost more in terms of health spending). It is also essential to understand the virtuous dynamic which can develop between users and suppliers which is central to the development of new technologies, especially in the engineering based health technologies which can respond and adapt to changing needs relatively quickly.

Review Question 8

8. How can UK health research funding be most effectively used to provide the appropriate infrastructure for basic, translational and applied research, whether funded by the UK public sector or other sectors? How can UK health research funding be most effectively used to support the work of NICE, facilitate innovation and collaboration with industry, and address market failures in the application of healthcare?

Funding of UK health research comes from a number of the Research Councils as well as charities. Charities collectively provide £650m in funding for medical research. Building collaborative programmes with these organisations as a means of leveraging additional funds to underpin applied research within the defined priority areas should be investigated. Indeed actively engaging charities and other research councils in the visioning process would ensure UK derived maximum value from medical research. This concerted approach to public health research funding would address the view that current approach is fragmented and lacking coordination.

⁹ Particularly 1. Device Evaluation; 2. Innovation: National Innovation Centre & Routemap & Brokerage; 3. Procurement Processes; 4. Building R&D Capacity (support for clinical research); 5. Healthcare Technology Co-operatives; 9. Training and Education;

Researchers often do not have the skills necessary to be effective in the process of technology dissemination. A mechanism that provides within each major funding project a structured approach to establishing contact between researchers, market place and practitioners is required. Leadership in the dissemination process could be introduced to each project by assigning an independent mentor (with commercial or health service background) to provide independent guidance on market relevant application re product, competitive products analysis, market access and impact, industry contacts etc on an ongoing basis. This could be achieved at modest cost and add enormous value to the dissemination process.

From a health technology industry viewpoint, the most important outcome associated with improving the economic benefit from Health R&D would be through:

- Supporting better networking and brokerage of linkages and collaborations to overcome the inherently competitive forces between research groups
- Recognising and managing an effective balance between large and efficient research centres, and small, nimble research groups
- Supporting research into the problems of assessing dynamic health technologies (where effectiveness can change very significantly within the timescales of any traditional assessment methodologies such as RCTs): this will involve research into both assessment methodologies and the generation of specific data for technologies which require investigation

Review Question 9

9. What lessons should the UK learn from other countries in making the proposed changes to the institutional arrangements for the funding of health research?

- Japan – there is an awareness in Japan that funding through separate channels has not been particularly successful in supporting the development of emerging health technologies which are increasingly based on convergent technologies. The integration of funding mechanisms is now being pursued but the effectiveness of the Japanese approach has yet to be demonstrated
- China – Research Institutes and universities have undergone major reform underpinned by growth in government R&D expenditure, which increased by 500% from \$14 billion (£8 billion) in 1991 to \$65 billion (£37 billion) in 2002. China's past and future five year plans underline the strategic focus of resources in developing science and technology capability in technologies relating to information technology, life sciences and biotechnology, and new materials (including biomedical materials). These are all areas of enabling technologies that may offer solutions to today's public health problems. Investing in national centres of excellence allied to universities and medical schools in areas such as Tissue Engineering, Stem Cells, Nanotechnology etc is the mechanism adopted that will in the coming years ensure that China, in both pure and applied science attains international excellence
- Israel – the major strength of this country is in the realisation of economic benefit arising from health R&D. This is substantially achieved through MATIMOP and BIRD (Binational Industrial Research & Development Foundation). MATIMOP is the Israeli Industry Center for R&D is a public non-profit organization, founded by the three major associations of manufacturers in Israel. Functioning as the interface between Israeli companies and their international counterparts, to promote joint developments of advanced technologies. MATIMOP provides databases listing hundreds of projects in diverse advanced technologies and profiles of Israeli companies looking for foreign hi-tech partners. BIRD was established in 1977 to stimulate mutually profitable cooperation between US and Israeli high-tech companies. BIRD has an income of some \$14.5 million a year, about \$8.5 million as interest on an endowment of \$110 million that

was equally contributed by the two governments. BIRD's vital contribution lies in matching the marketing know-how, distribution networks and global leverage of US corporations with the innovation and advanced manufacturing capabilities of Israeli companies. This is based on recognition of the limitations of domestic industry and the need to form linkages to exploit R&D effectively.

Review Question 10

10. In implementing the single fund for health research, to what extent should the MRC and DH / NHS R&D be merged or brought together? And to whom should the single, ring-fenced fund be accountable? Please provide reasons and any supporting evidence for your response.

In forming a single fund it is essential that activities of universities and MRC/NHS complement each other, especially in that each concentrates its efforts on different parts of the research spectrum. Universities emphasise basic and investigator led research; while MRC/NHS addresses strategic and public health directed research.

ABHI believes in the importance of diversity in research, and the role of funding in achieving this. **Our aspiration would be for funding to be managed by different groups with varying remits, all of which are informed and co-ordinated through an overall commissioning body which owns the 'Visioning' research outputs, and which would be accountable for the realisation of economic benefit as well as its health and science objectives.**

Review Question 11

11. To what extent does the success of recent innovations in health research (e.g. Clinical Research Networks) and the proposed structures rely on the new Connecting for Health NHS IT system, and to what extent should it do so?

ABHI believes that it is essential that Connecting for Health delivers the ability to access all relevant NHS health management data to UK funded and sponsored researchers. This should include as far as possible, access to appropriately anonymised health treatment and outcomes information.

Review Question 12

12. Given that NHS R&D is currently devolved, but that the work of Research Councils is not, how can these functions work best together to maximise the health and economic benefits to the UK?

ABHI believes that a well-defined health research Vision will be central to helping the broad range of researchers to work together more effectively. This needs to be underpinned by a Health Research co-ordination facility (or Knowledge Network) which would provide better access to health research (both past and present) from all funding bodies, and a signposting of the most appropriate funding sources for research projects at any stage in the 'research pipeline'. Funding of research networks¹⁰ for a period of 3 to 5 years to support the establishment of research communities across research institutions and organisations should also be considered.

Oliver Wells: Chairman, ABHI Research & Innovation Policy Group

31 July 2006

¹⁰ On a similar model to that used by EPSRC

Appendices

1. Visioning Research

ABHI feel that there is a strong case for 'Visioning' research which will:-

- Support a shared view of what technologies and knowledge development will be at the heart of the future UK health services. It needs to have a strong emphasis on assessing, identifying, understanding future patient and clinician needs; and on the scientific and technology developments which may be essential components of this.
- Be underpinned by an understanding of how to measure economic benefit of innovative health technologies measured on a basis of the benefit arising to the whole economy, and not just to local NHS departments or Trusts, or even just to the NHS itself
- Be 'owned' by government executive (e.g. Treasury, Cabinet Office or Dept of Health) and have clear links with Government decision making
- Address the views of all stakeholders of UK's health services and specifically understand the clinical and service delivery needs of the NHS in the future. Included in this will be a vision of how the patient of the future will interact with the NHS.
- Understand the similarities and differences in the future health technology needs in the UK and overseas healthcare environments.
- Use robust research methodologies to establish future healthcare scenarios and inform research priorities to enable the best scenario outcomes
- Make it clear how this will differ from preceding work, including Wanless, Foresight, DH Strategic Planning, Horizon Scanning etc,
- Be available for all stakeholders to contribute to, discuss and use to inform their own strategic decisions
- Provide an accumulation of existing and newly commissioned work to accumulate and make accessible the background information necessary to assess and justify estimates of impact; together with reliable and trusted methodologies for its use

Specification:

- Objective: provide an integrating view of health needs and delivery in the future;
- Mechanism: a research centre with some internal resource and strategic direction, with funding to commission specific research to meet knowledge gaps and to support and active dissemination and communication programme to both funders and all categories of funding recipients
- Horizon: defined by the technology pipeline timescales – 5 to 15 years, depending on complexity and risk

2. Research Pipeline Funding Concept

ABHI recommends that a new form of 'research pipeline' funding should be implemented. This would be able to recognise and support the continuing development of a promising technology continuously from an idea through to its adoption i.e. 'Concept-to-Clinic'

While public funding may not be appropriate for the entire pathway, there are numerous stages in the current process where public funding is vital, but the long-winded and risky process of re-application for follow-on funding lengthens the overall development process to a level where UK-based development of research ideas is internationally uncompetitive.

There is a need to find ways to bridge these gaps and establish 'research pipelines' which can take a concept through from basic science through concept and system research, design and validation. In particular, there is a need to find ways to fund 'development' of important health technologies.

A 'research pipeline' would recognise the need for changing collaborations, research focus and funding models throughout the process, but would eliminate many of the discontinuities which currently exist.

Value could be improved by implementing more industrial type stage gating of research programmes, rather than fixed term (e.g. 3 year) grants where a failed stage gate may be encountered relatively early but the project continues anyway.

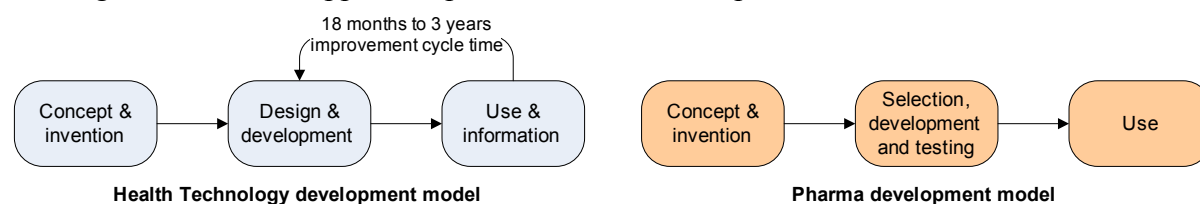
3. Background to Health Technologies Industry

With a globally ageing population, a major challenge is find ways to “compress morbidity” and enable people to contribute to society throughout a longer, healthier life. Health technologies are crucial to meeting this challenge.

ABHI is concerned that UK publicly funded R&D support for the engineering-based “health technology” sector is disproportionately low given its relative size and impact on healthcare delivery. Healthcare R&D is often seen as encompassing both pharmaceuticals and health technologies: the global product sales in these combined sectors is of the order of \$600bn, of which \$200bn comes from health technologies. Research within MRC is predominantly focused on advancement of basic science in the area of molecular biology¹¹. There is little targeted at product specific application of science¹². This profile differs significantly from that reported for activity undertaken by other Research Councils such as EPSRC and NERC. MRC’s exploitation links with industry¹³, primarily through its affiliated company, MRC Technology Ltd (MRCT), produce licensing revenues that are claimed to exceed that of all the other research councils combined: but the profile of start-up and licensing that the activity relates to is almost exclusively drug discovery opportunities as opposed to health technologies.

The absence of a strong health tech related programme to complement the drug discovery oriented activity is of concern to ABHI. Indeed healthcare problems arising within the seven research themes¹⁴ identified by DH as priority areas: cancer, mental health, coronary heart disease (CHD), ageing and older people, public health, genetics and diabetes are equally capable of being addressed through innovation in health technology as they are through drug discoveries. The opportunity to address problems within these priority healthcare areas through investment in medical technologies seems to have been overlooked in the UK. This review offers an opportunity to redress the balance of R&D investment.

The dynamics of health technologies and pharmaceuticals industries are essentially very different. Pharmaceutical development follows a very well defined and essentially linear track: significant value is accumulated at each phase; there are well defined regulatory processes; and at the end, a ‘pill’ is the product. The development pathway for health technologies is far more complex: our uniqueness resides in our enormous diversity and the breadth of our innovativeness, valuation is less defined and the final product often is a system which must integrate within a healthcare environment. Feedback from doctors, nurses and patients enables us to constantly improve our technology, and our products typically have an average lifecycle of only 18 months before an improved product becomes available. The user training and technical support we provide are often indispensable.



In addition, the diversity of health technologies is so great that there is frequently difficulty finding a domestic company which is strategically able to take on the development of a new technology, even a highly promising one. Therefore, health technologies require their own

¹¹ www.mrc.ac.uk/mrc_delivery_plan_06.pdf

¹² Analysis: New Scientist, 1 July 2006; p58

¹³ www.official-documents.co.uk/document/hc0506/hc03/0316/0316.pdf

¹⁴ www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchPriorityAreas/fs/en -

specific measures to encourage their development and support their adoption in global healthcare markets.

To achieve this balance we propose the adoption of a research commissioning body with representation from a cross-section of experts from within the biomedical and device communities to develop and agree with government a “Vision for healthcare research and development” to identify priorities for the funding agencies to address new health technology development from “Concept to Clinic”. The commissioning body would then be given the authority to implement the Vision and monitor its impact.

It is because health technologies are both strategically important for improved health and are so integrated within the healthcare environment, that there is a need for an executive body with influence supported by “Visioning Research”.



4. ABHI Paper: “Medical Devices: how the NHS fails to demand innovation in technology and what the government should do”

- *technology as a key enabler for future productivity in the NHS*
- *the medical devices industry and sustainable employment in the knowledge economy*
- *how to create a virtuous circle*

Summary

1. This paper looks at aspects of the NHS approach to medical technology and in particular at the way it acquires medical devices, as seen from the perspective of the medical devices industry. The Government has set out what it believes influences growth in productivity for the economy as a whole (1). There are significant ways in which the NHS appears to be pulling in the opposite direction to wider Government policy.
2. The central conclusion of this paper is that specific influences in the NHS interact with those economy-wide drivers for productivity growth, to produce poorer performance than might otherwise be achieved: both as regards the NHS itself and for industry and the wider economy. Trends in the development of NHS procurement are one aspect of this; however, some important details of NHS performance management are also adverse and there is in effect little interest in innovation on the demand side of the NHS against the background of much more demanding financial and performance delivery regimes. Whilst a good deal has been done in recent years to stimulate and coordinate the supply side for healthcare innovation, this is insufficient to ensure that the Government’s objectives for innovation overall will be supported to any significant extent by the NHS. The paper proposes:
 - 2.1. that technology, as a key enabler for process redesign, targeted at improved quality and cost effectiveness, should be factored into NHS improvement processes, with an explicit link to wider drivers of productivity in the economy; and
 - 2.2. that there should be local NHS accountability for performance against benchmarks for adoption of innovation, with links to wider NHS improvement programmes and strategy.
3. Medical devices are understood in the context of a wider definition of medical technology, as acknowledged in the interim Wanless Report (2):

“not just physical equipment, instruments and pharmaceuticals, but also clinical procedures and knowledge and the organisation and support systems within which health care is provided.... consistent with the World Health Organisation definition of technology.”

This is important context for medical devices, many of which are created as a result of problem solving by clinicians, directly engaged with patients. Unlike pharmaceuticals, many medical devices need to be operated directly by clinicians and are part of a package, bundled with knowledge. As Wanless set out, the effects of technology are complex: some reduces costs, some tends to increase it. This paper argues that the NHS can and should take a more strategic approach to this tension.
4. The Healthcare Industries Task Force concluded that

“the UK-based healthcare products industry plays a significant role in contributing to patient care, public health and the national economy... There is considerable

potential for growth in this knowledge-intensive sector, leading to expansion of manufacturing activities and job creation.” (3)
This is a sector with a positive balance of trade¹⁵, but more needs to be done in order to assure continued investment, including inward investment, taking into account the effect of the NHS approach to technology in general.

Policy context: five ‘drivers’ of productivity

5. *Productivity in the UK 6: Progress and new evidence* (1) discusses the underlying components of economic growth and the effect of the reform programmes which the Government has set in place to influence the five ‘drivers’ which interact to promote productivity growth. These drivers are identified as competition, innovation, investment, skills and enterprise.
6. The Treasury recognises that “programmes for more efficient public services ...also have a direct and significant impact on the productivity of the economy as a whole”¹⁶ so the way in which the NHS interacts with these wider drivers is likely to be significant in itself. In that light, some elements of *competition* are effectively introduced into the NHS through a range of current policies; *investment* and *skills* are ‘taken as read’ in the light of developments from the NHS Plan onwards. This paper focuses on *innovation* and is relevant also for *enterprise*.

Policy context: investment and innovation: Government aspirations for technology and where the NHS fits in

7. The *Science and innovation investment framework 2004-2014: next steps* (4) notes that “UK investment in R&D has historically been lower than most countries in Europe, with UK overall expenditure on R&D as a percentage of GDP just below the EU-15 average. Low levels of business expenditure on R&D contribute to this. There is also evidence that the UK under-performs in terms of capturing the benefits from the R&D it carries out.” (page 9, 1.8)
8. As part of the Government’s response, the *next steps* document says that there will be “... an enhanced role for UK Trade and Investment in marketing the UK science base to business and attracting foreign R&D investment...” (page 13), acknowledging that there is an international market for R&D investment and that a range of drivers is involved for businesses as they make these strategic decisions.
9. The Technology Strategy Board recently launched *Developing UK Capability* (5), which recognises medical devices as a priority theme for action. The opportunity is there to build a stronger R&D base. Given that the market place for R&D investment is an international one, the Government will wish to consider how to encourage additional investment in this sector and what contribution NHS will make to this. Many key investment decisions will be made by larger companies, operating internationally and in

¹⁵ Metrics 2003 – Healthcare Industries Task Force: <http://www.advisorybodies.doh.gov.uk/hitf/sigmeeting231105metrics.pdf>

Manufacturing UK	£4,692m
Exports	£3,538m
Trade Balance	£578m

¹⁶ <http://www.archive.official-documents.co.uk/document/cm48/4807/chap05.html>

the overall context of the markets available. As for other high value research-based industry, the UK will want to retain a high quality scientific workforce, protection of intellectual property, a supportive regulatory framework, and an environment conducive to research. Decisions on manufacturing base will often be linked to R&D. SMEs built around innovation (often generated in the NHS) are also being forced overseas for market development due to the slow pace of adoption in the UK. Work led by the Bio-Industry Association on market failure in the funding of clinical trials is relevant to this theme.

10. At present there is a risk that these preconditions will not be available to maintain, still less create, the kind of virtuous circle which would encourage further investment in R&D for medical technology. A great deal of technology innovation and diffusion work has been carried out under the auspices of the NHS Modernisation Agency, its predecessors and its successor in the form of the NHS Institute for Innovation and Improvement. However, this work has to date focused more on organisational processes than on the medical technology products which support substantial aspects of how the service delivers. The significant investment in the NHS since 2002 has been relatively more focussed on labour cost (increased staff numbers and pay rates) and on renewal/expansion of the physical infrastructure asset base. There has been recognition of the need to exploit technology to improve the fundamental architecture and productivity of the system: but the focus has been on information technology, through *Connecting for Health*, rather than on wider medical technology for service improvement.
11. The new NHS Innovation Centre is mandated to drive productivity on a healthcare technology front. At present, however, NHS purchasing and procurement processes are not integrated with NHS research and innovation work streams. For the purposes of technology acquisition, medical devices are isolated from the medical technology which they support. This does not encourage innovation. The Supply Chain Excellence Programme run by the DH Commercial Directorate, said to be on track to deliver £500m of savings (6), seeks to deliver efficiencies but does not acknowledge any role in the supply chain for technology diffusion, nor does it appear to interact with any of the innovation activities of the NHS Institute (or its predecessor programmes). At the level of local NHS organisations, there is neither measurement of nor accountability for adoption of technology to support service improvement. As in other fields, what isn't measured doesn't count; and what isn't counted doesn't get done.
12. This lack of joining up is important. Wanless found that spending on technology was likely to need to grow at a faster rate than in the past (2, 10.69; 7, especially within the *fully engaged* model, page 9). With that driver and given the scale of the National Health Service, there is the potential to develop a new business model for the NHS: one which would better define the relationship between innovation, resource use and delivery of high quality service. One of the consequences of the current disconnect is that the invaluable role of technology as a catalyst for system redesign and productivity improvement is not being fully exploited. Current data suggests that increases in spend on medical devices are significantly lower than for health expenditure overall.
13. The risk of not seeing innovation as an issue for all aspects of technology can be illustrated with reference to the adoption of endoscopy, which can be described as a 'disruptive' technology¹⁷ (8), in the sense that it leads to a completely different approach to tackling problems. This (2, 10.2) took around 20 years to be routinely used in the NHS, in turn supporting innovation in a variety of areas of medicine and surgery.

¹⁷ "cheaper, simpler, more convenient products or services that ultimately let less expensive professionals provide sophisticated service in affordable settings" (8)

The need for a business model which aligns the Government's objectives for technology with those for the NHS

14. To drive innovation in the NHS, a business model is needed which positively identifies and diffuses new and potentially disruptive technologies, as well as supporting continuous, incremental improvement to existing technologies. It is taken as read that this needs to happen whilst maintaining financial balance at a local level and getting best value in all areas of procurement. The supply side of innovation in the NHS, linked to the R&D strategy and to NHS Institute innovation work streams, needs to be 'of a piece' with the demand side from NHS service and clinical management.

15. A business model for this would go beyond seeing technology in general as troublesome; and medical devices in particular as an issue only for price management within a procurement framework. Instead, the approach to technology should build on the range of activities led by the NHS Institute, linked to *Best Research for Best Health* (9), to provide a clear context for service improvement. Health technology, with its supporting medical devices, should be valued on the basis of its potential to contribute to this. Whilst appraisal at present takes place through the National Institute for Health and Clinical Excellence (NICE), the separate strands of activity across the NHS do not yet feed into a single business model for service improvement. As of now, procurement activity is part of cost management rather than linking coherently to service improvement across the NHS as a whole. Technology, however, has the potential to enable 'turnaround'¹⁸.

16. Such a business model should also align with the Government's vision as set out in *Science and innovation investment framework 2004-2014: next steps* (4):

"The Government wants to ensure the UK's health research is more closely aligned with wider health objectives, builds on scientific progress to date, and translates the results of research into economic benefit." (page 35)

Any business of the size of the NHS needs a consistent approach to acquisition and deployment of technology at operating unit level to maximise value and improve results. Four years on from Wanless (2, 2.61), this is does not in place and the approach to technology remains 'top down', led by NICE, with few discernible strategies at Trust level.

17. It is important not to confuse 'best practice' with innovation through technology. World class businesses maintain their edge through making good decisions about innovation. Given its scale, the NHS should be in the same class. The NHS has promoted best practice in a number of respects, for example aspects of the work of the NHS Modernisation Agency, building on NHS Collaboratives. But the approach to promotion of innovation through medical technology is much less certain at a local level.

A more local focus and responsibility?

¹⁸ The NHS turnaround teams were set in place to "support the NHS in identifying opportunities to deliver services with greater cost-effectiveness and to make financial savings" (DH press notice, 1/12/05). To date they have focused on financial management, necessarily on the near term. There is no apparent link between the work of these teams and a strategic vision for NHS Trusts' use of technology. See also Annexes A and B.

18. With the development of NHS Foundation Trusts there is increasingly transparent local responsibility for the planning and delivery of services, complemented by an increasing emphasis on commissioning. Given this context, there is potential to create stronger local leadership and accountability for adoption of technology in the NHS, to reconcile the Government's objectives for technology, innovation and healthcare. This should go beyond financial balance and performance against key targets.
19. One approach would be for each Trust to assess how effectively it uses healthcare technologies. It could then make strategic choices about clinical areas where it wants to lead and innovate, and where it wants to follow. This process could be supported by the NHS Institute and would be consistent with helping commissioners and providers identify where to focus for the greatest potential productivity and efficiency gains, as set out in *Delivering Quality and Value* (10). Trusts would need to allocate clinical and managerial resources according to the strategies they adopt. They should then make demands on suppliers consistent with improving value. This could for example mean seeking improved service, in support of a type of product, rather than simply seeking reduced prices for the product itself. The approach being taken in implementing the national decontamination strategy, for modernising the provision of decontamination services through 'supercentres', provides a sense of what is possible.
20. The effect of the introduction and diffusion of technology is not straightforward and it is important to acknowledge the Wanless 'cost effect' and 'volume effect' at this point.¹⁹ It is recognised that developments in technology frequently drive costs, as they enable an increase in volume of treatment (2, 10.6). What is at stake is not to prevent this happening nor to promote technology, or medical devices, in a simplistic way. Instead, it should be possible to take strategic choices at local level about where and how to adopt technologies in the context of finite resources. At present, whilst there is strategic advice from NICE at a national level, local adoption is inconsistent. The NHS approach to acquisition of technology and to devices in particular is relatively crudely related to budgetary considerations. It is not obviously related to strategy for either cost or volume in innovation or to longer term plans for service development. Nor as yet is there much sophistication in the extent to which aspects of technology have been considered as suitable for differential adoption at local level. Despite this, the NHS is grappling with a number of challenges where a more coherent long-term approach to innovation and technology could contribute. This would include the need to secure continuous improvements in productivity²⁰: the NHS is unusual for organisations of its size in that it has no explicit policy to harness technology, in order to increase productivity and reduce workforce costs.
21. Innovation can help to produce better outcomes. However, measurement of those outcomes will need to become more sophisticated. The NHS has achieved many outcome improvements in terms of patient experience and morbidity. There is agreement that this needs to go further (11), to develop the incentives which will help to drive provider improvement and feed back to stronger commissioning. One aspect of outcomes will be the ability to return patients more quickly to fuller participation in working life, for example by carrying out laparoscopic cholecystectomy rather than through open surgery which requires more days in hospital to recover. Laparoscopic

¹⁹ Wanless identified the pressure to "adopt and diffuse both new and existing technologies at a fast rate... in order to keep up with international best practice..." (2, 10.71). The interim report was clear that whilst some technologies may reduce unit costs: "in general, new technology tends to result in an increase in the **volume** of activity undertaken" (10.8) as technologies expand the range of possible interventions and open them up to a wider group of people, in turn enabling people to be treated for longer".

²⁰ Recent evidence (10) suggests some improvements in productivity can be identified but there is doubt about improvement in workforce productivity (11).

surgery increased the overall cost of gall bladder surgery by 40%, though a cheaper procedure in itself by 25%, through increased usage (11%) (2, Box 10.1). However, the reduction in working days lost is likely to have been considerable; such issues should more routinely be factored into overall costs, as has begun to be brought about through the work on mental health led for the Department of Work & Pensions by Professor Lord Layard²¹.

What this means for the market place

22. To promote innovation in technology along the lines sketched above means emulating the kind of relationships in the market place which characterise other businesses with a turnover in the order of £80bn. A strategy will be required to handle the 'volume effect' from new technology but, as suggested, a truly local approach to service management, already underway, has the potential to achieve this.
23. Whether services are bundled together and contested or whether innovative technology continues to be procured on a standalone basis, a range of procurement relationships is possible, ranging from combative through to collaborative (12). Innovation is more likely to be driven by discriminating and demanding customers than by those who seek to procure on price alone. The latter is unlikely to take into account overall value, in the case of products which have a substantial intellectual property investment, a close relationship with clinician practice and the potential to drive service improvement.
24. Market structure is critical to minimising the adverse impact of monopsonist buyer behaviour generated by national programmes focused on price reduction at the expense of long term value. Procuring on price alone is unlikely to support the kind of approach to new and/or inward investment which the Government seeks to encourage through its technology policy. Procurement should be placed in the context of an overall business model for the NHS: to procure for value rather than simply for price.
25. One example of this is the procurement of silver alloy catheters (Annex C). Hospitals procuring these devices (13) have focused on improving clinical outcomes on the basis of available research. Attending to the detail of procurement in the case of a product which had been seen as a commodity has also enabled cuts in the cost of the supply chain through more precise stock management and a nearer 'just in time' supply. There is in addition a Wanless 'cost effect' here: reduction of UTI leads to reduction in the number of bed days which significantly reduces cost and also supports the incentive provided through Payment by Results and use of Healthcare Resource Groups: so hospitals using this technology can see a direct effect in terms of value relative to the inputs made.

Conclusions

26. Wanless' final report saw a need to 'catch up and keep up' (14) to ensure that the NHS overcomes the effects of past technology lags and continues to do so. The report suggested that technology spend may vary according to the way in which the health

²¹ e.g. http://www.strategy.gov.uk/downloads/files/mh_layard.pdf

service grows; the highest spending projection (the 'slow uptake' scenario) is also the one with least technology take-up (14).

27. However NHS spend grows, an approach to technology is needed which recognises the potential 'volume effect' identified by Wanless and which takes that into account. Whilst all NHS organisations need to develop and maintain financial balance, it should also be possible for service commissioners' plans to be benchmarked in terms of technology uptake. Such plans could set out clearly what service improvements will be maximised and how technology will contribute, within available budgets.
28. As with all strategic decisions this will require choices, but the programme of work already led by the NHS Institute provides a framework, given the strong links between organisational improvement and the technology which supports that. Impetus is needed to ensure that desirable disruptive technologies, such as endoscopy, are introduced inside a 20 year timetable. "The way and the speed with which new technologies are taken up by the NHS" remains an issue (15).
29. This suggests the need for a local NHS "Technology and Innovation Plan", similar to that which would exist in a similar scale of operating unit in industry or commerce. It should cover a 0-3 year time frame, and lead directly to procurement of healthcare technology which meets the key criteria set out as the 'key points':
 - 29.1. technology as a key enabler for process redesign targeted at improved quality and cost effectiveness, with local NHS accountability for performance against benchmarks for adoption of innovation, with links to wider improvement programmes strategic decision making about deployment of budgets.
 - 29.2. Procurement processes designed to consider value and build this into costing.
 - 29.3. Supporting operation of an open, effective market mechanism and hence a dynamic business sector; this means procuring in partnership for value rather than combatively, solely against price.
30. Ultimately, the current climate will exacerbate the existing NHS position of being a *'late' and 'slow' adopter of new technology* (2, 10.13). Patients will slip further behind their European counterparts in terms of choice and access to modern treatments. There will be cost and service shortfalls as well as disincentives for innovative suppliers to engage with the market.

ABHI

July 2006

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Better diagnostics to avoid unnecessary treatment costs

Studies in the USA have indicated that up to 70% of healthcare decisions rely on the use of diagnostic devices. Diagnostic devices range from inexpensive at-home pregnancy and blood glucose tests to sophisticated imaging machines²². Appropriate application of such devices enables better healthcare decision-making for patients and physicians and better targeted care, thereby avoiding unnecessary treatment costs. The cost benefits of accurate, early diagnostics are potentially substantial. However, an appreciation of this requires going beyond simple comparison of the cost effectiveness of respective devices and wider consideration of the total costs associated with missed, incorrect or late diagnosis that may result from inadequate access or use of diagnostic technology.

Technologies that enable earlier diagnosis and therefore intervention drastically improve health outcomes. Diagnostic scanning such as MRI and PET are proven to be both clinically and cost effective in cancer care. Early detection of cancer means patients may avoid unnecessary surgery, with its associated risks, and achieve an improved quality of life. In turn the NHS benefits from reductions in both immediate and long run treatment costs. Access to timely, highly accurate diagnostics are absolutely critical to achieving the 18-week targets from first presentation to successful surgical intervention

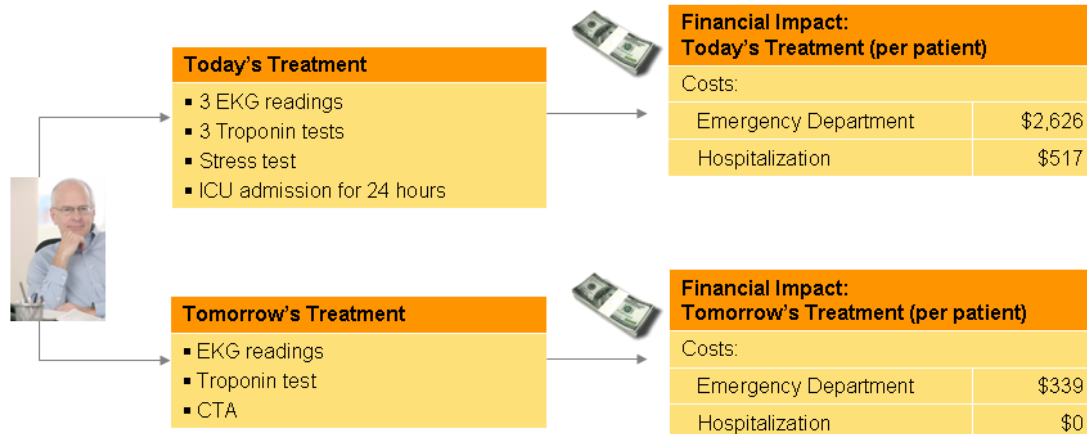
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²² The Value of Diagnostics – Innovation, Adoption and Diffusion into Health Care: prepared for AdvaMed by The Lewin Group, Inc: July 2005 <http://www.advaMed.org/publicdocs/thevalueofdiagnostics.pdf>

CTA scans clinically and cost effective diagnosis

Economic evaluations by in the United States have found that the cost of hospital treatment (in A&E followed by admission) can be drastically reduced with the application of diagnostic imaging over traditional care pathways. In US emergency departments, patients who present with chest pain are typically diagnosed with the aid of EKG readings, troponin and stress tests and monitored over night at a total estimated average cost of \$3,143 per patient. The vast majority of patients (over 75%) do not experience a heart attack but result in unnecessary admissions. By diagnosing patients early on with the help of sophisticated three dimensional cardiac imaging (such as Computed Tomography Angiography) patients requiring further treatment or monitoring can be quickly and easily identified at an estimated cost per patient of \$339.

Case Example: Patient Comes to the ED with Chest Pain and Is Not Found to Have Cardiac Disease



Traditional diagnostic testing and monitoring: \$3,143 per patient

Diagnosis with Computed Tomography Angiography: \$339 per patient (a single,

SAVINGS PER PATIENT: \$2,804

Data and graphics provided by Sg2 Healthcare Intelligence

Clinically superior pacemakers are also less expensive

More than 22 million people worldwide suffer from congestive heart failure (CHF), a potentially debilitating disease. Until recently, lifestyle changes, medication and, sometimes, heart surgery were the only treatment options. Patients with severe symptoms, however, received little, if any, relief from such approaches. To make matters worse, up to 40 percent of patients with CHF also have an arrhythmia that further reduces the heart's ability to beat properly.

Cardiac resynchronization therapy (CRT) is an innovative new therapy that can relieve CHF symptoms by improving the coordination of the heart's contractions. CRT builds on the technology used in pacemakers and implantable cardioverter devices. CRT devices also can protect the patient from slow and fast heart rhythms.

Studies from patients at Good Hope Hospital, Sutton Coldfield have quantified the cost benefits of CRT implantation by reviewing not just the initial implantation cost, but by looking at follow-up over a 2 year period²³. CRT has a higher initial cost but enables substantial savings in subsequent follow up care. Important but not quantified in the study is the benefit of a quicker return to a productive lifestyle for these heavily debilitated patients. The break-even for the NHS is as short as 1 year. After 2 years the saving per patient is almost £150,000 and continues to accrue.

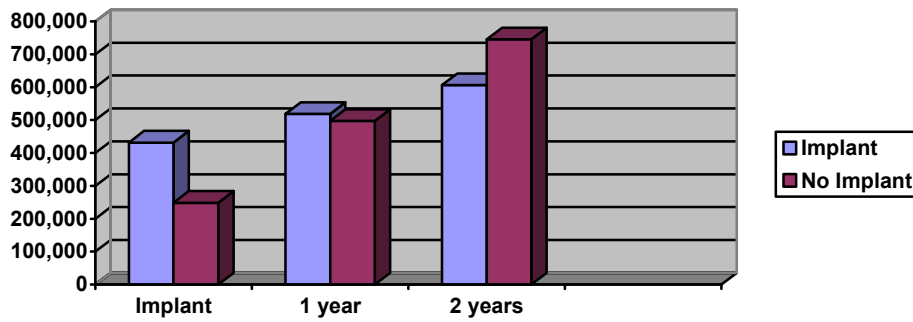
- Following CRT implant, patient hospitalisation rates decreased over 80% from 493 to 98 days.
- Individual patient quality of life scores improved by 41% and significant decreases (58%) in GP visits also resulted from CRT implantation.

The study considered the cost of hospitalisation, GP visits, drug costs, implant and service costs. At the time of treatment, the average cost of treating a patient with the use of a CRT was £431,598 and traditional medical treatment was almost half that at just £248,573. However, after keeping track of the costs of treatment for just one year following implantation, the average cost per patient with and without the CRT are roughly equal (£518,811 versus £497,146) and patients with the implant can be expected to remain more active and productive. Two on, the total average treatment costs of patients without the CRT (£745,719) is significantly higher than treatment that included the implant (£606,024). On a time horizon of just two years treatment with a CRT, already understood to be the clinically better option, is actually cheaper than less effective medical treatment.

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²³ Modelling the economic and health consequences of cardiac resynchronization therapy in the UK. Caro, J. Jaime; Guo, Shien; Ward, Alexandra; Chalil, Shajil; Malik, Farzana; Leyva, Francisco. Current Medical Research and Opinion, Volume 22, Number 6, June 2006, pp. 1171-1179

Total average treatment costs at Good Hope Hospital (n=45)



Treatment costs per patients without implants are higher than those with implants just two years later (£745,719 vs £606,024).

Silver Alloy Catheters reduce hospital acquired infections

Hospital acquired infections (HAI) represent a serious concern for patients and a huge cost for the NHS. At the spring 2006 *Procuring for Health* conference Ian Shepherd (Chief Executive Officer, East Midlands Collaborative Procurement Hub), discussed the impact of HAIs and strategies for prevention citing the cost of urinary tract infections (UTI) and the projecting savings of adopting infection-reducing urinary catheters*.

Urinary tract infections represent 35-40% of all HAIs, the vast majority of which are associated with the use of urinary catheters. The 133,000 cases per year in the UK significantly delay recovery and add to treatment costs both in antibiotic resistance and adding an average of six extra days of hospitalisation. The risk of infection is due to several factors including catheter material, duration of catheterisation and clinical care. Shepherd reported that infections can be reduced with catheter materials with high anti-microbial activity and low human toxicity (e.g. www.hpa.org.uk/infections/topics_az/rapid_review/pdf/bardex2.pdf).

Studies of Silver Alloy catheters in UK clinical settings, applying a model developed by the York Health Economic Consortium, have found an *average* 51% reduction in urinary tract infections (reductions as high as 72% in some settings) with an estimated saving in hospital treatment cost of over £6 million on a national basis.

Cost saving calculations from York model:

Patient data	Acute	Primary
# Patients catheterised	34,248	30,000
# Patients acquiring a UTI	8,220	2,760
Total treatment cost	£12,847	£233
Savings achievable		
Net projected savings with 50% effectiveness	£6,307,189	£232,250

Infection reduction with use of Silver Alloy Catheters is estimated to be capable of saving over £6 million in additional hospital treatment costs. This analysis does not include the additional benefit of returning the patient to normal productive life more quickly. This benefit does not accrue to the NHS but is a real cost to the national economy.

*Debjani Duncan and Ian Shepherd. *Adopting Innovation in Practice*. 9 March 2006. Procuring for Health Conference, The Belfry, Warwickshire.

5. ABHI Paper: Report to HITF SIG – July 2006
STRATEGIC IMPLEMENTATION GROUP (SIG)
THIRD MEETING 12 JULY 2006

Innovation in the NHS and the Procurement Landscape :
An industry perspective

Summary points

- The SCEP programme has done nothing to address the chronic late adoption of new technology in the NHS identified by Wanless. The evidence suggests that adoption has slowed further during the implementation of SCEP. Anecdotally there is evidence that in 2005 purchases may even have declined in several categories.
- It remains critical that a procurement landscape designed to advance the use of appropriate technologies is developed. Collaborative work by the ‘Procurement Process’ team is key to delivery of a mutually beneficial environment.
- A robust channel for dialogue on the evolution of the procurement landscape is badly needed. Stakeholders both inside and outside of the NHS remain confused regarding how the different elements will interact and address the needs of patients for choice, NHS and trusts for innovation and industry for a dynamic market.
- Careful consideration of the design of the procurement landscape could lead to a dynamic environment which is ‘fit for purpose’ to deliver long-term innovation. Elements should include:
 - * Appropriate sized hubs (North West London Collaborative Hub?)
 - * Procurement professionals reporting to operations directors rather than financial controllers would promote collaborative behaviour involving clinicians.
 - * ‘Value’ based decisions based on cost to treat, outcomes over longer timescales and across the continuum of care.
- Monopsonistic national procurement initiatives are likely to act as a significant drag on use of technology to enable more effective and efficient care pathway re-design (arguably repeated attempts to control procurement from the centre are one of the core reasons for the situation that exists at present).

Taking all five points together, the general trend has been for control or attempt to influence the ‘supply’ side. Little has been done to encourage or even measure ‘demand’ for innovation at the level of the NHS Trust. In the round, this means that there has been no effective action responding to Wanless’ points on technology.

Overview

HITF was instigated in order to address some longstanding and apparently intractable issues relating to the behaviour of the NHS in the context of uptake and utilisation of innovation. The tendency for procurement mechanisms to operate as a barrier to change rather than a catalyst of change was high on the agenda for discussion.

As the reform of the NHS approaches the peak of disruptive change and faces the prospect of continuing in a much more fiscally constrained environment, following the 5 year injection of ‘Wanless’ related funding, it is clear that the system and suppliers to the system still face a number of shared challenges.

Wanless was very clear in outlining the reasons why the NHS lagged its European peers in performance. Two elements were ‘absolute funding’ levels, addressed in the subsequent spending plans, and technology adoption. Technology adoption was clearly identified as a driver of cost in two dimensions:

- Some technologies clearly reduced the cost of treating specific conditions
- Some technologies make it possible to treat previously un-treated conditions

The sum of these drivers is a complex web of increased outputs in terms of productivity and increased numbers of patients treated.

Wanless stated:

‘over the next 20 years, spending on technology and medical advance will need to grow at a faster rate than in the past to catch up and keep up with other countries, including as envisaged in the National Service Frameworks (NSF’s) and to meet increasing patient expectations’

It is not at all clear that the relative spend on technology has increased as described over the period of ‘Wanless’ funding. In fact, HITF data for 2003 shows a growth of spend on medical technologies of less than 4% in a year when total NHS spending growth exceeded 10%.

In the past 3 years the environment has been overlaid by the ‘value for money’ agenda driven out of the Gershon Review and, more, recently the well publicised fiscal difficulties being experienced by many of the Trusts in the NHS. The combination of these initiatives has contributed to a slowing of service innovation in the NHS and this is reflected by a worsening of the technology adversity described by Wanless.

This situation is bad for patients, the NHS and industrial development in the sector in the UK.

Innovation

In order for the NHS to deliver the expectations of patients and voters in the United Kingdom it will be essential to accelerate the pace of innovation in service delivery. The NHS Confederation in their excellent pamphlet entitled ‘Why we need fewer hospital beds’ has explained the contribution of a number of drivers to reducing the relative size of the hospital infrastructure and why this is good news for patients and the taxpayer. Technology is specifically identified as a driver and sits behind four other drivers as an enabling force.

The rhetoric regarding doctor and nurse numbers in the NHS is unhelpful as it has suggested that the answer to all of the performance challenges is to throw people at the problem. Commercial organisations faced with similar performance challenges and 70% of costs tied up in people would look for means to improve quality and cost whilst reducing payroll expense. Almost inevitably the key to achieving this goal is to use technology as an enabler. The NHS is no different and the key to productivity and quality improvements lies in effective utilisation of technology.

HITF had a core objective of addressing the technology aversion of the NHS and it is far from clear that any progress has been made towards achieving the goals set out. This is in spite of an enormous effort from both government and industry champions of change. The key barrier to progress remains reform of the procurement landscape and the attitudes of those who manage and interface with the procurement function in the NHS.

Role of Procurement

Procurement lies at the heart of effective service improvement and if the goals of the procurement teams are not effectively aligned with the goals of the broader organisation then the desired shift from people intensive care pathways to quality and cost driven pathways will

not occur. In this context, the work of the procurement methodologies theme of HITF is absolutely crucial and the fixation with short-term cash fixes is detrimental to progress.

Specific barriers to innovative adoption include:

- Buyers who work solely on cash saving targets who are strongly incentivised to buy yesterday's technologies at lowest price regardless of the impact on both total cost and quality of care.
- Overly aggregated purchasing which is slow to reach conclusion, relies on long contracts and tends to not involve clinicians and managers in the decision making process.
- Use of a 'one model fits all' mind-set for procurement. Very large contracts are often entirely sensible for high volume, widely distributed and mature technologies and both suppliers and Trusts agree that a drawing from an efficient intermediary is very effective. The NHS Logistics model has served all members of the supply chain well. For other, often more specialist, technologies the value proposition involves elements of service that are much needed by user and managers and therefore need to be contracted locally and often on the basis of more dynamic contracts which reflect the pace of technological change.

In order to create a more innovation friendly and yet efficient landscape for the future it is essential to continue the work of the Procurement Processes sub-group of HITF in order to generate solutions which are fit for purpose and workable for all stakeholders. Careful deliberation involving key stakeholders from the clinical community, NHS management, industry and procurement professionals is essential if we are to develop sustainable models of procurement which address the critical innovation issues and bring about lasting behavioural change from all parties.

Key suggestions

- Supply chains must be allowed to evolve according to the nature of the products and the distribution of users
- Hubs are a key element of the procurement landscape but should be sized in order to:
 - Facilitate truly collaborative behaviour between members
 - Allow effective interaction with clinicians and managers charged with redesigning and developing new patient pathways which improve productivity and quality
 - Allow an effective market to operate by creating enough independent transactions to encourage and reward both innovative suppliers and innovative buyers. The structure should also facilitate the development of business in manageable increments for small and medium sized enterprises (SME's)
- Current developments of Procurement Hubs towards units that are sized around the new strategic health authorities are, arguably, too large to deliver on the above. Units the size of the current North West London collaborative seem to function well.
- Procurement professionals should not respond to finance directors as this tends to reinforce a culture where purchasing is viewed as a source of cash savings rather than delivery of value.

- Demanding and innovative customers are critical to the successful exploitation of the UK science base and the creativity of staff within the NHS. With significant focus on medical technologies as drivers of industrial growth in the knowledge economy (Technology Strategy: Developing UK Capability, DTI, 2006) both the DTI and Regional Development Agencies are increasing focus on this sector. The time is now right for taking the disparate streams of activity and support and binding them together in a cohesive industrial strategy.

In order to maximise the potential contribution of the HITF process to the evolution of the NHS, it is essential that there is transparency and alignment of objectives between the Department of Health and the stakeholders involved in the HITF working groups. This means a clear reconciliation of the objectives of the Supply Chain Excellence Programme with those of HITF. The prize in terms of long-term productivity in the NHS is enormous compared with the short-term goals of the Gershon Efficiency Review and the objectives of the SCEP process need to be balanced against those outlined in the Wanless report if mutually satisfactory outcomes are to be achieved.

6. Observations from health technology participants

Observations from Pankaj Vadgama and Tony Anson

Tradition can be a barrier to new approaches/new visions. The best I have seen has involved:

- (i) direct governmental/local state intervention.
- (ii) Leadership by one strongly supported individual.
- (iii) Challenging research agenda - not duplicating small scale HEI activity (The Sanger Centre is a UK example).

The UK equivalent should be to establish a complementary (not competitive) cross-Trust network to tackle priorities in R&D. A good model is the way we are planning UK lab services (via The Carter Report).

For make any endeavour to work, it requires a single one person to spearhead it. That person needs certain special qualities: resilience, foresight, and doggedness. Unfortunately in the world we live in, the mention of autocracy as opposed to team working, may land you in trouble! History shows that the real achievers were all autocrats. This continues today: cf. Bill Gates, Richard Branson, and other successful business people.

Co-ordination throughout UK is necessary to ensure that R&D is not excessively duplicated. At several UK Universities, there are examples of research duplication: e.g. the currently fashionable area of numerical modelling of biological processes.

Observations from Saeed Zahedi OBE FIMechE MISPO MioD: Technical Director - Product Development, Chas. A. Blatchford & Sons Ltd.

The MDT event in London (2005) was the largest gathering of Medical Device technologist in recent years composed of mainly, product designers, tool makers moulders, and medical researchers. However, most of the workshop was dominated by moulders looking for partners.

Despite London area having as many medical researchers and product designers as MIT and Stanford put together, it has no real visible output due to fragmentation and the large gap between, industry, academia and NHS. The Triad or triangle of these three sectors must be linked better to promote Medical devices in UK.

However DTI and EU funded networks have not delivered obvious results after so many years and so much money. The same group of people go around from one body of experts to another and link with other network groups with no where else to go, dominated by QinetiQ, IBM, NPL, TWI, and a few others.

In the Prosthetics & Orthotics industry for example, we now have validated technology to vision, direct design and manufacture medical devices for the disabled and aging population. There are proven 3D body scanners (portable for home use), 3D printers (flexible for rigid and flexible material use), and the pressure of reimbursement to reduce the cost of manufacture while maintaining a high level of functionality. While the investment required to demonstrate to NHS users the viability of central fabrication and local /home diagnosis and delivery of prognoses medical devices is not a huge amount, it is out of the reach of the majority of small to medium size companies currently contracted to provide such services to NHS, even through the industry spends nearly 15% of turnover on R&D to produce medical devices to suit the UK market. The market is increasingly threatened by lower cost devices by made in the Far East; and in absence of MRHA policing capability, these so-called CE marked products are by no means on a true level playing field. The situation therefore has become very fluid and unsustainable.

Philip Owen: Welsh Optoelectronics Forum

I have a generic comment triggered by several recent attempts to find funds.

There is no linkage between DTI & RDA funding flows (for example Collaborative R&D, SMART, KEF) and NHS requirements. The DTI & RDA's fund bright ideas rather than needs. The NHS has excellent corporate antibodies for rejecting bright ideas. There could usefully be a mechanism for various bodies with demands for new products to review the output of the bodies that fund ideas - joined up government.

7. Case Studies Evidence

Exploitation case studies of health technology exploitation from BTG

Magnetic Resonance Imaging

Magnetic Resonance Imaging (MRI) is one of the major breakthroughs in medical diagnosis this century, comparable in its importance with the discovery of X-rays. It is now used routinely to generate detailed pictures of tissue structure deep in the human body.

A number of key MRI inventions have been made at the Universities of Nottingham and Aberdeen. BTG worked closely with the inventors during the 1970's to secure patent protection for their ideas.

Once it became clear that MRI would become a multi-million pound business, it was necessary to confirm the validity and relevance of the BTG patents. Confrontations between BTG and the major manufacturers resulted. These were settled out of court after BTG demonstrated its belief in the patents by preparing for US court action. The cost and effort was enormous but has proved worthwhile.

A key factor in this foreign domination of a UK invention was the delay in use of MRI in UK. It is estimated US was at least 5 years ahead in buying patterns. Add to this the small relative UK market and it was very difficult for UK based companies to compete on a global basis. This indicates the importance of a responsive home market is for final development, user feedback and credibility for export.

Licence agreements have been signed with most of the major manufacturers, including the Japanese. MRI

This account is detailed in the Wellcome report - Making the Human Body Transparent²⁴.

Glass Ionomer Dental Cement

Glass ionomer cement was developed as a dental restorative at the Laboratory of the Government Chemist by Dr Alan Wilson and his colleagues during the early 1970s. The aim was to produce a material that would overcome the shortcomings of traditional dental products.

BTG funded the development and glass ionomer cements are now established as practical materials offering a unique combination of properties: colour and translucency closely matched to tooth enamel, direct adherence to dentine and enamel with a fluoride leach into the surrounding tooth to protect against further deterioration.

As work progressed, BTG built up a portfolio of patents relating to various types of cements. To settle a dispute over US patents, with a Japanese company, BTG paid for the inventors to

²⁴ Making The Human Body Transparent: The Impact of Nuclear Magnetic Resonance and Magnetic Resonance Imaging. [The transcript of a Witness Seminar held at the Wellcome Institute for the History of Medicine, London, on 2 July 1996; Edited by D A Christie and E M Tansey]

go to America to carry out controlled tests and experiments in the presence of officials from the US Patent Office.

BTG granted licences under its patents to companies in the UK, West Germany, the USA and Japan. In 1988 the vital contribution of the Laboratory of the Government Chemist was acknowledged by a Queen's Award for Technological Achievement.

Medical Prosthesis

The original concept of a replacement hip joint comprising a metal ball in a plastic cup was never patented. BTG has, nonetheless, protected many later prostheses, including the Stanmore hip cup and the Exeter hip cup, both of which have been commercial successes. The Exeter hip cup was licensed to Howmedica International Ltd.

Knee joints have presented a considerable technical challenge over the years; a major advance was made with the Oxford Three-Part Knee devised by a surgeon at the Nuffield Orthopaedic Centre, Mr Goodfellow, and engineers Drs O'Connor and Shrive at the University Department of Engineering Science. This was licensed to the major orthopaedic companies.

The long-term nature of the innovation process is illustrated by the fact that in 1988 – 15 years after their original invention – Goodfellow and O'Connor made a significant improvement to their original idea which BTG protected with patents. This is now also licensed to major orthopaedic companies.

One prolific inventor in Medical Engineering was Dr Martin Wright, whose first patent was taken out in 1954. Between 1975 and 1977, while at the Clinical Research Centre, he produced three major inventions. These have resulted in successful products widely used in hospitals, hospices, clinics and homes, namely the Mini-Wright Peak Flow Meter, Syringe Driver and Neonatal Respiration Monitor.

These ideas were patented by BTG and the licensees built up substantial businesses in them.

Mini-Wright Real Flow Meter

Dr Wright recognised that people suffering from asthma, chronic bronchitis and emphysema needed a low-cost device to check on their condition that was simple enough to use unsupervised at home.

The Mini-Wright Flow Meter, which is a miniature version of the Wright Peak Flow Meter developed in 1954, satisfies both of the above needs providing a reliable and repeatable measurement of the patient's peak flow rate.

BTG secured patent protection for the new meter in the UK and overseas and negotiated licence arrangements with Clement Clarke International Ltd, who sold well over one million units.

Neonatal Respiration Monitor

Apnoea monitoring had been available for some time using special mattresses that detected the babies breathing. These, however, could be inconvenient and thus restricted their use to hospitals. Dr Wright's invention overcame these limitations and enabled monitoring for 'sudden infant death syndrome' (cot death) to be carried out at home.

A small pneumatic sensor is taped to the baby's abdomen and detects its expansion during breathing. If breathing ceases, an audible and visible alarm is triggered to alert parents or nursing staff.

The device was licensed by Graseby Medical Ltd.

Portable Syringe Driver

Syringe pumps have been available for many years as large, mains driven devices when Dr Wright led the development of a compact, portable, battery operated device.

To ensure the safety of these devices in the event of a malfunction which could lead to inaccurate delivery of medication a novel feedback mechanism was included to provide a warning of such a failure.

The products have proved invaluable for a variety of patients from pain control in the terminally ill to feeding milk in premature babies.

The common feature of all three of Martin Wright's inventions is that they used existing technology creatively in a manner that could be implemented relatively easily by a commercial manufacturer.

Obtaining useful patent protection for these devices has not been straight-forward and involved considerable effort on the part of BTG. The effort and cost has proved worthwhile but success has been a long term achievement.

Roger Fenely: Bristol Urological Institute

The BioMed Centre

Summary of Research Activity

The BioMed Centre was established to improve the management of intractable urinary incontinence in older and disabled people. The project highlights the problems of obtaining a sufficiently comprehensive and rapid response for the UK to establish a significant lead in a healthcare field that seeks scientific and technological input. The clinical need has been published in the medical literature over the past three decades yet the outcome will probably be too little and too late to make this a major commercial success for the UK.

The concept of the BioMed Centre was initiated through a charitable establishment, namely the Bristol Urological Institute in 1998, following demands for assistance from nurses, patients and carers. The time and effort required to highlight, then fund a subject of such fundamental importance to the provision of care for older and physically disabled people represents a pivotal problem that needs to be addressed.

Fundraising for the BioMed Centre

Funds of £1.6 million have been raised for the new building for the Bristol Urological Institute which houses the BioMed Centre. The building project commenced in January 2003 and was completed in December 2003. The donors included a pharmaceutical company (£500,000), a local charity, the John James Bristol Foundation (£250,000), the North Bristol NHS Trust (£250,000), the Wolfson Foundation (£250,000), Dunhill Medical Trust (£100,000), Henry Smith Charity (£100,000) and Garfield Weston Foundation (£50,000). . Further money has been raised from local activities including sponsorship for runners in the London Marathon (£16,000) and just over £100,000 from a specific appeal for funds to support research and care of patients with prostate cancer

Conclusion

The idea of the Biomed Centre, dedicated to the problem of intractable urinary incontinence, started as a result of the demand for help from nurses, patients and carers. The subject is not a glamorous one but it is of fundamental importance to care for older and physically disabled people.

Despite financial support from both statutory and charitable bodies, the programme of research has failed to introduce as yet any new marketable urine collection system.

The research funding, despite efforts to do so, does not reflect the innovative pathway. Matched funding schemes assume that the industry partners will commercialise, when in reality expensive studies may still need to be done: a number of products have reached a hiatus partly due to this problem.

Ideally IP should be assigned/managed by the organisation best suited to commercialise: this could be a Health Technology Co-operative (HTC). However, where ownership resides in an academic institution that is not expert in the field or where the potential rewards are limited, important product opportunities may get lost.

Regionalisation of schemes can be a hindrance as well as a help.

Emphasis at Bristol BioMed is on clinical need as a market driver. How this is articulated and captured is critical. There seem to be conflicting ideas on how this works (or should work) and as to whether clinicians identify the problems or find solutions or both. Patients are customers and HTCs should be able to provide good market research for SMEs in collaborative ventures.

Mike Pearson: Pearson Matthews

We work primarily in the area of design based R&D work in healthcare. One area of interest would be a project we worked on with the Design Council that was carried out with Newcastle University²⁵.

We are at the leading edge of the use of design as an important R&D tool during the early stages of research. We have been successful in securing two DH HTD grants for healthcare projects when the original applications were rejected due to lack of commercial focus. A lesson that this work shows is that design has the techniques and tools to help direct the most fundamental research toward useful commercial objectives.

The work with Newcastle put us in contact with a research project that is looking at ways to monitor atrial repolarisation (as opposed to ventricular polarisation or ECG). Whilst their research is essentially funded to explore whether such measurement is possible and what it can tell us, we were able to work with them to explore some of the potential it has as a diagnostic tool. The effectiveness of design involvement, as this project showed, was in its ability to explore potential outcomes of the research, identify devices and IP that would emerge, and then both speed up and redirect the research itself toward commercial goals.

A major proportion of our work is with technology transfer organisations of Universities, where the design input is used to explore technology and unearth potential and suggest commercial direction. It often able to make the difference between technology push and market pull, focusing research on valuable goals.

On the other hand we are associate members of the Parliamentary Health Group and have been involved with the DH who fund policy research, such as through NPSA, but, in my experience, only very recently have the policy objectives of the DH been in any way matched with the needs and commercial aim of commerce. It is the closing of the loop between policy and commerce, and a willingness to work with commerce, that will allow wider health policy to be implemented through cooperation rather than legislation.

John MAISEY: Cardiff and Vale NHS Trust

This brief response (as someone who supports much of this research (in the NHS) by providing engineering solutions to support it, some of which are innovative and have commercial potential) is that the IP generated is not managed efficiently or effectively and

²⁵ <http://www.design-council.org.uk/webdav/harmonise?Page/@id=94&Asset/@id=9765&Document/@id=9629>

that the majority of its value is being lost to the researching bodies, and as partial payback for the supportive funding.

Kevin Wilson, Medical Devices In Scotland

Here are two examples that have come through Scottish Health Innovations Ltd.

Touch Bionics

The history of Touch Bionics goes back to a programme of work conducted at the Princess Margaret Rose Hospital in Edinburgh from 1963; starting with comprehensive research into developing prosthetic solutions for children affected by Thalidomide. In 1988, work began in earnest on electronic arms, including shoulders, wrists and hands. In 1993 a partial hand system received international publicity and in 1998 major international profile was achieved through the fitting of the world's first electrically powered shoulder.

In early 2003 the company was spun out from the NHS, with significant shareholding held by Scottish Healthcare Innovations Limited (SHIL) and became the first SHIL spin-out to receive significant funding. An initial SMART award from Scottish Enterprise got the company going, and it has now received confirmation of a £1m funding package from existing and new investors including Archangel Informal Investments and the Scottish Co-investment Fund. A subsequent SPUR award was also achieved in 2005.

The company was initially called Touch EMAS, EMAS standing for Edinburgh Modular Arm System. In 2005 it was rebranded Touch Bionics to communicate the dynamism of the company's products and the future focus of its technology.

Touch Bionics has developed a revolutionary system - the i-LIMB™ System - of modular prostheses based on a very lightweight endoskeleton taking full advantage of the advances which have been made in motor and battery technology.

Touch Bionics has developed a range of products including electrically powered prosthetic shoulders, elbows, wrists, hands and powered digits.

www.touchbionics.com

Mosquito, Scotland On Sunday – 25th June 2006²⁶

'Mosquito' surgical aid is a life-saver for SHIL: Bill Magee

Scottish Health Innovations Limited (SHIL) has struck a deal with a group of Swiss technology experts to help manufacture a medical aid expected to become the global industry standard used by surgeons when they tackle delicate and often lifesaving cardio-vascular operations.

SHIL, an independent firm set up to commercialise NHS Scotland-based inventions, is behind 'The Mosquito', a vibrating needle holder devised by Tayside-based consultant surgeon Peter Stonebridge.

The move follows the success of SHIL's equity stakeholding in Lothian prosthetics firm TouchBionics (formerly TouchEMAS) in launching the world's first bionic shoulder this summer.

The US is a strong target market for The Mosquito, where more than 12 million people suffer from cardiac artery disease, with 400,000 new cases each year. The suture market alone is worth \$1.3 billion.

And the latest ISD Online Scottish health statistics list 2,735 cardiac artery bypass grafts each year within NHS Scotland treatment, and around 700,000 worldwide.

²⁶ This story comes from Scotland On Sunday – 25 June 2006

SHIL and other team members have secured a patent for The Mosquito and a co-development agreement was signed last week with Switzerland's Active Ultrasonics.

They now intend to move swiftly towards manufacturing the product. Collaboration with the Swiss may extend to marketing, otherwise a third party with a global reach will probably secure commercial rights.

Mario Plasencia, director of Active Ultrasonics, said the firm is combining its in-house design and marketing expertise in the field of ultrasonic equipment with Ninewells' clinical experience and medical physics department.

Nigel McLean, a business development manager with SHIL who has worked closely with the inventor, said: "The Mosquito will solve a massive headache for cardiac surgeons."

Up to 60% of patients with coronary artery disease experience calcification of blood vessels when bypass operations and aortic surgery are performed. This leads to a risk of an embolism, which can be fatal.

Vascular surgeons face such problems when suturing hardened and calcified blood vessels, other tissues and even grafts. They often have to resort to using larger needles, which are more likely to damage the graft and blood vessels, which in turn can lead to amputation in serious cases.

McLean added: "To date, no technology or device attempts to overcome such frequently encountered problems.

"Fine needles frequently become bent or their tips damaged during insertion. This renders it difficult to complete procedures."

Stonebridge, a consultant vascular surgeon at Dundee's Ninewells Hospital, said that he and colleagues have previously looked at various pneumatic devices without success.

These included those used for insulin injection - but the pressure was too high and damaged vessels - and even devices used by tattoo artists, but these also proved unsuitable.

Stonebridge, who also works closely with Tayside Flow Technologies, added: "The calcification of artery walls, particularly those close to the heart, is a major and frequently encountered problem.

"A device such as The Mosquito will be of great benefit to vascular surgeons and will improve the standard of care we can offer the patient."

www.shil.co.uk

from Ian Barr, UK T and I East Midlands News²⁷

Hospital Gloves Raise Surgical Spirits For Leicester And Nottingham Companies

27 June 2006

The gloves are off for two East Midlands firms who worked together and fought off tough competition to secure a 3-year contract supplying 36,000 pairs of a new high protection surgical glove into the Italian health service.

The cut-resistant glove provides surgeons and theatre staff with enhanced protection from blood-borne infections such as hepatitis and HIV/AIDS. It is made with a Dyneema yarn, which is used in bullet-proof vests and during ballistics operations.

The glove was developed and is manufactured by Nottingham-based Sallis Healthcare Ltd, which has been supplying the NHS since 1948. The all-important packing and sterilisation prior to sale is handled by Fairefield Medical in Leicester.

²⁷ <http://www.emids.uktradeinvest.gov.uk/news/default.asp?nwSC=&viewArticle=454>

UK Trade & Investment (UKTI) in the East Midlands and Business Link Nottinghamshire supported the companies by helping them set up hospital trials in Derby to prove the gloves' effectiveness.

UKTI International Trade Adviser Ian Barr, said: "Initially, the companies were not sure how best to approach this issue".

"I advised that the gloves were much more likely to win approval, whether in the UK or overseas, if they were supported by a clinical trial. Purchasing decisions are increasingly evidence-based and I encouraged the companies to consider investing in this approach."

"I also discovered that Derby Hospitals NHS Foundation Trust had considerable experience in this field. With Pat Needham, Regional Biosciences Adviser at Business Link Nottinghamshire, I introduced the companies to the researchers. Sallis Healthcare had enough faith in their product to put it through extensive and rigorous tests, which they part-funded."

Both companies are delighted that the gloves, which are also available to the UK market, have recently come successfully through the clinical trials and are now achieving commercial success.

Robert Sallis Sales Director of Sallis Healthcare said, "We are extremely pleased and excited by this new product which creates opportunities for us in the NHS and in export markets".

"We intend to take the product forward by demonstrating to surgeons and other theatre staff its potential importance in protecting them against cross-infection when staff are operating on medium- and high-risk patients. It could save lives."

Robert added, "Charles Whait of Fairefield Medical, who assisted in the development, has taken over responsibility for marketing the product and we are looking forward to the Sallis-Fairefield partnership going from strength to strength as new markets are opened up."

On the clinical trials, Pat Needham explained:

"Clinical testing can be difficult to arrange if you are a company that is unfamiliar with the procedures. In addition, hospitals are unfamiliar with dealing with small companies so there were initial problems to overcome on either side before the trial could really get under way.

"I liaised between the Research & Development department at Derby Hospitals NHS Foundation Trust and the two companies to develop a mutual understanding.

"The hospital agreed to undertake a clinical trial and the results were very good. It was proven that wearing the gloves on top of the latex gloves significantly reduced cuts and tears during operations. This substantially benefits the wearer because it lessens the chances for blood-borne infections such as hepatitis and HIV/Aids to spread."

Dr Judith Tanner, an authority on surgical gloving techniques, is based at Derby Hospitals NHS Foundation Trust's Research and Development department, and organised the clinical trials. She added:

"Surgeons currently use two pairs of latex gloves during operations to minimise the risk of cross infection but latex gloves are very fine and offer limited protection during heavy operations.

"Tests were randomised so that some staff wore two pairs of latex gloves and the remainder wore a pair of latex gloves with the knitted glove over the top. We found inner latex glove perforation was reduced from 23% when double latex was used, to 6% when the knitted glove was used.

"The knitted gloves certainly offer a better degree of protection than double latex gloving and would be particularly appropriate for operations that use heavy machinery such as orthopaedic surgery.

“Despite being knitted, the gloves are actually very fine and delicate, offering good precision and handling which some theatre staff were impressed with.”

The clinical trials are the largest and most comprehensive of its kind yet undertaken and give Sallis Healthcare and Fairefield Medical the strongest possible platform to develop both the UK NHS and additional export markets.

Sallis and Fairefield are now actively seeking additional marketing partners to promote their product into these areas.