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Healthcare Technology Co-operatives

Filling a niche in the
English R&D landscape

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Prepared for the Department of Health (England)

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Preface

The Department of Health commissioned this evaluation of the pilot Health Technology Cooperatives in England. Its purpose is to explore how this funding stream has affected relationships between clinical, industrial and academic partners; how the Health Technology Cooperatives fit into the current health innovation landscape; and the alignment of their activities to the goals set out in the NIHR strategy.

The review investigated how medical device development is being pursued by the Health Technology Cooperative scheme, as well as other similar entities in England, Australia and the USA. An important question was whether the institutional relationships initiated by the Health Technology Cooperatives are influencing the health research system and if this scheme is the most appropriate way of pursuing these relationships.

This report presents the findings of our review, based on the evidence presented by those we interviewed. The study was a perceptions audit and we tried, as far as possible, to ask interviewees for examples of the views they expressed and the claims that they made. The views presented in this report are those of study informants only.

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Summary

The Department of Health has commissioned this evaluation of the pilot Health Technology Cooperatives (HTCs), which are part of its research infrastructure. Its purpose is to explore how this initiative has affected relationships between clinical, industrial and academic partners; how the HTCs fit into the current health innovation landscape; and the alignment of HTC activities to the goals set out in the NIHR strategy¹.

Since the HTC scheme was intended to focus on medical devices, this review investigated how medical device development is being pursued by other similar entities in England, Australia and the USA. The key question was whether the institutional relationships initiated by the HTCs are contributing to the health research system in England and if this scheme is the most effective way of pursuing these relationships.

This review had no specific theory or hypothesis to test, so information was gathered so as to allow key conclusions to be drawn and linked to existing theories. This review used documented evidence from the institutions involved as well as interviews. As the interviews are essentially a perceptions audit of senior people at the HTCs, we tried, as far as possible, to encourage interviewees to support the views they expressed and the claims they made with tangible examples. However, given our wider knowledge of the health research system, we felt that the claims made by interviewees were reasonable and credible.

The pilot HTCs, Devices for Dignity (D4D) and Bowel Function HTC (*enteric*), initially pursued different operational models: the former pursued a structured management model with defined roles within the management team, while the latter adopted more flexible management responsibilities. Both have now settled into formalised project evaluation systems, supported by wide-ranging stakeholder networks.

Both pilot HTCs have established a pipeline of products that range from near-market technologies to longer-term development projects and have found other sources of funding to develop these technologies.

Both pilot HTCs have reached the initial stage of becoming national services through the development of expert networks. There remain some issues with their level of profile, mainly due to the 'pilot' label, which may hinder the development of new relationships.

¹ Department of Health. *Best Research for Best Health*. 2006. [Available at: http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4127153.pdf].

There is an identified need to engage NHS clinical staff and management in medical device development and also to encourage greater involvement of small companies. The HTC concept is currently the only medical device-specific entry point into the innovation pathway and both pilot HTCs have found enthusiastic NHS collaborators. Both HTCs agree that being hosted by a NHS Trust has been key to their progress.

All HTC-like organisations have found themselves dealing with unexpectedly high numbers of potential, and high-quality, projects, including some that may not have been identified otherwise. All are considered to be providing a unique service by their users, according to the interviewees.

All HTC-like organisations state that some form of Government funding is required to support basic administrative functions and initial scientist/clinician time. Currently this is obtained from charities, foundations, donors, or the Government.

Most other HTC-like organisations around the world serve a sustained function, with the exception of those in Australia which have fixed terms.

There is general agreement that intellectual property rights cannot provide a viable income stream for HTC-like organisations and that fee-charging could present a barrier to developing many new innovations.

The pilot HTCs have shown that there are different, but equally legitimate, management approaches to the clinician-industry-patient relationship. These different approaches are reflections both of the disease field and the host institution culture. Neither HTC has concluded how best to sustain activities in the long term, particularly core management facilities such as supporting initial meetings with potential partners and early development of technologies from non-commercial sources.

These core HTC activities are unlikely to attract private sector funding as they are providing a 'public good' in their initial contact and evaluation stages.

Core funding should cover the costs of full-time staff for project management and relationship management, with part-time funding for administration and both clinical and research leads. Funding must also cover clinical evaluation time, including that of specialists whose roles are difficult to replace at their host institutions.

Given the remit of the HTCs and the experiences of those managing them, it would be appropriate for competition-based Government funding to cover core management functions which, for medical device innovation, seems to be a key public good.

Abbreviations and labels

BRC - Biomedical Research Centres

BRU - Biomedical Research Units

CLAHRC - Collaborations for Leadership in Applied Health Research and Care

CRC - Cooperative Research Centres (Australia)

D4D - Devices for Dignity HTC

DH - Department of Health (England)

enteric – Bowel Function HTC

GDP - Gross Domestic Product

HITF - The Health Industries Taskforce

HTA - Health Technology Assessment

HTC– Health Technology Cooperative

HTD - Health Technology Devices

I4I - Invention for Innovation

IPR - intellectual property rights

KTN - Knowledge Transfer Network

NHS - National Health Service

NICE - National Institute for Health and Clinical Excellence

NIH - National Institutes of Health (USA)

NIHR - National Institute for Health Research (England)

R&D - research and development

STHFT - Sheffield Teaching Hospitals Foundation Trust

TDP - Technology Development Partnership

TSB - Technology Strategy Board

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Any errors or omissions that remain are our own.

This report presents the findings of an evaluation, commissioned by the Department of Health, of the pilot Healthcare Technology Co-operatives (HTCs). It will assess their role in supporting the development of medical devices, and in doing so, will explore how the pilot initiative has affected relationships between different parts of the research infrastructure.

This chapter has three sections. The first section offers a brief context for understanding how HTCs emerged. The second section provides a description of the HTCs and the challenges that they seek to address. The final section gathers insights from different perspectives to develop our understanding of the role and value of health research in the economy and broader society.

1.1 **Policies and past recommendations for UK health research: a brief history**

The National Health Service (NHS) is the largest UK customer of medicines and technologies produced by life sciences companies. If health research is to fulfil its potential as a major industry driving future economic growth and prosperity, it is vital that the NHS values and uses cost-effective innovations and provides an excellent environment for clinical trials and investigations.² The need for the NHS to use and adopt new medical technologies and devices has been supported and promoted in Government policy and several independent reviews of NHS performance.^{3,4,5}

There is a perception by some, as expressed in the Wanless Review⁶, that the NHS is a late and slow adopter of medical technology. The Wanless Review noted that new medical technologies are key drivers of increased health expenditure and, if costs are to be prevented from spiralling uncontrollably, the introduction of new technologies must be

² Life Sciences Blueprint: A statement from the Office for Life Sciences. July 2009. [Available at: <http://www.dius.gov.uk/-/media/publications/O/ols-blueprint>].

³ Sir Derek Wanless. *Securing Good Health for the Whole Population*. 2004. [Available at: www.hm-treasury.gov.uk/Consultations_and_Legislation/wanless/consult_wanless04_final.cfm].

⁴ Sir David Cooksey. 'A Review of Health Research Funding'. 2006. [Available at: www.hm-treasury.gov.uk/independent_reviews/cooksey_review/cookseyreview_index.cfm].

⁵ Lord Darzi. *Our NHS, Our Future: NHS Next Stage Review. Interim report*. October 2007. [Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/dh_079077].

⁶ Sir Derek Wanless. *Securing our Future Health: Taking a Long-Term View*. April 2002. [Available at: http://www.hm-treasury.gov.uk/consult_wanless_final.htm].

based on an assessment of their clinical and cost-effectiveness. In addition, a House of Commons Health Committee Report on the *Use of New Medical Technologies within the NHS*⁷ addressed the fact that the potential benefits of new medical technologies are not being realised within the Department of Health (DH) for a number of reasons. These include the complex funding structure of the NHS' federation of Trusts; inconsistencies in policies and practices related to the development of new technologies; and problems with the Department's application and purchasing policies. This report recommended:

- Greater efforts to strengthen links between health and social services
- Greater engagement of clinical champions for new technologies
- Improved techniques for determining the cost-effectiveness of new technologies

In response to these reports, the previous Government acknowledged that safety and efficacy issues were important concerns with the introduction of any new healthcare technology.⁸ In particular, it was accepted that much needed to be done to realise the benefits of new medical technologies for patients and other service users. The *NHS Plan*⁹ and the *NHS Improvement Plan*¹⁰ were DH initiatives targeted at reforming and modernising the NHS. Improving the speed of adoption of new medical technologies was a key objective of these strategies. The DH research and development strategy, *Best Research for Best Health*, included specific proposals designed to support medical devices research. *The Cooksey Review*⁴ had recommended that increased funding be made available to support expansion of the NHS Health Technology Assessment (HTA) programme. Additional funding was called for by the Health Industries Taskforce (HITF) to enhance the evidence base to inform decisions on the effectiveness and cost-effectiveness of technologies.¹¹

The HITF was established in 2003 as a joint venture between the Government and the UK healthcare industries. The HITF's key objective was to facilitate medical innovation and improve access to medical technologies for both users and industry. The HITF was the first strategic collaboration of its kind in this country. HITF published its final report in November 2004.¹² The foreword to this report states that '*focusing on this industrial sector reflects the Government's agenda by stimulating innovation as a means to maintain the UK's*

⁷ House of Commons Health Committee. *The Use of New Medical Technologies within the NHS: Fifth Report of Session 2004-05*. April 2005. [Available at: <http://www.parliament.the-stationeryoffice.co.uk/pa/cm200405/cmselect/cmhealth/398/398i.pdf>].

⁸ Department of Health. *Government response to the Health Committee's report on the use of new medical technologies within the NHS*. [Available at: www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4120880&chk=PtJqE5].

⁹ Department of Health. *The NHS Plan: A Plan for Investment, a Plan for Reform*. July 2000. [Available at: www.dh.gov.uk/publications].

¹⁰ Department of Health. *The NHS Improvement Plan: Putting People at the Heart of Public Services*. June 2004. [Available at: www.dh.gov.uk/publications].

¹¹ Strategic Implementation Group (SIG), Healthcare Industries Taskforce. *Innovation for Health: Making a Difference*. March 2007. [Available at: http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_072866.pdf].

¹² Healthcare Industries Task Force. *Better health through partnership: a programme for action. Final report*. November 2004. [Available at: www.advisorybodies.dh.gov.uk/hitf].

edge as a market leader in science - and innovation-intensive markets [...] The domestic and global business environment is evolving rapidly, and both Government and the industry need to be able to keep pace with new technology advances so that we can provide a modern health service.' The report set out nine key objectives and included the first published data sets in a new series of metrics on the UK-based medical technology industry. This report also launched an action plan to deliver the HITF outputs, involving stakeholders from the Government and its agencies, industry, the health and social care services in England, patient groups and others.

The central theme that emerged from the HITF's deliberations was how to improve the adoption of beneficial new medical technologies by the NHS and social care services. Making this happen more quickly and with greater consistency was crucial to achieving the HITF goals. The HITF recognised that although innovative technologies are often more expensive, the benefits – clinical and financial – that occur further downstream needed to be taken into account. A better understanding of the value of innovation would encourage uptake and help counter the NHS' tendency towards short-term approaches to procurement. This would in turn stimulate trade and innovation in the industry, create a significantly more competitive domestic market and make beneficial, state-of-the-art treatments more readily available to patients.

It is notable that the aforementioned reports place a heavy emphasis on adoption and diffusion as being exogenous to the NHS, which seemingly has little to do with the development of technologies and innovation processes. It may be worthwhile to consider changing this narrative into one that makes the NHS more involved in the innovation process to ensure that technologies are more relevant and taken up effectively. It is this more active involvement that the HTCs are attempting to mediate.

1.2 Healthcare Technology Co-operatives

The HTCs emerged out of the HITF's discussions on research and development (R&D) issues. Specifically, the HTCs were established to fulfil a recommendation of the HITF by supporting clinically-driven, innovative new technologies as part of collaborative ventures that harness the expertise of medical workers in the NHS, academia and industry. HTCs developed from the HITF's recognition of the need for a forum to sponsor high levels of interaction between clinical users of technologies, academia, inventors and developers. The HTC pilot initiative has to create a model for engagement between the NHS, industry and academia to identify unmet needs for new technologies.

The HITF defined a HTC as: *'[...] a clinician-led formal, but responsive, collaboration between clinicians, patients, academia and industry which acts as a focus for 'technology pull' into the NHS. Based in an NHS Trust, it is a national resource, established to address areas of unmet clinical need, where innovations in treatments and technologies have the potential to make a high impact by both reducing morbidity and improving quality of life for a large*

*population of patients; and improving the effectiveness of the health and care services supporting them.*¹³

In May 2006, the Healthcare Technology Co-operative Working Group's Final proposals on HTC pilots for the HITF Strategic Implementation Group endorsed this definition of a HTC, adding that *'The importance of the collaborative element of HTCs has been emphasised and hence it is recommended that collaborating Trusts (HTC 'nodes') are identified and involved at the inception of the pilot HTC.'*¹⁴ The pilot initiatives were intended to facilitate an environment where clinician-led collaborative teams, involving users/patients, industry, and academia, can act as 'a national resource', benefiting both health and wealth agendas.¹⁵

Importantly, the value of collaboration between academia, the medical profession, and industry to innovation in medical technology and devices is widely established in the literature and the HTCs evolved as a response to this.

A number of challenges face the pilot HTCs:

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

The National Institute for Health Research (NIHR) and the Technology Strategy Board (TSB) with support from the Engineering and Physical Sciences Research Council and the Medical Research Council agreed to invest up to £250,000 a year for five years in each of the two pilot HTCs.

1.3 The economic and social value of health research

1.3.1 Observations and measurement approaches

The medical technology industry in the UK is extensive, diverse and innovative. It covers a wide range of medical consumables, hospital supplies and equipment, devices used in the community and services. It is a significant component of the UK economy and has

¹³ Healthcare Industries Taskforce. *Healthcare Technology Co-operative Working Group: First report to the Healthcare Industries Task Force Strategic Implementation Group*. November 2005. [Available at: <http://www.advisorybodies.doh.gov.uk/hitf/sigmeeting231105overview2.pdf>].

¹⁴ Healthcare Industries Taskforce. *Healthcare Technology Co-operative Working Group's Final proposals on HTC pilots for HITF Strategic Implementation Group*. May 2006. [Available at: <http://www.advisorybodies.doh.gov.uk/hitf/htcpilotproposals.pdf>]

¹⁵ National Institute for Health Research. *NIHR Invention for Innovation (i4i) Programme: Healthcare Technology Cooperatives*. [Available at: http://www.nihr-ccf.org.uk/site/docdatabase/i4i/i4i_fs_docs/i4i%20HTC%20text.pdf]

potential for considerable growth.¹⁶ The industry in the UK consists of approximately 4,800 companies, with 85 per cent having a turnover of less than £5 million per year.¹² It employs in excess of 55,000 people, has combined annual sales of £6 billion, and accounts for £3 billion of export earnings.¹⁷ Advances in technology and medical science will open up new opportunities – and with them public expectations – but also create new cost pressures.

In its assessment of the use of medical technologies in the NHS, a House of Commons Health Committee found that methodologies are needed that can determine the social and economic benefits of new medical devices that fall outside the direct costs to the NHS.¹⁸ For example, it identified the need to develop new ways of evaluating the qualitative benefits of new medical technologies in the long-term budgetary cycles. Whilst it did not go so far as to specify health gains in areas like patient satisfaction, dignity, comfort and well-being, these are now beginning to be addressed through the 2011 NHS Operating Framework.

Medical research contributes in two different ways to society: directly by improving population health, and indirectly through economic improvement. According to one source, four types of measures must be considered when evaluating the benefits of medical research:¹⁹

- Measuring the intrinsic value to society of the health gain.
- Measuring the direct cost savings that could arise from research leading either to new treatments or to developments such as vaccines or new devices that reduce the number of patients needing treatment.
- Measuring the value to the economy of a healthy workforce that leads to the avoidance of lost production.
- Measuring the gains to the economy in terms of product development, consequent employment and sales.

The first two represent the health gains of medical R&D; they can be approximately measured by an indicator that economists developed in the sixties to perform a cost-effectiveness analysis: Quality Adjusted Life Years (QALY).²⁰

The second two can be summarised in monetary terms as the impact of medical R&D expenditure on the economy (GDP). The *spillover* effect is included: investment in medical

¹⁶ House of Commons Health Committee. *The Use of New Medical Technologies within the NHS: Fifth Report of Session 2004-05*. 2005. [Available at: <http://www.parliament.the-stationeryoffice.co.uk/pa/cm200405/cmselect/cmhealth/398/398i.pdf>].

¹⁷ ABHI. 'UK's medical technology industry has hit £3bn exports.' *ABHI press release*. 10 February 2005

¹⁸ House of Commons Health Committee. *The Use of New Medical Technologies within the NHS: Fifth Report of Session 2004-05*. 2005. [Available at: <http://www.parliament.the-stationeryoffice.co.uk/pa/cm200405/cmselect/cmhealth/398/398i.pdf>].

¹⁹ M. Buxton, S. Hanney, and T. Jones. 'Estimating the economic value to societies of the impact of health research: a critical review.' *Bulletin of the World Health Organization* 82 (2004): 733–739.

²⁰ H. Klarman, J. Francis, and G. Rosenthal. 'Cost effectiveness analysis applied to the treatment of chronic renal disease.' *Med care* 6:1 (1968): 48-54.

research by one organisation, public or private, may benefit not only that organisation but also other organisations in the medical sector, in other sectors, and also in other countries.

Cost effectiveness analysis (CEA) is a way to summarise the health benefits and resources used by health programmes in a single indicator. It summarises all programme costs into one number, all programmes benefits into a second number, and it prescribes rules for making decisions based on the ratio between the two (see Appendix C for details).

One issue that complicates the evaluation of innovation in medical devices is changes in the uses of existing devices. Blurring the boundaries between developing new devices in a way that is useable, and developing techniques for using existing devices has important implications for measuring the contributions of R&D for new technologies. Much of the benefit of new technologies comes from the skills and experience accumulated by users in other parts of the health system. Therefore, improvements in health care depend not only on producing better technologies, but also on using technology better.²¹ The other side of the coin is that having a skilled workforce that is capable of using technologies better is also more likely to help develop new technologies.

Although technological innovation can improve health outcomes, the precise magnitude of its contribution and its value are not easily measured. Correlations have been observed between improvement in heart attack outcomes over time with spending on medical products and services, and contradictory reports on the benefits of technology spending have been explained by stressing the differences in regional practice patterns in response to constraints.²² In contrast, it has been argued that it is not a choice between valuable but inexpensive care and more costly care with worse outcomes, but '*a choice between responses to regional inefficiencies.*'²³

1.3.2 Insights from innovation literature

The innovation literature offers some important insights that are relevant for an evaluation of medical devices. It has been recognised for a long time²⁴ that innovation depends on two broad forces: a set of supply-push factors, which increase the knowledge base required for innovation, but also a set of demand-pull factors which articulate economic demand and societal needs. The second key insight from the literature is that the balance of these two broad forces is highly variable by sector.²⁵

The innovation literature later developed frameworks that went beyond simply presenting a list of supply-push and demand-pull factors to say that the way the two forces interacted with each other over time was crucial to explaining how innovations come about²⁶.

²¹ Alan M. Garber. 'Perspective: To Use Technology Better'. *Health Affairs* 25 (2006): 51–53.

²² J.S. Skinner, D.O. Staiger, and E.S. Fisher. 'Is Technological Change in Medicine Always Worth It? : The Case of Acute Myocardial Infarction.' *Health Affairs* 25 (2006): 34–47.

²³ David M. Cutler. 'Perspective: Making Sense of Medical Technology'. *Health Affairs* 25 (2006): 48–50.

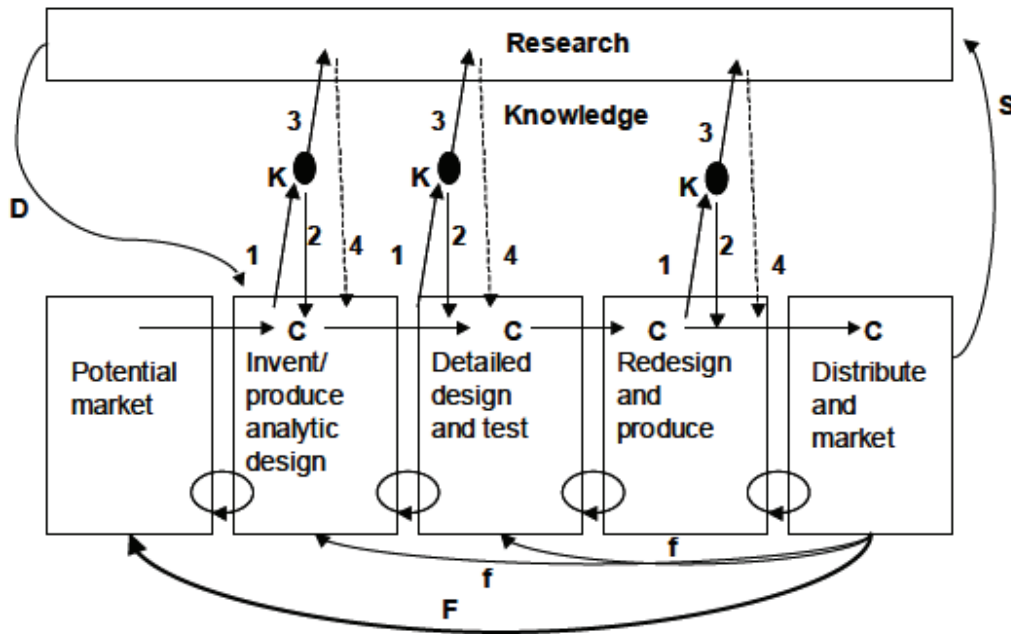
²⁴ Kline, S. and N. Rosenberg. 'An Overview of Innovation.' In R. Landau and N. Rosenberg. *The Positive Sum Strategy: Harnessing Technology for Economic Growth*. Washington DC, National Academy Press, 1986.

²⁵ Pavitt, K. (1984). "Sectoral patterns of technical change: Towards a taxonomy and a theory." *Research Policy* 13(6): 343-373.

²⁶ R. R. Nelson, and S. G. Winter. *An Evolutionary Theory of Economic Change*. Cambridge, MA: Belknap, 1982.

Importantly, these two forces were thought to interact in a process that is profoundly non-linear²⁷. As the diagram below shows, this is a point that some scholars went to great lengths to emphasise.

Figure 1 The Chain linked model - Innovation is a non-linear process with (lots of) feedback loops



Source: Kline and Rosenberg 1986.

This recursive and iterative growth of technical knowledge involves scientific understanding, technical expertise, market knowledge, skills, techniques and routines.²⁸ Much of the list cannot be articulated and codified into information that can be easily understood by others.²⁹ This all has important implications for an evaluation of medical device innovation organisation.

The first is recognition that innovation in medical devices is different from innovation in other areas of health and medicine, particularly pharmaceuticals. There are major differences in who does the R&D, the nature of that R&D, and the public policies that affect it. For example, a direct comparison of the device industry with the drug industry shows more ‘*smaller companies taking the lead, a more fluid innovation process, and looser regulations on medical devices.*’³⁰ It may be the case that the need to access the market where patients and clinicians are situated is more important and amenable to smaller companies.

²⁷ S. Kline and N. Rosenberg. ‘An Overview of Innovation.’ In R. Landau and N. Rosenberg. *The Positive Sum Strategy: Harnessing Technology for Economic Growth*. Washington DC, National Academy Press, 1986.

²⁸ G. Dosi. ‘Sources, Procedures, and Microeconomic Effects of Innovation.’ *Journal of Economic Literature*. 26:3 (1988): 1120.

²⁹ N. von Tunzelmann, F. Malerba, P. Nightingale and S. Metcalfe. ‘Technological paradigms: past, present and future.’ *Ind Corp Change* 17:3 (2008): 467-484.

³⁰ Alan Kahn. ‘The Dynamics of Medical Device Innovation: An Innovator’s Perspective.’ In Annetine C. Gelijns and Ethan A. Halm, eds. *The Changing Economics of Medical Technology*. Institute of Medicine, 1991.

The capabilities that large firms bring may not be needed as much or not needed until medical devices become very technologically complex.

In an analysis of the innovation literature, one might offer that medical device development requires more skills and techniques in the way that they are used than, for example, a pill that needs to be swallowed at the right times of the day. This emphasis on skills and techniques of use means that there is likely to be a greater need to engage with clinicians and patients through the medical device development process. These notions have been highlighted by scholars using terms such as ‘user-innovation’ or ‘open innovation’.³¹ The question that is pertinent for this evaluation is how that body of knowledge, emanating from those that are situated near practice and use, can best be fed into the innovation process.

Recent studies have increasingly recognised the relevance of external sources of innovation. In addition to relying on internal R&D, organisations are reported to increasingly engage in ‘open innovation’ and user led innovation.³¹ Innovation is increasingly regarded as resulting from distributed inter-organisational networks, rather than from single firms.³² A recent report by the Royal College of Physicians identifies the need for ‘*solid collaboration*’ between the medical profession, academia, and industry. It observes that changes to the regulatory environment in the UK, shifts in NHS priorities, and various competitive forces from abroad mean that now, more than ever, the partnership established between physicians, industry, academia and the NHS needs to be improved if the place of the NHS in R&D is to be sustained.³³

The innovation literature is clearly not alone in citing the importance of collaboration, and many other bodies of literature, including policy literature, have resonated strongly in emphasising the need to collaborate. However, it is not always clear whether we should simply be collaborating more or whether we should be collaborating more effectively, particularly as there are some significant barriers to effective collaboration. For example, a Royal College of Physicians report identified a failure of trust between the NHS and industry as well as issues in the relationship between industry and the medical profession: ‘*Well respected physicians contend that continuing professional development programmes are too dependent on industry support, while the industry cites widespread ambivalence within the NHS and academia towards working with them as a key obstacle to future innovation.*’³⁴

Furthermore, the report argued that the UK's recent comparative advantage in medical research has now been lost to European competitors, and it advocates the introduction of more proactive research leadership - clinically and managerially - within the NHS,

³¹ E. von Hippel. *Democratizing Innovation*. Boston MA: MIT Press, 2005; H.W. Chesbrough, H. W. *Open innovation: the new imperative for creating and profiting from technology*. Boston, MA: Harvard University Press, 2003.

³² R. Coombs, M. Harvey and B. S. Tether. ‘Analysing distributed processes of provision and innovation.’ *Industrial and Corporate Change* 12:6 (2003): 1125-1155; W.W. Powell, K. W. Koput, L. Smith-Doerr and J. Owen-Smith. ‘Network Position and Firm Performance: Organizational Returns to Collaboration in the Biotechnology Industry.’ *Research in the Sociology of Organizations* 16 (1999): 129-159.

³³ Royal College of Physicians. *Innovating for Health: Patients, physicians, the pharmaceutical industry and the NHS. Report of a Working Party*. February 2009.

³⁴ Ibid.

alongside a better alignment of incentives to promote and sustain research and research careers.

In the academic sector, some of the economic and social benefits of universities, such as educating cohorts of graduates, generating scientific knowledge and creating instrumentation infrastructures, have long been recognised as an important source of industrial innovation.³⁵ The concepts of open, networked and interactive innovation, however, would suggest that active relationships between universities and industry – rather than structural links – play a stronger role in generating innovations.³⁶

The innovation literature also identifies a number of factors that influence the pace of diffusion of technology, such as financial reimbursement for using the technology or restricted Government-controlled budgeting.³⁷ For example, ‘*in restricted budgeting environments, such as with Canada and the United Kingdom, a new technology will diffuse only after cost-benefit analysis shows significant improvement over existing technology and then only minimally, rationing the amount of technology available.*’³⁸

1.3.3 R&D spillovers

Health gains, although the most important, are not the only benefit to societal well-being when R&D is developed in the medical sector; the overall economic gains are a second aspect that should be considered.

Benefits in other areas of economic activity can arise because investment in medical research by one organisation, public or private, may benefit not only that organisation but also other organisations in the medical sector, in other sectors, and also in other countries; these are what the economics literature refers to as *spillovers*.

When public research (R&D carried out or funded by public and charitable organisations) and private research (R&D carried out by privately owned enterprises) is performed, new products and new services are generated. These outputs tend to improve productivity and generate additional wealth as measured by the economic indicator - gross domestic product (GDP). Where innovations may not affect GDP, they can often serve other social purposes that are not captured by traditional economic indicators.

An overall conceptual framework of how public research generates GDP and economic rent for UK residents can be found in Appendix D.³⁹ However, some ideas stand out.

³⁵ C. Freeman. *The Economics of Industrial Innovation*. London: Penguin, 1982; K. Pavitt. *Technology, Management and Systems of Innovation*. Cheltenham: Edward Elgar, 1999; A.J. Salter and B.R. Martin. ‘The economic benefits of publicly funded basic research: a critical review.’ *Research Policy* 30:3 (2001): 509-532.

³⁶ Markus Perkmann and Kathryn Walsh. ‘University–industry relationships and open innovation: Towards a research agenda.’ *International Journal of Management Reviews* 9:4 (2007): 259-280.

³⁷ E. Rogers. *The Diffusion of Innovations*. New York: Free Press, 2003; T. Greenhalgh, G. Robert, F. MacFarlane, P. Bate and O. Kyriakidou. ‘Diffusion of innovations in service organizations: Systematic review and recommendations.’ *Milbank Q* 82 (2004): 581-629.

³⁸ Mary Cain and Robert Mittman. *Diffusion of Innovation in Health Care. Prepared by Institute for the Future*. California Healthcare Foundation, May 2002.

³⁹ HERG, OHE, Brunel University, RAND Europe. *Medical Research: What’s it Worth? Estimating the economic benefits from medical research in the UK*. London: UK evaluation forum, 2008.

The empirical literature, particularly in the medical and biotechnology sectors, has focused primarily on quantifying how much private R&D is generated by publicly-funded R&D. Recent studies based on US data show that basic medical and applied clinical research funded by public agencies, mainly undertaken in university and not-for-profit laboratories, stimulates and supports private investment on R&D in the pharmaceutical and biotechnology sector.^{40 41} Similar arguments have been presented by the US Congressional Budget Office: “*It is seldom possible to identify particular cases in which the private sector would have performed research if the Government had not. Thus, most of the available empirical evidence is based on aggregate studies. On balance, that evidence suggests a positive relationship between public and private pharmaceutical R&D.*”⁴²

The literature provides empirically-derived quantitative estimates of this effect in two stages. First, it estimates the amount of private medical R&D stimulated by public medical research, as well as public research more generally. Second, it attempts to express this extra private research stimulated by public research in terms of a pecuniary effect on GDP.

In the US, it was found that a 1 per cent increase in basic research expenditure by the National Institutes of Health (NIH) leads to a 1.69 per cent increase in pharmaceutical industry R&D with a lag of eight years.²⁰ Public clinical research expenditure has a lower impact in that a 1 per cent increase in public clinical research expenditure leads to 0.4 per cent increase in private pharmaceutical industry R&D during a period of three years. It is thought that for every \$1 spent in public clinical R&D in a year, a further \$2.35 is generated in private pharmaceutical R&D.

In the UK, a 1 per cent increase in public research expenditure leads to 1.05 per cent increase in private medical industry R&D. This indicates that a £1 increase in public spending on biomedical and health research can be expected to increase private pharmaceutical industry R&D spending by £2.20 to £5.10 in the UK. In turn, this additional private R&D is expected, based on a range of studies, to yield a total social rate of return of approximately 50 per cent to the national economy as a whole. This means that the £1 invested in private R&D now can be expected to yield a stream of future benefits to the economy as a whole that are equivalent to £0.50 per year in perpetuity.⁴³

However, these figures need to be interpreted with a considerable degree of caution. Many of the empirical studies on which the calculations are based draw on US data from as far back as the 1950s and relate to the agricultural sector.⁴⁴ Even where empirical data does relate to the pharmaceutical sector, the context of medical devices is likely to be significantly different. For example, even where firms are large enough to capture all the spillovers in research from one device to another, they may still find it difficult to monetise

⁴⁰ A. Toole. *The impact of public research and industrial innovation: evidence from the pharmaceutical industry*. Stanford Institute for Economic Policy Research, 2000.

⁴¹ A. Toole. ‘Does public scientific research complement private investment in research and development in the pharmaceutical industry?’ *Journal of Law and Economics* 50 (2007): 81–104.

⁴² Congressional Budget Office. *Research and Development in the Pharmaceutical Industry*. London: CBO, October 2006. 31.

⁴³ HERG, OHE, Brunel University, RAND Europe. *Medical Research: What’s it Worth? Estimating the economic benefits from medical research in the UK*. London: UK evaluation forum, 2008.

⁴⁴ Z. Griliches. ‘Hybrid Corn: An Exploration in the Economics of Technological Change.’ *Econometrica* 25:4 (1957): 501–522.

some of the benefits of these devices. Benefits, such as dignity and comfort, are not likely to show up in econometric calculations, and the social value of not allowing anyone in society to suffer certain indignities would need rather different tracking methods.

1.4 Chapter summary

This chapter began by providing the policy context from which the need for a HTC evaluation, and indeed HTCs themselves, came about. The Wanless review identified medical technologies as a significant source of increased costs, and a House of Commons Health Committee Report highlighted the importance of assessing their clinical efficacy and cost-effectiveness. The Wanless Review and a number of NHS Plans also indicated that the NHS was slow to adopt new medical technologies, but conceded that ensuring the safety of new medical technologies were very important. The HITF is a collaboration that is intended to address each of these five concerns: a steady supply of new medical technologies; speedy adoption; safety; clinical efficacy; and cost effectiveness.

The second part of the chapter described how HTCs were conceived and how a pilot initiative was established. The HITF defined a HTC as: *'[...] a clinician-led formal, but responsive, collaboration between clinicians, patients, academia and industry which acts as a focus for 'technology pull' into the NHS.* It was hoped that HTCs could act as a national resource, benefiting both health and wealth.

The third section described approaches to observe and measure the contribution that these pilot HTCs might be making. A brief excursion into the scholarly innovation literature found some important concepts that can serve as an important backdrop to any evaluation of a HTC. It identified the medical device innovation process as highly non-linear, where users (patients and clinicians) play critical roles, but their knowledge and input has to come together with complex technical and market dynamics. It also indicated that investments in HTCs might have spillover benefits that extend beyond the more straightforwardly measurable health gains.

2.1 **Introduction**

As the HTC scheme was intended to focus on medical devices, this review also explored how medical device development is being pursued in England, Australia and the USA. The key question guiding this exploration was whether the institutional relationships initiated in those countries are contributing to their health research systems and, related to this, if the English HTC scheme is the most effective way of pursuing these relationships. Whilst in most cases we find that new conversations and collaborations are occurring, the question remains about their ability to influence the wider health system.

It should be noted that this is an area where there is limited peer-reviewed literature and our analysis of relevant initiatives taking place elsewhere must be considered in light of this caveat. However, we still consider it useful to explore these programmes in the spirit of real-time evaluations, even if that means a certain loss of robustness in the provision of timely evaluations.

2.1.1 **Australian Co-operative Research Centres (CRC) Programme**

Background

A similar initiative to the UK HTCs exists in Australia where pilots were undertaken in two hospitals. The rationale behind the Australian model was to ‘*catalyse the process of developing new technologies*’ in areas of research that have traditionally been under-funded. The Australian programme is backed by both their Ministry of Health and their Ministry of Science and Innovation. As with the UK model, the Australian programme brings together clinicians, scientists, engineers and business people to focus on unmet patient needs.⁴⁵ The HITF literature discusses lessons learned from the Australian model, particularly in relation to the time lags between the set up and delivery of innovative products, a process that took nine years in the case of the Australian HTCs.

The Cooperative Research Centres (CRC) Programme was established in 1990 to improve the effectiveness of Australia’s research and development effort by linking researchers with industry to focus R&D efforts on progress towards utilisation and commercialisation. The Australian model is thus at a much later and more developed stage than the UK-based

⁴⁵ Medical Technology Association of Australia. *Review of the National Innovation System*. April 2008. [Available at <http://www.innovation.gov.au/innovationreview/Documents/96-MTAA.pdf>]

HTCs. Since the CRC Programme began, there have been nine CRC selection rounds, resulting in the establishment of 158 CRCs over the life of the Programme. More than \$9.6 billion has been committed to the CRC Programme since it started, including \$2.2 billion from the CRC Programme, \$2.6 billion from universities, \$1.8 billion from industry, and more than \$1 billion from CSIRO.⁴⁶

The 2006 Programme Guidelines state that the measure of successful CRCs will be ‘the extent of the contribution that they will be able to make to Australia’s industrial, commercial and economic growth.’⁴⁷

Observations of General features⁴⁸

The objective of the CRC Programme is to deliver significant economic, environmental and social benefits to Australia by supporting research partnerships between publicly-funded researchers, industries and other end-users to address clearly articulated, major challenges that require medium- to long-term collaborative efforts.

Since 1990, 185 CRCs have been funded or approved for funding. The Australian Government has committed more than \$3.3 billion in CRC Programme funding. Participants in CRCs have committed a further \$10.8 billion in cash and in-kind contributions.

Of the 48 CRCs currently operating across Australian industry sectors, there are 8 medical services and technology CRCs. CRCs are national collaborative ventures that provide important frameworks for bringing industry, community, Commonwealth and state governments, and university and other researchers together to focus on solving major challenges.

CRCs have developed innovative structures to make it easier for small to medium enterprises to collaborate. As well, the CRC model allows different consortia to pursue different mixes of economic, social and environmental outcomes. For example, some medical science and technology CRCs are highly commercially oriented, while others have a strong public good focus.

Once a CRC has completed its maximum funding period within the CRC Programme, it must exit the Programme. A range of alternative funding options is available to CRCs, and they are encouraged to pursue these. These include becoming self-funded, accessing complementary Government innovation programmes such as the Australian Research Council Centres of Excellence, or seeking to become a part of another organisation such as a university.

⁴⁶ Collaboration Working Group of the National Innovation System Review. Collaborating to a purpose: Review of the Cooperative Research Centres Program. July 2008.

⁴⁷ Australian Government: Department of Education, Science and Training. *Cooperative Research Centres Programme: 2006 Selection Round Guidelines for Applicants*. 2006.

⁴⁸ Source: Paper-based version of interview questions completed by Toni Dam and Jacinta Cortese in April 2010.

Observations of Specific activities

CRCs must involve end-user driven research pathways that result in measurable economic, social or environmental benefits. When assessing applications from prospective CRC consortia during a selection round, the Department seeks advice from relevant Commonwealth agencies particularly in relation to whether the agency supports the application, whether it addresses key priorities, and whether it duplicates or complements other initiatives.

CRCs engage in both radical innovation and incremental innovation, however CRC funding is contingent on the satisfactory outcomes of rigorous reviews by an independent panel of experts. CRC applications are evaluated based on research, results and resources.

The CRCs themselves can add criteria. For example, the HEARing CRC also looks at the environment and context in which their proposed research will be taking place to ensure that they are not undertaking '*me too*' type of research or even research on the periphery of a field. They undertake environmental scans to identify niches that are yet to be explored/exploited, areas where there are currently no existing products or services, or places where savings could be made. While at the Oral Health CRC, collaboration between CRC staff and industry partners is vital in developing and selecting projects.

Research risk is minimised through the use of key criteria to ensure that research is end user driven and will bring a benefit to Australia. An element of the application process, called the 'Impact Tool', provides CRC applicants with an open and transparent way of consistently assessing these benefits and involves a risk assessment that is taken into account when calculating the impact of the CRC. The 'Impact Tool' enables CRCs to make a realistic, transparent and defensible assessment of the monetary and non-monetary impact of the proposed research programmes.

CRCs are encouraged to engage globally. Currently, CRCs have 516 alliances with at least 56 nations. International engagement can include research collaboration, education/training partnerships, commercial licensing, conferences, consultancies and other activities.

These international collaborations are not restricted to industrialised countries. For example, in 2008-09 the Vision CRC reported 29 collaborations with 12 countries, including Cambodia, Mongolia, Sri Lanka and Swaziland. The aim of this CRC's research programme is to establish Australia as a world leader in research, education and to deliver vision correction by improving international eye-care and maximising commercial opportunities for the CRC, Australia and the eye-care industry.

Within Australia, CRCs may also work with organisations with specific community-oriented or social objectives. As of November 2009, 24 not-for-profit organisations are participants in CRCs; 16 of these are in Health CRCs. If the CRC decides to pursue new directions as a result of unexpected outcomes, they are able to amend their Commonwealth Agreement (contract with the Australian Government) to include new Activities, new Participants or to adjust timeframes for milestone completion. CRCs are able to undertake activities outside of their agreement with the Australian Government as long as CRC grant funding and contracted Participant funding is not used. CRCs are able to produce commercial spin-off companies, consistent with the arrangements outlined in their Participant Agreements (agreement between the collaboration partners).

2.1.2 CIMIT⁴⁹

Background

CIMIT (Center for Integration of Medicine and Innovative Technology) is a non-profit consortium of Boston teaching hospitals and engineering schools. It fosters interdisciplinary collaboration among world-class experts in medicine, science and engineering, in concert with industry and Government, to rapidly improve patient care.

CIMIT 'Site Miners' are a critical element in how the consortium identifies and connects clinical champions with scientists and technologies. 'Site Miners' are well-established professionals on the staff or faculty of the CIMIT Member institutions (the "Site"). These individuals are paid by the Site (on a part-time basis) to serve as a liaison between the Site and the CIMIT Consortium.

The 'Site Miner' is a scout, mentor, project manager, matchmaker, dealmaker, visionary, and reality tester. Each strives to improve connectivity between clinicians with unsolved clinical problems and scientists/engineers with potentially useful technology. The overarching responsibility of the 'Site Miner' is to ensure that the Site benefits from all expertise and resources of CIMIT and to guarantee each Site is thoroughly mined for opportunities to rapidly translate enabling technology into healthcare.

CIMIT operates by identifying entrepreneurial clinicians and engineers from among the over 40,000 doctors and 20,000 technologists who work at the CIMIT consortium institutions. It provides these innovators with resources to explore, develop and implement novel technological solutions for today's most urgent healthcare problems. CIMIT is dedicated to helping develop medical technology that will aid both military and civilian patients.

CIMIT is funded by the Consortium institutions and public donations.

Observations of General features⁵⁰

CIMIT is a 12-year-old consortium, with 120-150 concurrent projects, that funds early high-risk research. It focuses on devices and procedures that will change the delivery of healthcare. They have a heavy emphasis on US Department of Defence needs, as well as healthcare at large. The consortium includes 12 of the leading teaching hospitals and universities across Boston.

They believe that their value-added is that no project is funded without an engineer or a clinician working together to solve a patient care problem. The focus is on clinical need. The 'virtual consortium' business model is meant *'for the good of all'*, so that the young innovative investigators of member institutions, who are otherwise competitors, can work together to change healthcare. The model is about collaboration that would not be possible in other circumstances.

⁴⁹ Source: CIMIT website. Accessed on May 10, 2010. [Available at: <http://www.cimit.org/>].

⁵⁰ Source: Interview with Colleen Kirgin on March 11, 2010.

CIMIT only gets involved in early innovation to prime them for other funding sources. They do not want to replace the NIH, charitable foundations, or industry-sponsored research. They want to be a niche for projects that cannot get funding otherwise and need to get to a proof of principle or prototype, which makes them eligible for other funding.

Overall CIMIT believes that its model influences individual careers, collaborations and individual approaches to care that would not have happened otherwise.

Observations of Specific activities

All applications for funding must have interdisciplinary support. After a strict science review and selection, CIMIT supports the applicants as the project progresses, but actively monitors if the original innovative idea is worth pursuit or if it does not work. CIMIT claims to focus on disruptive innovation, so does not fund incremental research.

CIMIT works with the researchers during a project and supports their efforts to collaborate with industry and ask for other outside funding. CIMIT uses industry to determine the value of the product, identify any interest in a licence, or indicate if further work is required.

Tacit knowledge of the review panels is important since CIMIT is looking for ideas that are not in the literature. The panels attempt to relate proposals to other work and look at the logic behind the promise. It is expected that some projects will fail; otherwise, there is an implication that project selection is not testing the environment of innovation.

CIMIT offers one year of project funding at \$100,000 and fund 50 new projects every year. Although many projects take two years to finish, they are reconsidered annually. An example of a spun-out technology is Optical Coherence Tomography (OCT). CIMIT funded the initial research of this technology for \$70,000 to build the first prototype. This funding resulted in a laboratory of 40 people and \$8 million a year in income.

2.1.3 **MIMIT**⁵¹

Background

MIMIT (Manchester Center for Integrating Medicine & Innovative Technology) is the first international affiliate of the CIMIT, based in Boston, USA. MIMIT is a joint venture of the University of Manchester and Greater Manchester NHS and Primary Care Trusts. It was founded to facilitate collaborations between clinicians, scientists, engineers and industry to develop innovative technology for patient benefit and is funded by its founding partners, with other Government sources being brought in as much as possible. MIMIT aims to broaden the scope and to accelerate the development of new healthcare technologies; thereby enabling new technologies to reach patients faster and more effectively. The primary focus of MIMIT is on unmet clinical need in relation to diagnostics, safety, prevention and restoring or improving health.

A key asset of MIMIT is its identification of senior representatives within each partner organisation to identify both clinical need and clinical exploitation potential in science and

⁵¹ Source: MIMIT website. Accessed on May 10, 2010. [Available at: <http://www.mimit.org.uk>].

engineering. These ‘Site Miners’ are the catalyst for forming collaborative relationships amongst clinicians, scientists and engineers. ‘Site Miner’ Meetings and MIMIT Forums give innovators in all disciplines an opportunity to both brainstorm ideas and build interdisciplinary teams.

MIMIT provides early investment in interdisciplinary translational developments. This enhances and accelerates opportunities for transfer of knowledge and expertise, and provides pump-priming catalytic grants for technology development. It also works closely with business and industry partners, as early engagement with industry provides a strong competitive advantage, particularly for small- to medium-sized technology-based enterprises.

Observations of General features⁵²

MIMIT is an international affiliate of US-based CIMIT, whose operating model is used. For example, their model relies on using ‘site miners’. However, MIMIT differs from CIMIT in having a closer partnership with IPR professionals. MIMIT helps the research team to leverage further funding/investment. This active help differs from CIMIT, where a project is let go once development is complete.

The main driver of MIMIT is the unmet needs of its NHS partner. MIMIT position themselves at the beginning of the innovation pathway by planning on 12 months of pump-priming a project before it is picked up by a NIHR Biomedical Research Centre or Unit. Their aim is to increase the pipeline for unmet needs and establish the right linkages early in the development cycle ‘*to improve quantity, quality and pace of development.*’⁵³

One of their success measures is the amount of follow-on funding raised by their projects. Over its first two years, projects have leveraged £500k of MIMIT funding to £5million (combined).

Among their partners, they work with the University of Manchester, Trustech (who provide a formal link with IPR officers), Academic Health Science Centres, the National Technology Adoption Centre, Medilink and BioNow.

Observations of Specific activities

The ‘Site Miners’ are the core project selection team and, together with IPR officers, make up the MIMIT operational team. The ‘Site Miners’ have protected time, funded by the partner organisation, and meet with all parties every three weeks. Most project options come from the ‘Site Miners’, although industry is increasingly coming to MIMIT for project scoping.

The use of tacit knowledge in project selection has created debate and discussion because the project selection group must validate opinions, but it ‘*generally fits into the selection process.*’⁵⁴

⁵² Source: Interview with Jackie Oldham on March 9, 2010.

⁵³ Ibid.

⁵⁴ Ibid.

MIMIT can make the decision to disinvest before the 12-month pump-priming period, if necessary. This can happen either if there are too many problems in a project, or if a project is developed faster than anticipated.

The majority of MIMIT projects are incremental research, but they have had three high impact applications, or what one source referred to as ‘killer’ applications:

- Point of Care testing for respiratory disease - a metabolic device that can help target right antibiotic to disease based on breath analysis
- Severed nerve – a tissue engineered nerve conduit
- Incontinence - a portable and disposable elective tampon

MIMIT is a partnership, not a legal entity, so it cannot interfere with IPR. This is a deliberate structure to avoid discouraging project participants and potential downstream investors.

2.1.4 Bristol BioMed⁵⁵

Background

The BioMed Health Technology Co-operative (HTC) was set up in April 2005 with funding from the Department of Health's Health Technology Devices (HTD) Programme. Its purpose is to accelerate the development and adoption of new technologies, treatments and devices for patients with intractable urinary incontinence. This is to be achieved through close collaboration and consultation between users – people with long-term indwelling catheters and their carers, industry, researchers and healthcare providers. Their approach to innovation hinges on a sound research base and good communication, with all parties being consulted at the earliest possible stage.

The HTD funding provided infrastructure support towards an initial three-year programme of research and innovation. This included studies on the needs and abilities of patients with long term indwelling catheters and the development of tools to compare cost effectiveness and quality of life. There is an ongoing programme designing and developing new products and testing them in our laboratory. Patients are then given the opportunity to try new devices through a clinical trial.

The BioMed HTC is an expanding network of doctors, nurses, continence advisors, researchers, users, user representatives, designers, consultants, manufacturers and others who have an interest in improving the healthcare and quality of life of people with this condition.

Observations of General features⁵⁶

Bristol BioMed started in 2005. HITF was still meeting when the application to the Health Technology Devices (HTD) programme for funding was submitted. It was realised

⁵⁵ Source: Bristol BioMed HTC website. Accessed on May 10, 2010. [Available at: <http://www.biomedhtc.org.uk/>].

⁵⁶ Source: Interview with Adele Long on March 10, 2010.

that the proposal appeared to describe a HTC, so it was initially called the BioMed HTC, even though it preceded the HTC pilots. The HTD support was infrastructure funding as opposed to project funding.

The HTD funding was expected to run for three years and there were specific deliverables, including working with industry. At the beginning, industry partners came with very specific projects; however, funding was insufficient to support all projects. Industry partners now contribute significant in-kind contributions toward their projects and recently have provided a further 50% match funding.

The Bristol BioMed HTC took the HITF report as '*an opportunity to stimulate the market*'.⁵⁷ This was done by publicising specific clinical needs and offering a place for people to develop their devices.

Successes during the initial funding period led to further work for other industry partners. In 2010, only two specific projects with initial Bristol BioMed partners are ongoing, while approximately 23 projects (some are sub-projects of projects) are with new partners. Bristol BioMed HTC is now starting to turn projects down or direct them towards D4D and is working with the latter on how things can be done over different sites.

Observations of Specific activities

Projects are sourced from many sources: companies, lone inventors, patients or carers with an idea or product developed for another use. Bristol BioMed wants to be the place for people to come and obtain a commercial judgement. Thus, Bristol BioMed sees itself as steering people down those routes that maximise the likelihood of success. This has ranged from doing some *in vitro* work to straightforward evaluation trials (i.e., testing incontinence pants on patients) and early clinical trials.

Half of Bristol BioMed partners are UK-based and half are European or American, with a mix of small companies and multinationals.

For project selection, Bristol BioMed prefers face-to-face meetings, rather than paper-based selection. Although this increases time and cost requirements, they believe that this allows a multidisciplinary team to discuss the different aspects of the project proposal. These aspects include technical and clinical feasibility, as well as personal interactions with the applicant.

Bristol BioMed considers one of its key services to be the provision of a microbiology laboratory and a neurophysiology laboratory to provide independent and robust methods for bench testing that allow for either the elimination or refinement of a technology at an early stage of development.

Bristol BioMed is '*very focused on delivering new technologies and devices and working with industry to do that*'.⁵⁸ It has established a centre for a very specific clinical area and work at being a delivery organisation.

Through experience, Bristol Biomed has learned that financial sustainability is built on delivering services and demonstrating added-value. Networking is difficult to charge

⁵⁷ Source: Interview with Adele Long on March 10, 2010.

⁵⁸ Ibid.

against. To date, the most valuable projects have been with companies that already had an idea and a first generation prototype, and they asked Bristol BioMed to help take the project further.

Turnover has increased from £200,000pa to £700,000pa, of which the proportion of funding from Government has been reduced from approximately 80 per cent to less than 50 per cent.

2.2 Lessons learned

2.2.1 Australian CRCs

The Government should actively consider the challenges and coping strategies submitted by CRCs in their Annual Reports. Prompt communication with CRCs on these matters is required. Leading up to the end of their funding period, CRCs are required to complete a wind-up plan, detailing how the CRC will wind-up its activities at the end of the grant period. The wind-up plan provides CRCs and Government with an opportunity to address any uncertainties they face upon completion of their grant funding term.

CRCs have different strategies in regards to their function after the completion of Government funding. Those with commercial spin-off companies will distribute the IPR developed by the CRC amongst participants as agreed in their Participant Agreement.

An explicit objective of CRCs is that they address '*major challenges that require medium to long-term collaborative efforts*'.⁵⁹ Thus, there is an assumption that the initial Government funding must continue for several years.

2.2.2 CIMIT

CIMIT has found it difficult to turn products around in three-five years, which they consider a very short timescale. However, they stay within that parameter in a deliberate attempt to be '*high and quick impact*'.

CIMIT feels that the financial sustainability of initiatives like theirs is a huge issue because it is not easy to continue to get core funding from philanthropic or similar sources that '*understand that their process is the right investment*'.⁶⁰

2.2.3 MIMIT

Since MIMIT is explicit about being a pump-priming facility, its main challenge has been finding funding to support speculative research. Although new partners have brought additional funding, MIMIT feels that to scale up, they will require core funding.

Although MIMIT has designed its selection procedures to develop confidence in project viability, there remains an uncertainty in understanding if there is a procurement pipeline for products.

⁵⁹ Source: Paper-based version of interview questions completed by Toni Dam and Jacinta Cortese in April 2010.

⁶⁰ Source: Interview with Colleen Kirgin on March 11, 2010.

MIMIT considers main lessons are to be selective in choosing key partner organisations and avoiding '*reinventing the wheel*' in project selection.

2.2.4 Bristol BioMed

Bristol BioMed has found that physical proximity is a factor in successful projects. Their academic partners, in particular, are often located nearby. This is partly due to the nature of their urine and pelvic floor specialty, since having fresh samples is key to some of the studies and tests.

Although Bristol BioMed claims to be struggling in terms of meeting demand, they feel that Government funding is still necessary to cover certain core expenses. These expenses relate to time spent working projects up. For example, staff act as reviewers on other NIHR funding streams or, due to working within a hospital, attend mandatory training and meetings. Other examples include the initial meetings with innovators, which require a half or full day for reading through the paperwork, and require '*face-time for advice and encouragement*'.⁶¹

Bristol BioMed feels that this is not incompatible with self-sustainability. From their perspective, these activities are in the public interest and therefore should be funded as such. Government funding is seen as a different funding stream for a different element of what they do, but that element is as important as the others.

2.3 Chapter summary

This chapter explored similar initiatives from around the world that could be used to relate observations and evaluations of the pilot HTCs.

The Australian CRC programme is a highly advanced and well-funded programme that has global reach in terms of its network of collaborations. It fits into a system where funding support is offered for a limited time, but then the wider system offers a reliable range of follow-up options. This allows small to medium organisations to participate with confidence.

CIMIT and its UK-based affiliate, MIMIT, receive less funding than their Australian counterparts and the scales of their programmes are smaller. They focus on individual innovations, identified through 'Site Miners' and seek to provide the resources and interdisciplinary support to turn such ideas into a prototype that can go on to find further funding. As such, it is a high-risk endeavour. MIMIT's projects so far have all been fairly incremental (though high impact), suggesting that all innovations in this field involve significant risks, and that key individuals and bright ideas are only a part of what is needed for innovations to come to fruition.

Bristol BioMed is an even smaller enterprise, with funding in hundreds of thousands, that seeks primarily to play an advisory role to those seeking to develop a device. In order for its ambitions to go beyond that, it is likely that it will need additional funding, akin to some of the programmes mentioned above.

⁶¹ Source: Interview with Adele Long on March 10, 2010.

3.1 **Introduction**

The key objective, from a HTC perspective, is ‘*to identify otherwise unmet clinical needs, design research projects to create technology solutions and apply to external funders for financial support for them.*’⁶² *Unmet clinical needs* was defined by HITF as: ‘*restricted to disorders associated with high morbidity, which place a large burden of care on the NHS and its interface with social care but which do not currently attract significant research funding or academic interest.*’³²

The two pilot HTCs chosen to receive funding were the Bowel Function Healthcare Technology Co-operative (*enteric*), and the Devices for Dignity Healthcare Technology Co-operative (D4D).

Since the purpose of the HTCs is to identify need and design the projects but then obtain funding from external partners, it is important to highlight the implication that it is pump-prime funding that is provided by the DH.

3.2 **Bowel Function HTC (*enteric*)**

3.2.1 **Background**

The Bowel Function HTC is hosted within the Centre for Academic Surgery at Barts and the London NHS Trust and School of Medicine and Dentistry with associated nodes in academic clinical units in Bristol, Edinburgh, Durham and Hull. Working together with industry and charities, the business plan is committed to identifying and developing new devices and procedures to improve the healthcare outcomes for those affected by disorders of bowel function. Initially, *enteric* is to focus activities on problems of the colon and rectum, including new technologies for the diagnosis and management of disorders of evacuation. Initial projects include an operative procedure to preserve the sphincter and avoid a permanent stoma in a particular group of patients better stoma care technologies; and a novel training system for healthcare professionals.⁶³ According to literature produced

⁶² D4D contract, 21 Feb 2008.

⁶³ National Institute for Health Research. *NIHR Invention for Innovation (i4i) Programme: Healthcare Technology Cooperatives*. May 2008. [Available at: http://www.nihr-ccf.org.uk/site/docdatabase/i4i/i4i_fs_docs/i4i%20HTC%20text.pdf].

by the Health Technologies KTN, the main aim of this HTC is ‘*to be the foremost national centre for the identification, development and implementation of techniques and technologies that improve healthcare and quality of life for those affected by problems of bowel function.*’⁶⁴

The initial project bid documented a business plan for *enteric* and set out a structure through which these objectives would be delivered in a scalable, cost-effective manner. This structure has been established and evaluated over *enteric*'s initial 18 months of operation. This initial period identified a number of weaknesses in implementation and operation that, if left unchecked, would inhibit *enteric*'s ability to continue to meet its primary objectives. These were addressed in the business plan for the next three years so as to allow *enteric* to fulfil its mission to become the leading national resource for the identification, development and implementation of technologies and systems to improve the treatment and quality of life of all those affected by disorders of bowel function.⁶⁵

3.2.2 *enteric* Interviews⁶⁶

Observations on general features

enteric sees itself as a cooperative based on interventional medicine. It is based around treatments involving patients that also involve technology. From *enteric*'s perspective, they follow a different R&D strategy compared to that of pharmaceuticals (i.e., not phase 1, phase 2, clinical trial, and randomisation).

enteric differentiates itself in two ways, with specific reference to the National Innovation Centre. First, their clinical focused and core team expertise earns them the respect of clinicians. Second, they are national and entirely independent. Thus, they intend to present project evaluations processed through one of their clinical centres as an impartial evaluation.

The core team who were involved in the original *enteric* proposal came from different perspectives: active surgical innovation and laboratory-based medical science. They believed that the intervention innovation landscape was fragmented and required a system for supporting the research process. As well, they noted that whilst industry was kept at arm's length from the NHS at an institutional level, there were still interactions at a personal level. On the basis of these personal interactions, and the value derived from them, it was felt that innovation could be moved faster with increased industry involvement.

Overall, the core team see the HTC concept as bringing interested parties together from the early stages in a collaborative and cooperative way. They are especially interested in bringing people together who did not previously know or work with each other.

⁶⁴ Mehdi Tavakoli. *An Introduction to HealthTech & Medicine Knowledge Transfer Network: Working Together to Support and Accelerate Innovation in Healthcare*. [Available at: <http://www.bath.ac.uk/research/bridging/docs/MTavakoli29-6.pdf>].

⁶⁵ Source: Bowel Function HTC website. [Available at: www.bowelfunctionhtc.org.uk].

⁶⁶ Source: Interviews with Mike Grahn and Norman Williams (during a site visit on March 30, 2010) and Michael Coleman (April 26, 2010).

enteric now has two near-to-market technology developments. The ostomy project has gone the furthest and has attracted just under a £1 million worth of funding from the TSB.

Observations on Specific activities

Structure

enteric has noted that a clinician is very often the innovator or at least the instigator of the technology. This means that the most likely major end user for many medical technologies, particularly for diagnostic ones, is engaged from the start. However, one problem noted by *enteric*, particularly within surgery, is that while clinicians are productive in ideas and needs, few of them are able to develop them into fully functional innovations. The *enteric* core team believes that, to a certain extent, the resistance to change is cultural, but also that clinicians are busy and this is a low priority. *enteric* seeks to cross that gap.

enteric have expanded the original number of partner nodes, which they felt were not enough as the original HTC plan assumed an in-house development model with a clinical partner. *enteric* wanted something that was ‘*more open and more failure proof*’, since they did not want to succeed or fail on the basis of one project. They are trying to sign up all the innovative bowel surgery units in the country (currently they have 12).

Process

enteric sees themselves as facilitators who can pump-prime, for example, an initial clinical evaluation to give enough confidence to support a grant application. But since those initial funds do not lead to a direct payback, they believe that those funds need to come from somewhere with a longer-term view.

For selecting projects, the core team (clinical director, deputy clinical director, and operations director) would discuss them and produce a little information package for each one. The information package includes market, quality of life gain, NHS gain, stakeholders, core stakeholder factors, amount of input needed from *enteric*, and the risk. In choosing projects, financial viability for whoever is bringing the innovation is important, but the prime criteria is actually benefit. Viability includes a product’s manufacturing process and marketability.

However, *enteric* claims not to have the resources to fund projects; rather they put them together and help them gain funding. *enteric* has a project status called the Technology Development Partnership (TDP) that is a group of people who have a defined aim over technology they want to develop. The TDP obtains the external funding to do the development and evaluation to, at least, proof-of-principle or clinical demonstration stage. There are now five TDPs,

Although *enteric* offers governance and direction to projects, the value of the technology resides within the TDP. Thus, they have a collaboration agreement where the baseline technology and development risk remains with the partners. However, if the technology is developed and then shared, *enteric* would have some royalty-generating ownership of the technology.

enteric feel that that their current project system is no longer sufficient. One reason is that they are getting bigger and have more project proposals. They feel they need to introduce

peer review and are ‘*latching*’ onto the hospital medical school peer review panels, supplemented with their own experts.

enteric stated that the main risk of minimal core development funding is the necessity of going to venture capital. In their view, that sort of business-led funding for early projects is difficult and is also less attractive for the partners involved because they see their interests being completely overtaken by the commercial interests.

Projects

Although *enteric* focuses on clinician-led technology, there are user-focused technologies in their field. Their first technology is the ostomy bag, which has required effort for scoping user needs and improving the product.

The ostomy bag is an area of need, according to *enteric*. After surgery for bowel cancer, there is often a big opening left that needs a bag on it to collect the waste that comes through. Regularly changing and emptying it has an enormous impact on patient lifestyles. There are about 100,000 people at any time in the UK with ostomy bags, so it is a large patient population. The patients bags have to be changed between once and four times a day; most people change them two or three times. This is a large cost to the NHS. If anything goes wrong with an ostomy, then the patient comes back to the clinic and extra healthcare is needed. However, the main burden is actually on the patient’s quality of life. As an *enteric* interviewee stated, ‘*There are some patients who carry on with life but, for a sizable minority, it is a sentence to living at home and never going out.*’ The estimated market for that project is, conservatively, £30 million over five years.

Another successful project is a surgical innovation called APPEAR (Anterior Perineal Plane for Ultra Low Anterior Resection). This method of lower bowel cancer removal makes it possible to reconnect the bowel so a patient can subsequently evacuate naturally. According to *enteric*, this could lead to approximately 20% fewer ostomies every year. This, in turn, would translate to thousands of people without the associated quality of life deficit. The operation depends on various tools and APPEAR has developed and marketed a new surgical stapler.

Looking forward, *enteric* will be setting up stakeholder panels. They are recruiting to them representatives from the national patient representative organisation and the ostomy association, as well as bowel and cancer researchers. However, they are also going to some self-formed patient groups (i.e., the Bishop Auckland Ostomy Group) and a local collaboration with the Bangladeshi community in Tower Hamlets.

enteric is also trying to tie in with the Royal College of Nursing and their professional networks. This resulted ‘*from a sense that it’s not just about surgeons, and even nurses in surgical departments, but it could apply right down to primary care, where issues revolve more around prevention*’.⁶⁷ *enteric* pointed out the importance of the nurse consultants who specialise in bowel function since, during the patient experience, a surgeon does a defined activity but the nurse consultants will do more in terms of patient education, patient support, and guidance. Hence, they are more likely to identify and be able to communicate

⁶⁷ Source: Interviews with Mike Grahn and Norman Williams (during a site visit on March 30, 2010) and Michael Coleman (April 26, 2010).

the problems faced by patients. These problems could then be the focus of future inventive efforts.

Training is a key activity for *enteric*. They explained that it is not enough to simply develop the invention because its handling and technique have to be taught as well. This becomes a step in the adoption process. During the training, surgeons are shown how the invention benefits the surgical procedure and that convinces them to use it. They become '*clinical champions*'.

The '*clinical champions*' are surgeons who carry out the trials of surgical innovations throughout centres in the UK. They are trained so that everyone is doing the same procedure, making comparative evaluations possible. For *enteric*, this results in the '*clinical champions*' supporting evidence based innovations, as opposed to new inventions being promoted by anecdote or personal connections to the inventing company.

Future

A main challenge for *enteric* is growth. From their perspective, as *enteric* grows and gains visibility, then more people will come to them with ideas. They believe that just keeping and maintaining the current TDPs is going to be a challenge. Their strategy is to expand the core team.

With respect to the issue of self-sustainability, *enteric* is trying to arrange a licensing agreement for APPEAR where part of the payments for it should flow back into *enteric*. In addition, winning more grants would support overhead costs and when their industrial partners start doing the clinical trial, they will have to pay *enteric*.

enteric is interested in both radical and incremental innovation. However, they stressed that there are important decisions to be made about not getting into a field that can be done better elsewhere. Their example was surgical robotics, which is high profile at the moment, and *enteric* felt that others are better placed to enter this field and secure funding to develop devices. The challenge for *enteric* is that many ideas have to be balanced against the delivery expectations of technology corporations. In a way, they feel that this limits their ability to innovate.

3.3 **Devices for Dignity HTC**

3.3.1 **Background**

D4D was developed to drive innovation from within the NHS by identifying the unmet clinical needs of patients, users and healthcare professionals. D4D's goal is to develop solutions to those needs using partnerships with academia and industry to provide fit for purpose devices that enhance independence and preserve dignity. D4D is based at the Sheffield Teaching Hospitals Foundation Trust (STHFT), with collaborators selected from Trusts and Universities across England, with a key aim of accelerating the development of innovative medical devices to the market. With industrial input, it aims to be a national resource focused on the design, development and evaluation of medical devices to improve healthcare quality and well-being for patients/clients with long-term conditions. Its chosen

themes for initial emphasis are assistive technology, urinary incontinence and continence management, and renal technology.

D4D's mission is to '*deliver innovative medical devices to support patients with long-term conditions, which preserve their dignity and independence.*'⁶⁸ The rationale for D4D is to deliver innovative medical devices '*which support and promote, and do not undermine, users' self-respect regardless of any difference*' and place the needs of their users (patients/clients/carers) at the centre of the design and development process. D4D is to focus on the design, development and evaluation of medical devices to improve healthcare quality and wellbeing for patients/clients. In addressing dignity and utility, D4D is to exploit a generic device development and evaluation methodology which crosses clinical boundaries and delivers healthcare benefits across the age spectrum. A key aim of D4D is to accelerate the development of innovative medical devices to the market.⁶⁹

3.3.2 D4D Interviews⁷⁰

Observations on General features

D4D considers the HTC concept to be about bridging the gap between industry and the NHS while having patient input. Their concept is of a one-stop shop that can be either a facilitator or a sign-poster or provider of technology development within the NHS is key for D4D. Their vision of the HTC is being able to define the unmet need and draw attention to it - particularly in unglamorous, and therefore underfunded, areas. As well, the HTCs are about '*trying to get things done*', rather than just putting people together.

The core activity is engaging the healthcare professionals who deal actively with patients. D4D puts together clinical experts with academics who have experience in subjects such as health economics or materials science, along with industrial partners, to develop new technologies and devices. D4D believes that HTCs are unlike other NIHR infrastructure initiatives such as Collaborations for Leadership in Applied Health Research and Care (CLAHRCs), Biomedical Research Centres (BRCs) or Biomedical Research Units (BRUs) that build on well-established scientific and academic research bases. The idea behind D4D was to be much more flexible as a cooperative rather than have fixed processes and deliver applied research to the end user.

Stakeholder engagement is quite broad and, having a small core team, all team members have access to the industrial partners, expert patients and healthcare professionals. Over time, D4D has evolved and become more mature and balanced in terms of stakeholder participation, with a stronger steering committee and patient focus. The latter was difficult in the early days, especially trying to find the routes and access to patients.

The aim in their early phase was to identify projects that could become '*quick wins*' and thus demonstrate their potential. D4D wanted to address the issue, cited in the HITF

⁶⁸ Wendy Tindale. *Devices for Dignity Healthcare Technology Co-operative*. [Available at: <http://www.medipex.co.uk/data/files/Word%20and%20pdf%20docs/Wendy%20Tindale.pdf>].

⁶⁹ National Institute for Health Research. *NIHR Invention for Innovation (i4i) Programme: Healthcare Technology Cooperatives*. May 2008. [Available at: http://www.nihr-ccf.org.uk/site/docdatabase/i4i/i4i_fs_docs/i4i%20HTC%20text.pdf].

⁷⁰ Source: Interviews with Chris Harris, Nicola Heron, Oliver Wells, and Wendy Tindale during a site visit on April 1, 2010.

Report, of device development taking up to ten years to come to market. This aim was met with quick to market technologies such as the halo traction device and the dignity commode. To balance their portfolio, D4D has accepted more complex projects such as the portable 'self care' portable home haemodialysis machine. This has raised over £9 million in investment funding and is expected to go into 'first in human' clinical evaluation at the end of 2010 or early 2011.

According to those we interviewed, people generally see the benefit of D4D immediately. In particular, healthcare professionals within the NHS have been very willing to contribute. Furthermore, D4D has set up their website to accept enquiries from a range of sources, and both patients and medical device companies are increasingly getting in touch.

D4D sees its uniqueness in being a multidisciplinary team embedded within the NHS, with easy access to the healthcare professionals that are dealing with daily problems. They have access to a broad range of NHS professionals, such as consultant researchers, nursing staff and carers.

D4D does not focus on a single clinical specialism and see their strength as crossing different clinical and age boundaries. Thus, they look at both elderly people and children's activities, hence the linkage with STHFT. Their core aim is patient dignity related to long-term conditions and making sure that, through their devices, patients preserve their dignity and independence.

Observations on Specific activities

Structure

D4D hired a Commercial Director at the beginning of its launch. Initially this outward facing role was to help negotiate the contracts and then put together the steering groups, the executive committees, the governance structure and the business plan. Now the role is the link to all the NHS Innovation Hubs, the NHS Adoption Hub, the medi-links and the Knowledge Transfer Networks (KTNs).

A Project Manager oversees the project selection process and ensures that procedures, timelines and budgets are maintained. The Project Manager is the point of contact for many enquiries and ensures that all relevant parties are involved in the flow of information. This mainly inward facing role was created since many of the D4D team are full time healthcare professionals who have allotted time to D4D. Formalising the input from their clinicians, that is paying for one day a week to do D4D activities, is very helpful.

Process

A big change has been the realisation that D4D will always have more demand than capacity, so a robust selection process is needed. Their operational structure looks at the potential for a device to affect patients' dignity and independence, quality of life, savings to the NHS, and impact on service delivery. However, strict processes need to be balanced against not losing the lone inventor who does not have immediate answers to all those questions. From the interviewees' perspective, this is D4D's niche: to bridge that gap between something that has development potential but is not yet quite ready.

D4D do not have to be centrally involved in a project. They mix facilitation with actually running collaborative projects. They input in a number of different places, from helping to

source funding to giving advice in medical device regulations, which is something that small companies can find confusing and difficult. Further benefit for industry includes access to patients, facilitation of the user-centred design, clinical validation, endorsement, and help with legal issues related to intellectual property rights.

D4D have engaged with a broad mix of companies to ensure that the small- to medium-sized enterprises are well networked with healthcare professionals and between each other. It is a diverse and growing pool that continues to attract companies. One of their stated achievements is to have built a large group of industrial contacts and people that are all aware of the clinical agendas.

The interviewees stated that most of their projects are coming from people who are already involved with them. One of the things D4D do is to use their clinicians to promote D4D through clinical networks, to be a national resource that new clinical people can get involved with through a network.

Although D4D try not to spend too much of their clinical sessions on projects that will ultimately not proceed, they still do a lot of the facilitation. For example, the initial healthcare professional feedback for a company with a new device for moving and handling patients without touching them was negative. D4D facilitated another opportunity for the device to be demonstrated to a different group of professionals who did see great value in the device. Thus, D4D was able to write a report on the probable patient sections. With the report, the company could revisit their health economics and seek venture capital funding because they have support from a population and a setting within the NHS. D4D therefore considers it important in their niche that innovations presented to them have at least some effort invested to develop an informed and constructive response, if only to signpost it to another organisation.

D4D want to bring economic analysis into the process, but since many of the ideas that come to them are early stage, they do not have the data to be able to use any of the 'plug and play' economic models. They have the 'Match' tool, which allows an assessment of the potential of a new medical device, but they try to limit its use to projects that have passed at least a few stages in their selection process. However, if something clearly shows an ability to make an impact on an unmet need and quality of life, then the economic analysis would not stop D4D from wanting to take on that project.

Projects

One of D4D's products, the Dignity Commode, has attracted £200,000 from the Regional Innovation Funds. This project will help them understand the dissemination and adoption barriers to take up by the NHS. They anticipate that this project will allow them to develop a 'generic' device adoption blueprint that can be used on devices coming through the D4D product development pipeline in the future. If successful, this tool would be a very powerful endpoint for D4D to be able to control the uptake of their devices. That ability would be an attractive aspect for industry as D4D could assist with the process of adoption.

Future

D4D interviewees were clear that they do not want to duplicate existing activities on the innovation landscape and so try to collaborate with other established programmes. For

example, they are in contact with clinical research units, BRUs (for academic input), clinical trials units (for assistance with clinical trials and evaluations), Medilink (an industry interface), and the NHS Innovation Hubs (for NHS Policy and IP expertise).

Working with other NIHR structures in the South Yorkshire region has come easily because D4D is very high profile and people want to be involved with them. The South Yorkshire CLAHRC has a technology arm, so D4D acts as a part of that technology arm. D4D have been granted an additional £600,000 from NHS Innovation to expand their capacity and the plan is to link up with structures that align with their themes. They plan to look proactively at the CLAHRCs and BRUs.

Their small proof of concept fund, from NHS Innovation, came from recognition that there is a period in the lifecycle of a device when it is too early to apply for a grant. Therefore, this fund will provide pump-priming to determine a project's viability that D4D cannot necessarily do within the capacity of their existing clinical sessions.

3.4 **Quotec interview⁷¹**

Observations on General features

Quotec is part of the secretariat for the NIHR Invention for Innovation (I4I) programme, and, through that, supports the activities of the HTC programme board. Representatives from Quotec sit on the programme board, not in a voting capacity, but for facilitation and management. As such, Quotec has an overview of the HTC programme and activities.

From Quotec's perspective, the HTCs are still building awareness in their audiences of their roles in a changing landscape. It seems clear to the interviewee that the HTCs have an important role to play in terms of focusing on unglamorous, unmet clinical needs, which other initiatives may not necessarily prioritise. In addition, they have funding for clinical time, so the HTCs are clinically grounded. Overall, however, the HTCs would appreciate more feedback from the Programme Board and sponsors on where the latter see the HTCs.

HTC funding supports a mix of business development, administration and, crucially, clinical session time in order to obtain professional time. According to Quotec, this combination of factors is the unique selling point of the HTC.

The HTC role is to identify an unmet clinical need, characterise it in terms of necessary development and the market opportunity, then bring together the partnership needed to address that problem, and help them secure funding. They may look for grant funding to help develop a product or technology in which the HTC may not necessarily be involved. For example, they may receive funding from I4I, or maybe from collaborative R&D grants, and one or more of the HTC partners would be involved in that project where the HTC would only be facilitating. Thus, the HTC is there to bring people together for them to deliver solutions themselves - HTCs do not manufacture, supply or develop any products/technologies.

⁷¹ Source: Interview with Matthew Chapman on March 10, 2010.

In practice, the HTCs are involved in all sorts of technology development projects with varying timescales of levels of impact. They are being encouraged to establish a fully populated pipeline of projects and technologies, including everything from technologies that require significant development through to products that might come onto the market quite quickly.

One example from Quotec was that, under D4D their project pipeline encompasses ranges from a patient score card system, a fairly modest technological approach for patients to record certain information that is important for their clinical care, to a quite complex technology-developed project based around portable renal dialysis. The former could be relatively easily implemented, though have few direct financial benefits, while the latter could have a major impact both on patient care in addition to being a large market opportunity.

Observations on Specific activities

Structure

In terms of structures, the HTCs are embedded in and led by an NHS trust. They also have other clinical partners who are bundled into their contracts. Thus, they can identify and validate a clinical need, which does remove risk for any company who is coming in to exploit it. The HTCs would like to develop some kind of 'kite mark' equivalent over time but first they need to establish a track record and clear evidence of value. Importantly, they have links with companies that can actually help to deliver solutions. Although those companies are not contractually bound to the HTC nodes, within individual projects they will have contracts and collaborative agreements.

By necessity, to measure success the HTCs are looking at early indicators of potential long-term outcomes and process-based indicators. The reason, which is not unique to the HTCs according to Quotec, is that they will not be able to point to many impacts or outcomes, such as new products on the market, savings to the NHS, or patient episodes affected by products until sometime down the timeline.

One of the important achievements that the HTCs have made relates to getting patient and end-user representation embedded in their main steering committee. It reflects the emphasis the DH has put elsewhere under the I4I programme and elsewhere in the NIHR. The importance of having end users involved from an early stage to make sure that the product is relevant and correctly specified is an achievement, in terms of process, that will hopefully lead to patient-relevant products and technologies.

Projects

According to Quotec, the actual products the HTCs are facilitating vary from incremental versus radical innovations. Some of the things they are looking at are modest because that is all that is needed to address that clinical need. In other areas, they are looking at very novel approaches to problems, which are reflected in the fact that they are successful in securing grant funding for various activities. These funding panels look for novel approaches not just incremental product development-type approach. For example, the I4I streams three or four committees, which award collaborative R&D funding and have rewarded the HTCs, look for novel approaches and anything considered incremental is unlikely to be funded.

For Matthew Chapman, the HTC purpose is not to generate scientific knowledge or scientific outputs. They should deliver solutions to the NHS that impact on patient benefit and ultimately on UK PLC. In order to do that they may have to help groupings to generate scientific knowledge to deliver solutions, but that is not the primary role.

On the issue of HTC involvement with project IPR, Quotec answered in two parts. One is about '*IPR around identifying and characterising an unmet need*', and the other part is about '*IPR in the solution*'. In terms of the solution, if outside commercial companies are needed to exploit an idea, then they will need to see some sort of protection for their investment. Quotec feels that IPR is generally very important to securing its share of business in medical devices. In terms of technology development funding, grant funders would expect to see IPR being generated and they would see that as part of the fact that it is a radical rather than incremental approach.

Chapman stated that the HTC itself would not necessarily have any stake in particular IPR. There are a number of models around on how the HTC can derive benefits, cover costs, and whether to take some sort of stake in the outcomes from these processes. He has seen that both HTCs are looking at different models to allow them to move towards some form of commercially sustainable way of facilitating that process and getting some benefit back.

Future

Quotec stated that the HTCs ability to communicate results have been relatively low profile so far. They are doing a lot of work within their own communities (industrial, academic, clinical) to try to spread the word, but they are resource-constrained so they only have a limited amount of time to go out and engage with their communities.

One message that has come forward from the funders and from the programme board representatives is to try and get the HTCs to engage more with individual committee members and with the individual funders, particularly to understand their perspective and how the HTCs fit into the funders' area.

Looking at different business models, Chapman believes that the HTCs would require a degree of long-term Government funding, but should expect to see that decreasing year on year. One suggested option may be to establish a separate commercial division, which is self-sustaining and then a Government-funded division that focuses specifically on Government goals. This would be similar to some KTNs.

Chapman feels that there may be scope to apply some of their lessons-learned more widely, but it has not yet been discussed. If successful, however, then HTCs can be rolled out on a larger scale with a larger profile.

3.5 **Economic evaluation**

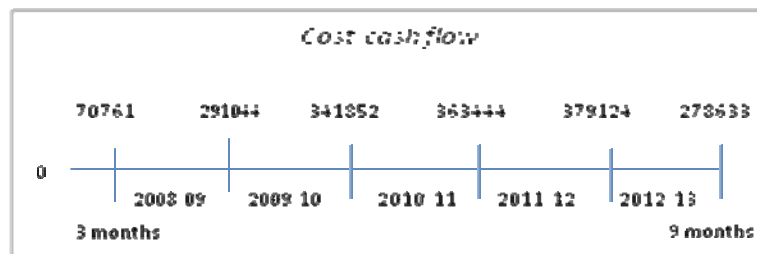
An overview of the pilot HTCs' business plans shows high level of similarity in assumptions about revenue generation. Therefore, for the purposes of this report, a full economic evaluation is presented for only one of the pilot HTCs, *enteric*, which was chosen solely based on its provision of slightly more comprehensive data.

According to the business plan published on the 14th December 2007 *enteric* is funded through different sources such as DH contributions, development funding, sponsorship, contributions from research grants and charitable trust support. *enteric* is not expected to generate revenues during years 2007-2013.

In order to evaluate whether *enteric* will be cost effective, this evaluation will look at whether its grant funding will generate an outcome that justifies the investment. Since the pilot will not generate revenues during the contract period, and hence it is not possible to compare them with the costs, a different evaluation method is necessary. When a new device or procedure is invented as consequence of *enteric* R&D, it is expected to generate a positive health outcome that has a monetary value. Hence, it is possible to compare the costs with the monetary value associated with the improvement of the health condition.

Several assumptions are necessary for this evaluation. First, the National Institute for Health and Clinical Excellence (NICE) threshold of £20000-30000 per QALY is used to approximate the willingness to pay for one additional life year in a healthy state.⁷² Second, *enteric* is expected to generate new devices or procedures to improve healthcare outcomes for those affected by disorders of bowel function by 2012/13. Since it is unknown *a priori* in how many years it could generate a positive outcome, a simulation method is adopted to consider this. Third, the comparison between different monetary flows over time is possible only by considering a discount factor. A yearly rate of 3.5%, as suggested by NICE, is used. Fourth, it is assumed that the cost cash flow happens at the end of each period.

Figure 2 enteric cost cash flow



The compounded cost or future value (FV) cost is the cost (C) projection in the future and is given by the following formula:

$$FV(C) = C(1 + r)^t$$

In order to sum the initial cost (C_1) and the following year cost (C_2), the total cost (TC) must take the compound rate into consideration. Thus, the total cost is given by:

$$TC = C_1(1 + r) + C_2$$

In general, the total cost at a given time in the future (F^t) is given by the sum of all the compounded costs:

⁷² NICE Guideline Manual. *Incorporating health economics in guidelines and assessing resource impact*. [Available at: <http://www.nice.org.uk/niceMedia/pdf/GuidelinesManualChapter8.pdf>].

$$TC(t^*) = \sum_{j=1}^{t^*} C_j(1+r)^{t^*-j}$$

The following table gives the total compounded cost each year according to the data given in the *enteric* business plan and is presented in figure 1. It takes into account that the year 2012/13 contains a 9-month period:

Table 1 enteric total compounded costs

Total Compounded R&D Costs					
2007/08	2008/09	2009/10	2010/11	2011/12	2012/13
70,761	386,571	863,723	1,529,470	2,208,879	3,498,831

The next step is the computation of the minimum QALY necessary to make *enteric* cost-effective. According to NICE methodology, the range of £20000-30000 per QALY for a new treatment to be cost-effective also represents the willingness of an individual to pay for one additional year of completely healthy life. By introducing a parameter “k” that represents how many years of healthy life the new treatment generates, it is possible to infer it by the willingness to pay and by the costs incurred until that moment. “k” will represent the minimum healthy years of life that are required to make *enteric* cost effective. For example, using the average value of £25000, the minimum “k” necessary is given by:

$$\frac{£25000}{1 \cdot QALY} \cdot k \cdot QALY = £Cost \rightarrow k = \frac{Cost}{£25000}$$

where (Cost) is the total compound cost in a certain year given in Table 1.

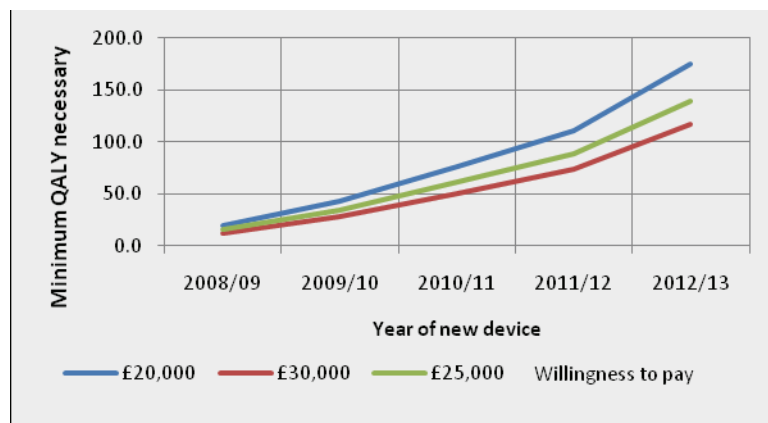
It is also important to know the year of the new invention. In a model with only one device developed in the five-year pilot period, an invention developed in the first year involves less cost than an invention in the last year where the cost is given by the sum of all compounded costs in each year.

The following table shows “k” as a function of the invention-time given the willingness to pay (£20000 or £30000 or its average £25000):

Table 2 k as a function of time to invention

		Willingness to pay		
		£20000	£30000	£25000
Years to new device	2008/09	19.3	12.9	15.5
	2009/10	43.2	28.8	34.5
	2010/11	76.5	51.0	61.2
	2011/12	110.4	73.6	88.4
	2012/13	174.9	116.6	140.0

Figure 3 Minimum QALY necessary for the new device as function of time to invention



As can be seen, combining higher costs and slower willingness to pay for a additional life year in healthy state leads to a higher QALY necessary to make *enteric* cost effective.

Another important factor is the demand for the new device or procedure that is represented with the letter “d”. A higher demand with higher aggregated quality adjusted life gains will lower the minimum QALY necessary for *enteric* to be cost effective.

A more realistic model can relax the aforementioned stricture of only one new device in five years and assuming that the effectiveness of *enteric* is determined only at the end of the five-year contract. This new model thus introduces the variable “n” to indicate the number of new devices invented during the five-year contract.

Using the average NICE threshold of £25000 per QALY, the following formula gives the average minimum health gains per device and per patient necessary to the *enteric* investment to be cost-effective:

$$k(d,n) = \frac{Cost_t}{d \cdot n} \cdot \frac{1}{25000}$$

Where $Cost_t$ represents the compounded R&D cost at the end of the contract (2012/13).

The following table simulates the above formula for $d = [1,10]$ and $n = [1,5]$:

Table 3 Minimum QALY necessary per patient and number of devices invented

		Number of new devices				
		1	2	3	4	5
Demand for each device	1	140.0	70.0	46.7	35.0	28.0
	2	70.0	35.0	23.3	17.5	14.0
	3	46.7	23.3	15.6	11.7	9.3
	4	35.0	17.5	11.7	8.7	7.0
	5	28.0	14.0	9.3	7.0	5.6
	6	23.3	11.7	7.8	5.8	4.7
	7	20.0	10.0	6.7	5.0	4.0
	8	17.5	8.7	5.8	4.4	3.5
	9	15.6	7.8	5.2	3.9	3.1
	10	14.0	7.0	4.7	3.5	2.8

For example, if in five years only one device is invented and the demand for that device is 1, *enteric* should not be funded again since its research is not cost-effective in that the probability of inventing a new device that generates 140 years of healthy life to one patient is zero.

It is different if, at the end of the five-year contract, five devices are invented with each one serving ten patients for a total of 50 patients. In this case, the minimum QALY per person and per device necessary for *enteric* to be cost-effective decreases to 2.8. It is worth noting that this result is identical to all the cases in which the product of the demand for each device and the number of new devices is equal to 50.

3.5.1 A cost effectiveness calculation

In conclusion, the higher the number of new devices produced and the higher the demand for each device, the lower the QALY per device and per patient necessary to make *enteric* cost effective.

The above formula and table do not take into account the additional cost of producing the new device. Hence, a slightly different formula is necessary. Indicating the average cost of producing one device with “c”, the amended formula is represented by:

$$k(d, n, c) = \left[\frac{\text{Cost}_e}{d \cdot n} + c \right] \cdot \frac{1}{25000}$$

The inclusion of an average unit cost per device increases the minimum QALY per patient and per device necessary to make *enteric* cost effective. A more flexible formula that takes in consideration different unit producing cost and different demands for each device and

different inventing time is possible. However, it is not presented here to avoid further complicating the report.

It is worth noting that the above analysis is not exhaustive in judging the investment in R&D for two reasons:

- the higher the R&D cost, and implicitly the time spent in R&D, the higher will be the probability of inventing a new device or procedure;
- there is a considerable time-lag between R&D investments and their positive impact. Hence, a five-year period may not be appropriate to evaluate the cost-effectiveness of *enteric*.

R&D undertaken in areas where there is complementary R&D going on is also likely to be more successful. In other words, there may be spillover benefits to the R&D, reducing the minimum QALY to make a HTC cost-effective.

3.6 Chapter summary

This chapter described the structure and activities of two HTCs, *enteric* and D4D. We bring together some of the issues that were raised in the course of this project regarding the work that HTCs do at the micro, meso, and macro levels.

At the micro level, *enteric* has acknowledged that clinicians may have ideas for what sort of devices are potentially needed, but few have the time to develop these ideas into fully functional innovations. *enteric* allows them to build up the necessary entrepreneurial skills and capabilities. *enteric* also seeks to draw on the detailed knowledge of nurses and other professionals that work with patients on a day-to-day basis. These professionals are familiar with the daily challenges that patients face, and have valuable input into the innovation process. D4D seek to highlight the unglamorous and underfunded areas of need, and focus on ‘*trying to get things done*’ rather than just putting people together. D4D is also aware that there is considerable path dependency at the micro level, where most of their projects are coming from people who are already involved with them.

At the meso level, *enteric* provides governance and direction rather than funding, and helps clinicians negotiate the funding landscape. For this advice, it seeks a royalty should the device become commercially successful. There are also meso level issues around ensuring that devices, once developed, are used – this may require ‘clinical champions’ to help promote awareness. D4D approach this by having a small core team but with an overtly broad stakeholder engagement strategy with strong steering committees. At the macro level, *enteric* is cautious about the role of venture capital, fearing that the development process may become subject to excessive commercial pressures. It is aware that its sustainability relies on a stream of funding for core development, and for this some kind of licensing system may be needed in addition to Government funding. D4D has recognised an important feature of its macro environment, in its acknowledgement that by not focusing so heavily on supply, D4D will always have more demand than capacity. It seeks to occupy a unique part of the healthcare landscape, distinct from CLAHRCs, BRUs, BRCs, and has a Commercial Director to negotiate contracts with other structures. This

will allow it to link with KTNs, NHS Innovations Hubs, and NHS Adoption Hubs. D4D has also made efforts to engage with small and medium sized organisations.

4.1 **Summary observations of all HTC-like organisations**

There are different, but equally legitimate, approaches to the clinician-industry-patient relationship. These different approaches are affected by both the disease field and culture of the host institution.

Some form of non-income funding is required to support basic administration functions and initial scientist/clinician time. This can come from charities, foundations, donors, or Government.

It is generally agreed that an income stream based on IP rights provides insufficient long-term viability.

The concept appears to be validated in all cases since, after a few years, all HTCs find themselves evaluating too many potential, and high-quality, projects. Many of these are considered likely to have been otherwise unidentified.

Radical and revolutionary innovation takes time, while incremental innovation may provide earlier R&D impacts. A mix of projects is needed to demonstrate effectiveness and also substantially affect patients.

Overall, delivering a very specific programme and becoming self-sustainable with the same funding may not be mutually exclusive, but are not necessarily compatible. The reason is that self-sustainability requires providing something that customers will pay for, which may not exactly match funder deliverables. There is little consensus on navigate between delivery and self-sustainability. A possible strategy is to set up and deliver the projects that are specific funder deliverables as soon as possible with external funding and then do some marketing with one of their industrial partners.

4.2 **Summary of NIHR HTC observations**

Initially D4D and *enteric* pursued different organisational models: the former went for a 'professional' model; the latter pursued an 'ad-hoc' management system. Both have now established streamlined and auditable project evaluation systems. Much of the constraint on their activities was due to a perceived shortfall in funding compared to expectations.

Both HTC have established a pipeline of products that ranges from near-market devices to longer development horizons. To enable this, both HTCs have successfully leveraged funding from other sources to develop technologies.

Both HTCs have established themselves as desirable partners for medical device development in their respective fields. They have raised their profile among both clinical and academic partners, as well as industry contacts. The latter are a mix of small, medium and large enterprises. However, they are only at the early stages of becoming national services.

Both HTCs report that they are considered unique by their collaborators.

Neither HTC has come to a final decision about how to sustain activities in the long term. This is partly due to uncertainty about the intentions of Government funders. The main issue relates to the support of initial meetings with potential partners and project evaluations. There is also a question of whether or not to provide seed funding for product development.

The large projects cited by the HTCs (ostomy project and home dialysis) are unlikely to lower direct costs to the health service. However, they are demonstrations of R&D that could noticeably improve the quality of life of affected patients.

4.3 **Summary of HTC relevance to NIHR strategy**

There is an identified need in medical device development to involve NHS clinical staff and management and also to encourage greater involvement of small- to medium-sized companies. The HTCs appear to be answering this need.

There is also an identified gap in implementing innovations in the NHS. Though the HTCs are the sole device-specific entry point into the research pathway, there is an issue of the limit of influence for NIHR funding. The HTCs are actively developing implementation plans, which may be seen as being beyond the NIHR remit of supporting/enabling research to assess medical devices. There is also the issue of the NIHR relationship with industry – it actively promotes the use of NHS research capacity by companies, but is not there to provide services directly to industry.

4.4 **Lessons learned from pilot HTCs**

4.4.1 ***enteric***

Surgical innovation differs from pharmaceutical development:

While surgery was described as a conservative field, its R&D process is not as long as that for pharmaceutical products. However, in order to work and work well it has to be very interpretive. A randomised clinical trial with a medical device is rare, partly because the medical device industry cannot support the associated costs due to market fragmentation. Another reason predicted by innovation theory would be that devices require skill and experience to operate. Simply providing instruction in a leaflet with the device is unlikely to suffice, as it might with a pill. So randomised clinical trials for medical devices are more

difficult to control because of the variability in their use, and their development has to rely on a more interpretive and inductive process that is sensitive to the context-dependent variations in use.

HTCs can encourage academics to innovate:

It was also mentioned that a HTC could help break the barriers between academics in medicine and industry. Academics in medicine may be put off to some extent because of lack of recognition or advancement for industry consultancies, but that can change if companies realise that there may be a profitable benefit to their interaction, and as academics realise there may be scope to emphasise the impact of their work in assessment exercises, such as the forthcoming Research Excellence Framework.

Business assumptions may need updating:

enteric considers pharmaceutical development to be driven by more of a push-process. In contrast, they see themselves as using more of a pull-process, dominated by the clinician and the patient. However, innovation theory has developed beyond push and pull models and it may be of benefit to revisit some business assumptions with new knowledge about the role that users play in changing technologies and innovation processes. Innovation is now understood to be a more iterative process of knowledge going back and forth between users and designers, and this seems to be the case with medical devices.

Membership of core team needs attention:

A HTC needs a strong steering group of committed people who are paid for their time. At its outset, *enteric* relied on volunteers, and still does to some extent, but reimburses expenses at the least. As well, the right balance of experience and skills, with industry for example, that are relevant for that particular HTC needs to be brought into the steering group. A committed chair who understands the purpose of the HTC is key, along with a business manager from day one. Ideally, whoever is in charge of running the HTC should be an innovator themselves.

The importance of communication:

With *enteric*, it seems that the DH expected something much more rigid, whereas they moved to a model that was fairly fluid and responsive. This caused some confusion when *enteric* were changing things and the DH would point out that the new activities did not meet the agreed evaluation criteria. One example given was that *enteric* understood that the DH intended them to fund the technology development, but insufficient funding was given to achieve this aim.

Level of involvement in adoption is uncertain:

enteric are aware that adoption is out of their hands, but *enteric* has to be part of that and at the very least produce a package of information, as evaluation and clinical champions across the country. This should help small companies, particularly in the UK, get further along the adoption pathway than they have managed in the past. This should also help the development process as adoptees suggest improvements. Innovation theory indicates the boundary between adoption and adaptation is very blurred and that they are two sides of the same coin.

Unique role is demonstrable:

For the ostomy project, *enteric* were able to enter a partnership with industry and academia to apply for a TSB grant that the partners would not have got on their own. It has been a mutually beneficial situation that would not have happened without the HTC.

For the stapling gun project (part of APPEAR), there had been unsuccessful attempts to work with large companies. Then HTC, however, was able to attract a consultant who put them in touch with a healthcare company. *enteric* helped bring that partnership together and put in place the appropriate governing structure through Queen Mary College Bio Enterprise.

enteric believes that other parts of the NIHR, such as the Clinical Research Networks, are not set up to do surgical equipment trials very easily. Interventions do not lend themselves to a controlled trial, so it is very difficult to get funding. There is a need for better organisation of interventional research. *enteric* can be part of that, but not the entirety.

It costs money to say no:

At their 18 month review, *enteric* have formally said that they will not be financially self-funding. The reason for this is that their kinds of activities generate benefits, not only to industry but also to the NHS and to patients, for which there is no direct payback. In addition, the only kind of payback it is possible to get from industry is from licensing or royalty agreements, which is a very precarious income source. Thus, *enteric* argue that they need funding and support based on the value they provide to all of their stakeholders. They argue strongly that one of their lines of support needs to be income from funding sources based on a recognised matrix of impact and effectiveness.

4.4.2 D4D**HTCs need to be embedded in a Trust:**

The power and expertise within the Sheffield Teaching Hospitals Foundation Trust has been crucial for supporting the fledging D4D. If HTCs are rolled out then they need to be embedded within a Trust that understands what their role is all about and who are willing participants in the project.

A HTC needs to be connected with the broader innovation landscape:

A HTC has to make connections with everyone on the innovation landscape because they cannot do everything themselves. It requires a significant commitment to build a library of capability, so if someone comes along with a device needing a particular material, then the HTC can provide specific information. Part of this lies in having a balance of facilitation and collaborative projects that develop varied capabilities in the HTC; at least enough to recognise when capabilities are needed and where one should go if further capabilities are required.

It costs money to say no:

This is what makes HTCs unique – the lack of upfront charging from day one. However, there is difficulty in running an effective core team with a limited amount of time and funds. For example, one challenge was the way that funding for the clinical sessions was allocated. They needed to bring in specialists such as medical engineers, but often it was

very difficult to find a replacement for that specialist. This meant the specialist's institution had to be somehow compensated. Therefore, although it was originally thought that D4D might be using some nurse time and some medical time, it was not expected that they would necessarily be using specialists who cannot easily be replaced. The localised knowledge that makes these specialists useful and helpful to the D4D endeavour also makes them less replaceable.

Sustainability is a big issue:

Small companies or lone inventors will not get through the door of a big company unless risk is mitigated. D4D helps mitigate risk by supporting them to the point where a business angel or a venture capitalist starts getting interested. However, this has required leveraging the Government funding to get enough to support proof of concept and business development. There are clinical needs that do not necessarily make commercial sense, but can make a huge difference to a patient in the NHS. The issue is how to fund those improvements and innovations.

A HTC cannot take something to market:

Part of the original concept was that the HTC helps to define the project; produce an early prototype; and perhaps builds the testing prototype. The HTCs do not have the funds to invest in marketing devices.

HTCs have a niche in the NIHR:

The BRUs and the CLAHRCs are different to HTCs. Firstly, the BRUs have a much bigger picture about general healthcare of medical conditions whereas HTCs focus on medical devices and D4D have focused on three specific areas. The CLAHRCs are more about evaluation and implementation further downstream along the innovation pathway.

Training is important:

The training aspect is often overlooked in that there are many little companies that are too small to make a big impact by themselves. The HTCs could be a vehicle for allowing people to cooperate and share their experience and skills. This could help to put the UK in a good position to do that on an international basis.

Communications are important:

There is a tendency for HTCs, because there are only two in their pilot phase, to be dwarfed by other NIHR initiatives, even though they believe they are filling a unique role.

Innovations can be valued differently:

The D4D example of a no-touch patient-moving device is difficult to reconcile easily with rhetoric about simply needing to value innovations more and adopting innovations more quickly. This is because the value of not being touched is different for different people. There are clear qualitative differences in how innovations can be valued, ranging from gender, race, age, and ethnicity.

4.5 Wider issues

In an era of globalisation, international trends in, for example, migration, production techniques and energy consumption have a profound effect on an outwardly-facing nation like the UK. Global competition places a premium on productivity and flexibility. Harnessing new technology, developing new, high-value skills, and embracing change have all enabled the UK economy to respond to these challenges, but only because companies, communities and individuals have had to learn to adapt to rapid change. As the pace of change quickens, skills and flexibility will become even more important. Just as these trends have required a major change in the behaviour of all parts of UK society – corporate, community and individual – the challenges of the future require a response from Government too. If the State, through public services, is to enable the UK to thrive over the decades to come, public services and those who deliver them must also become more flexible and adaptable, more individual, more expert and more professional. In the face of growing technological costs and scientific advances, it becomes ever more necessary to assess and direct the development of new treatments and medical technologies to ensure clinical and cost-effective care.

The literature identifies a number of factors that place pressure on available health resources, including an increasing range of treatments and technology, rising public expectations and an ageing population. Co-operative responses to these pressures are widely discussed in the literature as being the most effective method for driving innovation in the public sector. According to a British Medical Association report, responses to these pressures need to be clinically-led: *‘Innovation should not be driven from on high, but by local professionals working to improve services for patients.’*⁷³

However, there may be problems if the system and network of local professionals does not have anyone with the incentives to develop cost-conscious technologies. If the researchers are solely concerned with novelty and claiming originality in research, the clinicians are concerned only with the efficacy of products and benefit to patients, and industrialists are concerned with profit, then nobody is looking out for making incremental cost reductions. The failure in this case is a systemic one, so claiming that the solution is to become more systemic is not enlightening. What may be needed is thought for the kind of support that should be provided in order for a range of skills and capabilities to emerge and develop, and consideration for the incentives of individuals to engage in collaboration.

The collaborative, or interaction, model can be seen as an approach that aims to increase the implementation of research by undertaking applied health research that is directly relevant for the healthcare system. The absence of an effective link between research programmes and NHS service delivery and efficiency was first identified in 1988.⁷⁴ The Government of the time responded with a new research commissioning structure and time-limited research programmes. It recognised the research shortfall relating to service delivery by setting up the NHS Service Delivery and Organisation (SDO) research

⁷³ British Medical Association. *A rational way forward for the NHS in England A discussion paper outlining an alternative approach to health reform*. May 2007 [Available at: http://www.bma.org.uk/images/rationalwayforward_tcm41-147064.pdf].

⁷⁴ House of Lords Select Committee on Science and Technology. *Priorities in medical research*. London: HMSO, 1988.

programme in the 1990s, along with smaller programmes aimed at promoting technical innovations, such as the New and Emerging Technologies Programme (NEAT).⁷⁵ The collaborative model has been most comprehensively developed in the 'linkage and exchange' model used by the Canadian Health Services Research Foundation.⁷⁶ In recent years, the creation of the NIHR has been an attempt to consolidate and build on the earlier attempts to build the health research system into the healthcare system.

One area where the UK has pioneered new approaches is in the development of a health research system that attempts to meet the challenge of providing better healthcare.⁷⁷ The NHS R&D Programme in 1991 was an attempt to integrate the new NHS R&D programme into the management structure of the healthcare system, which no other country had ever attempted.⁷⁸ The DH R&D system in England had already experienced an attempt to ensure research was generated that met the needs of customers in the form of policy makers. The evaluation of this so-called Rothschild experiment emphasised the importance of the users of applied health research and the researchers themselves working closely together to develop agendas that would meet the needs of the healthcare system.⁷⁹ This UK initiative was also seen as a pioneering step in the international account of the origins and importance of the collaborative approach.⁸⁰

There has been an attempt at constructing a conceptual framework for implementation through a wide-ranging systematic review of the literature regarding the diffusion of innovation in the health sector, and other service organisations in the UK.⁸¹ It identified some key attributes of successful innovation and built a model that captures many of the features of implementation of innovation in a health service context. For example, the report noted that implementation is a non-linear process, depending on a number of variables including organisational structure; leadership and management; human resources; funding; intra-organisational communications; intra-organisational networks; feedback; and the ability to adapt. The report also stressed the need for links to the development stage and effective, credible change agents offering a range of support from training to communication.

⁷⁵ Derek Wanless, John Appleby, Anthony Harrison and Darshan Patel. *Our Future Health Secured? A Review of NHS Funding and Performance*. London: King's Fund, 2007. [Available at: <http://www.pensioneronline.co.uk/docs/Wanless%20NHS%20Sep%202007.pdf>];

A. Harrison. *Public Interest, Private Decisions: Health Related Research in the UK*. London: King's Fund, 2002.

⁷⁶ J. Lomas. 'The in-between world of knowledge brokering,' *BMJ* 334 (2007):129-32; J. Lomas. 'Using 'Linkage and Exchange' to move research into policy at a Canadian foundation.' *Health Aff* 19 (2000): 236-240.

⁷⁷ S. Hanney and M.A. Gonzalez Block. 'Building health research systems to achieve better health.' *Health Research Policy and Systems* 4:10 (2006).

⁷⁸ N. Black. 'National strategy for research and development: Lessons from England.' *Annu Rev Public Health* 18 (1997): 485-505; M. Peckham. 'Developing the National Health Service: a model for public services.' *Lancet* 354 (1999): 1539-1545.

⁷⁹ M. Kogan, M. Henkel and S. Hanney. *Government and research: thirty years of evolution*. Dordrecht: Springer, 2006.

⁸⁰ J.L. Denis and J. Lomas. 'Convergent evolution: the academic and policy roots of collaborative research.' *J Health Serv Res Policy* 8: S2 (2003):1-6.

⁸¹ T. Greenhalgh, G. Robert, P. Bate, O. Kyriakidou, F. Macfarlane, and R. Peacock. *Diffusion of Innovations in Health Service Organisations: A Systematic Literature Review*. Oxford: Blackwell Publishing, 2005.

The long-term leadership strategy eventually developed by Government and the pharmaceutical industry created a framework to improve outcomes for patients while strengthening the environment for industry in the UK.⁸² However, the literature identifies a range of areas identified for further research. For example, it identifies the nature of social influences and the role of social networks in implementation as an interesting area for further research, with particular reference to the role played by champions and change agents in different settings. It also suggests further work is needed to look at how absorptive capacity can be created and sustained to make organisations receptive to change, as well as how this can be supported.⁸³ A further area of interest is inter-organisational networking and how this influences knowledge transfer and learning.

4.6 Recommendations

There are activities across all of the HTCs and HTC-like organisations for which private sector funding is unlikely to materialise; essentially, all of them provide a ‘public good’ in their initial contact and evaluation stages.

There is no ‘right’ way to approach the issue, thus a one-size-fits-all (prescriptive) funding solution is not applicable. This would preclude structural support from a funding body, but lend itself to competitively obtained grants to support device development.

Such competitions should be open to any organisation with a focus on medical devices and with formal support from a NHS Trust, but funding should be limited to the contact and evaluation stages of the process. Thus, sufficient funding must be available to cover the costs of full-time staff for project management and relationship management, with part-time funding for administration and both clinical and research leads. Funding must also cover clinical evaluation time, especially specialists.

The aforementioned recommendations do not necessarily imply that HTCs must be sustained indefinitely in their current institutional form, as it is their function that is of greater systemic importance. It is possible, as lessons are learned from the HTCs, that the dissemination of those lessons throughout the wider NIHR system may be a more cost effective way to achieve long-term change. Conversely, the impacts of HTCs could be also enhanced by changes to the wider system.

⁸² Capability Reviews Team. *Capability Review of the Department of Health*. 2007. [Available at: http://www.civilservice.gov.uk/Assets/Capability_Review_DfH_tcm6-1057.pdf].

⁸³ W.M. Cohen and D.A. Levinthal. ‘Absorptive Capacity: A New Perspective on Learning and Innovation.’ *Administrative Science Quarterly* 35:1 (1990): 128.

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APPENDICES

Appendix A

4.7 **Site visits**

The structure of site visits to NIHR pilot Health Technology Cooperatives and interviews with HTC-like organisations is presented below.

4.7.1 **Pre visit information**

Aims

- To see how the HTC concept fits into the current medical innovation landscape.
- To determine how the pilot HTCs contribute to the health and wealth of the nation.

Purpose

- To see how the pilot HTCs are interpreting the Health Industry Task Force recommendations and in relation to the Government policy outlined in Best Research for Best Health.
- To provide information to the current funders of the HTCs that can be used to decide the next steps for the HTC concept.

Key points

- This evaluation is looking at the whole timescale of the HTC programme, not just a current snapshot.
- This evaluation is not looking to determine if there is a 'best' way of managing a HTC.

Question categories

- General: the participants' perception of what a HTC is/should be.
- Specific:

the benefits of the HTC

how projects are selected

how projects are managed

how things will look in the future

It would be most helpful if specific examples were cited and quantitative evidence provided.

4.8 HTC Interview protocol (semi-structured)**4.8.1 General Questions:**

What do you think distinguishes HTCs from other innovation landscape initiatives (e.g. CLAHRCs, BRCs/BRUs etc)?

How do you think the HTCs can best relate to other initiatives in the innovation for patient benefit landscape – both providing knowledge to and getting it from them?

What do you think falls within the process of HTC-enabled innovation?

4.8.2 More specific questions about the HTC

What value do you see your HTC adding to the innovation for patient benefit landscape?

Do you see your HTC engaging in radical innovation or incremental innovation building on previous advancements?

Overall, which category(ies) best describe(s) the majority of work of your HTC:

- Generating scientific knowledge of wide potential application
- Generating knowledge relevant to non-commercial health community objectives
- Generating knowledge that contributes to benefits for commercial companies but cannot be IP protected
- Commercial IP
- Product development
- Other

In selecting projects, do you go beyond formal evidence/published literature?

In selecting projects, do you consider secondary/alternate uses for the technology?

Can you tell us a bit about if/how you engage patients in your HTC?

What are your uncertainties? What lack of information do you encounter?

How do you address and spread development risk?

How do you respond to below-expectation results? What are the consequences?

What are the main formats of communication within/and outside HTCs, in pursuing your objectives?

What is your sustainability strategy?

CHAPTER 5 **Appendix B**

5.1 **Australian CRC examples**

The CRC for Vision is an example of a CRC with both a commercial orientation and a public good focus. The CRC is developing breakthrough technology and products for the correction of myopia and presbyopia as well as developing models which provide effective, affordable, and sustainable eye care delivery to communities in need.

The CRC for Aboriginal Health is an example of a CRC with a strong public focus, conducting high quality strategic Aboriginal health research and engagement in effective development activities with Aboriginal communities, service providers, policy formulators and decision makers. The Centre has a commitment to research that will lead to improved health outcomes for Indigenous Australians, and to stakeholder involvement and partnerships in research to achieve that.

CRCs for Biomedical Imaging Development (CRC BID) and Cancer Therapeutics (CRCCT) are new CRCs. CRC BID will produce new and improved radiopharmaceutical tracers with high specificity for cancer and neurological diseases, together with chemical processes for their on-site production and new detectors capable of significantly improved sensitivity and resolution. The CRCCT will produce several high quality small molecule drug candidates licensed to external partners for clinical development within the life of the CRC.

Current CRCs, Vision CRC and Hearing CRC, are building on the knowledge of their two previous CRCs. In the case of Vision CRC, the first 12 years were focused on research into contact lenses, biomaterials, polymers and polymer surface chemistry, ocular physiology and microbiology, and optometry. Vision CRC is now developing breakthrough technology and products for the correction of myopia and presbyopia. Research activity has also evolved across the three Hearing CRCs. The first centre focused on the profoundly deaf, while the second had a broader remit to include other types of hearing loss. The current Hearing CRC builds on previous research by adding new research into the prevention of hearing loss.

5.2 **D4D example**

D4D may have had relatively low impact in terms of number of cases, but claims to have had high impact in a few cases. There are perhaps 15 cases across the country from which immense benefit has been arisen. One example was a clinician, whose specialty is paediatric spinal injuries, who came to D4D with a difficult case concerning a young girl:

‘[Her] consultant said the girl wouldn’t lie in traction. They needed to do an operation on her spine and the kid would have to lie for days in traction very still while everything’s just straightened out and she wouldn’t do it. She was crying, very unhappy, and her parents didn’t want to put her through it, so she didn’t have the operation that was planned. It was a waste of a lot of people’s time and money and really upsetting for the family and he’d asked if we could put something together because he’d seen something in America that would allow her to have halo traction in a sitting position.’

D4D took a wheelchair and made a mount with a halo on the back of a wheelchair so the family could take her home. This allowed the girl to sit in traction, and allowed her to sit ‘in the park feeding the ducks.’ She also managed to have her operation.

The clinician will present the device as a keynote at the next major meeting for spinal injury specialists. He will let his audience know that the device is available, but D4D is not manufacturing it because it does not anticipate a huge market. However, if it is needed and requests are made for a few individuals, D4D has the ability to manufacture these things and ultimately change their lives.

5.3 **Enteric example**

The main ostomy bag project has funding from the Technology Strategy Board under the high value manufacturing scheme. It involves a university, national physical laboratory, clinical partners and a company, Welland.

CHAPTER 6 **Appendix C**

6.1 **Cost effectiveness assessment**

There are four steps in CEA:⁸⁴

Step 1: Define the programme to be analysed: its focus, process and limits.

Step 2: Compute the net monetary cost given by the difference between the present values of the gross programme cost and the present value of the monetary savings (the sum of all costs of avoided treatment that otherwise would have been obtained). The present value computation is necessary in order to compare values in different time periods.

Step 3: Compute the health effect or benefits of the programme to be implemented in terms of Quality Adjusted Life Year (QALY). This indicator ranges between zero and one, but can also assume negative values when it is expected that medical treatment can produce inconveniences for the patient. The QALY is developed through medical expertise, since clinicians know the effect on health of the new treatment, and patients' interviews, in which a value is assigned to all possible health states.

For example, if a preventive intervention postpones death by one year, during which perfect health is maintained, then the effect is one additional year of life. If the effect is a postponement of death, but perfect health is not maintained during this time, then the patient can assign a value less than one but larger than zero since an additional year of disease is not desired as a year of perfect health. A third type of effect is an improvement in health without affecting survival: the benefit in this case is the differences between the value of a year at lower life quality and the value of the year at the improved level of health. The fourth type of effect is negative and happens when some health programmes are inconvenient or have some associated morbidity or restricted activities.

Step 4: In order to allow comparison between different years a present value discount is necessary. Apply a decision rule based on the net costs and net health effects. The table below shows the decision-rule also when a choice has to be taken when different programmes need to be evaluated: for example if two health programmes appear to have a net health positive but also a net cost positive, it is opportune to chose the programme with the lowest ratio.

⁸⁴ D.S. Shepard and M.S. Thompson. 'First Principles of Cost-Effectiveness Analysis in Health.' *Public Health Report* 94:6 (1979): 535-543.

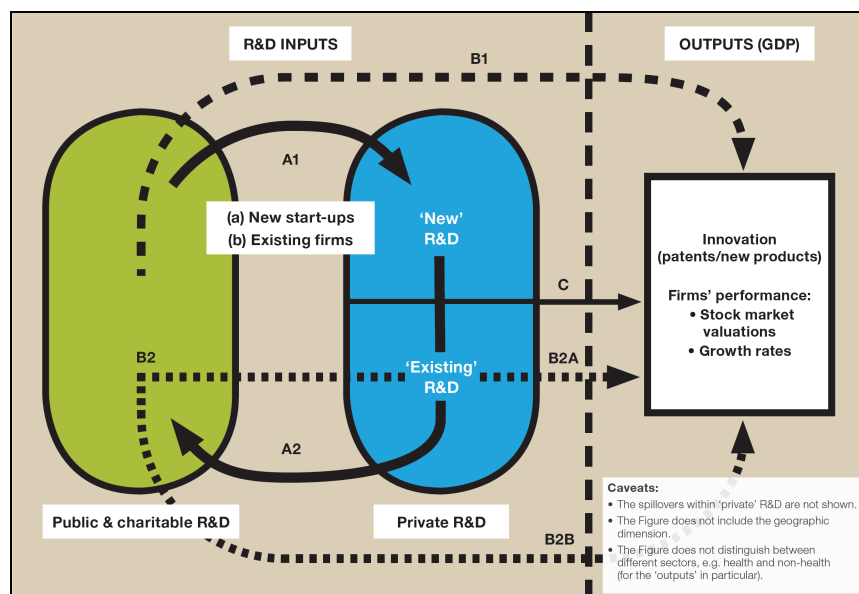
Table 4 Decision rules in cost-effectiveness analysis

		Net costs positive	Net costs zero or negative
Net health positive		Cost effectiveness = Net Costs/Net health effects. Select most efficient programs for improving health (lowest ratio).	Programme economically valuable. Should generally be implemented.
Net health zero or negative		Programme benefits offset by morbidity and inconvenience. Programme generally should not be implemented.	Cost effectiveness = Net Costs/Net health effects. Select most efficient programs for containing costs (highest ratio).

CHAPTER 7 Appendix D

7.1 Research Spillovers

Figure 4 Research spillovers



Source: *Medical Research: What's it Worth? Estimating the economic benefits from medical research in the UK*

UK public and charitable research leads to increased UK GDP. Some, or all, of the effect is mediated via the UK private sector increasing its research (shown in the middle of the diagram). The arrows A1 and A2 illustrate the two-way relationship between public and private R&D. A1 illustrates the fact that some private R&D, labelled 'new' R&D, takes place in the UK thanks to public R&D in the UK. Some private R&D would take place even if all public R&D activities were to be eliminated, and this is labelled 'existing' R&D. Moreover, as the literature suggests, some public sector R&D is stimulated by the existence of private R&D – arrow A2, which stems from both 'new' and 'existing' private R&D.

There is wide agreement about the importance of universities and other public laboratories in generating economic growth. Also, centres of commercial innovation and entrepreneurship are linked to proximity to universities. The literature has identified two potential effects of university research spillovers on:

- Innovation (patents/new product innovations; arrow B1 in figure);
- Performance/growth of firms (arrow B2A/B in figure).

The link represented by the arrow B1 is included in the literature on the (modified) ‘knowledge production function’. The knowledge production function explores the relationship between knowledge inputs, such as public and/or private R&D, and innovative outputs, such as patents and new products. This strand of the economic literature provides some evidence of the importance of proximity in reaping the rewards from public research. Indeed, public research has been found to have a positive and significant effect on both patents and new product innovations.

Arrow B2 is included in the literature that argues that public research has a positive impact on private firms’ performance and growth. A number of papers suggest that geographic proximity and university/public laboratory spillovers are complementary determinants of firms’ performance. A combination of both factors results in significantly higher stock market performance and productivity for firms. Arrow B2 shows potentially (at least) two channels for this university spillover. One channel implies that the firm’s performance improves because public R&D improves the productivity of the existing R&D carried out by existing firms, which in turn leads to better performance (arrow B2A). The other channel by which public research can improve firms’ performance is a more direct impact on their productivity, other than via their own private ‘existing’ R&D (arrow B2B). Unfortunately, the literature leaves relatively undefined the exact mechanism by which this occurs, which is why we show arrow B2 with two ‘branches’.

The literature has identified three types of spillovers generated by private R&D:

- Improving the productivity of other firms’ R&D;
- Encouraging entry of potential competitors;
- Reduction of production costs.

For the first effect, the evidence presented in a number of articles suggests that the productivity of a firm’s R&D is dependent not only on its own internal R&D, but also on the R&D of other firms. This strand of the literature has explored this type of spillover in the pharmaceutical market in particular. For instance, Cockburn and Henderson⁸⁵ find that competitors’ research appears to be a complementary activity to a firm’s own R&D: rivals’ R&D results are positively correlated with own research productivity. The authors interpret this as evidence of significant spillovers of knowledge across firms. Additionally, there is the issue of absorptive capacity. Not all firms reap benefits from external research to the same the degree. This is because they do not have the absorptive capacity to do so.

⁸⁵ I. Cockburn and R. Henderson. ‘Racing to invest? The dynamics of competition in ethical drug discovery.’ *Journal of Economics and Management Strategy* 3:3 (1994): 481–519.

Absorptive capacity is achieved principally by doing R&D in a similar related field, but there are also other complementary assets a firm must have in order to reap spillovers.

Existing private R&D has also been shown to affect the entry decision of new firms. For instance, Aharonson et al.⁸⁶ argue that new entrants are influenced systematically by factors promoting the benefits of co-location, and seek locations that would allow them to benefit positively from knowledge spillovers. A number of papers have also explored how knowledge spillovers generated by existing firms shape the locational dynamics of the new entrants to the biotech sector, especially in the USA. The third type of spillover effect generated by private R&D is reduction in production costs. For instance, it has been estimated that a 1% increase in the R&D spillover can decrease average costs between 0.05% and 0.2%.^{87,88}

Arrow C represents these effects taken together. Note the arrow comes out from the private R&D ‘bubble’, without distinguishing between ‘new’ and ‘existing’ R&D, because spillover effects could arise from either or both ‘types’ of private R&D.

The economics literature distinguishes between two types of return to investment:

- ‘private’ or direct return to R&D investment, meaning the economic benefits generated by a specific R&D programme and accrued by the organisation (whether in the public or private sector) undertaking that research, through royalties and/or sales of a new product or process;
- ‘social’ or total return to investment, which incorporates not only the benefits captured by the organisation undertaking the R&D but also the benefits spilling over for third parties to exploit.

The literature provides quantified estimates of the extra GDP resulting from extra public research expenditure, but not specifically for medical research. However, there are empirical estimates of the amount of private medical R&D stimulated by public medical research, and literature quantifying the extra GDP that results from extra private R&D. Hence, the following two stages approach is adopted to quantify the extra GDP created as a result of extra public medical research expenditure:

- estimating the private R&D stimulated by public research (which is represented by arrow A1 in Figure 4);
- estimating the social rate of return to the private R&D so stimulated (which is represented by arrow C of Figure 4).

The study relevant to the economic evaluation of HTCs is focused on the estimation of the effect that public R&D expenditure has on private pharmaceutical industry R&D expenditure in the US.²¹ It was found that a 1% increase in basic research expenditure by

⁸⁶ B. Aharonson, J. Baum and M. Feldman. ‘Desperately seeking spillovers? Increasing returns, industrial organisation and the location of new entrants in geographic and technological space. Working paper.’ Toronto: University of Toronto. 2006.

⁸⁷ R. Levin and P. Reiss. ‘Tests of a Schumpeterian model of R&D and market structure.’ In Z. Griliches, ed. *R&D, Patents and Productivity*. Chicago: NBER and University of Chicago Press, 1984. 175–204.

⁸⁸ J. Bernstein and M. Nadiri. ‘Research and development and intra-industry spillovers: an empirical application of dynamic duality.’ *Review of Economic Studies* 56 (1989): 249–68.

the NIH leads to a 1.69% increase in pharmaceutical industry R&D with a lag of eight years. Public clinical research expenditure has a lower impact in that a 1% increase in public clinical research expenditure leads to 0.4% increase in private pharmaceutical industry R&D during a period of three years. In other words, every \$1 spent in public clinical R&D public generates \$2.35 in private pharmaceutical R&D.

Translating these findings into the UK, under the assumption that the above estimation applies also to other medical therapeutic classes, a 1% increase in public research expenditure leads to 1.05% increase in private medical industry R&D.

The last step of the two-stage calculation is to estimate the impact on the UK economy of the private R&D that is stimulated by the public R&D (arrow C of Figure 4).

Table 5 summarises the findings of the empirical literature on the total economic returns – i.e. the ‘social’ returns – to private R&D spending.

Table 5 Social return to private R&D

Study	Private rate of return	Social rate of return
Bernstein & Nadiri (1988)	9–27%	10–160%
Bernstein & Nadiri (1991)	14–28%	20–110%
Goto & Suzuki (1989)	26%	80%
Griffith <i>et al.</i> (2004a)	N/A	40%
Griliches & Lichtenberg (1984)	N/A	41–62%
Jaffe (1986)	N/A	30%
Mansfield <i>et al.</i> (1977)	25%	56%
Nadiri (1993)	20–30%	Approx. 50%
PICTF (2001), Garau & Sussex (2007)	14%	51%
Scherer (1982, 1984)	29–43%	64–147%
Sveikauskas (1981)	10–23%	50%

Note: In this table the ‘private’ return is that accruing solely to the firm making the R&D investment. The ‘social’ return is the total return to all organisations and individuals.

The rate of total (i.e. social) return to all parts of the economy is typically around 50% and greatly exceeds the rate of ‘private’ return captured by the firm doing the initial R&D (typically around 20%) in every case. The difference between the social and private returns is the return captured by firms, organisations or individuals other than the firm that made the original investment. A social rate of return of 50%, for example, means that for every pound invested now the economy earns a return that is equivalent to 50 pence every year.

Hence, an £1 extra spent on public medical R&D in the UK leads to an estimated increase of £2.2 in R&D by the private pharmaceutical industry in the UK, which in turn yields a 50% rate of return to the national economy as a whole. Overall, for every extra £1 spent in public R&D and the extra £2.2 consequently spent by the private sector, the national economy earns a return equivalent to an extra £1.1 of GDP. This represents a social rate of return to the total sum of public and private R&D investment (i.e. £3.2 in our example) that is equivalent to 34%. Thus, the total social rate of return to the marginal ‘investment

project' that commences with £1 extra of UK public medical research spending is estimated to be 34%.