The adoption space of early-emerging technologies: evaluation, innovation, gatekeeping (Pathways to Adoption of Technologies in Healthcare – PATH)

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This report contains transcripts of interviews conducted in the course of the research and contains language which may offend some readers.

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<td>ADE</td>
<td>adverse drug event</td>
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<td>AF</td>
<td>atrial fibrillation</td>
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<td>AHSN</td>
<td>Academic Healthcare Science Networks</td>
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<td>BCMA</td>
<td>barcode medication administration</td>
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<td>BIS</td>
<td>Department of Business, Innovation and Skills</td>
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<td>BMP</td>
<td>stimulating bone morphogenetic protein</td>
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<td>BSA</td>
<td>burn surface area</td>
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<tr>
<td>CEAs</td>
<td>cultured epithelial autografts</td>
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<td>CHF</td>
<td>chronic/congestive heart failure</td>
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<tr>
<td>CIS</td>
<td>clinical information system</td>
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<td>COPD</td>
<td>chronic obstructive pulmonary disease</td>
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<td>CPOE</td>
<td>computerised prescription order entry</td>
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<td>CQUIN</td>
<td>Commissioning for Quality and Innovation</td>
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<td>CRP</td>
<td>C-reactive protein</td>
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<td>CSSD</td>
<td>central sterile services department</td>
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<tr>
<td>DDD</td>
<td>degenerative disk disease</td>
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<td>DERS</td>
<td>dose error reduction systems</td>
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<td>DH</td>
<td>Department of Health</td>
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<td>EBM</td>
<td>evidence based medicine</td>
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<td>ECG</td>
<td>electrocardiogram</td>
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<td>eMAR</td>
<td>electronic medication administration record</td>
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<td>EPR</td>
<td>electronic patient record</td>
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<td>HRV</td>
<td>heart rate variability</td>
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<tr>
<td>HS&amp;DR</td>
<td>Health Services and Delivery Research programme</td>
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<td>HSR</td>
<td>health services research(er)</td>
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<td>HTA</td>
<td>health technology assessment</td>
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<td>INR</td>
<td>international normalised ratio</td>
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<td>iTAPP</td>
<td>Innovative Technology Adoption Procurement Programme</td>
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<tr>
<td>Abbreviation</td>
<td>Definition</td>
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<tr>
<td>LPP</td>
<td>London Procurement Programme</td>
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<td>LRTI</td>
<td>lower respiratory tract infection</td>
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<td>MIS</td>
<td>minimally invasive surgery</td>
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<td>MTAC</td>
<td>Medical Technologies Advisory Committee</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>National Institute for Health and Clinical Excellence</td>
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<td>NIHR</td>
<td>National Institute for Health Research</td>
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<td>NPSA</td>
<td>National Patient Safety Agency</td>
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<td>NPT</td>
<td>near patient testing</td>
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<td>NTAC</td>
<td>National Technology Adoption Centre</td>
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<td>OAT</td>
<td>oral anticoagulation therapy</td>
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<td>PbR</td>
<td>payment by results</td>
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<td>PCA</td>
<td>patient controlled analgesia</td>
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<td>participant information sheet</td>
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<td>Preventative Technology Grants</td>
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<td>QIPP</td>
<td>Quality, Innovation, Productivity and Prevention</td>
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<td>QOF</td>
<td>Quality and Outcomes Framework</td>
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<tr>
<td>R&amp;D</td>
<td>research and development</td>
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<td>RCT</td>
<td>randomised controlled trial</td>
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<td>SCG</td>
<td>specialised commissioning groups</td>
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<td>SDO</td>
<td>Service Delivery and Organisation</td>
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<td>SLA</td>
<td>service level agreements</td>
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<td>SME</td>
<td>small and medium enterprise</td>
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<td>STS</td>
<td>Science &amp; Technology Studies</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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<td>WSD</td>
<td>Whole System Demonstrator</td>
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The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the NIHR SDO programme or the Department of Health.

This research assesses technology adoption processes, not particular products.

Contributions of authors

Zelda Tomlin (Research Fellow, Health Services Research) conducted two case studies, led the coding and data analysis, and led the writing of the report.

Susan Peirce (Research Associate, evaluation of medical technology) conducted three case studies, undertook coding and data analysis, maintained the database and contributed to writing the report.

Glyn Elwyn (Professor, Primary Care Research) conducted one case study, provided clinical advice and project direction and reviewed the report.

Alex Faulkner (Principal Investigator, Senior Research Fellow, sociology of healthcare and medical technology) conducted two case studies, undertook coding and data analysis, and contributed to writing the report.

All authors contributed to the concept development of the research.
Executive Summary

Background

Introduction of new technologies into healthcare systems emerged as a major National Health Service (NHS) innovation policy issue in the UK during the 2000’s. There was a dual policy discourse; on the one hand, ‘slow’ adoption by the NHS (the need to promote technology) and on the other, ‘technology creep’ (the need to control technology). Compared to pharmaceutical technologies, nonpharmaceutical (device) technologies are generally exposed to less intensive evidence production and subject to what are perceived as less stringent regulatory regimes. Despite their substantial costs and impact on healthcare budgets, there has been little in-depth understanding on central factors implicated in their adoption. The National Institute for Health Research (NIHR) Service Delivery and Organisation (SDO) programme issued a call for proposals in 2008 to study the adoption of device technologies.

Aims

The study aimed to provide insights into the underlying mechanisms of adoption of device technologies in the NHS, to contribute to defining ‘appropriate’ technology adoption, and to produce an analysis that could contribute to developing better decision-making for practice and policy. Our specific objectives were:

- to explore the adoption pathways of selected technologies and the factors and issues with formative influence on these pathways
- to explore the empirical fit of a preliminary conceptual framework (the adoption space) and to explore its utility as a sensitising concept in exploratory research
- to develop an explanatory model/framework of technology adoption
- to explore the feasibility of developing a typology of technologies
- to produce an analysis that could contribute to defining ‘appropriate adoption’

Methods

The study drew on theoretical approaches from Science & Technology Studies, especially sociology of technology, and actor-network and technology-in-practice approaches. The role of technology itself was given

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due attention as a factor potentially shaping adoption. The concept of the ‘adoption space’ – an all-inclusive map of key actors, processes, influences and decisional junctures relevant in technology adoption - was introduced at the outset.

A comparative case study design was used, with four main (detailed) and four ‘rapid appraisal’ technologies. The following data collection methods were used:

- semi-structured in-depth interviews (NHS, industry, patient, academic)
- email/telephone contact with informants
- documents/websites (NHS, government, industry, other)
- media reports
- scientific literature
- observation of conferences/smaller meetings
- prescribing data.

A total of 106 informants provided 127 interviews with staff from 38 NHS trusts contributing to the study. Between 10 and 27 interviews were conducted for the main case studies, and 5-15 for the rapid appraisals. For the main cases (except the spine implant), data were collected in at least two NHS sites whereas the rapid appraisal studies were not focused on specific sites.

Interview, documentary and media data were analysed using constructivist grounded theory with: fine-grained conceptual coding using the Atlas.ti software, constant comparison, discourse sensitivity, interpretation and divergent case analysis. Content analysis was used as appropriate. The emergent elicited analytic ideas and conceptual explanations were compared within and between technologies and synthesised to develop generic conclusions. Analysis was developmentally discussed by the research team at data sessions.

Results

The four main case study technologies were:

- cell therapy for severe burns
- coagulometer for self-monitoring or near-patient monitoring of anticoagulation therapy
- robotic surgery for prostatectomy
- spinal fusion device in degenerative back pain.

The four rapid appraisal technologies were
electrocardiogram (ECG) telemonitoring
C-reactive protein (CRP) point-of-care test device
’smart’ infusion pumps (dose error reduction systems - DERS)
handheld ultrasound (imaging and Doppler blood flow).

We have developed an ‘adoption process map’ and an ‘adoption space model’ that show that adoption and non-adoption are the outcome of intricate sociotechnical and sociopolitical interactions between individuals, professional groups, NHS organisations and the industry.

We offer a key explanatory construct that we believe will advance the understanding of factors shaping adoption decisions: technology identity. This construct encapsulates the integral material and social aspects of the technologies, unavoidable demands that they bring, local expectations and agendas, and structural frames such as the health economy, budgets and costs.

‘Technology identities’ are heuristic, transportable ideas about the technology that are centrally implicated in constructing the value propositions relating to the technology’s:

- Biography – plausibility, distinctiveness/novelty, visibility, future
- Effectiveness – clinical and cost effectiveness
- Rationale and utility – clinical rationale and market, clinical, semi-clinical and non-clinical utilities
- Risks – clinical, organisational, financial
- Requirements – financial, use-related, organisational (including disruptive potential).

‘Evidence-for-confidence,’ combining health technology assessment (HTA) type (cost)effectiveness evidence with craft and everyday forms of evidence, was instrumental in the construction of technology identities. Contingent and fluid compositions of identities helped determine the technology’s adoptability. We found, for example, that an identity as institutional image maker and income generator resulted in the acquisition of the robot by many NHS trusts despite other identities indicating high-cost and contested cost-effectiveness. The coagulometer in self-monitoring had an identity among clinicians and managers as a niche technology carrying high risks; this resulted in low diffusion despite its identity as safe/clinically-effective and widely applicable in formally produced evidence.

We found that the multi-variable interactions between different identities of the same and different technologies did not easily fall into categories, making the construction of a technology typology difficult. But we noted two adoption-relevant differences between technologies. First, technologies could be classified as either stand-alone or service-embedded, depending
on whether they slotted into existing services relatively unproblematically or necessitated systemic service changes. Second, we found that technologies differed in terms of how they could be adopted. We identified three main types of adoption:

- ad hoc, typically pay-as-you-go, clinician-driven;
- intermediate, more organised, requiring some initial commitment
- single, capital investment, high level authorisation.

The first two types of adoption made trialling within the service setting possible.

A key feature of NHS adoption processes was their informal (undocumented) and political nature, involving promotion of the technology, resistance, negotiation and persuasion, rendering them relatively opaque. Availability of funds was not always a constraining factor, with a striking degree of creativity and ingenuity exercised in obtaining funds and/or devices directly. NHS know-how relevant to adoption (information retrieval and processing, independent NHS-owned assessment, whole-system/long-term approach) was limited, and informal networking and a reliance on industry-generated information and forecasting were common. Imagined and formally planned diffusion scenarios contrasted with actual diffusion; the extent to which adoption and diffusion could or should be planned or managed varied between technologies.

The adoption space model posits that adoption and non-adoption are the outcome of three inter-related processes:

- the co-construction of technology identities
- organisational structures and processes for decision-making
- relevant organisational know-how and evidence use.

Through organisational structures and processes of assembling, examining and weighting evidence, particular identities gain legitimacy and result in adoption or non-adoption. We further suggest that the appropriateness of adoption/non-adoption has to be understood as a local phenomenon and we define appropriate technology adoption as the use of local expertise to conduct impartial scrutiny in order to establish whether adoption would best serve the interests of the local health economy and patients.

Since our study indicates that local adoptive practices generally fall short of this ideal, we propose three mechanisms that could be introduced to improve technology adoption in the NHS:

- critical reflexivity to enable more systematic and independent scrutiny of available evidence
- auditable processes to ensure deliberation and decisions are documented
• post-adoption monitoring to ensure projections relating to use and anticipated benefits are realised and where feasible, adoption decisions are reviewed.

Further, we put forward the idea of a decision aid, the ADOPT Profile tool, designed to operationalise these objectives. In addition, we make suggestions for other types of input that may improve adoption decision-making and for future research.

Conclusions

This research has spotlighted to date ill-understood sociotechnical processes that influence how new technologies enter the NHS at micro and meso levels, in the context of commercial environments. The policy-rational perspective, with an emphasis on high-level formal cost-effectiveness evidence as a basis for adoption decisions, emerges as inadequate given the highly socially mediated, multi-perspective and contingent nature of adoption evident in this study. We plan the development of an ADOPT Profile tool, drawing on the empirically grounded notion of technology identities with the potential to enable a more confident and appropriate NHS response to healthcare technology innovation.
The Report

1 Introduction

1.1 Background to the research

Innovation of new technologies into healthcare systems emerged as a major policy issue in the UK during the 2000’s, expressed in a series of policy initiatives and appraisals. The key policy analyses approached the ‘technology adoption’ issue in somewhat different ways.

- the Wanless report (2002) promoted a view of the National Health Service (NHS) as a slow and late adopter of new technologies
- the 2006 Cooksey report highlighted a translational gap between products and their implementation in practice (Cooksey, 2006)
- the Darzi report (Darzi, 2008) put innovation itself centre-stage calling for simplified pathways for uptake of device innovations allied with highly challenging calls for benchmarking and monitoring of innovation processes
- finally the Carruthers consultation and report of 2011 on innovation policy (DH, 2011) again emphasised an alleged shortfall in the NHS’s ability to capitalise on indigenous inventiveness by commercialising and introducing new technologies.

These somewhat contrasting policy statements reflect the tension between policy directions that we noted in our original research proposal, namely: “Speedy adoption on robust evidence or political endorsement is countered by attempts to restrain diffusion (HITF, 2004; NHSTAC, 2007; DH, 1998). Standardisation of evidence-based procurement conflicts with the need for local innovativeness and decision-making (House of Commons Health Committee, 2005; Cooksey, 2006). Health technology assessment (HTA) and technology appraisal has developed, and research has focused on the research-practice ‘implementation’ gap (Grimshaw et al, 2004; Haines et al, 2004; DH, 2007a). But shortcomings of the linear, evidence-centred, context-free model of innovation are recognised (Black, 2001; Rosen & Gabbay, 1999).”

It was notable, as recognised in the National Institute of Health Research (NIHR) Service Delivery and Organisation (SDO) programme, that nonpharmaceutical technologies were starting to receive long-overdue increased attention in these policy developments. It was also notable that the National Institute for Health and Clinical Excellence (NICE) introduced its medical technology evaluation programme and the Medical Technologies
Advisory Committee (MTAC) toward the end of the 2000’s, and various innovation initiatives were launched and reconfigurings implemented during the decade, including the National Technology Adoption Centre (NTAC) whose remit has been to improve uptake of innovations whose evidence base is considered to be strong.

The SDO programme issued a call for proposals on ‘Technology Adoption’ in 2008. The present research derives from one of the successful proposals. The call for proposals emphasised a wide range of possible topics for relevant research. Our research set out to address: “professional, inter-professional, organisational and inter-organisational factors that accelerate or decelerate adoption and evaluation; issues of evidence and information sources that decision-makers draw upon; the roles of NHS managers and the commissioning process; different forms and configurations of clinical and profession organisation; and the producer role and interactions between technology users, producers and NHS gatekeepers/regulators”. The call for proposals also used the concept of ‘appropriate adoption’ and this research aimed to “provide empirical and conceptual groundwork which will advance the broader task of defining different pathways of adoption and the variable criteria by which their appropriateness might be assessed”.

Several of the technology case studies in the research focus on named products (see Chapter 4). We obtained agreement with representatives of the companies producing and/or distributing these products to include them in the research. We emphasize that the research assesses adoption processes in which these products have been involved, and we do not comment on or evaluate the products themselves.

1.2 Theoretical background to the research

The research reported here also aimed to build on a diverse range of existing conceptual and theoretical research, which we identified as coming mainly from both Science & Technology Studies (STS)/Sociology and Health Services Research, and which provided a starting-point that recognised the shortcomings of linear evidence-based conceptualisations of uptake of new medical technology, and a need for context-sensitive, contingent, ecological approaches (Greenhalgh et al, 2004). Thus, we noted the importance to technology adoption of “clinicians’ and others' understandings on evidence, risk and safety, and perceived needs for trial or 'pragmatic science' or practical experience (which) constitute important early-phase adoptive behaviours”. We noted that strong evidence in the evidence based medicine (EBM)/HTA paradigm was not necessarily correlated with rational adoption, and pointed to case studies showing that ‘practice’ can prevail over ‘evidence', such as in the diffusion of laparoscopic surgery (Fitzgerald et al, 2002) and osteosynthesis (Schlich, 2002); and in the re-orientation of telemedicine into telehealth (May et al, 2001; May 2006). Likewise, the Innovation Studies branch of STS had
shown the importance to organisational innovation processes in technology of 'personal trial and error' (Metcalfe et al, 2005), and interaction between dispersed institutional actors including but not confined to those in healthcare delivery systems (Ramlogan et al, 2007).

Considering the key issue of 'Evidence', given the EBM/HTA paradigm, we noted the 'crisis of evaluation' where many new technologies 'creep' into practice without formal (randomised controlled trial - RCT) evaluation (Gabbay & Walley, 2006) and that this was due, in part, to loss of equipoise - uncertainty about comparative effectiveness (Fried, 1974; Freedman, 1987), frequently during early adoption (Chalmers et al, 1972; Mowatt et al, 1997; Robert et al, 1999; Lilford et al, 2000; Department of Social Medicine, 2008/9; Tomlin, 2011). Co-ordinated, rational, evidence-based adoptive strategies appeared to be the exception rather than the norm.

The present research was thus designed given a perceived need for a more systematic and conceptually sensitive approach to technology adoption issues, one which should focus on the grassroots of early emergence and adoptive behaviour to examine complex factors at the micro level of individuals and small teams, and at the meso level of networks of practitioners, managers, triallists and other evaluators, commissioners, the industrial and commercial producers of healthcare products (cf. Swan et al, 2007), and technologies themselves. From STS we aimed to draw, in particular, on the concept of the 'actor-network' (e.g. Law & Hassard, 1999) where interacting 'actors' may be individuals, institutions/organisations and technology itself, thus giving due (and hitherto neglected) attention to the role of different types of device technologies themselves, and extra-NHS actors in healthcare innovation processes. This approach would draw attention to the complex interactions of the range of actors involved. 'Technical' and 'social' aspects would be conceived as closely interconnected, as apparent in some instances of successful adoption strategy (cf. Obstfelder et al, 2007). In order to develop this approach and apply it to the Technology Adoption issue, we devised the notion of the ‘adoption space’ in which these heterogeneous actors could be seen to ‘co-produce’ various forms of adoptive behaviour or non-adoption, conceived potentially as occurring in technology-specific networks of actors both within the healthcare system (cf. ‘communities of practice’) and between technology producers/distributors and the healthcare system. We posited, as an ambition of the research, that it might be possible to derive from a set of empirical studies of different technologies produced by different types of producer and considered and adopted into different types of healthcare setting, a ‘model’ of the workings of this adoption space. The research reported here, therefore, was designed to fulfil these aims and to follow these orienting assumptions. The Methodology is described in the next chapter (Chapter 2), and the adoption space is discussed in Chapter 3.
In this way, drawing on the approach summarised above, it might be possible to build resources that could, at the least, contribute to laying the foundation for a better understanding of factors contributing to what we identify as the over-arching aim of the SDO Technology Adoption research programme, namely defining ‘appropriate adoption’.
2 Methods

This study aimed to provide insights into the adoption of health care technology in the UK NHS and to produce outputs that might inform practice and policy.

Key research questions were:

- Can an ‘adoption space model’ help construct a restricted, useful typology of healthcare technology?
- What is the typical pattern and alignment of factors that determine the pathway of early adoption for different types of technology?
- How is (and how might be) gate-keeping and regulatory activity geared to different technologies?
- How does the inter-relationship between demand-generating activities of industry interests and expectations, and enthusiasms of users and potential users, shape the evaluation/innovation pathway?
- Can typical critical ‘passage-points’ be characterised? (Organisational/evidential hurdles that technologies contend with, where intervention might be possible.)
- Which parameters/factors are associated with which types of evaluation methodology?
- What constitutes successful or unsuccessful alignments of different elements in the adoption space? Can we assess in what ways adoption-evaluation pathways might be modifiable so that optimally acceptable (‘appropriate’) pathways can be planned and pursued?

2.1 Theoretical orientation

The study was located within a sociological tradition that emphasises the ‘socially constructed’ nature of social reality. Particularly relevant to the study were the STS perspective and the ‘technology-in-practice’ approach (Latour, 2005) which recognises the role of both the material and the social aspects of technology. The study additionally used actor-network theory (Law & Hassard, 1999) to map the territory and acknowledge the technology’s role and structuration theory (Giddens, 1984) to delineate the framing influence of macro social structures and economic conditions. The notion of the ‘adoption space’ was formulated as an organising and orienting construct at the outset (Chapter 3) to guide data collection and analysis.

2.2 Methodology

The study used an ethnographic comparative case study design, with technology as the main unit of analysis. Four main cases/technologies and
four less detailed ‘rapid appraisal’ technologies were studied using predominantly qualitative methods. The aim was to compare the empirical findings within and between cases to arrive at more transferable conclusions and from these to develop a policy relevant model/tool.

2.2.1 Data collection

We used the following data collection methods

- semi-structured in-depth interviews - NHS/industry/academic informants
- email/telephone contact with informants
- documents and websites
- media reports
- scientific literature
- observation at conferences/smaller meetings.

We had intended to conduct observation/recording of relevant NHS managerial meetings; this was not possible for reasons that are explained in Section 2.4. Data were collected both retrospectively and prospectively, tracking real-time and historical events. ZT, SP, AF and GE all contributed to data collection.

Case technology selection

As set out in our original proposal, the main technologies were of importance to the NHS and had a variety of salient features and some of them were familiar to the research team from earlier work. The coagulometer, used in point of care services or in patient self-testing, represented a community based technology that had a relatively strong evidence base and wide applicability but had diffused little. The robot represented an expensive technology with a public profile and subject to aggressive marketing, expected to diffuse possibly inappropriately. The spinal implant represented a clinically controversial intervention (surgery for back pain) with little robust evidence; this was an area where multiple products were offered by multiple companies, offering end users a possibly bewildering ‘choice.’ The cell therapy represented technically promising technology with a number of ‘issues’ that limited diffusion and one with particular evaluation challenges; here, the initial candidate technology had to be replaced by another due to a continuing absence of EU regulatory approval.

The rapid appraisal technologies were selected once the analysis was under way and a combination of maximum diversity and a degree of theoretical sampling was also used for these, e.g. high requirements, clear versus ill-defined identity, disorganising/disruptiveness potential (Table 1). Smart infusion pumps required the collaboration of many stakeholders from
Table 1. Study technologies

<table>
<thead>
<tr>
<th>Purpose/function</th>
<th>Robot</th>
<th>Spinal implant</th>
<th>Cells</th>
<th>Coagulometer</th>
<th>CRP</th>
<th>Hand-held ultrasound</th>
<th>ECG* telemonitor</th>
<th>Smart infusion pumps (DERS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Potentially) large-scale</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (telemonitor)</td>
<td>X (ECG)</td>
<td>Drug delivery/Patient safety</td>
</tr>
<tr>
<td>Niche</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory issues</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technology creep</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary sector</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary/community sector</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High cost</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medium/Low cost</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strong evidence base</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X (other cell therapy)</td>
</tr>
<tr>
<td>Contested evidence base</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Sparse evidence base</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X (ECG)</td>
<td></td>
</tr>
<tr>
<td>One/two specialty/user group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X (telemonitor)</td>
</tr>
<tr>
<td>Multi-specialty/user group</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policy endorsed</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>High requirements</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>High visibility/expectations</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Problematic relations</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

*Both the ultrasound and telemonitoring are not intended as diagnostic tests, but more as a screening tool for individual patients. They may provide information about a patient's state of health, but are not alternatives to full-scale diagnostic tests. #ECG telemonitoring was the intended case study technology. However, due to the timeliness of several Department of Health (DH) related projects in this generic area and because many of the adoption issues will be common across the different platforms we have included information both specific to ECG and generic to telemonitoring.

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different professional groups within a hospital and represented relatively 'low visibility' technology. The hand-held ultrasound represented the digitalised, miniaturised, 'gadget' technology and had a potentially disruptive impact, enabling a wide range of professionals to undertake simple imaging in community settings (provided they were trained). ECG home monitoring was another patient-used technology, introduced novel health data collection (regular ECG readings in chronic conditions) and belonged to the class of telehealth, with intense policy interest during the study period. C-reactive protein (CRP) point of care testing (POCT) was not adopted in the UK but somewhat widely adopted in Scandinavian countries, providing an opportunity to study non-adoption.

Of the indicative list for rapid appraisal cases in the proposal, only one was selected (smart infusion pumps). The main criteria for selection of these technologies were the range of usership and range of subsectors/specialties represented in the total sample of cases. The others were rejected for the following reasons: too similar to main case technologies, i.e. hospital based intervention/surgery (thalamic deep brain stimulation, implantable miniature telescope, magnetic source imaging for epilepsy); access difficult (stammer therapy); very expensive technology likely to be adopted by only one or two centres in the UK (helical tomotherapy); superseded technology (dual headed gamma camera PET for coronary imaging); in the vascular field as well as related to surgery – ECG telemedicine already selected (non-invasive contrast enhanced MR angiography evaluation of carotid artery stenosis).

Setting

The intention was to study each of the four main technologies at two NHS sites different in character. Actual data collection took a more diffuse form for reasons explained in Section 2.4. As well as a number of 'sites,' data were collected from other NHS organisations as well as relevant individuals (clinical/managerial/academic).

Sampling of informants

Purposive and snowball sampling were used to locate key informants, both at NHS sites (individuals involved in adoption or consideration of adoption) and more generally within the technology's adoption space: clinicians, academics and industry representatives with knowledge about various aspects of the technology and its adoption. We tried to include both users and non-users and a variety of views about the technology in question. The number of interviewees for each technology varied, based on level of adoption/accessibility and the nature of the case (main/rapid appraisal). Some informants were interviewed more than once to track developments). Details are shown in Table 2.
Table 2. Data collection

<table>
<thead>
<tr>
<th></th>
<th>Robot</th>
<th>Spinal implant</th>
<th>Cells</th>
<th>Coagulometer</th>
<th>CRP*</th>
<th>Hand-held ultrasound</th>
<th>ECG telemonitor</th>
<th>Smart infusion pumps</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS organisation contributing to data collection</td>
<td>12</td>
<td>5</td>
<td>9</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>38</td>
</tr>
<tr>
<td>Clinician*</td>
<td>13</td>
<td>7</td>
<td>15</td>
<td>7</td>
<td></td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>46</td>
</tr>
<tr>
<td>Manager</td>
<td>10</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td></td>
<td>1</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>Commissioner</td>
<td>1</td>
<td></td>
<td>2</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Other NHS</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Academic (some clinical role)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Industry</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>19</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td></td>
<td></td>
<td>1 (patient)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Total no of interviewees</td>
<td>27</td>
<td>10</td>
<td>24</td>
<td>14</td>
<td>14</td>
<td>4</td>
<td>8</td>
<td>5</td>
<td>106</td>
</tr>
<tr>
<td>Total number of interviews</td>
<td>39</td>
<td>12</td>
<td>30</td>
<td>15</td>
<td>14</td>
<td>4</td>
<td>8</td>
<td>5</td>
<td>127</td>
</tr>
</tbody>
</table>

* Note that all the academics, commissioners and at least 1 manager in CRP also had some clinical role

# Many clinicians also had supplementary roles either as academics or service directors, commissioners, advisers to central bodies
Interviews

Interviews were semi-structured/in-depth (60-90 minutes), the majority were conducted face-to-face (with some telephone interviewing), all were audio-recorded and transcribed verbatim (with one recording failure) and covered the following areas: awareness of the technology, advantages and disadvantages, requirements, adoption decision-making processes, awareness of the evidence, data gathering/evaluation, impacts of technology, views on adoption/diffusion generally (Appendix 1). Topic guides were tailored to professional group/site as necessary.

Documents

We examined:

- industry produced promotional documents and websites
- NHS policy documents, reports, business cases, minutes, evaluation reports
- centrally produced policy documents on adoption/innovation
- centrally produced technology evaluations (HTA/NICE, etc)
- scientific literature on the technologies
- media reports
- patient and professional organisation documents and websites.

Conferences/events

We attended clinical specialty conferences and some smaller events for the main technologies (Appendix 2).

2.2.2 Analysis

Data were managed using Atlas.ti software. Constructivist grounded theory (Glaser & Strauss 1967; Charmaz, 2009) was used to analyse qualitative data including documents. Iterative analysis and data collection, systematic conceptual coding, constant comparison, discourse sensitivity and divergent case analysis were employed.

A baseline report on the state of adoption and evidence was prepared for each technology (summarised in Chapter 4). Following this, data were coded using a fine-grained interpretive and emergent approach; early ideas (e.g. adoption space) were used as sensitising concepts. Data sessions were held where ZT, SP and AF discussed code definitions and codes were merged/split/deleted to arrive at a jointly agreed frame (Appendix 3). During the second stage of analysis, similarities and differences within and between the technologies and conceptual patterns were identified, codes were grouped into themes and higher-order themes (e.g.
visibility/distinctiveness of the technology) and analytic abstractions (e.g. technology identities, Chapter 5) and conceptual explanations ( adoption process map, Section 9.2) were constructed. The idea of technology identities was developed about half-way into analysis, as a result of repeated interaction with the data: coding, reading all relevant quotes under the codes, making mental connections and writing memos. By then, the coding frame had more or less stabilised. In order to further develop, instantiate and verify the appropriateness and utility of the identity concept, the dataset was re-approached from this perspective and a large number of primary codes were grouped together according to the new analytic frame. For example, codes relating to expectations from the technology (optimal service, reputation/kudos, private patient income) were grouped under the higher-order theme ‘utility identities relating to service delivery and health economy.’ Codes relating to the technology’s market size and advantages, value of the intervention that the technology made possible and users’ rationale for the technology were grouped under the higher order theme ‘clinical utility identities.’ The two higher-order themes were then combined under the more general category of ‘utility identities.’ This process was repeated for other identity codes. While some codes were obviously relevant to specific identity themes, others were less so. However, the dataset was interrogated in order to draw out information relevant to the analytic frame of identities/requirements from all potentially relevant codes.

By contrast, the category ‘adoption work: adoption as political process’ (Section 6.2.1) was developed by de-constructing primary codes with a relatively wide scope: ‘politics/power/relationships’ and ‘adoption decision-making – clinician/NHS trust.’ This process led to the composite themes:

- persuasion
- finding allies
- political will versus bureaucratic reasoning
- resistance (giving in/pre-empting; ways of saying no)
- competition & clout
- expertise & co-option
- protectionism
- locus of power.

These processes were conducted using the entire dataset, in other words, using a cross-case approach. As data segments under each code were read, similarities and differences between technologies and sites were noted; the narrative of the findings chapters (Chapters 4 to 9) has a comparative focus designed to make these clear.

Interim analytic reports were discussed at team meetings and the insights gained informed subsequent analysis. Data collection continued through these processes.
Analytic units overlapped, alternating between technology-site and technology; comparisons were made between different sites for the same technology and between different technologies. Emerging patterns along professional lines (e.g. managers’ approach to evidence; clinicians’ role in organisational processes, etc) were noted. Where appropriate, geographical factors (within and outside the UK) were also considered. Cross-case syntheses were constructed using whole-dataset themes across the technologies to arrive at generic conclusions.

2.2.3 Reporting

The findings are reported in the following order: technology summaries; technology identity; organisational adoption processes; evidence and evaluation; early use and diffusion; main conceptual conclusions. The reporting incorporates a comprehensive account of all our analytic ideas and conclusions. In selecting materials – reported examples and data extracts – that illustrate the analytic ideas, we have tried to ensure that the dataset is represented in a balanced way and that the technologies are considered consistently. The prevalence of the views and ideas reported, that is the frequency with which they were offered by the interviewees, is indicated through the use of quantifiers such as ‘some, many, most, few.’

2.3 Research governance

We obtained ethics approval and also obtained R&D approval where feasible. Each prospective informant was given a study participant information sheet (PIS); the majority of informants gave written consent and some gave verbal consent (e.g. telephone interviews). Sample PIS and consent forms are in Appendix 4 and Appendix 5.

2.4 Methodological contingencies

The planned structure of data collection was modified during the research. We found that adoption was ambiguous and slippery. It was difficult to designate hospitals as ‘adoption sites’ because adoption had been partial/sporadic/reversed/informal. Sites that we believed were adopters turned out not to be at interview and vice versa. Additionally, sites that were considering the technology at the outset did not always end up adopting it. Data collection was therefore more diffuse than planned, taking in a number of sites that appeared to be productive sources of information on the basis of preliminary intelligence.

Related to this, researchers were not able to embed themselves at ‘sites’ and to collect ethnographic data, i.e. attending meetings and examining documents. This was partly because of the informal nature of adoption processes (a main finding - Chapter 6), making it difficult to pin them down and to witness. Another reason was lengthy research and development (R&D) processes (several months). As it was not clear initially whether the
prospective site would really become an adoption site this scale of time investment was not feasible.

The original working title of the study was modified soon after work began to render it more reflective of the nature of the study. The title ‘Pathways to adoption of technologies in healthcare’ with the acronym PATH was used in all documentation thereafter.

2.4.1 NHS R&D processes

Our experience with NHS trust R&D processes replicated the frustrations experienced by many researchers over the last decade. This made it necessary to request an extension to the project. If we had attempted to obtain R&D approval for each NHS informant, the number of study informants and the volume of data would have been significantly lower. We obtained R&D approval where it was feasible but made a choice to prioritise data collection and conducted some interviews without it; these were with senior clinicians who gave informed consent to participate in the study. Sometimes we found we had crossed into the R&D jurisdiction of another trust, through snowballing, without being aware of it. Similarly, we did not seek R&D approval for all telephone interviews; on one occasion, we obtained R&D approval to hold just one telephone interview.

It was clear to us that the difficulties we experienced with R&D systems were in large part due to two core problems: 1) a system designed with clinical research in mind (every interviewee deemed a ‘recruit’ by the system) and the corresponding assumption that it is possible to fit non-clinical research into this framework and 2) an overlap of ethics and R&D functions where many aspects subjected to scrutiny by the ethics committee appeared, at least on paper, to be re-scrutinised by R&D systems (with uncertain competence). We would like to repeat the wish, expressed by many in the HSR community, for a more sophisticated R&D system that recognises the different nature and scale of risks associated with clinical and non-clinical research, such as that reported here, and for designs of safeguarding systems appropriate to each.
3 Concepts and meanings

As briefly explained in Chapter 1, the concept of the technology 'adoption space' was conceived at the outset of the research as a working hypothesis, on the basis of the team’s previous work (Faulkner and Kent, 2001; Faulkner, 2009; Elwyn et al, 2008) and salient themes in the technology adoption and diffusion and STS literatures. The concept informed study design and the selection of data collection methods and was used as a sensitising tool in data analysis. As analysis progressed, the appropriateness and utility of the concept became clearer and specified in detail.

3.1 The adoption space

During the design stage, we hypothesized that the adoption of device technologies in the NHS was exposed to and shaped by many influences, beyond those operative in individual NHS trusts. We wanted the study to be capable of capturing all potential sources and types of influence on adoption/non-adoption and developed an all-inclusive ‘map’ of actors and influences. This we termed the ‘adoption space.’ In this initial form, the adoption space was conceived as comprising:

- the technology
- the network (all those involved in some way, including the industry, clinicians, managers, patients, the media, etc)
- evidence
- promotion
- gatekeeping.

The adoption space notion was iteratively developed and revised in the light of the empirical work. This process of continuously checking the fit between the original conceptualisation and the emerging evidence enabled the research to use the notion of the adoption space as an anchor to both fieldwork and analysis without being conceptually restricted by it. We believe that this dynamic process helped us to systematically pay attention to all relevant actors, processes, influences and decisional junctures.

The final definition of the technology adoption space derived from the research is:

*a dispersed spatial/temporal space populated by human and non-human actors from different social worlds, within which socio-technical processes (actions, interactions, practices and events) shape technology perceptions which are in turn instrumental in decisions about its use*

and has three dimensions:
• Temporal - the point in time when a decision or a series of decisions are made to use or not to use the technology (either for the first time or in early stages of usage); the lead-up to the decision; the immediate aftermath and early use

• Spatial – a social space populated by networks of actors (including the technology and associated technologies) transcending organisational and geographical boundaries

• Processual – ongoing socio-technical and socio-political processes and mechanisms have relevance to decision-making on the technology

The adoption space is a holistic and inclusive concept designed to account for the complexity of the topic. Its theoretical position is deliberately eclectic, a route also taken by others (Greenhalgh and Stones, 2010). It pays attention to the dynamic and constitutive role of both social structures and agents in social life by drawing on structuration theory (Giddens, 1984) and actor-network theory (Law & Hassard, 1999). It also attends to the materiality-sociality duality of technologies as represented in the ‘technology-in-practice’ approach (Latour, 2005; Timmermans and Berg, 2003) of the STS tradition. It recognises that macro conditions and social structural factors are at play; these exogenous factors frame social action not so much by moulding it from the outside but as a set of internalised forces constitutive of agent’s actions and practices. Although adoption decisions are made within the jurisdiction of NHS organisations, the technology-specific adoption space within which these decisions are socially shaped goes well beyond these institutions and includes the industry, media, patient organisations, academic, professional and government bodies and their outputs.

**Figure 1. The technology adoption space**

![Diagram of adoption space]

Conceptually, we divide the adoption space into four distinct domains (Figure 1):

- macro/meso and social structural
• rational-policy
• socio-technical
• decision.

Of course, this division is a conceptual device that delineates the different forces at play; in practice, the domains ‘leak’ into each other.

3.1.1 The macro/meso and social structural domain

This domain reminds us of the role of overarching economic, political, administrative and clinical structures, such as the free-market medico-industrial complex, the national economy, the NHS internal market, commissioner reimbursement, epidemiology, resources (e.g. hospital budgets) and regulation of technology in adoption decisions. It also highlights the role of social structures such as hierarchies – within and between the health professions, between health professions and managers and between health professions/managers and patients.

3.1.2 The rational-policy domain

This is the domain of evidence based policy and practice where the discourse of bureaucratic rationality speaks the loudest. Here, technology adoption is represented as part of a rational, linear process and positioned at the later stages of an innovation trajectory. In the influential Cooksey report (Cooksey, 2006), problems in adoption/diffusion were represented as the ‘second gap in translation’ where adoption/diffusion was the outcome of a sequence beginning with late clinical trials and HTA, through health services research to knowledge management. Technology adoption was situated within the EBM paradigm where the clinical and cost-effectiveness of the technology determined/should determine its adoption and diffusion (e.g. NICE evaluation pathways programmes).

This approach later developed into a more comprehensive vision with two government publications in 2011, the DH report on innovation (DH, 2011) and the Department of Business, Innovation and Skills (BIS) report on life sciences (BIS, 2011). These recommended:

• increasing access to relevant information
• harnessing patient demand for new technologies
• co-opting industry as a partner in strategically coordinated innovation
• reducing the burden of regulation
• increasing funding opportunities for health technology SMEs.

In this domain, technology adoption/diffusion is visualised as happening in a rationally ordered and cooperative world:
• health needs assessment and potential health and system impacts determine whether the technology receives attention from evaluators and policy makers
• technologies that merit such attention are evaluated using the ‘gold standard’ RCT
• the industry consistently cooperates in these evaluative endeavours
• local adoption decisions are made on the basis of the outcomes of such evaluations, technology-specific policy guidance and rational assessment of potential organisational impacts.

It has been understood for some time that the real world of technology adoption/diffusion has resisted this rational vision.

3.1.3 The socio-technical domain

This is the heart of the adoption space, where technology adoption is conceived as socio-technical ‘work’ collaboratively accomplished by human and non-human actors, notably the technology itself (Faulkner, 2009). The actors are situated within dispersed and fluid communities of practice and are shown in Figure 2. Human actor attributes such as perceptions, attitudes, practical reasoning, agendas, expectations and practices, and social phenomena like discourse and rhetoric act here. Mundane social interactions – a discussion over a glass of wine, a casual stop at a conference stall, reading a scientific paper, a formal meeting, a patient request, a visit to a hospital website - are some of the occasions where different voices meet and shape decisions about adoption.

A vitally important aspect of this domain is its mediating and transformative power. New, revised meanings are co-constructed for phenomena that habitually reside in the rational policy domain: evidence, clinical/cost-effectiveness. These concepts are mobilised, just as they are in rational policy discourses, to justify adoption/non-adoption, but the adoption space versions are semantically different.

3.1.4 The adoption decision

The key phenomenon of interest in the study and in the adoption space is the decision on whether to adopt a technology. Our conceptualisation places decision-making at the centre of the adoption space. The most immediate influence on decisions is exerted by the socio-technical domain while the others are mediated through it.

In understanding the decision, it is crucial to explore the locus of decision-making. Officially designated decision-makers are not always the de-facto decision makers. Politics and the distribution of power in the socio-technical domain (between professional groups, between NHS organisations and between the NHS and industry) may mean that decisions are effectively made by those who wield the greatest power.
Figure 2. Actors in the technology adoption space

<table>
<thead>
<tr>
<th>Human</th>
<th>Technology</th>
<th>Organisations</th>
<th>Textual documents</th>
<th>Websites</th>
<th>Abstract phenomena</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health professional</td>
<td>Primary technology</td>
<td>NHS trusts</td>
<td>Published evidence</td>
<td>Journals</td>
<td>Evidence</td>
</tr>
<tr>
<td>NHS manager</td>
<td>Subsidiary technologies</td>
<td>Professional organisations</td>
<td>NHS documents</td>
<td>Hospitals</td>
<td>Clinical/cost effectiveness</td>
</tr>
<tr>
<td>Industry rep</td>
<td>Competitor/ alternative technologies</td>
<td>Patient organisations</td>
<td>Media reports</td>
<td>Media</td>
<td>Policy</td>
</tr>
<tr>
<td>Patient/Public</td>
<td>Governmental/evidentiary organisations</td>
<td></td>
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<td></td>
<td>Regulation</td>
</tr>
<tr>
<td>Academic/Researcher</td>
<td>Regulatory organisations</td>
<td>Government publications</td>
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<td>Patient organisation/campaigning material</td>
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<td>Professional organisation reports</td>
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<td>Professional organisation</td>
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</tbody>
</table>

3.1.5 Socially constructed technology identities

We have identified a key construct in the socio-technical domain that emerges as an output of sociotechnical activity and largely explains adoption decisions: technology identities.

Technologies are repeatedly subjected to local, informal evaluation under conditions of uncertainty and ambiguity (about the technology’s functioning, effectiveness, value, etc), making it inevitable that local actors engage in sense-making. As a result of these sense-making processes, technologies acquire a number of identities that relay information about the technology’s technical capabilities, effectiveness and future as well as its unintended, sometimes non-clinical, impact and demands on health services and people (Chapter 5).

We define technology identity as:
a narrative or discursive presence for the technology that delineates a particular set of attributed characteristics and performative expectancies as centrally relevant to and representative of the technology’s distinctiveness and value

- The interpretations and attributions that shape technologies’ identities draw on a diverse set of phenomena:

  - the technology’s physical, material and functional properties that are unarguably and inflexibly ‘given’
  - the broad social, political and economic ‘givens’ that regulate relations between industry and the NHS and between NHS providers and commissioners, etc as well as the movement of finances between these sectors
  - social structural givens, such as the hierarchical relations within NHS organisations and between health professionals and patients
  - centrally produced health policy that attempts to place a normative frame around technology adoption decisions
  - individual, collective and institutional agendas and expectations.

Identities are produced in actor networks, through interaction and textual representations in documents and websites, narratives and rhetoric. Neither the EBM paradigm nor the marketing paradigm can explain identity construction, although both contribute to it. Technologies differ in the type and number of identities they acquire as they travel through their adoption pathway and can change over time. While some types of identity draw more on interpretation, others are more tightly constrained by the physical properties and functionality of the technology.

The theoretical proposition put forward here on the basis of our analysis is that constructed technology identities are powerful determinants of adoption decisions. As identities begin to circulate in the adoption space, for example from one NHS trust to another, and to capture the imagination of human actors, they also begin to exercise a framing effect on adoptive behaviours through influencing what types of technology-relevant information are sought and accessed, how the information is evaluated and how much weight is put on particular types of information.

Throughout this report, we use some common concepts and terminology that may have ambiguous or even contested meanings. For clarity, we define the meanings that we ascribe to these terms in Appendix 6.

In the following chapters, we report our empirical findings on technology adoption, showing how the concepts and phenomena we have described here are enacted in practice.
4 Technology case study summaries

The four main and four ‘rapid appraisal’ technologies covered diagnosis, long term care monitoring and treatment and a variety of conditions; they spanned primary, community and secondary care sectors (Table 1). Below, we provide brief descriptions of their features and present the main issues relevant to their adoption/non-adoption in the UK.

4.1 Spinal implant for minimally invasive fusion

4.1.1 Description

This is a minimally invasive spinal fusion technique for: lower back pain due to degenerative disc disease; failed previous fusion (pseudoarthrosis) or displacement of a vertebra (spondylolisthesis, grade 1 or 2). The technology consists of the implant, a titanium alloy axial rod, and various instruments. The implant is only used at two specific levels on the spine. Fusion (open or minimally invasive) is thought to reduce or eliminate pain, although it also restricts movement to some extent.

Innovation and advantages: The most innovative aspect - the one that is patented - is the surgical route. The spine is accessed through a small incision at the back under general anaesthesia. Guided by continually updated still images from a fluoroscope, the surgeon uses dilators, cutters and drills to open a working channel to the affected disc. This channel is claimed to be a ‘safe zone’ away from nerves and organs. The implant is then put in place and bone graft inserted. The technology is promoted as a safer technique than traditional (open) fusion with fewer complications as well as having all the claimed advantages of minimally invasive surgery (MIS), i.e. less tissue damage, blood loss and postoperative pain and faster recovery.

Costs: The technology does not require major capital investment. Generally, it is provided on demand, when a suitable patient presents. The cost per case is just over £3,000. The titanium implant costs around £2,000, the disposable instrument kit £1,000 and reusable instruments - generally loaned to hospitals per case - £300 to hire. There is, however, a trend to include the implant in tender packages of spinal implants, screws, etc.

4.1.2 Clinical market

Back pain affects one-third of the UK adult population each year (NICE, 2009) and is reported to be the largest cause of absence from work (NHS Choices, 2012). However, surgery is controversial and performed only in a small minority of cases, with most treated with exercise and manual therapies (e.g. physiotherapy).

The technique was developed in the US where open fusion surgery often requires a second ‘access’ surgeon to open the surgical field; the spinal
surgeon then performs fusion. In that context, the technology represents a radical change in service provision, as it allows a single surgeon to perform the whole procedure in a minimally invasive way. In the UK, spinal surgeons have always performed fusion single-handedly. In the US, the rate of fusion surgery is higher and the technology and other spinal MIS are promoted as ‘easy’ solutions to back pain, with the fusion market set to grow by 12 percent annually to 2014 (Spine-Health, 2012, a patient education website financed through fees for directories of spine units and surgeons). The UK clinical community – and patient organisations – are more conservative in their attitude to spinal surgery.

4.1.3 Industry and competition

The implant was first marketed in 2005 by the US manufacturer which has been operating with losses since the launch ($3.3 million in the third quarter of 2011). The product has been available in the UK since 2006 and is distributed by a Midlands based company selling a range of spine products from a number of manufacturers and with a customer base in around 150 hospitals.

There are several MIS fusion technologies available, although the status of some of these as minimally invasive are disputed (due to the size and number of incisions). However, they are not necessarily competitors as surgeons differ in their preferred approaches and will often select one technique and stay with it. While not constituting ‘competition’ in the commercial sense, there are many other surgical and non-surgical treatment modalities for back pain, so that the implant is one small part of a large picture. These include open fusion techniques, non-fusion surgery and total and partial disc replacement (open or minimally invasive).

4.1.4 Adoption space, actors and issues

Clinical novelty and risk: The novel surgical route, while marketed as an advantage, may lower the implant’s acceptability to surgeons who are not used to the particular anatomy and feel unconfident about operating there. Furthermore, the surgical route is associated with risk of bowel perforation.

Private healthcare market: Spinal surgery is potentially a lucrative private income generator for surgeons. However, although its first UK use was on a private patient, the implant lost this marketing advantage when several US and UK private health insurers designated it as ‘experimental’ and refused to reimburse for it. These decisions were being reversed from 2011, with potential impact on adoption by NHS surgeons with private practices.

Evidence: There are no RCTs. Several non-UK case series have reported fusion rates of between 86 and 98 percent, improvements in pain and function of 50 to 94 percent and complication rates of 0.6 to 22 percent; the longest follow-up period was two years (Stippler et al, 2009; Patil et al, 2010; Tobler et al, 2011). The technology was said to be exciting and a true departure from existing approaches. High US fusion rates may be partially
due to use of fusion-inducing bone morphogenetic proteins (BMPs), little used in the UK and x-rays may indicate a higher fusion rate than more accurate CT scanning. While a company sponsored study reported 0.6 percent bowel perforation rate (Gundanna et al, 2011), another study reported a 2.9 percent rate (Lindley et al, 2011). There is some evidence that the learning curve is associated with complications (Patil et al, 2010). Following reports of problems, the implant is now normally supplemented with pedicle or facet screws placed in the back of the spine to achieve a 360° fusion (compulsory in the US but not in the EU).

NICE guidance (2011): The guidance says that current evidence is ‘limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation.’ The procedure was designated as ‘for use with special arrangements.’

4.1.5 Diffusion

The manufacturer website indicates that eight UK spinal surgeons in seven hospitals (three in London) offer the technique. By summer 2011, a total of 10,000 procedures had been performed in the US; in the UK, 85 and 55 cases were performed respectively in 2009 and 2010 and 22 cases in the first half of 2011. Several surgeons who had been on company provided training were yet to take up the technique.

4.2 Tissue engineered cell therapies for burns

4.2.1 Description

This is an autologous tissue engineered product used to treat patients with severe burns. It consists of the patient’s own skin cells (autologous keratinocytes) multiplied in a laboratory and supplied on a silicone backing or suspended in a solution. The cells adhere to the wound bed and proliferate across it, gradually maturing and providing a permanent outer skin layer. The product was developed at a UK university and commercialised by a spin-out company in 2000. It was launched in 2004 as a 5cm diameter circular disc, but following user feedback was changed to a larger rectangular sheet and later a spray formulation.

For this technology, a skin biopsy is taken by the surgeon and delivered to the manufacturer where cells are separated and multiplied. These are available for use after around one week for the spray, or two weeks for sheets and are delivered by courier. Cells are part of a multi-modality care package for burns, including wound preparation and skin grafting. Repeat applications can be made and cell expansions can be stored by the manufacturer for up to six months.

In this report, we will occasionally refer to a second, similar cell therapy that uses donor (allogeneic) keratinocytes that encourage normal healing rather than transferring skin cells to the wound surface. This is available as
frozen sheets and can therefore be purchased in bulk and stored on site or delivered as required. It requires 30 minutes to thaw before use and is applied as a dressing. Throughout the report, when we refer to ‘cell therapy’, ‘the technology’ or ‘the product’ in the context of burns or chronic wounds, this will mean the main case technology. We will refer to the second technology as the ‘allogeneic product.’

**Innovation and advantages:** The innovative aspect of this cell-based technology is the coating on the silicone backing, enabling skin cells to continue to proliferate after seeding onto it but also encouraging transfer onto the wound bed. Previously hospital or university tissue laboratories grew keratinocytes into sheets a few cells thick (cultured epithelial autografts – CEAs). These were delicate and could only be used within a window of 2-3 days, leading to wastage. The cells also become less active. The advantages of the technology are therefore ease of handling, flexibility of timing and more active cells.

**Costs:** There is a fixed fee of £2450 for processing the skin biopsy. The product price is in the region of £900 for a 7x11cm sheet or vial of spray (coverage of approximately 100cm²). Cost depends on the size of the burn area, e.g. for one adult with 82 percent burn surface area (BSA) the product costs were approximately £65,000 (data from interviewee). The allogeneic product is £700 for a 10x10cm sheet. Alternative pricing structures are available.

### 4.2.2 Clinical market

The gold standard treatment for severe burns is autologous skin grafts from unburnt skin. However, extensive burns may leave insufficient spared skin. Data are lacking but the incidence of patients with more than 40 percent BSA is probably less than 80 per year in the UK (National Burn Care Group, 2008) but with increasing survival rates. There are around 11 hospitals and 30 specialist burns surgeons in England and Wales treating the most severely burned patients. Several either have their own tissue laboratory providing autologous cell expansions or use that of another Trust. This leaves around 6 specialist burns services as the most likely potential users.

The technology (and the allogeneic product) can also be used for the treatment of chronic wounds (diabetic ulcers, venous leg ulcers, pressure sores, unhealed burns, etc). The prevalence of these is in the 100,000’s; however, the majority are treated in the community with cheap dressings. Patient compliance and treatment of underlying chronic conditions are essential for healing but not often achieved. The product is not suitable for use in patients’ homes and repeated applications are required making this a very high cost alternative¹.

¹ This market is not currently being pursued for the product.
4.2.3 Industry and competition

The original spin-out company went into administration in May 2008, was bought by another company which itself went into administration in April 2009 and eventually was taken over by a third, a subsidiary of a university spin-out. The two cell products are one of three business streams for this company which employs around 5 full-time staff and has laboratory capacity for 5-6 concurrent patients. These products are subsidised by the other work streams and development grants. Various distributor arrangements have been used but the company currently contracts its own distributor specialists who have substantial experience with the products.

The cell product competes principally with hospital tissue laboratories. The only similar product licensed for use in the UK is a kit for immediate use in theatre by clinicians to produce a spray of keratinocytes from a small biopsy. It does not involve proliferation of the cells.

4.2.4 Adoption space, actors and issues

Cost/reimbursement: These products are expensive compared to existing treatments for chronic wounds, but comparable to other treatments in severe burns. Specialist burns services are commissioned on a regional basis, under a variety of payment models and are not covered by the PbR tariff.

Organisation of burns services: Small numbers of regional burns centres with consultants who tend to be budget holders and have a significant degree of procurement freedom.

Geography: The product contains live cells and can be available at half a day’s notice so it is mostly in use close to the manufacturer.

Market: The severe burns and chronic wounds markets are very different. Patients with severe burns are rare, unpredictable, emergency cases who are high-risk, complex, individual and very expensive to treat.

Evidence: There are three peer-reviewed clinical papers, conducted in collaboration with the developers. Two are case series involving 11 patients with chronic wounds and 2 treated for burn and donor site wounds (Moustafa et al, 2004; Zhu et al, 2005). The last is a randomised controlled multi-centre trial of 12 patients with diabetic ulcers (Moustafa et al, 2007).

Evidence is very difficult to produce, and users discuss products and results informally to a large degree. Studies in patients with chronic wounds are much easier to conduct but very expensive as high quality data on large numbers of patients would be required to demonstrate efficacy and cost-effectiveness.

Regulation: When the product was released there was no regulatory framework for such technologies so UK approval was initially obtained from the MHRA under a Good Manufacturing Practice license; later it was regulated by the Human Tissue Authority. For historical reasons, the products are regulated by different UK bodies. Following the EU Advanced
Therapy Medicinal Product (ATMP) Regulations 2007 the products remain available until December 2012 by which time the company aimed to gain marketing authorisation for the cell product for burns. However both products are also available in the UK as ‘unlicensed medicines’ on a named patient basis. No claims for efficacy can be made and the promotional information available is therefore limited.

4.2.5 Diffusion

The company do not supply cells outside the UK. There is a preference for sourcing cells from a close supplier so trialling and use of the product has mainly occurred at sites near the production site.

4.3 Near patient (NPT) and self-testing of blood anticoagulation therapy

4.3.1 Description

This is a handheld device for monitoring blood viscosity for patients undergoing long term anticoagulation (usually Warfarin) therapy. An earlier version of the coagulometer was introduced to the NHS in about 1994. Since then, measurement time has been reduced to around one minute, and the size of the device reduced. The device uses a fingerprick drop of blood on a testing strip to provide a digital international normalised ratio (INR) reading, a measure of clotting time. A version of the device designed for near patient testing (NPT) in general practice has more features for data-storage and linking. The patient use version recently introduced a facility to download readings to a PC which can be emailed to a health professional. Frequency of monitoring typically varies between once a month and once every three months.

Innovation and advantages: The technology miniaturises a service that is otherwise provided in hospital pathology labs. The primary innovations are portability, empowerment, convenience and speed. It can be seen as part of the trend to POCT and NPT.

Costs: Testing strips are available on NHS prescription by PCT agreement; the device itself has to be acquired privately. Both can be purchased direct from the manufacturer. The self-monitoring meter is currently priced at £399; for the latter half of 2011 the manufacturer introduced a temporary £100 discount. The strips can be bought direct from manufacturer in packs of 24 at around £80, i.e. £3.30 per test. PCTs or service providers can negotiate volume discounts.

4.3.2 Clinical market

Around 1.25 million people in the UK receive long term anticoagulation therapy (DH, 2011). The main conditions eligible are heart disease, deep vein thrombosis, stroke (and risk of stroke) and patients with artificial heart
valves. The potential size of the market depends on a variety of clinical, service provider, patient profile, funding, socioeconomic, patient preference and other factors. It is known that targeting of the technology/service to people at risk of atrial fibrillation (stroke) is low, and so the potential market is considerably larger.

The conditions monitored by coagulometer are highly risky, and so the need for patients to remain 'within range' and adjust Warfarin dosing is critical. This has major implications for clinical, managerial and commissioning responsibilities. Self-monitoring patients should be part of a clinical regime of measurement checks and dosing.

4.3.3 Industry and competition

NPT systems were provided by at least three manufacturers in the early 2000s. The market is now dominated by a major international company, with one other small company also active. A further home-use product was being trialled in the UK in 2011-12 with launch imminent. This device, which claims to require less blood than other devices, is targeted at US and German markets initially, apparently due to reimbursement issues.

4.3.4 Adoption space, actors and issues

NPT reimbursement: Most long-term anticoagulation services have recently been, or are currently in the process of moving to a more near-patient model of care. This has been partly fuelled by inclusion of NPT in the GPs’ Enhanced Service agreement by which practices can obtain funding for additional service provision.

Market/marketing: Increased marketing effort by the company appears to be leading to increasing uptake. The approval of novel alternative drugs in 2012 which do not require monitoring is one motivation (NICE, 2012a,b), as the company seeks patient populations that are likely to most benefit from and remain loyal to self-monitoring modalities.

Cost/funding: The need for patients to acquire their own meter is undoubtedly a brake on adoption. Some European countries reimburse the device itself (Germany, Netherlands, Sweden).

Organisational models: The device is used as part of anticoagulation services organised on a PCT and/or hospital area basis. The traditional model for anticoagulation monitoring is the 'warfarin clinic' usually attached to hospital haematology departments. Patients typically keep a ‘Yellow Book’ in which their INR level and dose adjustment are recorded.

Evidence: It is widely agreed amongst service providers and commissioners that published research supports self-monitoring as being at least as effective as clinic-based models. A Cochrane review (Garcia-Alamino et al, 2010) is the evidence often quoted by participants in this research. UK trials (notably Fitzmaurice et al, 2002) also support self-monitoring and selective self-management (i.e. including dose adjustment).
4.3.5 Diffusion

Less than 25,000 patients use self testing in the UK. In England in 2009 there were around 2800 prescriptions for testing strips per quarter for the patient version meter and around 4300 for the NPT version (FOI data). However, there is large variation between PCTs (Figure 3), although there is no systematic variation in self-testing between urban and rural areas (rates in London are similar to those in Cornwall).

Figure 3. Variation in PCTs’ quarterly prescriptions for coagulometer testing strips (England, 2009)

4.4 Robotic surgery for radical prostatectomy

4.4.1 Description

The robot is used to perform MIS in a number of specialties, but especially radical prostatectomy for localised prostate cancer. (This is the indication on which we will concentrate.) Initially developed in the 1980s for the US military (Thaly et al, 2007), the robot was commercialised and formally launched in 1999. It comprises a surgeon console, the patient cart with robotic arms and the stack (electronic components). The surgical instruments are modelled after the human wrist.

The surgeon sits at the console away from the patient with a 10x magnified 3-D image of the surgical field and uses hand and foot controls to manipulate the robotic arms. Two of the surgical arms represent the surgeon’s hands, the third arm holds the endoscope and an optional fourth arm can hold additional instruments. The patient is fixed to the operating table at a head-down angle and five or six 0.5 cm to 1.5 cm incisions are made; the prostate gland is removed through a slightly larger incision.
**Innovation/Advantages:** Like laparoscopic prostatectomy, the robot eliminates the need for a large incision, but there are several functional advantages over the former:

- the surgeon is in a sitting position
- the endoscope is held by a robotic arm rather than an assistant
- 3-D instead of 2-D image
- the instruments have more freedom of movement, reproduce the surgeon’s actions and filter out tremors

The clinical advantages claimed are:

- reduced tissue damage, blood loss, hospital stay, catheterization time and rates of incontinence/impotence
- better cancer control
- shorter learning curve.

**Costs:** The system costs around £1.5million to purchase and involves considerable operating and maintenance expenditure. Limited life instruments (typically 10 uses) cost between £1,800 and £3,000 each and there is an annual service charge, around £100,000. In leasing arrangements, annual costs are around £400,000 depending on usage.

### 4.4.2 Clinical market

The robot can be used in multiple specialties (urology, gynaecology, general, cardiac, thoracic and paediatric surgery) but in the UK is currently used mainly for radical prostatectomy. Prostate cancer is common and incidence is increasing. Recommended management ranges from ‘wait and see’, through radiotherapy to radical surgery. Radical treatments can cause ‘significant disturbance to quality of life’ due to bowel toxicity, incontinence and erectile dysfunction (NICE, 2008) and ‘wait and see’ regimes can cause anxiety. The robot’s market in prostate cancer would depend on the perceived effectiveness of radical surgery. If other surgical specialties used it regularly, its market could be vast. There is a general perception that ‘the future is robotic.’

### 4.4.3 Industry and competition

The robot is manufactured by a US company formed in 1995 specifically to develop surgical robots, with around 1,730 employees. The company reported a gross profit of $1billion in 2010, with around 34 percent growth at a time when the average for the US medical device market was 5 percent (company website, 2010). It has a direct sales presence in the UK with up to five staff but no office base. The company currently has a worldwide monopoly having taken over its main competitor in 2003.
4.4.4 Adoption space, actors and issues

Visibility/marketing: The robot represents highly visible technology, subject to intense global marketing utilising the media, politicians, health care providers and (to a lesser extent in the UK) patients and patient organisations. There is extensive (and colourful) media coverage.

Marketing ‘message’: This is a strong message, promoting both the robot’s clinical ‘success’ in reducing unwanted complications and, more significantly, its capacity to build surgeon and hospital image as providers of cutting-edge technology and sites of forward-looking medicine. Extensive but selective reference to ‘evidence’ is made in support.

Usership/organisation: The robot is a large piece of equipment with significant space requirements and is difficult to move between operating theatres, thus limiting use across specialties.

Clinical risk: Additional risks are related to the patient’s head-down position with fixation of their arms and legs. This creates potential for swelling in the brain and damage to nerves and muscle and makes it difficult for the anaesthetist to access the patient.

Cost/reimbursement/business case: Robotic prostatectomy is not included as a separate item in the NHS national tariff and many PCTs refuse to pay an uplift to cover the difference in cost between this and laparoscopic surgery.

Evidence: There are no RCTs comparing open, laparoscopic and robotic prostatectomy. A pilot RCT was initiated in the UK during this study but was experiencing severe recruitment problems. A systematic review found some advantages over open but not laparoscopic prostatectomy, although the data were ‘inadequate and difficult to compare’ (Ficarra et al., 2009). A well-publicised study in 2009 found, contrary to other reports, that while laparoscopic and robotic prostatectomy led to shorter lengths of stay and reduced certain surgical complications, it also resulted in a higher rate of genitourinary complications, incontinence and erectile dysfunction (Hu et al., 2009). NICE decided not to include robotic prostatectomy in its guidance programme as it was a ‘direct substitute for pre-existing procedures’ (i.e. laparoscopic prostatectomy - NICE, 2006a).

4.4.5 Diffusion

The robot was first used in Germany and France in 2000 with the first UK robot installed at a central London hospital in 2001, although it was little used for three to four years. A second London hospital acquired one in 2003. By November 2011 there were 22 robots in NHS and three in private hospitals, all in England; there was none in Scotland, Wales or Northern Ireland. The company claims to have captured 20 percent of the UK prostatectomy market. In the US and European markets robotic surgery is significantly more popular than the UK.
4.5 Handheld ultrasound imaging

4.5.1 Description

This is a hand-held ultrasound imaging and Doppler device produced by a major international company for point-of-care use, originally developed by and produced for cardiologists. It was unveiled at a global IT conference/exhibition in 2009 and launched in 2010, receiving a great deal of national media attention. It was suggested that it could ‘replace the stethoscope.’

The device uses a rechargeable battery with a life of more than an hour. A probe is used to scan the body surface producing a black and white real-time image on a small monitor similar to a smartphone. Doppler blood flow can be displayed colour-coded. The device allows voice recording, PC connection and can store ‘hundreds’ of scans. These can be uploaded to patient records or data systems or printed out for communication between healthcare professionals.

Costs: The basic unit price is £5,000, although warranty packages for maintenance and insurance can raise the price to around £8,000-£9,000. The manufacturer experimented briefly with lowering the price below the £5k threshold for more formal NHS procurement processes but abandoned this when it appeared not to affect sales. The cost compares to over £100,000 for state-of-the-art high-end systems, or £40,000-£50,000 for portable laptop-style devices.

Innovation/Advantages: Small size and portability are the main innovations, though it may not be regarded as lightweight (390g for unit and probe). It is claimed to be a visualisation or screening tool rather than a definitive diagnostic device, thus its main use would be to rule out or confirm a need for full scale ultrasound scanning or echocardiography. These are expensive and time-consuming, thus the advantage may be a reduction in referrals as well as enhancement of clinical confidence at the point of care. Images can be shared with the patient.

4.5.2 Clinical market

The clinical applications claimed for the device are very broad: cardiac function and defects, abdominal, urology, obstetrics and gynaecology, paediatrics, some peripheral vascular applications, and thoracic/pleural fluid and motion detection. Some of these applications are conventionally managed with a full ultrasound scan, others not. In terms of healthcare sector, the range is also very wide including community, triage, A&E, critical care, paramedics, wards & clinics, out-of-hours and the military. The manufacturer appears to be targeting the cardiac and urology markets primarily. It is difficult to estimate the potential market sectors and sizes, but it is clearly very large.
4.5.3 Industry and competition

The manufacturer is one of the world’s largest medical device companies. It uses its own direct sales and marketing team alongside a number of subcontracted distributors.

The main competitor for handheld devices is one claimed as the ‘first pocket ultrasound’ device, launched in 2008 and available in the UK. There is also a third that is cheaper and smaller, but it is currently only available in USA and Australia.

4.5.4 Adoption space, actors and issues

Key actors in the adoption space are the media (and high profile clinical opinion leaders quoted), the user interface of the device, the manufacturer and its marketing and sales force, multiple clinical specialties, image interpretation expertise, clinical work patterns and diagnostic patient pathways. By the same token notably absent potential actors appear to be patients and an explicitly mobilised effectiveness or organisational evidence base.

Usership/risk/training: Professional resistance is in evidence on various grounds including risk. Clinical governance issues arise around accuracy and reliability and interpretation by users inexperienced in ultrasound use. Clinical staff with expertise in interpreting ‘echo’ images are more likely to use the device more competently.

Organisation of services: Re-organisation of workflow patterns both for individual practitioners and patient pathways may be required.

Cost/reimbursement: The company loans devices to some interested NHS clinicians for evaluation. Lack of inclusion in the NHS tariff is a major issue.

Marketing ‘message’: The marketing message is unclear, for example whether the device is simply a real-time individual visualisation aid or whether it could be a more formalised addition to diagnostic pathways.

Evidence: There are few published studies of clinical use of the device with most of the publications being simply ‘equipment reviews.’ One American single-centre study in cardiology comparing it to standard echocardiography drew cautious conclusions (Liebo et al, 2011), while a clinical study from a single site in France was more positive (Dijos et al, 2012). These are validation studies. The manufacturer’s web pages for the device introduced references to published evidence during the course of this research.

4.5.5 Diffusion

The device is being marketed in many parts of the world including some developing countries. (The manufacturer donated 10 scanners to the Vatican’s Good Samaritan Foundation for use in Africa.) In the UK the rate of sale according to our informants is modest, with about half of sold devices going to cardiology centres.

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4.6 Telemonitoring incorporating ECG

4.6.1 Description

Telemonitoring (also called remote or home monitoring) measures and records data about a patient’s health status and transmits it to a remote clinical observer. The patient is often located in their home, suffers from one or more chronic conditions and does the measuring themselves once or twice a day. Such devices measure vital signs (e.g. pulse rate, blood pressure) and/or ask the patient symptom questions (e.g. breathlessness, cough, tiredness) and the data are transmitted via broadband, telephone or wireless communication. The technology usually consists of a communication hub with one or more peripherals for clinical measurements. The clinician is often a community nurse (specialist cardiac/respiratory nurses, community matron) but may be a GP or hospital specialist.

Some devices can be used to make a short recording of a simple ECG, either at regular intervals or when symptoms occur. The patient usually either holds the device on their chest or touches their thumbs or fingers to the sensors. It is much simpler than the standard 12-lead diagnostic ECG but is of limited diagnostic capability. This additional functionality is generally a recent addition to telemonitoring systems; one UK supplier has this capability since their first model in 2001 and another added it to their range approximately ten years later.

Innovation/advantages: The innovation is the use of established technologies (clinical measurement devices and telecommunications) to enable remote communication of a patient’s status. Purported advantages are to the patient (greater independence, understanding and confidence), clinician (prioritisation of caseload) and service provider (increased staff efficiency, reduced hospital admissions and attendant cost-savings). The advantages of remote ECG are disputed but have included the ability to detect occasional non-emergency arrhythmias.

Costs: There is no standard pricing structure or business model for this technology. There is usually a cost per communication hub in the patient’s home, different versions of which may be available depending on the measurements required. Alternatively the measurement peripherals may be purchased as additions. Most multi-measurement hubs are in the region of £500-£1500 each although a standalone ECG device may be cheaper. The central monitoring/clinician access software is usually additional; the company may provide data storage and/or monitoring services. A renewable license/fee may also be required for each patient. Discounts may be available for bulk and leasing agreements are possible. Low cost modalities are available where the patient sends their data to a clinician by text message.
4.6.2 Clinical market

Telemonitoring has principally been promoted for patients with advanced chronic conditions who have had multiple emergency admissions: cardiovascular, respiratory, diabetes. Patients in remote rural or island locations are also suitable. ECG telemonitoring is most often aimed at patients with low risk arrhythmias, particularly atrial fibrillation (AF), and is considered unsuitable for detecting higher risk arrhythmias. An alternative market could be patients prescribed medication that affects the heart rhythm.

4.6.3 Industry and competition

There are multiple suppliers of telemonitoring equipment in the UK. Twenty-eight are listed on a UK national procurement agreement\(^2\), four of which have telemonitors capable of ECG recordings. At least two other companies are also supplying such products.

4.6.4 Adoption space, actors and issues

**Usership:** Telemonitoring tends to be implemented by PCTs hoping to reduce costs for patients with chronic conditions by keeping them out of hospital. Alternatively it is used by individual GP surgeries or specialists in acute Trusts. Companies are highly active in these sectors.

**Technology:** Hardware and software changes are rapid and overlapping given the multiple vendors in the UK market. Interoperability of hardware and clinical information is an issue. Hardware is likely to become more mobile, intelligent and smaller, including wearable sensors.

‘More pilots than British Airways:’ There have been numerous small NHS telemonitoring pilots, usually funded by discrete grants or unallocated monies and intended to run for about a year. These can end up as ongoing services and are beginning to become part of mainstream clinical care. How to effectively mainstream these is a big issue.

**Organisational changes and integration:** Some change in the organisation of primary care services may be required depending on the clinical users and the degree of integration with other services. Currently telemonitoring data are generally not integrated into GP or hospital records.

**Clinical utility of home ECG:** A single lead ECG may not contain enough information to be clinically useful and irregular rhythms could be detected by existing monitoring (e.g. blood pressure). Non-specialist primary care clinicians may not have the skills to interpret an ECG trace.

\(^2\) Government Procurement Services: Telecare, Telehealth and Telecoaching (TTT) framework (since August 2010).
Evidence: There is a reasonable volume of studies of telemonitoring interventions, but quality is often low with many descriptive, feasibility studies or before-and-after trials with small numbers of patients, short follow-up and little or no economic analysis (Bolton, 2011; Maric, 2009). Many NHS-run trials are either not reported or are only reported at conferences. A few published papers include ECG home monitoring but very few of these involve trials or report clinical outcomes (Scalvini et al, 2005; Sprenger and Oeff, 2009; Zucca et al, 2010; Zugck et al, 2010). In 2008 the Department of Health began the widely-publicised ‘Whole System Demonstrator’ (WSD) trial which has had some controversial positive publicity (see below). That study did not include ECG telemonitoring. By the end of 2012 only one peer-reviewed paper from one of the five strands of the WSD evaluation had been published (Steventon et al, 2012). This indicated statistically significant but small reductions in admissions, mortality and bed days primarily due to increases in the control group at the start of the trial.

Future/government investment: Government policy and funding (Preventative Technology Grants - PTGs) promoted telecare/telemonitoring in 2006-8 (Clark & Goodwin, 2010). In December 2010 the Prime Minister announced the “huge success” of the WSD trial based on headline results that predated any peer-reviewed publications and declared a “drive to roll this out nationwide” with the 3 Million Lives campaign. The Technology Strategy Board DALLAS\(^3\) programme aims to implement telemonitoring and telecare for to up to 50,000 people in 3-5 communities.

4.6.5 Diffusion

Use of technology to capture physiological data from patients at home has been increasing, assisted by the spread of broadband in the UK. There are no definitive data on the number of telemonitoring units in use although more than 5000 people were estimated to be using it in around a third of the 151 PCTs in England (Clark & Goodwin, 2010). However, this figure probably includes the 3000 patients enrolled in the WSD trial and is very small compared to the estimated 1.6 million users of telecare (pendant alarms, falls detectors, etc). There are probably no more than around two hundred patients using home ECG (data from industry participants).

4.7 Point of care C-reactive protein (CRP) testing in lower respiratory tract infections

4.7.1 Description

The CRP test kit allows a finger-prick blood test to be performed by a health practitioner to ascertain the levels of CRP, a biomarker of inflammation. The

\(^3\) Delivering Assisted Living Lifestyles at Scale

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result provides an indication of whether the infection is likely to be viral or bacterial, informing the decision to prescribe antibiotics. CRP testing, as a monitoring tool in long-term inflammatory diseases, has been in use in the hospital laboratory setting for a considerable time. A POCT version was introduced in 1989 and was taken up widely in Scandinavian countries, but has not been adopted in UK general practice.

**Innovation/advantages:** The test kit allows GPs to supplement their judgement (based on history taking and examination) of the aetiology of lower respiratory tract infections (LRTI) and to objectively confirm the presence of bacterial agents before prescribing antibiotics. The capability to produce results during the patient’s attendance at the surgery is an important innovation.

**Costs:** The CRP test kit costs between £1,000 and £2,000 and the cost of reagent and strips is around £5 per patient. While GP practices could buy the kit, there is an expectation that the cost of use would need to be reimbursed by commissioners. One of the two kits on the market is a multiple-analyser with the HbA1c test (diabetes) and ACR test (diabetic renal disease/cardiovascular disease) built in. There are also indirect costs such as GP/nurse time.

### 4.7.2 Clinical market

LRTIs are very common, especially during the winter months. While many episodes are likely to be viral, a combination of a perceived desire by patients for antibiotics and uncertainty on the part of the GP may result in over-prescribing, in turn potentially contributing to antibiotic resistance in the population. CRP testing is promoted as leading to more appropriate antibiotic prescribing.

The test is also used to differentiate pneumonia from LRTI, although a systematic review found the test was not sensitive or specific enough to be used in isolation (van der Meer et al., 2005). Additionally, the test can be useful in evaluating the severity of chronic obstructive pulmonary disease (COPD) (thought to affect three million people in the UK), detect concomitant ischaemic heart disease and guide treatment decisions.

### 4.7.3 Industry and competition

There are two main manufacturers, one registered in Scotland and selling the kit throughout Europe and China and the other based in Finland. The first company has tried to enter the UK market but has met with a lack of interest from GPs (see below).

### 4.7.4 Adoption space, actors and issues

**Policy alignment:** There was a view that commissioners were not interested in the issue of over-prescribing of antibiotics and antibiotic resistance. Unless these moved up the policy agenda, CRP was thought not to have
potential for adoption in the UK. However, a growing interest in Clostridium difficile prevention could change this, as over-prescribing of antibiotics is implicated as a risk factor. The HTA’s clinical evaluation and trials board has identified this as of interest (NIHR, 2012).

**Commissioner reimbursement:** There was a common belief that without commissioner reimbursement, UK GPs would not be interested in adopting this technology as they would not want to pay for ongoing costs. There was some evidence for this view. One manufacturer had provided the kit free of charge to a GP practice where it was used regularly and seen as helpful; however, when the informal trial ended, the GPs refused to pay for the kit and stopped using it.

**Clinical utility:** Despite some favourable published evidence of effectiveness, academic GPs contacted believed that the test produced ambiguous results that were difficult to interpret and could lead to even more uncertainty. Careful history taking and examination were thought to be just as effective in identifying bacterial infections. Furthermore, over-use was predicted with patients keen to have the test in future episodes once they had experience of it. On the other hand, some thought that it could help persuade patients that antibiotics were not needed.

**Disruptive potential:** Hospital laboratories are seen as resisting many POCT regimes and to see their development as a threat to their professional status and jobs; this is also thought to be the case with CRP. Additionally, there is concern over less stringent (internal and external) quality control systems that apply to POCT and the risk of misdiagnosis; standardisation, electronic data recording and links with hospital laboratories are seen as critical (DH, 2006).

**Evidence:** Two systematic reviews have concluded that evidence of benefit was ‘limited and contradictory’ and ‘inconclusive’ respectively and did not support its routine use (Engel et al, 2012; Rausch et al, 2009). However, two RCTs have reported that it was useful in reducing antibiotic prescribing, although one also found that GP communication skills training was as clinically and cost-effective (Cals et al, 2010). An audit in six European countries with more than 500 GP participants found a 25 percent ‘relative reduction’ in antibiotic prescribing (Bjerrum et al, 2010).

### 4.7.5 Diffusion

As noted above, the CRP test in a POCT application is not in use in the UK, although interest could develop, especially as its use increases in Europe. It is widely used in Sweden and Finland and in 2011, the test was endorsed in national guidelines in the Netherlands.
4.8 ‘Smart’ infusion pumps (dose error reduction systems - DERS)

4.8.1 Description

Infusion pumps are used to deliver medication and other fluids to patients at controlled rates. Variations include:

- syringe drivers – compress the plunger on a syringe
- volumetric pumps – control flow from a reservoir, e.g. saline bag
- patient controlled analgesia (PCA) – deliver boluses on demand
- anaesthetic pumps – for use in theatres.

Pumps are programmed by the clinical user, usually a nurse. ‘Smart’ pumps have a range of software functions designed to reduce errors, collectively known as dose error reduction systems (DERS) (CEP, 2008). Such pumps contain a drug library and event log. The drug library is a list of medications and allowable dose ranges which may be ‘hard’ (absolute) or ‘soft’ limits (can be over-ridden). Profiles allow for multiple limits for a single drug in different settings across a hospital (e.g. paediatric versus adult wards). The programmed settings are saved in an event log that can be downloaded and analysed. Advanced functionality includes barcode reading of clinicians, patients or medications (BCMA⁴), wireless connectivity and the ability to communicate with electronic prescriptions (CPOE), pharmacy/clinical information systems (CIS) and patient records (EPR, eMAR).

Innovation/advantages: Medication errors are a significant risk and can occur at any point (prescribing, dispensing, mixing or administering), although few lead to serious adverse drug events (ADEs) (Husch et al, 2005; Rothschild et al 2005). There are several factors that contribute to this risk profile:

- high-risk intravenous drugs often have narrow therapeutic ranges and errors are difficult to detect (CEP, 2008),
- trusts often have pumps from multiple manufacturers with variable layouts and programming sequences,
- doses can be defined using multiple settings,
- medications often require dilution at the point of administration (Vincente et al, 2003; Hicks et al, 2007) along with significant calculations carried out by nursing staff.

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⁴ BCMA – barcode medication administration; CPOE – computerised physician order entry; EPR – electronic patient record; eMAR – electronic medication administration record

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DERS is claimed to reduce these risks in several ways: drug libraries are promoted as reducing the incidence of ‘wrong dose’ errors (Adachi and Lodolce, 2005; Grissinger, 2006; Pang et al, 2011); event log analysis can inform changes in practice or staff training; CPOE and BCMA systems may reduce ‘wrong drug/patient/concentration’ errors and unintentional repeat doses (Poon et al, 2010; Husch et al, 2005).

Costs: DERS functionality may be included in an infusion device at no additional cost or may represent an upgrade from the ‘standard’ model. In the former case the functionality may be available but not implemented. Additional hardware may be required to use barcode programming and the use of pre-filled syringes represents an additional cost. Software for interrogating the event log may be an additional cost, alternatively the data analysis and reporting may be a service provided by the manufacturer. Individual pumps cost between £500-£1500 each, although the pumps may not be paid for separately if a ‘commodatum’ agreement is used that stipulates the purchase of a defined number of consumables.

4.8.2 Clinical market

Infusion pumps are ubiquitous in hospitals and the clinical applications of DERS can extend across all inpatient use. Adoption may be (initially) limited to intensive or critical care units as these are relatively self-contained within the hospital structure and include staff trained in the use of specialist equipment.

4.8.3 Industry and competition

There are multiple suppliers of infusion devices in the UK, several of whom sell devices with DERS functionality (CEP, 2008). These vary in the size of the drug library, number of profiles, availability of wireless connectivity and bar-coding peripherals. Around 4-5 of these vendors dominate the UK and worldwide market.

4.8.4 Adoption space, actors and issues

Cost: Infusion pumps tend to be purchased in bulk, either across a hospital or across a patient area (e.g. ICU), so opportunities to adopt arise when old stock is due for replacement. This level of investment usually requires a tendering process.

Risk/safety: The NPSA recommends that such equipment is standardised across a Trust to reduce the variability of devices and to centralise it in an equipment library to manage resource use and for easier maintenance (Quinn et al, 2004).

Organisation: Defining the drug library requires significant collaboration between multiple clinical groups. Refinement of these settings is expected during the first few months of use. The degree of organisational change demanded depends on the degree of DERS adopted.
**Skills/Training:** Some additional training is required for the new functionality and the new systems are not usually implemented until a majority of staff have completed this.

**Evidence:** Numerous publications address the prevalence, cause and reduction of medication errors worldwide. There are several descriptive reports of the processes and outcomes of smart pump adoption (Eskew et al, 2002; Siv-Lee and Morgan, 2007), but there are also a number of (mainly observational) before-and-after studies (Nuckols et al, 2008; Pang et al, 2011; Rothschild et al, 2005). Robust research design is difficult; we found no RCTs and only one review paper from the UK (Quinn, 2011). As standardisation of devices (at least within a clinical unit) is likely to be important to reducing user error, randomisation of patients or administrations of individual drug doses to different systems is difficult and introduces an unnecessary risk of confusion. However, individual wards can be randomised. Observational studies are likely to affect user behaviour, and retrospective studies may rely on voluntary error reporting. The effect on error rates of adopting drug libraries/event logs in isolation from other DERS components may not be significant (Husch et al, 2005; Nuckols et al, 2008; Rothschild et al, 2005).

**Future:** New hospital buildings are increasing the proportion of single-bedded accommodation making wireless connectivity of equipment and records necessary. The future is likely to involve gradual adoption and integration of the multiple components of DERS technology and reform of related processes and roles.

### 4.8.5 Diffusion

Diffusion is earlier and much greater in the US; since 2002 ECRI\(^5\) has rated infusion pumps without DERS as ‘unacceptable’ (ECRI, 2008). In 2008, 25 percent of US hospitals had BCMA and 59 percent had smart pumps; only 15 percent of hospitals did not have BCMA or plan to (Pedersen et al, 2009). We found no equivalent data for the UK but systems incorporating multiple DERS technologies have not been implemented in the UK. There is a large volume of legacy pumps in current use and large investment is needed to replace them (Pedersen 2009). Bar-coding using the GS1 system for medications and patient identification is recommended by the UK Government (DH, 2007b, 2010), but is not yet mandatory and we found no use of these in order to link patients with infusions. Wireless connectivity and CIS are only just being introduced into NHS hospitals.

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\(^5\) ECRI Institute – a non-profit organisation that reviews medical technologies based in the US (although with overseas offices including the UK) and providing reports, etc, for subscribing members.
5 Technology identities

Our thesis in this study is that adoption decisions depend not only on the designated functions and (cost)effectiveness of technology but on a much wider range of properties that we have termed identities and their interaction with each other. The technology identities derived from our analysis were diverse. Some related to the technology as clinical tool, others to their system-wide role and impact. The technology’s public presence, its fit into the clinical landscape, its effectiveness, its conjectured future and the demands that it made on its users and the system could all contribute to adoption decisions.

In this chapter, we first look at how identities are constructed. We then examine in detail different analytic types of identity relating to the technology’s: biography, clinical and cost-effectiveness, utility, risks, requirements. We then summarise these findings.

5.1 The construction of technology identities

On exposure to a technology, the human actors began to interpret it, using intuitive and practical reasoning and judgement and drawing on material features of the technology, technological histories, observation of practices, published evidence and promotional materials among others. Technology identities were produced, reproduced and revised in texts and websites that broadcast information about the technology, as clinicians and managers considered how the technology might ‘slot’ into clinical and organisational practices and routines and during use. Cross-cutting these processes were abstract concepts such as evidence, clinical and cost effectiveness, risk and utility - or their adoption space manifestations. In this multi-vocal, contingent and continual process, the discourses of promotion, enthusiasm and certainty competed with those of gatekeeping, caution and evidential indeterminacy. HTA evidence did not play a central role in this process; references to this were vague and did not always distinguish between peer reviewed journal articles and non-reviewed information (such as conference presentations). Evidence produced by industry through versatile marketing activities and by users (Section 7.1) as well as other preoccupations, such as personal or organisational standing and the technology’s compatibility with current practices, were just as significant in constructing identities. Additionally, structural elements, such as the national economy and hospital budgets, regulatory requirements and company business models exerted indirect influences on defining and constructing identities for technologies.

The identities and the evaluations/expectations that they were based on were ‘networked,’ making them highly mobile and shareable by groups, organisations, localities and even countries. We use ‘networked’ to indicate the conversational nature of the process (in interactions and through documents) and to show how information and ideas about the technology traversed professional, organisational and geographic boundaries, rather
than in the formal sense of ‘network analysis.’ Interaction between adoption space actors ranged from a single telephone call or email message, through sporadic meetings to working together on a daily basis. Broadcast communications took the form of manufacturer websites, peer reviewed papers, NICE guidance, media reports and patient/professional organisation materials and websites.

Identities were not fixed; views and expectations changed over time, often from scepticism to a growing conviction about the technology as use increased and what one informant called a ‘critical mass of enthusiasm’ developed. Below, we describe the different settings through which identities were constructed.

National and international conferences were significant events where manufacturers and distributors advertised technologies and ‘educated’ clinicians through presentations by champion users. Importantly, these were also occasions for clinicians to exchange stories, ideas and plans about technology use. This kind of interaction also happened at smaller clinical meetings, educational events (sometimes sponsored by industry) and through informal contact between clinicians.

“I had a meeting in [City], which was just phenomenal... And I actually went out to dinner with these people, and I actually sat down, talking to people... And I came out from there saying and thinking, “yeah,” you know, “we need to look very hard at this”.“ (P9D1, robot, surgeon).

“At the burns forum... I discovered... that most people were putting [a non-study product] dressings... without using [proprietary system] cleaning... and saying, “well, you know, it’s ridiculously expensive to do it with [proprietary system]!”... we’d been using... [proprietary system]... on the basis that when the company came around, they showed us a video of people using it, and "this is the recommended way of doing it, and it makes it really clean"." (T4D1, cells, surgeon).

The company sales representative visit was a core resource in identity construction. Often, company staff and clinicians (and less frequently managers) had established relationships and repeated conversations about the same technology during successive visits.

Other formal/informal contacts between NHS managers, between managers and clinicians and between managers and industry contributed to identity construction. The ‘consideration’ stage in adoption involved numerous planned and unplanned, brief or lengthy ‘meetings’ between managers and clinicians, perhaps round a water-cooler, as well as more formal meetings between managers, clinicians and industry, to discuss the technology and the implications of its adoption. However, compared to clinicians, managers had fewer interactional opportunities.

“Unfortunately we don’t have a forum... If you’re a nurse or a medic, obviously you go to medical conferences specific to the
sort of area that you’re working in, but there’s no forum that I’m aware of where urology managers get together.” (P5M3, robot, hospital manager).

Clinic mobility - changing jobs - was another way in which the technology and its identities travelled.

“[Clinician] is a fairly new consultant and...very forward thinking... [they] brought a lot of these experiences with [them].” (T4M2, cells, hospital manager).

Formal evidential texts also contributed. ‘Studies’ reporting outcomes took many forms: publicly or industry funded, small or large, peer-reviewed publication or not. Professional guidelines and NICE guidance were sometimes referred to.

The media created awareness of the technology and generally constructed positive identities with novelty stories focusing on the technology’s technical prowess or emotive ones reporting successful use with happy endings. Rarely, stories reporting doubts/risks/bad outcomes also appeared, for example for the robot. Professional journals could also be important sources of identity.

“But what I’d like to do is write it up for the GP Magazine... because the experience I’ve had with [ultrasound] so far is very, very positive... it’s something to share with my colleagues.” (HUS-C1, ultrasound, GP).

Websites were key in identity construction, in particular company websites. These used a strong promotional discourse and made use of (selected) published evidence and statistics, celebrities, patient stories and graphic videos of the technology in action, as well as world-wide ‘locaters’ of user-clinicians.

“I know the robot has been a marvel of marketing over substance and... certainly if you go on the [manufacturer] website, you’ll be forgiven for thinking that [prostatectomies] should only ever be done robotically.” (P14D1, robot, surgeon).

Where patients were the end-users, as in anticoagulation self-monitoring, attempts were made to recruit them as active promoters, encouraging them to ask their GPs about self-monitoring. In the case of the robot, hospital websites were also used to promote the technology, using manufacturer-supplied ideas and publicity materials. Patient organisation websites provided generally more balanced identities. However, the web could also be a source of negative identities, as demonstrated by adverse stories on user blogs, for example for the spinal implant.

Other marketing activities also contributed to the process: patient-user directed activities such as a road-show touring the UK and the offer of patient training at NHS venues (coagulometer self-testing); ‘rumour’ among hospital managers (robot); political lobbying (robot); the offer of free samples/free trial was common for some technologies, e.g. cultured cells.
and ultrasound (Section 6.1.4). The technology’s identity could also be influenced by marketing that did not happen; for example, the distributor of the spinal implant had deliberately restricted media coverage because surgeons did not approve of media reports that triggered patient demand and maintaining good relationships with surgeons was a priority for the company.

Thus, the adoption space offered ample informational sources and opportunities for the construction of technology identities that provided elaborate, imagined and alternative accounts of the technology’s symbolic presence, capabilities and functions and its assumed clinical and non-clinical accomplishments. We now turn to the different forms of identities we identified and their implications for adoption.

5.2 Biography

These identities relate to the defining characteristics of the technology, rather than to what it does. They concern how convincing the technology appears (on the face of it) and the extent to which it captures professional and public imaginations as a distinctive, novel product. Identities of innovative potential and promise are also linked to the technology’s future and the extent to which it is seen as signalling radical advances in technological medicine.

One of the first identities that the study technologies acquired concerned their plausibility.

“'I think you need to develop the sort of mental discipline to be able to detach yourself and work out what the theories are involved in why [the technology] should work... Put it in your own picture of how the body works, how the pathological process works... Just so it kind of makes some sense why you should use it... and why it holds promise.” (T3D1, cells, surgeon).

“'You look at that and you think, “my god!.. I’m not the slightest tempted to try that!..” It just doesn’t look like a device that’s going to stay there for the rest of someone’s life... you know?.. Just on the face of it, a lot of surgeons would rule it out, yeah.” (S1D1, spinal implant (not study technology), surgeon).

Once plausibility was established, innovativeness/distinctiveness became another important attribute. For example, one surgeon who was ‘not in a hurry’ to use the spinal implant had been the first in the world to use another new technology.

“It supplied a treatment capability that I didn’t feel was out there that my particular patient needed... I felt was possibly a quantum better than anything else on the market... which [implant] isn’t really, you know?” (S3D1, spinal implant, surgeon).

In look and feel, the robot was unique among the study technologies: large, with shiny moving parts and a futuristic look, making it highly visible, both
in a literal and metaphorical sense. Closely linked to this was its inspectability: the robot was frequently on display at conferences and hospitals.

“[Surgeon’s] daughter, who was seven at the time, was sitting at the console, playing with it and actually doing quite advanced things on the machinery... And I thought “this surgery is going to be absolutely ... this is mind-boggling.”” (P10D1, robot, surgeon).

Personification was an extreme manifestation of the robot’s visibility.

“It’s effective for me as a fund-raiser in terms of the profile it gives... “Robbie” has effectively galvanised the community.” (P13Ch1, robot, charity fundraiser).

The robot was identified as a ‘startling’ technology that ‘will change medicine’ (Combs, 2006). Many study informants shared this view, adding that it was associated with envy among surgeons.

“My first thoughts were astonishment. I couldn’t believe what was happening... The two of us went to one of these food halls for lunch... and we both couldn’t speak for a while!.. and when it finally sunk in, we started thinking, you know, “this is the way to do prostate cancer surgery... “ And then we started thinking of how we would acquire such a mission.” (P3D2, robot, surgeon)

“I mean, there are some things that capture your imagination, aren’t there?.. that kind of scream out to you, “we’ve just got to do this, no matter what it takes!”” (P9M2, robot, hospital manager).

In these constructed identities, the robot was transformed from a tool for performing the prosaic tasks of surgery into a glamorous object of desire.

In sharp contrast, the cultured autologous cell treatment was a technology with a problem of visibility and distinctiveness. At first, it exhibited noteworthy technical capabilities (a ‘living bandage’ in early popular discourse): an innovative adaptation of an industrial process (plasma-polymerisation) to develop a surface on which cultured cells could sit ‘happily’ and from which the cells would equally ‘happily’ detach and transfer to the patient’s body where they would continue to proliferate and provide covering. The innovative surface was designed to overcome the main drawbacks of CEAs (Section 4.2): ‘graft fragility, difficulty in application and poor rate of uptake’ (Harding et al, 2002). The product attracted Wellcome Trust funding and was rated among the ‘top innovations of 2004’ by them. It promised to be ‘invaluable’ and to bring ‘relief’ to three million chronic wounds patients, including 1,000 with severe burns. The technology was featured in the media and reported to have attracted interest from companies in North America, Europe and Japan (Wellcome Trust press release, 2004).

But the manufacturer went on to have a troubled commercial life (Section 4.2) and had a low uptake by 2012. Our analysis identified several reasons...
for this. First, the product had low visibility as a distinctive technology and was perceived instead as a brand within a class of products, i.e. cultured skin cells. It was seen as one among several 'services' offered by laboratories where the main criteria of adoption appeared to be geographic location (with preference for the local laboratory), and cost (preference for cheaper NHS-produced cells). The inclusion of this commercial service in a formal tender reinforced this process (Section 6.4). The innovativeness of the sheets’ patented surface was thus ‘lost.’

“You send a biopsy, the cells are cultured, anybody is going to give you the same product back and they’re our local people to work with.” (T4D1, cells, surgeon).

Another factor was the cells’ visibility in relation to clinical outcomes. Cells were used as one component in a complex package of care in severe burns that included meticulous wound cleaning, skin grafts, dressings and possibly dermal substitutes. As a result it was not easy to attribute outcomes to the cells or any one element in the package. Similarly, in chronic wound care, good wound management involving regular review, careful hygiene and patient self-care were thought to contribute to or be sufficient to achieve healing. Additionally, some surgeons had asked for a spray version and the company had started supplying this, but this meant that the claimed advantage of the special surface was lost and the commercial product became truly ‘just another’ cultured cells product, evidenced by confusion over product names during interviews. It is also possible that the inability of the company to conduct a vigorous marketing and advertising campaign due to licensing restrictions may have contributed to this technology’s low visibility.

Thus, how plausible a technology was judged to be and how visible and distinctive it appeared to potential users impacted on whether it was accepted (or rejected) early on and its subsequent adoption patterns.

Some of the technologies were associated with more or less clearly discernible ‘futures.’ The robot was thought to be a precursor to more advanced and even better technologies, such as miniaturisation, natural orifice and single-port surgery, combination with imaging technologies and other, less specified, ‘developments.’ These promises were mentioned even by those who did not feel that the robot was a cost-effective option for the present.

‘... we are working with first and second generation robots, and what we will be doing in ten years time might be a seventh or eighth generation. So, knowing that we are on a development pathway means that... there will be greater benefits and easier to realise benefits’ (P1D, robot, surgeon).

An important element in the construction of technological futures was what has been termed ‘retrospecting prospects and prospecting retrospects,’ or remembering and learning from ‘past futures’ of other technologies (Brown and Michael, 2003). Informants remembered the past future of, for
example, laparoscopic surgery, which had initially been viewed with scepticism.

“And having seen how laparoscopic surgery did become the standard, I was very open and remained very open about new technology and developments that you can’t call whether or not they’ll be worthwhile, just on the basis of level of experience; they have to run the test of time.” (P1D1, robot, surgeon).

“The uptake [of laparoscopic cholecystectomy] at the beginning was very slow, and there were lots of complications. But then as it refined and people got better at it, and the training got better, more and more people took it on, and now it’s the gold standard. And I think it’s the same pretty much with all procedures really.” (S4D1, spinal implant, surgeon).

One handheld ultrasound user similarly predicted that it would become ‘part of our anaesthetic future’ despite the fact that in the absence of training, she was finding it difficult to use it at the time. She recollected how the use of ultrasound in the placement of anaesthetic lines had initially been criticised as unnecessary but had become routine.

A similarly expansive future was ascribed to community diagnostics such as CRP testing, as both leading to and benefiting from increasing decentralisation of services.

“I feel as though we’re probably on the cusp of... a bit of a revolution in terms of point of care testing...I can certainly see the day where you’ve got somebody in the practice who is, you know, dedicated to doing the testing...as well as doing ECG and perhaps phlebotomy, they’ll be doing CRP testing and INR testing and ...!” (CGD1, CRP, GP academic).

Promising future identities were harnessed by manufacturers: the latest model of the robot represented an attempt to ‘future proof’ it in anticipation of, for example, image integration. Hospitals were advised to select this to ensure better value. In fact, the NHS was said to be keen on future-proofing, perhaps unnecessarily.

“I think there’s a mindset in the NHS... “if we’re going to end up having a system that’s ten years old, we want to make sure when we buy it, it’s the best system possible.” And that means... systems... tended to be high-end and tended to be at the top end of expense as well... very much stacked with features. Whereas, if you then went to another country, they probably didn’t buy all those features’ (HUS-I-1, ultrasound, company representative).

In sharp contrast, the coagulometer had an uncertain future with the emergence, and NICE endorsement (NICE, 2012a,b) of, new drugs (dabigatran, rivaroxaban) that do not require blood monitoring. The coagulometer manufacturer was said to have stepped up their marketing with a view to recruiting as many self-testing users as possible who might
be reluctant to change over to the new drug. But the ethics of the NHS persuading/encouraging patients to purchase the coagulometer in the knowledge that it might become obsolete/unwanted within a short time was questioned by one NHS manager.

Learning that technologies evolved, perhaps becoming more effective and advanced over what could be a relatively short time, encouraged clinicians and managers to give technology a chance, even in the absence of effectiveness evidence or positive experiences. Some potential users had one eye on the future to ensure future capabilities. When obsolescence was discernible on the horizon, however, it was not clear how much and how quickly this impacted on adoption decisions.

5.3 Clinical and cost effectiveness

The comparative effectiveness of health technologies and interventions is a central concern for practice and policy. Within the EBM/HTA paradigm, the objective is to produce a single, reliable and universally applicable effectiveness profile that can guide technology adoption decisions; while this profile may be indeterminate (due to a lack of evidence) and is subject to revision as evidence accumulates, nevertheless, its production represents an authoritative account, based on the best available evidence, that is not easily contestable. Our adoption space data revealed a very different, multi-perspective picture with each technology acquiring multiple effectiveness identities, on a continuum from ‘very’ to ‘not at all’ effective. The evidential vacuum – except for the coagulometer which did have more or less conclusive evidence of effectiveness – was filled with contested accounts of clinical and cost effectiveness. Generally, as expected, the industry generated discourses of certainty, claiming effectiveness had been demonstrated adequately, a view not shared by others.

“No-one’s in any shadow of doubt about the benefit of telehealth. No-one’s in any shadow of doubt about the benefit that providing community based diagnostics brings” (EGI4, ECG telemonitoring, company representative).

“The evidence for pure clinical benefit is still a bit iffy... you know, in heart failure, yes, there’s a Cochrane Review that says, “this reduces mortality by a third and it reduces admissions by a fifth,” but that’s been followed up by three large scale studies that say, “well, actually it doesn’t make a great deal of difference at all”” (EGA2, ECG telemonitoring, clinical academic).

Many company websites referenced selected scientific publications to support claims of effectiveness; the robot’s website was notable in its declared ‘commitment to evidence-based medicine,’ but this was a different type of EBM, with the emphasis not on design and rigour but on the number of studies. The website noted that studies relating to robotic surgery (across several specialties) were increasing at a rate of around 100 publications per month and that since 1998, ‘over 4000 peer-reviewed publications’ had
been published (company website, 2013). However, a table on the website stated that of the 5731 published studies, only 31 were Level 1, 773 were Level 2 and the remainder (4920) were Level 3, 4 or 5. Nevertheless, the company claimed:

“These studies include hundreds of surgeons and cover thousands of patients in dozens of countries... While some critics cite the lack of clinical evidence for the efficacy of [the robot], the peer-reviewed literature is both deep and compelling across many clinical applications of surgical robotics” (company website, 2013).

These uncomplicated effectiveness identities were mirrored in the media, although, from about 2009, growing controversy about the robot led to coverage that produced a counter-identity as no better than the alternatives and potentially dangerous (Reuters, 2009). This was matched by a critical polemic in the peer-reviewed literature where the industry was accused of trading on ‘subconscious’ fears, anxiety and ambition among patients and surgeons (Touijer, 2010).

NHS trust business cases were other platforms for identity construction. Three business cases for the robot were available to the study; the effectiveness claims for the robot varied significantly in two and no detailed effectiveness data were given in the third (Table 3).

**Table 3. Cancer control and functional outcomes for robotic prostatectomy quoted in NHS Trust business cases**

<table>
<thead>
<tr>
<th></th>
<th>Business case 1</th>
<th>Business case 2</th>
<th>Business case 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive margin rate</td>
<td>n/a</td>
<td>Open: 35% Robotic: 15%</td>
<td>Open and laparoscopic: 24% Robotic: 5%</td>
</tr>
<tr>
<td>Incontinence</td>
<td>n/a</td>
<td>Hospital current: 5% Target with the robot: ≤2%</td>
<td>Complications (incontinence + sexual dysfunction):</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Open: 15% Laparoscopic: 10% Robot: 5%</td>
</tr>
<tr>
<td>Sexual dysfunction</td>
<td>n/a</td>
<td>Hospital current: 50% Target with the robot: 20%</td>
<td></td>
</tr>
</tbody>
</table>

In contrast to industry sponsored effectiveness identities, less certain and more provisional identities were presented in peer-reviewed literature, some policy documents and the interviews.

Typically, the clinical literature on the technologies began with early case series reporting feasibility and positive results with low rates of complications, progressing to studies with larger numbers reporting more mixed results and somewhat higher complications. The robot was the most intensively studied; only the coagulometer (self-monitoring) had been studied in an RCT (Fitzmaurice et al, 2001, 2002), although a pilot RCT was initiated for the robot during the study (Section 4.4.4). A common feature of the effectiveness literature for the surgical technologies and ECG

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telemonitoring was heterogeneity, notably in definition of outcomes, instruments used to measure these and the duration of follow-up, making comparison and synthesis difficult, with the exception of the self-monitoring coagulometer (Heneghan et al, 2006).

NICE guidance was available for three of the technologies. NICE’s conclusions on the robot were somewhat equivocal. On the one hand it defined robotic surgery as a modification of laparoscopic surgery and therefore not novel enough to be within its remit (NICE, 2006a), on the other it stated that it was ‘not yet clear’ whether robotic prostatectomy had ‘any advantage over conventional laparoscopy’ (NICE, 2006b). On the spinal implant NICE was undecided: evidence was ‘limited in quantity’ but showed ‘symptom relief in the short term in some patients’ (NICE, 2011). NICE’s guideline on atrial fibrillation was more conclusive on self-monitoring and stated that it should be considered for ‘physically and cognitively able’ patients (NICE, 2006c).

In the interviews clinicians displayed considerable ambivalence, based on practical reasoning, observation of own/peer practice and some vague recollections of papers read (Section 7.1). Although there were a few informants who believed that the technology was unquestionably better than alternatives, most (users and non-users) expressed uncertainty. There was a realisation that while the technology might be superior to alternatives in some respects, it might be equivalent or even worse in other respects and that there was no ‘black and white’ case for clinical effectiveness. Additionally, in the case of surgical technologies, effectiveness was surgeon-dependent and claims of effectiveness were qualified by ‘in my/our hands.’

“There’s no doubt it is very good technology; you know, the vision system is very good, the control system is very good, the dexterity enhancements are very good. But that’s singularly failed, in my speciality, certainly, to be demonstrated that it translates into benefit” (P8D1, robot, general surgeon).

“It’s not a “yes” or a “no” test... What it does is give you a range and, in the intermediate range, it might be adding to your confusion rather than reducing it” (CGD2, CRP, GP academic).

The complex accounts in the literature and the interviews indicated that clinical and cost effectiveness could not be considered in isolation (as they were in simplistic accounts) but were associated with a range of clinical and service delivery contingencies.

While clinical effectiveness identities reflected a combination of existing published evidence, reasoning from theory and observation, technologies’ cost-effectiveness identities were mainly conjectured, often projected into the future and based on speculations on unknown/unquantified present and future costs and benefits.

A central theme was justification, or whether the technologies’ use was justified in view of competing needs in a cash-limited health service.
“So, first of all, I have to try and justify the costing myself... because I don’t want to cripple the NHS by introducing something that’s hellishly expensive!” (S4D1, spinal implant, surgeon).

For many informants, justification derived from the fact that the technologies would prove to be cost-neutral if a whole array of assumed benefits, some immediate, some distant, were considered in an all-inclusive calculus (Table 4). Clinicians and industry representatives were frustrated by what they saw as hospital managers’ and commissioners’ failure to ‘see’ this and to focus instead on the short-term monetary burden of technology adoption. Contributing to this failure was thought to be the problem of ‘silo budgeting’ where the benefits, in particular cost savings, accrued not to the department or organisation incurring the costs of adoption but to others or even ‘the economy’ or ‘society’ – typically in the future. Where cost-neutrality could not be claimed, the technologies were justified on the basis of clinical benefits that ‘outweighed’ costs.

“Well, it’s probably quite a complicated equation for this, because the simple equation which is cost of antibiotics saved, set against cost of [CRP] testing, isn’t going to add up, because antibiotics are cheap as chips. So you have to start adding in things like antibiotic related adverse events prevented, which is a more difficult calculation” (CGD7, CRP, GP commissioner).

“Many of the men having prostatectomy are at work and if you can get someone back to work and paying taxes, actually, maybe that is a strong argument for doing that rather than treating them with open surgery” (P4D1, robot, surgeon).

<table>
<thead>
<tr>
<th></th>
<th>Costs thought to be offset by the technology and considered in assessing its cost-effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robot</td>
<td>Blood transfusions, hospital stay, complications, time off work</td>
</tr>
<tr>
<td>Spinal Implant</td>
<td>Blood transfusions, hospital stay, complications, time off work</td>
</tr>
<tr>
<td>Cells</td>
<td>ICU stay, repeat hospital visits over time, low quality of life</td>
</tr>
<tr>
<td>Coagulometer</td>
<td>Stroke etc, mortality, patient inconvenience</td>
</tr>
<tr>
<td>CRP</td>
<td>Antibiotic resistance, repeat consultation</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>Full-scale hospital scanners and technicians, unnecessary hospital tests</td>
</tr>
<tr>
<td>ECG</td>
<td>Stroke, MI, mortality, emergency admissions</td>
</tr>
<tr>
<td>Pumps</td>
<td>Handling complaints, litigation, extended hospital stay</td>
</tr>
</tbody>
</table>

The technologies, in particular the more expensive ones like the robot and cultured cells, had competing identities as not cost-effective or not justifiable, due to the magnitude of benefit compared to the expense as well as the opportunity costs.

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"Now if you’re spending £1.5 million on a machine, you don’t want to have the data so close... You want to have a glaring gap between what you’re doing at the moment and a new improved technique, if you’re going to spend that much money on the machine... I mean, for the same sort of money, I can get five cancer nurses" (P14D1, robot, surgeon).

"Cosmetically she’s done very well, you know, it looks better than previous people have looked when we didn’t use [cells]. But we haven’t actually got any objective evidence, so that’s a slight worry as well, when you’re spending so much money" (T4D1, cells, surgeon).

For ECG telemonitoring and the ultrasound, the economic (rather than clinical) impact of the technologies’ adoption was fore-grounded by the informants. These technologies were expected to lead to reduced hospital admissions and hospital tests respectively. But convincing data demonstrating this were sparse, despite numerous small-scale studies in the case of generic telemonitoring. On the other hand both technologies were capable of detecting asymptomatic conditions/health problems requiring further treatment and expenditure, potentially offsetting any savings.

“I think the main barrier really now is actually not whether the technology works, not whether people like it or don’t like it ...but it is understanding what the economics are and then turning that into business models, service delivery models, you know a case for investment“ (EGA1, ECG, academic).

There was also a view that healthcare technology rarely saved money.

“One particular feature of innovation in health care is that it actually drives up overall costs...(a) because you’re possibly picking up problems that you previously didn’t pick up; or it allows you to do more things, or it extends the range of patients that you’re able to treat. There’s a whole literature of economics which basically says 40-50 percent of inflation in healthcare is to do with technological innovation” (EGA1, ECG telemonitoring, academic).

Similarly, there was an expectation that smart infusion pumps might mean fewer staff once the system became more automated.

Cost-effectiveness emerged as context-dependent. For example, the post-operative advantages (and cost savings) offered by the robot were negligible if the hospital was already offering a laparoscopic service with similar advantages over open surgery. Cultured cells could be seen as justifiable in severe burns where many other products were just as expensive but not in chronic wound care where all other products/dressings were very much cheaper. Another factor affecting cost-effectiveness was volume and mode of use (Section 8.2).
The technologies acquired disparate and contestable clinical and cost effectiveness identities in the adoption space. In the absence of reliable and conclusive data corroborating particular identities, all of them had currency in different contexts and at different times. While clinical effectiveness identities relied mainly on experience, theory and to some extent published evidence, cost-effectiveness identities were premised on conjecture and expectation (and perhaps hope). Informants’ accounts indicated that these identities were mobilised as rationalisations, justifications or critiques of adoption decisions, rather than as reasons for adoption. The salience of these identities for adoption, related to other types of identity, is outlined in the summary to this chapter.

5.4 Utility

Technologies varied in terms of the nature and size of their clinical market and the multi-faceted utilities that they were expected to deliver beyond the obvious, narrowly defined clinical ones.

While some technologies were seen as suitable for use in multiple specialties on large numbers of patients, others were seen as ‘niche’ technologies, applicable to a more tightly defined class of cases or even individuals, and used just once or twice over two or three years. Half of the study technologies were perceived to be widely applicable, at least potentially. Cells, spinal implant, ECG telemonitoring and the coagulometer in self-monitoring, on the other hand, were thought of as niche technologies. The perceived clinical scope varied depending on context and perspective. Even the robot, a ‘general’ technology, had somewhat different identities in the US and the UK, being used routinely in several specialties and reportedly having captured 90 percent of the prostatectomy market in the US versus being used mainly in urology and only for 20 to 30% of prostatectomies in the UK. Generic telemonitoring, ultrasound and smart infusion pumps were promoted as routinisable technologies that might become embedded in everyday practice, replacing old technology. However, in 2012, they had made little headway and it was too early to know whether they would fulfil this promise; their adoption futures depended on a wide array of contingencies relating to NHS resources, the technologies’ variable identities including effectiveness and utility. At the other end of the continuum, autologous cells was an individually-tailored technology, both in terms of the decision to use it and in terms of its production.

The case of coagulometer self-testing illustrated the malleability of a technology’s potential market and usership. Self-testing was thought to be practised by less than 2 percent of the 1.25 million people in the UK on long-term anticoagulation therapy, compared to an estimated 30 percent who could benefit (DH, 2011). Self-monitoring was seen by GPs and other clinicians as a niche application, suitable for a minority of patients who ‘needed’ it (e.g. travelling) and who were competent and ‘responsible enough.’ In Germany, it was reported that training was provided to all the patients leaving hospital and there were 140,000 users. UK-produced
evidence that a very large proportion of patients on warfarin could self-test safely and effectively if trained before being discharged from hospital (Heneghan et al, 2006) had not become effective in the adoption space.

Lack of clarity over clinical rationale and usership posed a problem for adoption, as demonstrated by the ultrasound. Marketing had been ‘hard going’ and our analysis identified a number of reasons. There was a question over the diagnostic capability of this Doppler imager. The company marketing representative was careful to distinguish it as a ‘visualisation tool’ and not a ‘diagnostic tool’ while the company website constructed a somewhat ambiguous identity, describing it as ‘aiding speedy diagnosis’ and ‘helping make quick decisions’ on the one hand and - more nebulously - as ‘deepening the connection with the patient’ and ‘transforming the way physicians see their patients’ on the other. The company representative thought that this product could not replace traditional ultrasound and, because it was not ‘diagnostic enough’, it could not be promoted as a point-scoring technology within the Quality and Outcomes Framework (QOF). The opportunity lay in marketing the device as an addition to both the technological stock and the clinical repertoire, enabling practitioners to take a ‘quick look’ inside the patient’s body. However, any detected abnormalities or queries would subsequently need confirmation/clarification. But there were arguably too many potential specialties (cardiology, urology, paediatrics, obstetrics and general medicine) and settings (hospital bedside, outpatient clinics, home visits, ambulances and emergency departments) in 2011 in which this technology could be used. The company was investigating even newer markets such as veterinary medicine and the military as well as further technological developments.

“And the message from us at the moment is not clear... we’re all over the place trying to say, “you can use it for this, you can use it for that “or, you know, “you might want to use it for this!”.” (HUS-I-1, ultrasound, company representative).

Thus, while the ultrasound was presented in promotional discourses as the ’modern stethoscope’ (Liebo et al, 2011) to be used by ‘every single clinician,’ this was, ironically, a problem in its early adoption.

ECG telemonitoring shared a similarly problematic market and usership identity. This was also ‘not really a diagnostic device’ which had a poorly-defined purpose:

“But our thoughts, and I have to say I stand by it now, is what benefit would that be?...Why do I need to know a single-lead tracing of an ECG?” (E1N1, ECG telemonitoring, cardiac nurse)

One company representative indicated that the technology had proven useful in detecting undiagnosed AF in heart failure patients but that the original intention was to detect when AF was interfering with other telemonitored measurements. Portable versions could allow patients to take recordings if they suffered symptoms whilst away from home. In fact, the development and evolution of this technology poignantly illustrated the
importance of a clear clinical and usership identity in technology adoption. Finally, again like the ultrasound, there were issues around competence and training (Section 8.1).

Technologies’ clinical market and usership identities were by no means a fixed affair and could vary, depending on context and perspective and over time. Inevitably, some technologies were applicable to larger populations than others, but even here, the actual market size was socially shaped and open to change. Above all, having a clear identity increased adoptability; conversely, where clinical identities were diffuse and uncertain or had to be fabricated, this made adoption difficult.

The technologies also varied in the extent to which there was agreement over their clinical rationale and value, or the value of the interventions that they made possible. For example, a few of the informants pointed to the continuing uncertainty over whether surgery/active treatment was ‘needed’ in the management of localised prostate cancer and whether active monitoring might not be the best option. However, this view was in general ‘ignored,’ as one surgeon put it:

“Treating patients is a bit more than just seeing an epidemiological health benefit; people get very anxious about prostate cancer... From my view, you’ve got to have something to offer them and there is actually now quite good evidence to suggest that local treatment of prostate cancer has improved survival” (P4D1, robot, surgeon).

In fact, the rationale for surgery was confirmed in many discourses. One business case claimed that radical surgery was the ‘treatment of choice for intermediate and high risk men.’

The role of fusion in the management of back pain caused by degenerative disc disease (DDD) was similarly controversial, with the whole area of spinal surgery labelled an ‘experimental’ area.

“Surgeons’ experience of [fusion] is often that there are a number of disappointed patients and there’s no one out in the spinal surgical fields publishing vast quantities of spinal fusion success... it’s not that popular” (S1D1, spinal implant, surgeon).

The value of cultured cells in major burns was also contested. The question of clinical rationale and value was associated with that of the ‘need’ for the technology. A technology could perform effectively but might not be needed. The CRP test was labelled by one clinician an ‘expensive placebo’ because careful history taking and examination might be adequate in determining whether a lower respiratory tract infection was likely to be bacterial. Likewise, it was suggested that good staff training and incident reporting processes might prevent hospital medication errors without the need for smart infusion pumps.

Some technologies, like the robot (because the adoption space discourses successfully represented surgery as necessary) and the coagulometer,
more secure clinical rationales; where clinical rationales were less certain and had to be fabricated (in the non-derogatory sense), as in the case of the ultrasound and ECG telemonitoring, or were contested as in the case of the spinal implant and cultured cells, the technologies’ clinical utility was less secure.

The history of ECG telemonitoring illustrated how clinical utility depended on adoption space contingencies. An early version of one device simply reproduced a hospital bedside monitor, complete with ECG facility. However, the majority of telemonitoring recipients at that time were COPD patients for whom ECG had little clinical value. Later, more heart failure patients were provided with telemonitoring so the technology acquired a clinical rationale. Similarly, when the robot was first marketed, it was aimed at cardiologists who were not interested; only when urologists were targeted and embraced it was the robot seen as a valuable technology.

An identity as a useful technology that answered a clinical need was an important element in technologies’ adoption pathways. Clinical beliefs and practices and service delivery patterns were instrumental in constructing a ‘need’ for technologies and underwriting their clinical rationales.

Beyond their obvious clinical functions and putative effectiveness, technologies acquired a number of broader utility identities relating to supplementary clinical functions, impact on patients’ quality of life or service delivery. The type and number of utility identities appeared to impact on adoption considerations and pathways.

**Auxiliary clinical identities:** An important utility associated with the robot and spinal implant was their minimally invasive nature. So long as they were not less effective than alternatives (and most users and those considering use believed that this was the case), then, regardless of whether they were more effective, they could be the preferred option because they eliminated the need for more invasive procedures. They were also promoted as technologies that could widen interventional possibilities by enabling more successful surgery on obese patients (although published results were mixed). The spinal implant was additionally marketed as enabling easier revision surgery and some surgeons were reportedly interested in spinal implants only for this indication. The CRP test, ultrasound and smart pumps were seen as confidence-boosters to practitioners. CRP also ‘helped’ the GP decline inappropriate patient requests for antibiotics. CRP, telemonitoring and ultrasound were seen as patient educators, by making it clear that infections could be viral and by showing where the problems lay in the body, respectively.

**Promoter of the patient-centred agenda:** The coagulometer was promoted as a patient-centred technology because it enabled a more ‘local, convenient and personal’ service compared to ‘cattle market’ hospital clinics and because it empowered patients. Along with the robot, the coagulometer was represented as a patient-demanded technology. However, in other discourses the coagulometer emerged as serving organisational agendas. Self-testing was seen as a way of ‘moving patients around’ when GP clinics
ran out of space. Furthermore, there were reports that patients disliked near-patient testing because they were used to going to the hospital and also self-monitoring because they did not want ‘sharps’ in their home.

**Technology congruent with organisational agenda:** Sometimes a technology coincided with organisational concerns and priorities. At one hospital, smart pumps were promoted at a time when patient safety was being prioritised. The manager who initiated adoption had recently attended a patient safety programme at the US Institute for Health Improvement.

**Protector of surgeon health:** Due to its ergonomics the robot was seen as protecting surgeons’ spines, preventing long-term morbidity and extending their working life. As it was thought to be less tiring, it was suggested that surgeons could perform three prostatectomies in one day (though none of the interviewees had managed this).

**Surgeon skiller:** The robot was thought to enable open surgeons to be transformed into minimally invasive surgeons at much greater speed (after 20-40 cases) than traditional laparoscopy (200 cases). This was seen as significant for service delivery and was referred to as an important consideration in adoption decisions. However, the view that the robot was ‘easy’ to learn was contested by two surgeons who were experiencing the learning curve during the study.

**Service organiser:** Some technologies created an opportunity to re-design and re-organise (often unsatisfactory/dysfunctional) services, although this could be preceded by extensive dis-organisation (Section 6.3.4). This had been the case in the adoption of anticoagulation near-patient testing at one study site. Similarly, there was a view that the purchase of the robot by a ‘hub’ hospital could improve dysfunctional cancer networks. There were plans (not realised) for hospitals to buy a robot collaboratively, combining caseloads and effectively centralising services. It was suggested that future adoption of CRP testing in UK general practice might lead to greater decentralisation of diagnostics from central laboratories to general practice, but also possibly to pharmacies or other retail units.

**Cost saver:** Generic telemonitoring, the ultrasound scanner and smart pumps were promoted as cost-saving technologies that would reduce admissions, hospital tests, staffing or adverse incidents. There was, however, no conclusive evidence and some discourse of doubt about this potential.

**Image maker and income generator:** Perhaps the most striking technology identity to emerge was that of the robot as an image-maker and income-generator for both individual surgeons and, more importantly, for hospitals. The robot was thought to bring personal ‘kudos’ for surgeons with implications for ‘ability to be invited to give seminars.’ A race appeared to be on for hospitals to acquire the robot before their neighbours did so that they could attract top surgical talent and patients from outside the area. Having the robot would represent the hospital as a ‘cutting edge’ organisation; not having it could result in the loss of accreditation (as a
cancer centre), patients and surgeons as well as credibility. This identity was mobilised extensively in business cases and hospital websites in an attempt to ‘manage perceptions’ and was thought to have led to the concentration of robots in the South-East where there was also a lucrative private patient market. However, it was not clear to what extent this rhetoric represented reality. Some informants argued that the manufacturer engaged in ‘scare-mongering’ and referral patterns to date had not reflected the predicted patient flow to hospitals with the robot.

To a lesser extent, the first adoption of smart infusion pumps across a whole hospital was expected to be a source of organisational kudos for one hospital, creating a role as a demonstrator site and enabling competition for organisational awards, but adoption had taken very long and had been ‘not neat,’ so these aspirations were not fulfilled. The spinal implant could potentially be seen as an income-generating technology, in particular private patient income. However, its designation by US and UK health insurers as ‘experimental/unproven’ and their refusal to reimburse the procedure arrested the development of this identity. But in 2011 these policies were being reversed.

Clinical and non-clinical identities relating to technologies’ utility and accomplishments beyond the purposes for which they were designed indicated that technologies’ impact on the delivery of health services could be wider than afforded by narrow technological conceptualisations and were therefore important determinants in their adoption, in combination with other identities and factors.

5.5 Risks

All the technologies were naturally associated with risks. But the designation of risk identities, while arising from the technologies’ material features, was nevertheless actor and perspective dependent so that risks were variably fore-grounded or back-grounded. This depended on two factors: first, whether the risks arose from intrinsic, design-related aspects of the technology or from its use; and second, whether the risks were in proximity to users/those responsible or physically removed from them. Risks that arose from the technology’s use and were proximate to the responsible actors were perceived as more manageable and less of a barrier to adoption.

For example, it was rarely mentioned that the anaesthetic-related risks in robotic surgery (associated with the slanted position of the patient) were heightened for the initial cases which could take several hours (up to nine). When questioned, surgeons asserted that these were negligible provided the patient was properly positioned and prepared. Similarly, the risk of bowel perforation, the ‘main’ risk of the spinal implant, was played down as avoidable through surgical skill. But the risk of infection (not featuring in industry discourses), arising from the access route near the ‘dirty’ perineum, was represented as significant with ‘no amount of’ preventive practices, such as sterilization, guaranteeing prevention. For the cultured
autologous cells, the risk of patients’ cells being mixed up or infected at the laboratory, although occurring at some distance from the users, were nevertheless perceived as negligible on the basis of assumed quality control and accreditation systems. But the risk of wound infection due to the inability to use antibiotics (a design issue), was perceived as much higher and was only partially open to control.

The risk profiles of the coagulometer were illustrative of the centrality of perspective and context. While from the hospital clinic/laboratory perspective, delegating monitoring to GPs was seen as high-risk, this view was not shared by the GPs themselves. In fact, an entirely different risk identity was constructed by some GPs, where near-patient testing was represented as safer than hospital-based monitoring as poor communication with hospital clinics meant GPs could not track patients’ INR readings and the inability to ascertain ‘who was responsible;’ as a result, patients could and reportedly were ‘falling through the net.’ Near-patient testing enabled GPs to be in control and was an explicit reason for adoption at one study site. On the other hand, GPs viewed patient self-testing as highly risky but this view was similarly not shared by a patient representative or web-based patient testimonies. GPs’ view that self-testing was high risk meant that very few patients were judged to be appropriate and the possibility was not routinely offered. Distance and responsibility were the mediating factors: the technology’s users and those with ultimate responsibility for patient safety were not the same people. In near patient testing the users were GPs or community pharmacists but hospital staff (e.g. haematologists/specialist nurses) believed themselves to be accountable; in self-monitoring, patients were the users, but GPs and other community based professionals were accountable or ‘vaguely responsible.’ As in the case of cultured cells, what rendered these remotely located risks manageable was the existence of systems for clinical governance, accreditation and quality control as well as service protocols for case-selection and monitoring, in which those responsible could have confidence. Such systems were not always in place (Section 8.2).

The risk identity of CRP testing was similar to that of the coagulometer, with some anxiety from hospital laboratory staff about testing by GPs working within a tradition of ‘quick and dirty’ testing, unsupported by quality control systems. Smart infusion pumps had somewhat ironic risk identities: while safety was the raison d’etre of this technology the pumps were thought to inadequately control risks when used in isolation from other DERS technologies or even to introduce new ones. This was due to increased automation of the pump programming leading to deskilling of users and/or to a user expectation that the pump will prevent errors leading to a lack of manual verification.

Alongside clinical risks, some technologies were associated with financial risks, in particular the robot and self-monitoring. The risk of making substantial losses was acknowledged by most NHS trusts adopting the robot, but there was a conviction that the management would be able to control the situation and to raise funds in some way (Section 6.4).
Therefore, although very real, these risks were not perceived as prohibitive of adoption. In contrast, a reason cited for the lack of promotion of anticoagulation self-monitoring by GPs was the anticipation that patients would test more frequently, increasing prescription costs; this was a risk that was problematic for PCTs, some of whom declined to include the strips for GP prescription.

We propose that as well as the nature and level of risks, the extent to which they were perceived as controllable was important in enhancing or limiting the technologies’ adoption. Risks arising from technology design (and therefore unmodifiable) and those located at a distance from the user were perceived as less controllable.

5.6 Requirements

The technologies were inevitably associated with a set of requirements, or demands that they placed on users and systems, relating to their acquisition and/or use and its coherence with clinical and organisational habitats. Compared to other aspects of technology identity, requirements perhaps represent more directly the material and functional properties of the technology, with less room for interpretation. Nevertheless, the degree to which requirements were seen as tolerable or manageable did vary, and it is this variability in human/organisational response that renders requirements (in common with other aspects of technology identity) socially constructed or co-constructed. Requirements acted at three distinct levels: cognitive, practical and interactional and in three different spheres: financial, use related and organisational. The technologies varied in terms of the scale and nature of requirements that they were perceived to bring.

Financial: All the technologies were subject to a common requirement: the need to fund the attendant costs and in some cases to secure PCT reimbursement. For the very expensive technologies like the robot, cultured autologous cells and whole-hospital infusion pump systems, cost was a significant problem. Reimbursement was more important for anticoagulation self-monitoring and CRP testing (thought to be not adopted in the UK due to this requirement). However, it was not inevitable that either costs or the absence of reimbursement prevented adoption; the robot’s acquisition by many NHS trusts was testimony to how both could be circumvented or tolerated in certain cases (Section 6.4).

Use related: Some technologies introduced novel clinical ideas or risks that needed to be negotiated. Examples of this were the spinal implant’s novel surgical approach near the sacrum (with risk of infection) and primary care monitoring of warfarin (with risk of death); fears associated with both were thought to slow down adoption.

"Practitioner resistance in terms of, “we don’t really want to do it...” You know, quite a few that said, “you’re being very silly taking this in primary care - you’re going to kill patients!”” (A1M2iv, anticoagulation commissioner).
Daily telemonitoring creates a new kind of clinical data that users were still developing uses for. Additionally, GP and practice nurses were reportedly ‘uncomfortable’ with the idea of interpreting readings from the ECG telemonitoring unit.

“It seems to be a sort of nervousness amongst the nurses that they shouldn’t really be looking at that sort of thing, so they tend to shy clear of it” (EGI3, ECG telemonitoring, company representative).

For most of the study technologies, the need for and provision of training was not a major issue (Section 8.1). For the ultrasound, however, it presented as a significant technology requirement and posed a problem for its adoption. The problem arose because many of the diverse potential users did not have basic imaging skills as they were not traditional users of this type of technology. In attempting to re-shape (and democratise) the landscape of imaging, the device encountered a problem: if the company wanted to create a new class of users, it had to train them in the basics of imaging technology before offering specific training for the new device, but this kind of ‘training from scratch’ was a ‘big ask’ from a commercial entity. The lack of training also raised clinical governance and risk management issues, in particular the risk of false reassurance to patients. The company representative was aware of these issues and wondered if accreditation might not be a necessary condition of using the ultrasound device. The training requirement held back the realisation of the company’s vision to extend its use to a number of areas, e.g. outpatient clinics, home visits, ambulances, A&E departments, palliative care.

Ease of use was an issue for cultured autologous cells. The initial presentation in small discs proved unpopular as these left gaps in between and required a large number of sheets for large burns. This led to a change of format. A less resolvable problem was the inability to use topical antibiotics on the wound which would kill the cells, raising the likelihood of infection. More generally, it was important for users to understand that the product was biological and needed appropriate use to achieve successful clinical outcomes.

Organisational: When adopted, the technologies needed to be introduced into and embedded in established clinical and organisational routines, a process that either required certain changes or brought certain limitations (Section 8.2 and 8.3). For some technologies, this was extensive, involving different parts of a whole complex system of care delivery. The most salient example of this was the coagulometer in near-patient testing, necessitating a number of organisational steps that in themselves were major undertakings: de-commissioning hospital-based services; negotiating contracts with potential community-based providers (GPs, pharmacies, etc); coordinating across service sectors; establishing quality control and audit systems; training providers. A further issue was the need for (and lack of) compatibility across computer systems in different organisations and general practices, making it impossible for some features of the technology...
to be used. The technology could not be adopted quickly and in a self-contained manner; its adoption involved planning and work across organisational boundaries as a major project.

ECG telemonitoring could present similar problems where vendors provided a staffed monitoring service. Before installing any equipment at patients’ homes, communication infrastructure and response systems (e.g. call centres) needed to be set up. For the companies selling the technology this required a sizeable investment up-front before receiving the revenue from sales, as the systems were needed ‘from day one.’

Smart infusion pumps (dose error reduction systems), if adopted as completely integrated ‘total’ hospital systems, had high organisational requirements. This was a multi-modal technology with a number of components rendering the technology progressively more sophisticated, but the costs were thought to be ‘prohibitive’ and the NHS ‘not yet ready.’

“You know, we’re not talking about, “oh, let’s put up a syringe pump or a volumetric pump;” you’re talking about, “well, we can’t run the syringe pump unless we’ve got the bar-coding system. We can’t run the bar-coding system unless we’ve got the other, let’s say, dispensing aids in ward areas. We can’t run the dispensing aids in wards areas unless the whole of pharmacy is upgraded to take this type of technology...So to cover the whole of the risk factor there... is a very large investment” (I1H1, pumps, hospital equipment manager).

Organisational requirements were also implied, to a lesser extent, by the other technologies (Table 5).

The extent to which a technology required the dismantling, creation or revision of both service provision and working relationships emerged as a key parameter that differentiated it from others that required no or little such work. As we set out in Section 9.1, this requirement identity could be the first building block of a future typology of technologies.

*Disruptive technologies*: Four study technologies – anticoagulation near-patient/self-monitoring, ultrasound, ECG and CRP – could be said to be potentially ‘disruptive’ technologies. This is defined as cheaper, simpler, smaller technologies that may, to some extent, in time, replace established ones and achieve cost savings (Christensen & Overdorff, 2000). These technologies could be perceived as a threat by users and providers of established technologies because they could, eventually, lead to disinvestment from, for example, hospital laboratories and imaging departments.
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“Initially there was some resistance from the hospital...and it did require several meetings to persuade them that there was no reason why a pharmacist would not be equal to a nurse that had undergone additional training... and it might be much more appropriate for this low risk population” (A2D2, coagulometer, GP/commissioner).

“We’ve found that when we’ve got a GP interested, they’ve then gone off and spoken to their cardiology supervisor, for example, who has completely kyboshed the whole thing, because they see that it’s potentially a threat to their cardiology department” (HUS-I-1, ultrasound, company representative).

Sometimes requirements led to non-adoption, in other instances slowed it down or led to protracted pre-adoption negotiations. As well as an impact on individual and organisational adopters, a technology’s requirements were likely to have an impact on the diffusion of the technology across the NHS. For example, the need to construct a clinical market and a training infrastructure for the ultrasound scanner was likely to thwart widespread early adoption.

### 5.7 Summary

The technology identities outlined in this chapter were constructed discursively through reasoning, interactions and practices. They were instrumental in assigning meaning to the technologies regarding their significance, safety and effectiveness, accomplishments, promises and demands. With multi-perspective inputs from industry/marketing, users, the EBM/HTA paradigm, policy and the media, identities were simultaneously intertwined and distributed and were flexibly mobilised in adoption discourses and behaviours.

High visibility and distinctiveness were identities that made adoption more likely as did a secure clinical rationale and a clear clinical market and usership. Low visibility and distinctiveness, a new clinical rationale, a diverse clinical market and usership with no clear focus made adoption more difficult.

Clinical and cost effectiveness identities of the technologies were generally contested and were, on the whole, used to rationalise or critique adoption decisions rather than offered as reasons for them. The extent to which technology related risks were seen as controllable also had an impact on decisions.

Some technologies were perceived to accomplish functions beyond the clinical; building institutional images, generating income, reducing expenditure and fulfilling patient centred agendas. The future prospects of the technologies provided a backdrop against which their present value was assessed. What type of demands the technology required from users and
systems and how easy it was to respond to these and accommodate them also played a role in determining their acceptability. In short, technology identities determined the adoptability of technologies, both at micro and meso levels (individuals and organisations) and, we conjecture, at the macro level (diffusion). In the next chapter, we examine organisational processes associated with technology adoption and how technology identities were mobilised in these contexts.
6 Adoption processes

In this chapter, we turn our attention to micro and meso level processes within the sociotechnical domain through which adoption is accomplished. Our findings in this regard were in line with our initial, loosely-formulated conceptual framework. Adoption/non-adoption, we found, were the outcome of intricate social and political interactions between individuals, professional groups, NHS organisations and the industry. Technology identities, outlined in the previous chapter, emerged as integrative forces through which material and social aspects of the technologies, expectations and agendas and structural frames such as budgets and costs, all found a voice and shaped decision-making.

We first examine the different types of adoption and clarify what this term may mean in different contexts. We then look at organisational arrangements and how procurement and gatekeeping was enacted for different types of technology. Next, we show that political relationships and processes played an important role in adoption, that organisational know-how was limited and networked cooperation critical. We examine the industry’s crucial role in technology adoption in the NHS and also review relevant structural and macro factors. Finally, we examine the role of patients in technology adoption.

6.1 Adoption decisions: where, how and how often?

Our data indicated that adoption was not a homogenous concept but varied in terms of: type of decision-making, level of managerial passage point and commitment required of the users. It is best to think of these different forms as constituting a continuum, with more formal adoption at one end and less formal, ad hoc decisions at the other. Cost was not a criterion that determined the type of adoption; however, whether the technology required capital expenditure was.

6.1.1 Ad-hoc, individual adoption

At one end of the continuum were decisions made on an ad hoc basis, usually by a single clinician, for example for the spinal implant and cultured cells. This type of adoption decision was relatively opaque and unavailable for institutional managerial scrutiny. These required repeated adoption, with a new decision for each use and were typically obtained on a ‘pay-as-you-go’ basis, with no user commitment, an unstable model in turn necessitating a continuous marketing and sales effort. These were generally niche technologies with unpredictable demand and infrequent use, but were increasingly subject to the intermediate model explained below, as both the NHS and industry were keen to achieve financial predictability.
6.1.2 Intermediate model of adoption

Here, adoption required some commitment from users in that the technology had to be acquired (purchased or leased) at the outset, although this could be a small-scale, incremental or reversible process. The decision could be made by a single clinician, a variety of committees with clinical and/or managerial membership or trust boards. Adoption could be reversed, usually through non-use. Coagulometer in self-testing, CRP testing, ultrasound, ECG telemonitoring and (in some settings) smart infusion pumps were in this category. Increasingly cultured cells and the spinal implant were also subjected to this type of adoption.

6.1.3 Single-event corporate adoption

This kind of adoption involved capital expenditure and formal, trust board level decision-making, with the organisation locked into the technology for the foreseeable future. These decisions required considerable time (up to two years) and bureaucratic investment. In secondary care the process could involve hospital clinicians, one or more directorate managers, the finance and procurement departments and executive and non-executive directors. In primary care it was more complex still, spanning organisational and sectoral boundaries and involving several general practices, one or more PCTs and one or more hospitals. The most complex adoption model was one where a PCT-wide managed service contract was signed with a manufacturer for the provision of all telehealth/telemonitoring services for several long-term conditions. The robot, NPT anticoagulation and (when adopted as large-scale systems) smart infusion pumps and ECG telemonitoring required this type of adoption.

Commissioner initiated adoption: Primarily in the corporate model, but also to a lesser extent in the intermediate model, adoption of primary care technologies could be initiated, led and organised by the PCT as commissioner. In these instances, adoption was associated more or less explicitly with local policies on health care delivery and could also reflect national health policy.

6.1.4 Adoption by trialling

Cutting across the first and second types of adoption was a surprisingly common theme of adoption by trialling. The terms ‘trial,’ ‘study’ or ‘pilot’ were used interchangeably and with variable meaning. Trialling ranged from formal evaluation by a hospital department, a whole hospital or a PCT to opportunities for individual clinicians to ‘have a go’ at using the technology, with duration ranging from a couple of weeks to 12 months or longer. Examples of the more formal approach are in Appendix 7. Much trialling was enabled by the provision of the technology free of charge and facilitated through established relationships between the company and clinicians (and less frequently managers) or between the ‘champion’ clinician selected by the company and his/her contacts. For the companies, trialling provided two
benefits: pragmatic evaluation of an early version product for usability, signposting necessary modifications; and entry into the NHS market. For the NHS, it enabled evaluation prior to financial and service commitment.

“[A GP] who approached us, and said that he’d like to try it for different things. And then I personally use him as a sort of study, so that I see what he’s doing with it” (HUS-I-1, ultrasound, company representative).

“So, the way that we introduced our products to the clinicians was by doing clinical testing...those came about because of the very good links between [scientist] and the NHS clinicians that she’d worked with in the past...And they...gave us feedback on how it was performing” (TGI1, cells, company representative).

However, there was a shared view that trialling could and in some cases had become dysfunctional. Some ‘pilot studies’ appeared to continue indefinitely, amounting to unplanned and unacknowledged ‘back-door’ adoption, an especially widespread phenomenon in telehealth. Inadequate methodology and dissemination of findings was another problem.

“...consultants will sometimes have a good working relationship with a company, they’ll get a device in on loan or on trial... But then you find that two years later, it’s still there on loan, and at that point the consultant will say, “Oh, well, I’ve got to have it! I mean, you know, we’ve been using it for the last two years and it’s part of our clinical practice now”” (GGH1, generic, equipment manager).

“You get dozens and dozens and dozens of pilot projects that are just...any kind of evaluation is just an afterthought... the data are just not shared, or the knowledge stays locked in the heads of those who did that particular pilot” (EGA1, telemonitoring, academic).

### 6.1.5 Adoption for training

Another form of adoption was the acquisition of technology specifically for training (and research) purposes. For example, a consultant had purchased the ultrasound device with research funds because attempting to secure service funding would have been too ‘traumatic.’ The consultant planned to use the ultrasound device for training in diagnostic imaging as well as, at a later stage, to aid patient diagnosis. Another consultant had decided to opt for the more expensive dual-console robot in order to conduct teaching on it.

### 6.1.6 Inheriting technology

There were a few instances of NHS trusts inheriting technology following service reorganisation.
"I'd actually come along in 2007 and inherited this equipment, so somebody in the authority purchased this equipment some time before I arrived and it got stuck on a shelf, basically" (E2M1, telemonitoring, commissioner).

Another PCT had inherited 60 coagulometers used by self-testing patients.

"the previous PCT...decided to buy sixty or so meters, and handed them out to patients...It’s been kind of a botch-up job all the way through...they must have got a fund that they had to use...like a technology innovation fund... But in terms of long term planning it has now created quite a lot of issues for us” (A1M2iv, anticoagulation, commissioner).

6.2 Managerial passage points, gatekeeping and locus of power

The different types of adoption outlined in the previous section afforded different levels of control and gatekeeping to NHS management. Decisions by individuals were relatively opaque, undocumented and institutionally non-reviewable, as in the case of (when purchased by individual clinicians) ultrasound, telemonitoring, cells and spinal implant.

"The theatre sister will then ring the rep or ring us and say, "Mr So-and-so has asked me for this; I have no idea what it is”" (SI1, spinal implant, company representative).

However, while some adoption decisions may have been truly individual, many were discussed, however informally and transiently, with peers, especially where the technology was more novel or risky.

"If it’s something really new, so, for instance, I put in a new growing rod; I formally went to my colleagues, saying, "Look, here’s very new technology, very few of them done in the world. Do you agree that this is reasonable and safe to do?” (S3D1, spinal implant, surgeon).

The intermediate model of adoption in theory allowed more managerial control and could prevent what one informant called ‘maverick’ adoption. The different structures included less formal groupings of clinicians sometimes with managers, clinical directorates, formal bodies such as a new product/safety committee and formal tendering. The same technology could be subject to different managerial passage points at different hospitals. While clinicians were critical of these processes, representing them as barriers to adoption, in practice, their success in gatekeeping was uncertain.

"A lot of them seem to be able to get past the process... Because I regularly get a call to say, "Who allowed this to be used?" And I’m like, "I’ve no idea! I don’t know how it came in!” And all of a sudden, Joe Bloggs is happily working away with it, and the
company have managed to get it in the boot of the car!.. and then three months down the line I get a call from the surgeons saying, “Can we write a business case for this?” (T5M1, cells, manager).

Even where formal tenders were issued, clinicians were able to influence the process through, for example, scoring the technology consistently highly on tender questionnaires.

The most elaborate gatekeeping, formal decision-making by the trust board, requiring a business case and preliminary approvals, is examined in detail later in this chapter.

The different adoption models had some common features: while ‘evidence’ was used, this was a very broad concept (Chapter 7); involvement of stakeholders and professionals who might be in a position to contribute to the process (e.g. clinicians, technicians, equipment managers, clinical engineers, theatre staff, central sterile services department - CSSD, trainers, pharmacists, directorate, finance and procurement managers) was patchy; the processes were, on the whole, informal; and they were invariably political. We turn next to the political nature of technology adoption.

6.2.1 Adoption work: adoption as political process

Rather than being dispassionate, rational and ‘evidence based’ (in the EBM/HTA sense) adoption decision-making was, above all, a relational and discursive process with stakeholders either promoting or questioning the technology by mobilising various technology identities: the robot could be promoted as a potential income generator or as an expensive, non-cost-effective equipment; the spinal implant could be promoted as a safe, effective and useful technology or as dangerous and unnecessary. Thus, ‘adoption work’ by enthusiasts included incremental persuasion using information and evidence from a variety of sources and identifying and dissolving resistance. Technology identities, expectations and agendas framed deliberation and negotiation through conversations, organisational routines and discourses, texts, websites, the print and electronic media and encounters with the technology.

Power and its distribution between providers and commissioners and between professional groups had a formative role. The adoption of the surgical technologies was subject to three kinds of power relations within the NHS: between clinicians, between clinicians and hospital management and between the hospital and the local PCT. For example, a novice consultant interested in the spinal implant, could not use it because he had failed to secure the agreement of the senior consultants in the department. Gatekeeping attempts by management were often, but not always, successfully resisted by clinicians; however, managers did, for example, ensure that the use of the spinal implant at one hospital was subjected to a quota and, at another, that a tendering process was instigated for the autologous cultured cells product. The relative power of the PCT vis a vis
the hospital was variable, but, on the whole, negligible. Anticoagulation NPT was an exception, with the PCT in both study sites driving reconfiguration of services to entirely or partly community-based models.

The adoption of the robot provided a test bed for commissioner power. Robotic procedures cost more than open or laparoscopic procedures and hospitals faced a considerable shortfall in income unless the PCT agreed to reimburse the difference, but the majority of PCTs refused reimbursement. This refusal did not stop hospitals acquiring the robot and some did not even inform the PCT of their decision; one senior PCT manager had heard about the robot’s arrival on local television news. Another PCT had made a policy decision that the robot should be considered ‘low priority’ due to ‘limited evidence of effectiveness.’ Two years later, the local hospital had purchased a robot with charity funding and the PCT had not been consulted. In both cases, hospital managers were intending to open negotiations with the local PCT for reimbursement once the robot was already in use. Relations could become seriously impaired, as happened at one locality where PCT refusal to reimburse temporarily forced hospital management to stop using the robot except for private patients.

By contrast, adoption decisions by GPs were severely constrained by PCT reimbursement policies. GPs’ independent contractor status appeared to provide an effective financial leverage to the PCT in the adoption of technologies like the coagulometer (NPT) and potentially the ultrasound and CRP testing. If adoption entailed potential loss of income or profit, it was less likely to be considered by GPs.

When the PCT itself was the adopting organisation, as in the case of anticoagulation NPT (partially) or locality-based telehealth, it clearly exercised more power, but this was attenuated by powerful constituencies of GPs, pharmacists and hospital clinicians. In particular, haematologists running hospital anticoagulation clinics needed to be co-opted as they – more or less unilaterally - assumed continuing accountability for the community based service. The common perception was that hospital staff demanded unnecessarily high standards/quality control systems as a form of resistance to the potentially ‘disruptive’ move of services to community based settings. PCT willingness to negotiate and accommodate these high specifications ensured that consensus-based and stable service models could be developed.

**Forming alliances**

An important strategy in adoption work was forming informal alliances.

“I singled out two people, really. And one of them was the research nurse at the time, who was very good and on my side. And he went to the clinician and the head of nursing development and sort of, you know, kept pecking away” (A1N1, anticoagulation, nurse).
“within the directorate of surgery, you can use your local operational managers to support you, before you actually present it to the high level boards” (P2D1, robot, surgeon).

At the hospital where robotic surgery was stopped because of PCT refusal to reimburse, the consultants were concerned that hospital management planned to sell the robot. They enlisted the help of local GPs.

“We said, “Do you realise that your PCT is not paying for cases?” And...it’s give and take, you know, “you scratch my back, we’ll scratch yours...” They said they wanted less patients seen in secondary care, in outpatients, basically. We said, “OK, we can arrange that... provided you...help support our robot.” So the lead GP went to the PCT chair... and said, “listen, you need to support this robot because...” It’s basically politics...” (P10D1, robot, surgeon).

**Groundwork**

Adoption work conducted ‘behind the scenes’ was as important as or perhaps more important than surface work where a concerted case for adoption had to be built.

“So we...built up the case...I then was responsible for making sure that the executive directors were all up to speed...understood what the benefits were going to be. Because, obviously, they needed to be convinced as well...I spent quite a lot of time working behind the scenes and with other people...We gave [the non-executive directors] the CD-ROM that showed them all the gory details about how the operations work. And I set up a satellite link with America for the directors to go to, where we could see a live cardiac case being done...The medical director was a key. We had to have him on board, or it probably wouldn’t have gone anywhere” (P9M2, robot, manager).

This phase was decisive; when the adoption agenda failed, it failed at this stage.

“you don’t go away in isolation and develop a business case and go: “ta-da - here you go Board! What do you think?..” If we developed a business case on the current financials and took that to our board, they’d turn it down... part of my role in supporting directorate’s developed business cases, is to help them to get to a point where we’re confident that we can get them over the line” (P5M1, robot, manager).

**Resistance**

Resistance took the form of diverting attention, putting up obstacles and refusal to engage with the adoption agenda.

“And then we’ve had alleged reports around patients not being happy with it. And of course the practitioners who didn’t want to
do it would use that as a leverage to disengage from the process as well…” (A1M2iv, anticoagulation, commissioner).

“There were people who were going…” “Oh, well, I can see how that can work for adults, but it’s not going to work in paediatrics.” Or “I can see how that’s going to work for a ward, but I can’t see how it’s going to work for ITU”” (I2M1, infusion pumps, manager).

Where resistance was not perceived as a threat, it was simply ‘listened to.’

“There will always be people who are sceptical…they’ve been listened to and, you know, they can take part in any discussions that they want to really” (P9D1, robot, surgeon).

But when resistance had the potential to prevent adoption, strategies were developed to weaken it. One was to challenge views.

“If I…talk to my nurses and they are sceptical about something, then I say, “Show me your mobile phone?..” then they realise actually they wouldn’t accept a mobile phone which is five years old..I have the experience that if we approach...introduction of modern technology this way, then it is taken on by the staff” (I3M1, infusion pumps, clinical manager).

Another strategy was to create opportunities for the sceptics to encounter the technology, allowing them to construct a positive identity for it.

“We took the equipment out with us. We did a bit of a workshop with them really, showed them what the technology could do, showed them some potential uses, and applications of it, and really just kind of get some buy-in from them... And it was very successful” (E2M1, telemonitoring, manager).

Relying on hierarchical relationships to ‘impose’ the technology did not work well, for example with smart infusion pumps.

“Part of the reason they didn’t want it is because it was imposed...we were asked to take them with us - or, not even asked, told. “They’re having it!” So, immediately, you’re getting barriers put up” (IGI1, infusion pumps, company representative).

In fact, wielding managerial power productively was another essential strategy.

“Taking corporate ownership of all the defibs in the trust... enabled us to manage the introduction of new technology... It would have never been done effectively if we’d not done that.” (GGH1, generic, equipment manager)

One PCT had taken the decision to go for a complete overhaul of anticoagulation services, de-commissioning hospital-provided clinics, rather than opting for mixed provision, with some anticipation of resistance.

“So, doing it that way...made it...quite scary at times, in terms of making sure that the coverage was there...But I don’t think there
was any other way it could have worked...because if you give GPs, especially, too many options then you find that it won’t happen” (A1M2iv, anticoagulation, commissioner).

However, this had to be combined with compromise, a further strategy in dealing with resistance.

“Although our initial aspirations were that we will do a big bang, we kind of realised that that might not be so clever! So we kind of decided that we would withdraw from different trusts in a staged approach. So we did [Hospital] first where there was willingness, and their GPs were already used to it. And then a year later, we would follow in [Hospital]. And that kind of worked well” (A1M2iv, anticoagulation, commissioner).

This PCT also compromised in other ways, selecting a software package that was already in use by GPs and dropping one level of requirement for GP training and settling for a competency test. Informants pointed to the importance of ‘working with the GPs rather than around them’ in complex technology adoption/service reorganisation.

The innovator

In organisational adoption, the presence of one or more enthusiastic individuals moving forward adoption work at a strategic or administrative level appeared important.

The ‘innovator’ could be an influential clinician, bringing about adoption more or less singlehandedly: we found two instances where influential surgeons had insisted on the robot’s acquisition when negotiating their appointment to a new post. Sometimes, there were a number of innovators from different stakeholder groups, undertaking groundwork inside and outside the organisation. At one site, a surgeon and a senior manager worked in this way: the surgeon liaised with the company, chased progress with a mid-level manager, organised visits to see the robot in action and arranged for the robot to be brought to the hospital for a demonstration; the manager undertook background work with the executive and non-executive directors, similarly creating opportunities for them to ‘see’ the value of the robot and liaised with the company, the finance department and the CSSD for speedy contracting, delivery and operationalisation of the robot. At one PCT adopting/reorganising anticoagulation self-monitoring, one nurse ‘badgered’ managers and clinicians and organised the recycling of devices while a community pharmacist who was also a PCT member was described as the ‘driving force’ behind the changes. Innovators could act as conduits between their stakeholder group and the adoption team, gathering intelligence about views and helping develop strategies to challenge them. However, it is important to note that innovator-led adoption could be counter-productive. Such was the case with a GP who championed anticoagulation self-monitoring for a locality catchment area based at his own practice, which was seen to be disruptive by the PCT commissioners trying to design a standardised service for a wider county population.
The innovator’s role went beyond that of the enthusiast and required both strategic capability and detailed work. One surgeon enthusiastic about the robot had failed to have it adopted: his involvement had not gone beyond having sporadic ‘words’ with colleagues and the chief executive; a report had been presented to the executive directors but he had not seen it. Another surgeon keen on the spinal implant had delegated adoption work to a nurse; neither he nor the nurse was aware of or attended scheduled committee meetings where the issue was going to be discussed.

Even once the technology was acquired, its use depended on the presence of innovators. At one hospital, the robot had not been used for three or four years following its installation. Among the reasons offered were the absence of a senior clinician interested in ‘taking it forward’ (others were: resistance from a senior surgeon; absence of training). In one locality, several ECG telemonitors had been purchased (because a policy-initiated telehealth grant was available) but had ‘sat on shelves’ for 12 to 18 months because there was no one in post ‘concentrating on this area of work.’

The presence of one or more innovators able and willing to devote time and energy to a range of activities that could be defined as adoption work was a significant factor in adoption.

### 6.3 Adoption bureaucracy and know-how

In particular single-event corporate adoption involving capital expenditure, was a complex process that demanded location, appraisal and synthesis of information regarding: the technology’s technical features, its clinical significance, safety and effectiveness and the likely organisational, financial and patient-related impact. This was a tall order for most NHS trusts; there was no identifiable member of staff or department with expertise or time to undertake this task. Those charged with steering the technology through its organisational adoption pathway used a variety of sources: staff at other NHS trusts, websites and company sales personnel.

#### 6.3.1 Knowledge and intelligence gathering

Informal and sporadic networking was extensively used. Company sales staff and neighbouring or distant hospitals, GPs and PCTs who had already adopted the technology were valuable sources of information and advice on the technology, in particular for developing service specifications and writing business cases. Contact by email, telephone or in person and exchange of documentation such as business cases, service level agreements (SLAs), protocols and contracts was common. When staff were ‘stuck for people to go to and ask,’ the manufacturer put them in contact with users and also provided ‘sample’ business cases. This type of evidence constituted what we have termed ‘evidence-for-confidence’ (Section 7.1.1).

“We were just given a laptop and a [coagulometer] and told to find out for ourselves. So, obviously, the first thing we did was phone [manufacturer] and find out how to work the machines,
and what it was all about. And then we went to meet people who were actually using the machines...And watched them run the clinics and read their protocols” (A1N1, anticoagulation, nurse).

The preparation of ‘case studies’ in the form of service models from different sites was also a conspicuous activity of the manufacturer of the coagulometer. Similarly with the robot:

“Int: How did you go about producing the business case?
I researched the internet...And I did speak to [NHS Trust] because they’d already got a robot, I spoke to their managers, and they sent me some information” (P4M2, robot, manager).

When the experiences and strategies of others did not seem to be relevant, managers and clinicians used ‘synthesis’ and ‘reformulation’ to develop adoption plans that best suited their objectives and circumstances. Managers wished to have a degree of benchmarking to help build confidence in the appropriateness of their own approach to adoption; they sought this, again, through informal contact with industry and other NHS staff.

“We do get called sometimes by other PCTs who are looking to launch a service of their own, to learn from the issues we have had... We’ve been talking to [manufacturer] and they do say our specification is quite good” (A1M1, anticoagulation, manager).

Reliance on personal initiative and opportunistic networking led to information of variable type and quality, a point reiterated by one informant.

“I suspect that you could talk to ten hospitals and they might have done something similar...But we seem collectively, as the NHS, incapable of taking the learning from an organisation and transplanting it into another” (I2M1, infusion pumps, manager).

In assessing the technology’s evidence base, managers relied heavily on senior clinicians within the hospital, as they felt unequipped for the task.

“It was sold initially to us on the basis...“Look, it improves patient care, procedures are shorter, less blood loss, all those sort of things!” Fine! I accept all of that. Because I’m not in a position not to, necessarily... we were in the hands of our clinical colleagues to sort of help us verify that” (P6M1, robot, manager).

There were suggestions for formalising the evidence appraisal process. One clinician put forward the idea of knowledge brokers in each hospital/specialty who could conduct formal literature searches. Another informant proposed wider uptake of formal modelling exercises, not only as quantitative decision aids, but also as a helpful process bringing together staff from ‘far flung bits’ of the system. This notion of adoption as a networking project cross-cutting usual organisational divisions is explored further in Section 6.3.4.
6.3.2 Business case and financial planning

Adoption of the robot and PCT-wide anticoagulation near patient testing or telehealth services required the preparation of a business case. We obtained three examples of robotic business cases. Assumptions, expectations and faith appeared to be the premise of all three. As noted in Chapter 5, the case was built not on financial viability but on the robot’s identity as an image maker and income generator for the hospital. Expectations included projected annual increases in activity, which was in turn based on assumptions concerning increases in incidence and treatment rates and success in attracting out-of-area and private patients as well as research funds. Shorter hospital stay and reduced blood use were expected to lead to cost savings. Despite these expectations, however, all the business cases forecast significant losses.

- A loss of more than £366,000 in the first year and £314,000 in the second, based on 200 robotic procedures being performed in the first year (in fact, only 100 robotic procedures were likely to be performed in the first year).
- A loss of nearly £400,000 after four years, based on an income of £900,000 from charity fund-raising and more than £700,000 in research funds (two years after the robot’s installation, no research funds had been received).
- A loss of £558,416 in the first year and more than £370,578 in the second, based on 73 robotic cases per year (this hospital decided not to invest in the robot).

There were many reasons for projections not being realised: delays in establishing the robotic programme and longer than anticipated learning curves; the acquisition of the robot by more hospitals reducing the pool of out-of-area referrals (one hospital’s activity had gone down from 100 to 50 robotic cases a year); shortening hospital stays not readily translating to bed closures and staff reductions.

“Contrary to what the manufacturers tell you – there is no such thing as a viable business case for a robot in the NHS. Because… there isn’t a tariff for robotic prostatectomy” (P2D2, robot, surgeon).

“Its cost effectiveness is one of those things that you can only really evaluate once it’s in-house and look back and say, “Oh, gosh, that was quite an expensive way of doing something, maybe we’ll do it differently. Oh, well, we’ve got it now, we’ll put up with it!..” there may be hidden costs which you’re not aware of in terms of extra loss of operating time. “Oh, we said we’d do however many cases in our first year; well, we’re not going to do that!” (P9D1-2, robot, surgeon).

Optimism versus caution
The risk-taking approach and optimism contrasted with a more cautious, risk-averse approach and use of worst-case scenarios on future financial viability. It is likely that these different approaches reflected the dominant organisational culture. An illustration was provided by two hospitals, one with and the other without the robot.

At Hospital A, there were no funds for the robot, but a newly appointed consultant was keen, having failed to persuade his previous hospital. The case was built on the premise that:

- the hospital was a centre of excellence and had to have the latest technology in order to maintain its status and its attractiveness for top surgeons and academics
- NHS and private patients would be attracted to the hospital
- not having the robot would potentially lead to loss of status, patients and income.

The robot's use was to be financed through charity fundraising in the first two years; thereafter, it was hoped that an increased NHS tariff would cover the costs. Following intensive charity fundraising, the robot was acquired under a lease (around £300,000 a year). Soon afterwards, a newer version of the robot was launched and the hospital upgraded to this under a seven-year lease for an additional £750,000, to be raised once again through charities. Thus, the annual costs of the lease, the maintenance charge and operating costs were all planned to be met through ongoing charity fundraising. Failure to raise the monies would mean a substantial deficit while defaulting on payments to the company.

“It has to be a risk…I looked at all the models, and there was not a single model which had guaranteed low or no risk...I think what is reckless is to refuse advances on the basis that you cannot support...because it takes the health service and health care backwards, not forwards” (P7D1, robot, surgeon).

At Hospital B, one surgeon was equally keen on the robot but had failed to persuade management to acquire it over more than three years’ negotiating because the management was not convinced that it would be cost-effective or financially viable. This conclusion was based on consideration of a range of issues:

- the robot would be used very little initially, while depreciating, as the surgeons worked through their learning curve
- if charity funds were used to purchase or lease the robot, these would not cover maintenance and operating costs
- savings in bed days and blood use would not cover the extra expenses incurred
- the local PCT had agreed to pay extra funds for robotic procedures, but only for two years and the financial situation beyond this was uncertain
• neither patient referrals from outside the catchment area nor use by specialties other than urology would lead to enough extra activity and income.

“We don’t take things on a wing and prayer in this organisation... we’re open for innovation where there’s a fairly solid case” (P5M3, robot, manager).

While Hospital B was a foundation trust and Hospital A was not, foundation trust status did not appear to be a determinant, as we came across a number of foundation trusts that had also acquired the robot through charity funds with equally uncertain financial futures. Many of these hospitals were engaged in ongoing charity fundraising, advertised on their web pages, in order to continue to use the robot. In other cases, a decision to adopt was reversed as the economic downturn began in earnest; one hospital was preparing to sign the contract when this happened. Similar issues of financial planning and sustainability applied to anticoagulation NPT and ECG telemonitoring. At one site, NPT had been adopted in response to what had been a dysfunctioning and fragmented local service; the impetus to improve the service had been so great that financial aspects had not been a ‘priority’ and there had been no financial plan. One PCT had adopted ECG telemonitoring following a successful pilot phase; when the pilot ended, the PCT had to purchase the equipment (previously provided free of charge) and also commit to a £43,000 annual fee for a web interface. No budget had been identified for this fee prior to the adoption decision and efforts were continuing to identify a source at the time of the interview.

Our data confirmed that underlying the over-optimistic or unrealistic nature of business cases was their authorship: in many instances, the cases were written with extensive involvement of company staff.

6.3.3 Industry contribution to NHS decision-making

Company sales teams were highly proactive in engaging with managers and clinicians during the pre-adoption period and in many instances helped write NHS business cases.

“We’ve developed a whole profile protocol for a business case, which is in a sort of 30 page draft. All the text is basically written, we just work with [trusts] to change it around to suit their particular circumstances” (EGI1, telemonitoring, company representative).

“We’re generally dealing with people who really don’t know where to start with this...I essentially have to lead them by the hand through this process...that’s my job to say, “well, look, yes, it’s realistic that in year one, 75 percent of your prostatectomies should go home at day 1.5; so that’s a reduction in bed days of...blah!…” Essentially, I provide them with ideas which are then proofed by the surgeons and then modelled financially by the managers” (PI2, robot, company representative).
Once the numbers had been worked out, ‘colour’ was added about attracting private patients for the robot and increasing the hospital’s ‘prestige.’ However, it was clear to the company that the case was often difficult to fulfil in practice.

“Quite often the executive team will sign the cheque and then not really push people to implement it properly. And we quite often have ridiculous scenarios like people not using it because they can’t get access to a theatre on that day, or because somebody won’t swap an operating list...So, we have some hospitals which do about one or two cases a week.”

Int: “So they’re not realising the potential of savings that they said they would in the case?”

“No” (PI2, robot, company representative).

Two companies were developing modelling tools/templates to be populated by trusts which they believed would demonstrate the cost-effective potential of their technology.

Industry help was welcomed by some busy managers and clinicians both as a source of expertise and a time saver. However, some managers and clinicians were sceptical of industry involvement.

“We wanted to make sure that it was unbiased and we wanted to make sure that we developed the business case, and we knew what the implications of taking this on, if we were going to do it, would be, rather than a very rosy, best case scenario” (P4M1, robot, manager).

Savings only happened if beds were closed, an unlikely prospect.

“They were very fixed on this, “oh, you’re going to save all these bed days,” and they kept pushing that, and we knew ourselves that we weren’t going to save anything on bed days. So that was just a complete fallacy, to actually work a business case on that basis” (P6M1, robot, manager).

Informants thought that centrally produced NHS templates/evaluations would help prevent the need to ‘reinvent the wheel completely’ when a supplier turned up and said “Everybody’s buying one of these, why don’t you have one?”

There were other ways in which the industry sought to influence technology adoption. An important strategy was to identify, attempt to modify or align with national or local health policy.

“We’re having quite a bit of success at the moment with the Health Checks Programme, the cardiovascular screening programme” (CGI1-2, CRP, company representative).
The policy agenda for telehealth and the availability of ring-fenced funds had been important in the diffusion of the relevant technologies and devices.

“And then slowly you began to see pilots coming in in the UK, as policy began to change; you know, if there was no policy in place, there is no budget so there’s no market” (EGI1, telemonitoring, company representative).

The Quality, Innovation, Productivity and Prevention (QIPP) agenda was seen as a promising development for some of the technologies: the robot was marketed as enabling enhanced recovery through shorter hospital stays. The manufacturers of the coagulometer had succeeded in having it included in the Innovative Technology Adoption Procurement Programme (iTAPP) as a level 2 technology (‘on the market, with insufficient evidence for wide adoption’). While this fell short of endorsement, inclusion on the list ensured a marketing advantage and a valuable policy identity as a technology ‘likely to be of significance to the QIPP agenda’ (DH, 2011).

The industry sought to influence policy by topicalising particular clinical and financial concerns. In anticipation of GP commissioning, as set out in the Health and Social Care Act 2012 (Great Britain, 2012), one company producing point of care test devices was planning an electronic promotion campaign with emails to around 1,000 NHS staff including directors of public health, diabetes and health check leads and nurses.

“What we’ll be trying to do is actually raise that question in their mind, to actually try and start that debate so that individual commissioning groups will be thinking about, “OK, how much are we really being charged for these [currently hospital based] services? How can we improve our efficiencies?” (CGI1-2, CRP, company representative).

Companies also had to be skilled in locating actual decision-makers within organisations.

“... [senior management] create a budget, but it’s handed down to a middle level of management... Now, if that person becomes orientated towards technology, then they may present the case to their management to get a budget to try us out” (EGI1, ECG telemonitoring, industry rep).”

“Perhaps we’ve struggled in the past to identify a single decision-maker for this type of product within a PCT” (EGI2, telemonitoring, company representative).

Thus, the industry was a prominent actor in the adoption space at a number of levels, from promoting the technology generally through helping with micro adoption work to sustaining the technology’s use (Chapter 8). Its objectives were: to identify new clinical market opportunities and try to ‘create’ these markets; to identify sites in the NHS where marketing investment might be most fruitful; to identify organisational structures and
staff with real power to make change happen; to influence health policy and thinking around interventions and associated technology; to ‘configure’ users and decision-makers, i.e. discover their concerns, hopes and agendas and to speak the same language as them in promoting particular technology identities.

6.3.4 Whole-system approach?

One of the technologies, the coagulometer in near-patient testing, could only be adopted as part of hospital- or locality-wide service development; many others could be obtained by individuals but their full value could only be realised if adopted as part of service development, impacting on large numbers of patients (mini ultrasound, telemonitoring ECG kit, infusion pumps). In these instances, the technology was no longer simply a device but part of (and possibly a trigger for) service re-design. For example, the coagulometer was commonly adopted in the context of a near patient testing service for a sizeable catchment area covered by one or more PCTs, often as a replacement for hospital based or a mixture of hospital and community based services. This kind of adoption necessitated the orchestration of a multitude of elements; it was disorganising because it led to the dismantling of existing systems, routines and relationships and required their re-assemblage in alternative schema. Described in one site from the commissioner perspective as a ‘nightmare,’ these processes were organisationally, relationally and financially challenging and extended well into the post-adoption diffusion and implementation period.

“There have been many, many problems and are still ongoing problems with implementing that service across the PCT. You’ve got 96 practices in [City] PCT, you’ve got about between 8,000 and 10,000 patients who are on warfarin. We’ve got four or five different hospital trusts with anticoagulation clinics…it’s been quite difficult to estimate the cost of the service, and also trying to withdraw the money out of the acute contracts” (A1GP1, anticoagulation, GP).

At this site, one of the many different types of contract was a block haematology contract from which the anticoagulation element had to be somehow disentangled and withdrawn. At times, the PCT was paying for both the previous (unused) hospital service and for the new community based one. Alongside financial negotiations, a delicate process was necessary to engage hospital staff in organising ‘safe discharge’ of patients to the community, quality control procedures and training and supervision for community staff. There were also difficulties on the community side, such as ascertaining the number of GPs willing to provide clinics and negotiating service specification and contracts with them. However, once set up, these system-wide services were hailed as a success and, in any case, an improvement on the previous model. Whole-system adoption appeared to be triggered by the perception that existing services were dysfunctioning (e.g. fragmented, unworkable, unsafe).
The adoption of the coagulometer by self-testing patients and providers happened more accidentally or incrementally. The two study sites had not initially included it in the specification; a small number of patients using the technology had been ‘inherited’ and in some cases there was PCT anxiety that some patients could ‘fall through the net’ of protocols for training, supervision, and monitoring under a clinical regime, possibly leading to over-testing (a frequent clinical criticism of self-monitoring) and lower quality care. External quality control of the coagulometers was also a cause for concern. The omission of self-monitoring in the specification was partly due to the identity of self-testing/monitoring as a high-risk, niche technology applicable to a small minority of patients. During the study, both sites were beginning to pay more attention to self-testing/monitoring, one re-writing the service specification to include it and the other considering including it in the next round of tendering for providers.

In order for the value of the ultrasound scanner to be fully realised in primary care, the scan was seen as needing to ‘slot into’ a care pathway, from the patient presenting to the GP, through the hospital referral decision, to return to the GP. It was clear from the interviews that without a specification or protocol setting out the possibilities and limits of the device as a diagnostic tool and its place in clinical practice, its utility in primary care would remain uncertain and even raise questions over safety. Purchase by interested/curious individual clinicians, whether in primary or secondary care, was concerning in this respect. ECG telemonitoring also worked best as a holistically deployed technology. One PCT had dramatically reduced hospital referrals for AF by providing the device to 45 GPs who sent the traces daily to the cardiologist. Electronic link-up with hospital specialists was seen as crucial both to ensure patient safety (by providing expertise to generalists) and to realise the objective of reduced hospital referrals (by facilitating the confidence needed for a non-referral decision).

However, the whole-system approach was not universal and sometimes a short-term perspective was used.

“One GP presented this product to them, and asked us to come along to their meeting, where we did literally a five minute presentation...and they’ve now bought fourteen! So it was almost a snap decision” (EGI2, telemonitoring, company representative).

“The local authority and PCT said, “We have X amount of money that we need to spend on something. What can you buy with that?” And I think the thinking behind that is, if you don’t spend it, they’ll take it off you next year” (E2M1, telemonitoring, manager).

In order to fulfil their promise to reduce medication errors, smart infusion pumps needed to be adopted as ‘total systems;’ or they might simply re-locate risks or even add to them. According to one manufacturer, only a ‘handful’ of 40 adopting hospitals had them as hospital-wide systems. The company sold the pumps to ‘whoever wanted them’ and these were usually intensive care departments and high-dependency units where medication errors were generally less common; other departments, where errors were
more common, rarely purchased them. Many different types were purchased over time by the same hospital, with implications for standardisation, safety and training. The pumps’ identity as small items, both in size and in monetary value, appeared to work against the whole-system approach.

“It’s around £1,000 - but we’ve got 1,000 of them! So there’s £1 million worth of infusion pumps... the whole effort of managing that fleet effectively and safely is actually a much, much bigger piece of equipment management effort than managing a £1 million MRI scanner” (GGH1, generic, equipment manager).

For relatively self-contained surgical technologies such as the robot, cells and spinal implant, the whole-system approach was a less obvious strategy. However, even here, and especially with the robot which necessitated capital expenditure, attention to organisational impact was likely to yield better use. For example, one informant pointed out that in order to ensure value for money, the robot should ideally be used on a seven-day basis which would involve considerable organisational upheaval and reorganisation including changes to staff contracts. We came across no such plans, with the robot used, on average, two or three times a week or, at the most, once a day, five days a week.

### 6.4 Forms of procurement

We found diverse forms of procurement, both between and within case study technologies, partly due to flexibility of producers’ sales strategies and partly the varying NHS budgetary and organisational structures. Overall, the findings highlighted:

- the complex possibilities for acquisition and contract negotiation
- the creativity of innovating actors in acquiring technologies
- the different ways in which costs can be attributed to budgets
- the well-known and often-criticised effects of the annualised and siloed nature of NHS budgets.

**Robot** – a wide variety of modes of procurement were in evidence, mainly capital purchase or leasing (from trust funds or hospital/other charitable support) and second-hand purchase. PCTs might pay extra (over the tariff rate) as risk/benefit-sharing (depending on the accrual of savings); lack of agreement to this was preventing adoption at one trust. Use of Managed Equipment Services, where a third-party company purchases the equipment and leases and provides services to the user, was also considered. Many trusts had adopted a high-risk strategy, going ahead with purchase/lease without clearly identified budgets/sources of funding for substantial ongoing revenue costs.

**Cells** – regional burns services are funded by a variety of local arrangements managed by Specialised Commissioning Groups (SCGs).
Typically procurement was on a patient-by-patient basis, and clinicians were relatively free to make purchasing decisions. However, the supplier was encouraging sites to consider annualised SLAs to stabilise cash flows and reduce prices.

**Coagulometer** – PCTs commissioned local NPT and self-testing services through service agreements. Meters could be acquired by providers via an expired clinical trial, re-distribution of second-hand devices and charitable funding, but primarily patients acquired their own meters from the supplier. The PCT specification may or may not stipulate the brand of equipment and PCTs varied in whether they would reimburse prescriptions for the testing strips.

**Spinal implant** – the product moved from predominantly case-by-case to predominantly tendering and was included in broad packages of spinal products. The company was negotiating a pricing agreement at national level with the NHS Supply Chain, and with the London Procurement Programme (LPP) to become a 'preferred supplier' but local procurement staff may avoid this route and negotiate direct with suppliers. Under tendering, trusts’ procurement sections used scoring systems involving multiple staff groups and including cost, clinical utility, quality, training, surgical support, maintenance etc. The supplier noted confusion about the scoring system and its variability across trusts.

Analysis of informants’ comments about procurement processes revealed a number of issues that affected the timing and pathway of decision-making in the adoption space.

**Formal procurement processes** (tendering) were associated with several drawbacks. In some cases this was seen as delaying, diverting or confusing adoption projects.

“I’ve seen it many times where companies have said that they meet a specification, but in reality they don’t meet that specification...either to the letter...or to the spirit” (I1H1, infusion pumps, equipment manager).

It also slowed down adoption and trusts might have to wait for the next cycle of tendering. Trust-specific tendering procedures and scoring systems were difficult to manage for the industry.

Examples of good practice included whole-life approaches, for example medical physics departments holding responsibility for procurement and maintenance budgets, ensuring all the costs were considered.

**Negotiation of contracts** showed a high degree of flexibility between suppliers and users. A close relationship between customer and supplier was valued by both parties and could be conducive to negotiating a satisfactory adoption.

"Once a company becomes more arms-length, when it potentially is just dealing with...procurement departments, etc., the relationship between a customer and the supplier I think becomes
a bit more broken, a bit more fractured...[it] should be between the clinical staff and the company” (I1H1, infusion pumps, equipment manager).

In ECG telemonitoring, with high, up-front capital costs, contracting varied and initial purchases were often made with left-over funds. Telehealth has also been the subject of multiple government initiatives and funding, for example Preventative Technology Grants (PTGs), re-ablement funding (to improve hospital discharge) and the 3 Million Lives campaign.

**Payment by Results (PbR)** could be an obstacle for new technologies in acute trusts because a new technology-specific code did not exist and the existing codes did not adequately cover the new costs. Creativity was in evidence as trusts were attempting to subsidise NHS robotic procedures from privately performed ones. In the absence of a tariff code for the ultrasound device the company’s case to PCTs centred on avoided referrals. The tariff system does not apply to some clinical areas, such as burns where specialist commissioning applies. However, there is a suggestion that the use of tariffs may be expanded in future so there has been much recent work on establishing accurate costings.

In summary, our data show a variety of more and less formal models of procurement across the different technologies. There was a general movement towards more formal and transparent processes and towards awareness of cost issues by clinicians. On the other hand, these formal processes along with the unpredictability of PCT reimbursement were perceived to constrain adoption.

### 6.5 Structural issues

Underlying structural and macro economic factors played a constitutive role in shaping the technologies’ cost-effectiveness identities and their adoption. This was a particularly salient theme as, in the course of the research, the NHS became increasingly affected by adverse economic conditions and a loss of income in real terms was predicted (NHS Confederation, 2009). Significant changes to the structure of NHS England were also predicted as a result of the Health and Social Care Act 2012 (Great Britain, 2012), but these did not impact during the data collection for this study.

**Income and incentives**

As noted above, the status of GP practices as small businesses appeared to make technology adoption difficult because GPs were – or were perceived to be – reluctant to incur the related expense. The non- adoption of the CRP test in the UK and the low uptake of the ultrasound and ECG telemonitoring were attributed to this.

“GPs aren’t concerned about antibiotic prescribing: they don’t have to pay for the antibiotics, they don’t pay the consequences of increased antibiotics resistance. So, why would a practice, as a
business, spend £500 or more on something that they don’t have to spend their money on?” (CGD10, CRP, GP academic).

A patient representative reported that many PCTs were reluctant to reimburse testing strips, making anticoagulation self-testing a non-viable option for GPs and patients. However, according to one manufacturer, GPs responding enthusiastically to the Quality and Outcomes Framework (QOF) agenda and for diagnosing AF among their patients showed a greater interest in purchasing the device.

As described earlier, PCT reimbursement was an issue for the robot although not necessarily a ‘barrier’ to adoption. The tariff did offer some flexibility in the form of ‘innovation payments,’ but most hospitals had failed to persuade the local PCT to offer this.

The national economy

During the course of the research, the impact on the NHS of the economic downturn that began in 2008 became increasingly clear. The robot’s manufacturer reported slowing sales and cancellations; burns surgeons started to talk about ‘responsible cell use’; the spinal implant’s manufacturer reported restrictions on surgical activity; the coagulometer manufacturer believed that the enhanced service incentive for GP adoption of NPT was running out of steam. There were reports of ‘wiped’ NHS capital programmes, reduced tariff payments, decreasing charity funds and a growing reluctance by management to take financial risks.

“Well, in late summer last year, we were basically told that there was no more money in the system... did I want to expand urology and get the other consultant that I want, or did we want to spend the money on a robot? And quite clearly getting the personnel is more important than the robot” (P14D1, robot, surgeon).

Geography

The location of a hospital impacted on its potential to attract private patient income and therefore on its uptake of expensive technology, like the robot. The robot’s concentration in and around London, along the ‘M4 corridor’ was attributed to the presence of large numbers of private patients there.

Technology costs

Costs were cited as a limiting factor in adoption and diffusion for most technologies, more so for very expensive ones like the robot and cultured cells. For the robot, the manufacturer’s monopoly and inflexible pricing policy was a problem. Discounts were offered by the manufacturers of the ultrasound device and the coagulometer (sold directly to self-testing patients) and the distributor of the spinal implant had agreed to fix prices for three years to one hospital.

The industry

The structure, business model and commercial ‘health’ of the manufacturer/distributor also impacted on adoption. An extreme example
was cultured cells, which had survived two episodes of administration and company takeovers. The manufacturer borrowed heavily from venture capitalists 'impatient' for returns and expanded quickly, investing large sums in research and development. When it was not able to raise funds, it became insolvent. The interruption to production and sales, the change in company name, etc, would have adversely affected the product's identity and sales. This contrasted with other technologies produced by large and stable multinational companies with considerable marketing power.

The practices of distributors could also contribute to public (in)visibility of a technology. One other problem for the cultured cell product was thought to have been ineffective marketing during its early life. The spinal implant’s distributor identified it as a niche product, compared to the 'bread-and-butter' 'cost-effective' products that it also sold; the company had begun to concentrate its marketing effort on the latter in the economic downturn. Even entry into the UK market could depend on distributor decisions to market a product. In the case of the spinal implant, the distributor's decision had been based on potential PCT reimbursement problems, effectiveness evidence and the training infrastructure offered by the manufacturer.

### 6.6 Patients in the adoption space

We note that consultation with patients has become an obligation of the NHS. The technologies we studied varied in whether patients were directly, indirectly, or not at all involved or represented in adoption.

The only case of direct involvement, because patients had to make individual purchasing decisions, was the self-monitoring coagulometer. We found that the leading patient organisation, working closely with the company, was active in promotion, helping to arrange ways of obtaining it for patients, lobbying for policy changes and providing information for patients whose PCTs were reluctant to fund the prescribable strips.

The company’s marketing strategies included a publicity bus (fronted by nurses and the patient organisation) that sited at supermarkets and shopping malls where relatively large numbers of patients might be found, along with media campaigns, and leaflets for GP surgeries and hospitals. The device was promoted as a patient empowerment tool and as convenient (e.g. ability to go on holiday or for working people).

Activists and enthusiasts strongly believe that the use of self-monitoring could be massively increased.

"The campaign launches as results from a new survey reveal that more than two-thirds (70 percent) of warfarin users find regular clinic appointments inconvenient, yet more than half (55 percent) of those not using a monitor didn’t even know that self-monitoring was an option" (company website).
It was notable therefore that commissioners that we interviewed believed that there was little demand for such services from patients themselves, due partly to levels of education.

“The population locally, it’s not a population that demands very much” (A2M2, anticoagulation, commissioner).

Patient consultation varied. One PCT recognised that their proposed transition to a community-focused model would have been easier if more formal patient consultation had been conducted.

Interestingly, a prominent clinical EBM academic with an interest in self-monitoring had worked with the patient organisation to conduct a patient survey. The results were not deemed sufficiently robust for publication but it revealed that there were some patients using the device outside any NHS clinical regime.

Self-monitoring patients were often thought to monitor needlessly frequently by clinicians, but the counter-argument (supported by data) was that these patients stayed ‘within range’ (i.e. less at risk) more than patients attending clinics. It was clear that such issues figured in policies on self-monitoring.

In the cases of the surgical technologies and smart infusion pumps, as one might expect, there was little evidence of patient involvement. Surgical specialties were subject to some patient demand, in the NHS and in private healthcare. Media and internet coverage encouraged this trend, especially in the case of the robot. In the case of the spinal implant, private patients were the first to receive the intervention.

The autologous cultured cell product was said to have high acceptance because it seemed less threatening than other tissue engineered products.

“... people’s immediate...perception of what tissue engineering is, often goes back to that Vacanti picture of that mouse with an ear on its back...as soon as you say, “Well, it’s your own cells going back...” then...you know, then that disappears and people understand that” (TGI1, cells, company representative).

In the case of CRP, it was suggested that adoption of the device could provoke supply-induced demand from patients:

“If you had a test and you kind of medicalise these consultations you actually encourage further consulting, and people think, “well, I need to go to the doctor to get that test done!” (CGD1, CRP, GP academic).

Some technologies receive a great deal of general mass media attention and this can affect patients’ role in adoption. Examples are the robot, telehealth in general (as in the recent publicity for the DH Whole System Demonstrator - WSD) and the ultrasound, which was greeted with a fanfare as the ‘electronic stethoscope.’ The ultrasound was believed to offer an improved patient experience because of the immediately viewable image;
on the other hand, in the case of ECG telemonitoring, the technology’s role in making the patient more knowledgeable and more clinically aware raised socio-technical and socio-political design issues.

“In fact the very first models...would have said things like “tachycardia,” “bradycardia,” “AF” and I was like, "we really, really, really don’t want this,” because there is a trust issue between the doctor...and us. If we start selling a device that started saying...and the patient turns up and goes, “I’ve got AF!” The last thing we wanted also was for this device to be given to a patient to use at home!” (EGI2, ECG telemonitoring, company representative).

In summary, it is clear that the more or less active presence of patients in the adoption space raises issues that do not apply to technologies where they are effectively absent. Thus our data show that a variety of patient-related factors are important:

- patients’ presence, requests or demands
- how the patient population is understood by NHS staff
- how companies construct patients in medical terms and as a target market
- how patients understand the novelty of a technology in its service context.

These appear to be significant variables for distinguishing between different types of technology in terms of their adoptability, an association that could be usefully explored in future research.

### 6.7 Summary

In this chapter, we examined technology adoption processes in the NHS. Our study found three different forms of adoption: individual ad hoc; intermediate; single-event corporate. Adoption by trialling was common and could amount to adoption ‘by the back door.’ Gatekeeping structures and success varied, depending on the technology and organisational ecology; in general clinicians and providers had more power than commissioners in adoption in secondary care but PCTs (as commissioners) were powerful in determining adoption behaviours of GPs. Rational, evidence based (in the EBM/HTA sense) processes were mostly absent, with adoption predominantly a technology-specific ‘political’ process, open to the mobilisation of a number of variable technology identities. This, coupled with shortcomings in bureaucratic know-how, opened the way to considerable industry involvement in NHS decision-making. There was variability in the use of a whole-system approach. A number of structural and macro issues also influenced adoption; notably, the independent contractor status of GPs and PCT reimbursement were seen as barriers to adoption. Patients’ voice was limited, except where the end users were patients themselves.
In the next chapter, we examine how the concept of evidence was understood and used in the adoption space.
7 Evidence and evaluation in the adoption space

7.1 What counts as evidence?

Evidence was understood as a very broad concept by actors in the adoption space; Level I and II evidence (meta analyses and large RCTs), the focus of the rational-policy paradigm, represented one element in the patchwork of resources that constituted the ‘evidence base’ for the technologies. This evidential portfolio included:

- personal inspection of the technology and observation of its use
- personal use and results
- other users’ results and opinions
- informal discussions with colleagues
- published academic research
- conference presentations including company-sponsored talks by champion-users
- company websites
- discussions with company staff at sales visits and conference stalls
- media reports.

Personal and peer experience of the technology was reported as more influential in shaping local/personal evaluation than other sources. The interviews provided an occasion for the informants to reflect on the meaning of ‘evidence’. As they attempted (and sometimes struggled) to respond to questions, a complex cognitive picture emerged where different epistemologies (reasoning from theory, observation or probability-based evidence) appeared in interplay.

Many clinician discussions combined an intellectual appreciation of the need for RCTs as an ideal with a pragmatic, practice-based discourse. On the one hand, the clinicians reiterated the superiority of prospective design, the need to evaluate technologies during early-emergence and to have a population and resource use perspective; they thus judged published academic evidence base for the technologies (with few RCTs) as ‘low’ to ‘medium.’ On the other hand, they embraced a craft-based, decision-oriented attitude that placed a premium on observation, opinion and reasoning. This was accentuated amongst burns surgeons. Clinicians overall had contradictory views on RCTs, oscillating between EBM and practice discourses at different points in the interviews.

“There is enough evidence now - and I think the evidence has increased in the last two years because of the widespread uptake
of this technique - that it is as equivalent to open and conventional laparoscopic... in terms of outcomes.” “To collect cancer-based survival you need to do a long term randomised controlled trial, and you won’t get those answers for ten years, minimum” (P2D1, robot, surgeon).

Often, alternative paradigms converged in a complex evidential repertoire.

“We would listen to what [company] have to say...If what they had to say was logical, we’d think about it. If it was ridiculously expensive, we’d think about it for a second or two and probably say “no.” If they had some papers associated with it, which had some statistics, we would look at these and think, “well, that’s reasonable...” but I’d still have the scepticism to say “it’s not in our unit.” So, the next stage... would be if... we were able to use it and we found that it works well’ (T5D1, cells, surgeon, emphases added to indicate multiple criteria used).

“I am an advocate of it... But I think it is a very, very difficult service to demonstrate... You can say, “if we hadn’t provided this piece of equipment, would that person actually have gone into hospital anyway?..” The anecdotal evidence and the evidence [our experience] suggests is that it does help, because our domiciliary care budget has decreased as a result of it...it’s very difficult to prove, I think” (E2M1, telemonitoring, commissioner).

Below, we describe the adoption space meanings of the concept of evidence and offer a theoretical explanation for their salience.

7.1.1 ‘Evidence-for-confidence’

Observing the technology’s performance, either through one’s own or others’ use, was regarded as essential and perhaps more reliable than published evidence because the latter originated in an unknown elsewhere with questionable applicability.

“I very much base my clinical practice on my own clinical outcomes, as opposed to what it says in a paper that’s usually not related to the patient population that I’m dealing with” (T3N1, cells, nurse).

“[Company representative]... also had a lot of experience working within a PCT as a commissioner, so he understood... some of the challenges that we faced. He...demonstrated the equipment... And he also provided us with the evidence of other trials that he’d run across the country...we visited another PCT... who’d actually used their technology and introduced it as a service, just to get their thoughts around, “does it actually work, really,” you know, “when you’re dealing with real patients, in real time and trying to run a service?”” (E2M1, telemonitoring, commissioner).
Surgical technologies allowed immediate, highly visible observation of individual outcomes.

“Once I’d used them on this one patient who had extremely good results, very visible, clear delineation of where the cells had been used and where they hadn’t been used, I was very converted to using sheets because I felt it was very effective” (T4D1, cells, surgeon).

In fact, surgical technologies were adopted as personal technologies.

“We’re changing some of the instrumentation, because in, say, five or eight surgeons’ hands out of ten it works, but in two surgeons, for whatever reason, in their hands it doesn’t work so well” (SI1-2, spinal fusion, company representative).

Intuition and reasoning combining the technology’s material properties and capabilities and prior knowledge was also used in assessing the technology.

“So there was something about it that was rather obvious...which didn’t particularly need any evidence!” (I2M1, infusion pumps, manager).

“In theory, because you have such a good view of the anatomy, a magnified view, then you should be able to obtain superior functional outcomes” (P7D1, robot, surgeon).

These accounts encapsulated what we term ‘evidence-for-confidence.’ Clinical practice and the delivery of health services are inherently uncertain and risky occupations, a risk that is heightened when new technologies are introduced. The evidence required to manage these risks and to engender confidence was sought and found predominantly in observation, judgement, and reasoning, although research-based evidence also played a part.

Evidence-for-confidence:

- derived from trusted others
- made use of one’s knowledge and practical reasoning
- was premised on ‘naturally occurring’ data and ‘data’ produced in close interactions both informal and semi-formal between clinical and managerial colleagues
- had physical immediacy
- was open to personal scrutiny.

Thus, for the clinicians, it mimicked practices and values prevalent in the formative years of clinical training. For the managers and commissioners, observation of and stories about other NHS organisations’ experience with the technology was just as necessary to develop confidence that the technology would be safe and would ‘work’ in their own organisation/catchment area. Cognitively and emotionally these types of data were essential in signalling and confirming that the technology was safe and effective ‘enough.’ RCT results and meta analyses were consulted,
albeit somewhat cursorily, when available, but they alone did not provide reassurance of this type. In seeking a ‘warrant for certainty’ in an uncertain environment, the informants’ strategy was to combine everyday and expert knowledge, experience and science (Atkinson, 1984). The following extracts exemplify the discourse of risk and caution.

“At this point I can’t trust my own diagnosis when I look at it; I’m still early in the phase” (HUSC2, ultrasound, clinician).

“There was over a thousand patients on warfarin. So we decided to take it slowly as you would!.. with just small clinics... and then branched it out, bit by bit, as we got confident” (A1N1, coagulometer, nurse).

“You’ve got to make sure that the reading that the patient’s telling you is correct, and that they’ve not misread it...So that depends on the training, the initial induction that you give... and you’ve got kind of confidence in who’s doing it, and processes of how to deal with issues that arise, then, yes, you can run it” (A1M2iv, coagulometer, commissioner/pharmacist).

Even an enthusiastic early adopter gave an account of responsibility and caution.

“I’m an innovator. I’m ahead of early adopters... I enjoy doing that, but I’m not a mad academic... You know, I am a clinician scientist. I do look at my data very carefully. I do look at the implications very carefully of that data and over a period of time I question what I’m doing” (P3D2, robot, surgeon).

One consultant expressed the limitations of HTA type evidence.

“Even if I’d read about it, I’d still feel a little bit anxious...uncertain about how to go about using it... there’s a drug that’s known to be useful for major paediatric burns...and there’s very good Level 1 evidence that this is beneficial... but I’ve never worked in a place that’s used it... I’m still at that stage of “how do I actually go about it, how do we physically administer it?..” cases have come in... and I’ve thought, “oh, I’m not sure! I’m not sure of the dose! I’m not sure when you start! I’m not sure what to tell the parents!” So, although I know the evidence is there, I haven’t used it, even though I must” (T4D1, cells, surgeon).

In the adoption of technologies embedded in services and requiring extensive re-organisation, often initiated by commissioners, evaluation and comparison of one’s practice against that of peers was similarly important.

Potential adopters’ need to hear stories about the adoption of this type of service-embedded technology was picked up by the industry. The ‘evidence’ that companies commonly provided, alongside off-prints of published papers where available, were ‘case-studies’ reporting the experiences of NHS trusts. These could be clinical, with variable degree of formal evaluation and rigour, with samples ranging from under 10 to just under 100 patients and...
evaluation periods of up to a year, or could include case studies showing service models with protocols etc. Such studies in the case of the ultrasound device and telemonitoring were available on company web-sites but company representatives were also keen to introduce potential clients to established ones. This type of evidence had limitations.

“They will pick up on the fact that there was a two-thirds reduction in admissions, and those sorts of reports are available all over the place. And people will look at those and they’ll say: “well, look, if we have the same results as they did, we’ll save money!” And this is the big issue, that when people do it and they look at what happens locally, the benefits seem phenomenal” (EGA2, telemonitoring, clinical academic).

The potential for bias in company produced evidence was acknowledged by many clinicians, managers and commissioners. Close questioning and healthy scepticism were used. Tests of trustworthiness included the country of origin of the evidence (to the frustration of some sales staff who could only offer non-UK based evidence) and individual clinical reputation.

“I went to a talk by a Belgian guy who quoted...a few hundred without any issues. I’d previously heard an American guy talk about it. I never believe what the Americans say, to be quite honest, but the Europeans tend to be more honest!” (S4D1, spinal fusion, surgeon).

“There are no RCTs in burns, so you go on, you know, other people’s examples, case studies, evaluations, etc. But obviously...you tend to go for people who you know” (T3N1, cells, nurse).

As mentioned in 5.1 and 6.3.3, the industry played an important role in the construction of the technologies’ effectiveness identities, often through sponsored conference presentations and smaller scale meetings. It was difficult to disentangle the marketing/sales orientation of these events from their clinical/educational/evidential function. The objective of marketing was to ensure that the potential user went away with a ‘warm, fuzzy feeling that this is something they’d like to use.’ As one company informant explained, the contents of the presentations were at the clinician’s discretion and there was no explicit vetting; however, the company knew that ‘they were people who liked the product.’ One clinician offered an insight here:

“I don’t think we have enough material in our experience to stand up in an open scientific meeting. The presentation that my registrar gave was at a sponsored meeting which, to me, requires a slightly different level of rigour” (T1D1, cells, surgeon).

Company representatives’ response to the EBM/HTA agenda was of two types: tolerance and impatience. While some sales staff echoed the desire for high-level, RCT evidence and lamented its absence, others expressed exasperation.
“Do you buy your car based on the opinion of millions of people, you know, as many people as possible? It’s almost unscientific, that, because it’s like... “there was only a thousand people in the study!” And you think “well, that’s more than enough!”” (HUSI1, ultrasound, company representative).

Generally, a wide variety of information/documents from different sources was used by industry to assemble a persuasive ‘evidence base’ for the technology. Some directly related to its use, others were more indirect, including: DH policy papers on innovation, World Health Organisation (WHO) reports, the national enhanced service agreement, European governments’ decision to reimburse a particular technology, NICE guidance, HTA evidence, NHS trust produced presentations, user testimonies/case studies.

In summary, we have identified the concept of ‘evidence-for-confidence,’ an eclectic repository of information that might include Level 1 and 2 evidence but, crucially, was centred on practice-produced and interactionally exchanged ‘data,’ as the mainstream evidential stock in adoption decision-making. This applied equally to clinicians and managers, to surgical technologies and systemic technologies embedded in and requiring service reorganisation, albeit in slightly different formulations. We make a distinction between this type of evidence and ‘evidence-for-policy,’ that is, evidence from systematic reviews, RCTs and meta-analyses used in making local/regional/national health policy and macro technological investment decisions, for example, by NICE. This more structured and formalised commitment to evidence has been termed evidentiality. Our data suggest that evidentiality, as a legitimation project, while central to policy, has been less relevant to technology adoption processes, where reassurance and confidence – not political legitimation - are key objectives.

Nevertheless, our data provided views and documentation of how this formal evidentiality - evidence-for-policy - might be relevant in the adoption space, and it is to this that we turn next.

7.1.2 Evidentiality: contingent and contextual

Evidentiality as we have defined it above has emerged as a form of gatekeeping since the 1980s (Faulkner, 2009). We found that while the informants recognised its role in technology adoption, they did not consider it universally applicable and uniformly structured. Instead, they constructed a nuanced and contingent concept of evidentiality, one that changed from technology to technology and from context to context, reflecting technology-specific, clinical, financial and political particularities. We illustrate and discuss these factors below.

Financial/political factors

The costs of the technology were thought to be one factor in potential adopters’ considerations of evidentiality: generally, the higher the costs, the higher the evidential threshold, requiring high-level HTA evidence. Relevant
here were not only absolute but also relative costs. An example was cells, an expensive technology in absolute terms. Used in acute severe burns, where most other products and the treatment package as a whole were associated with equally high costs, the evidence threshold was perceived to be relatively low. But when used in chronic wounds (e.g. diabetic foot ulcers), where most other products cost very little by comparison, the evidential threshold for the same technology was much higher. In fact, it was so high (requiring RCTs with hundreds of patients) that the company had effectively withdrawn from this market.

“The per patient budget [in wound care] is actually quite low, and therefore the argument for using a high value approach like this has to be...has to be really robust, and we’re not quite there yet” (TGI1, cells, company representative).

A PCT policy on the robot also illustrated this relationship:

“At a price higher than that of conventional laparoscopic radical prostatectomy, the committee recommends that the treatment is LOW PRIORITY because of a lack of evidence of clinical superiority... However, if the procedure is offered to commissioners at a price no higher than that of conventional laparoscopic radical prostatectomy... then the procedure is RECOMMENDED as a treatment option” (PCT Priorities Committee, original emphasis).

The scale of investment and level of gatekeeping was another factor shaping perceived evidential requirements. For example, it was suggested that while a low level of evidence might be adequate for a single PCT adopting telehealth, wide-scale adoption in a region, involving a number of social service and health care institutions and expenditure running into millions of pounds, would require a much higher level evidence. Additionally, some form of structured evidence gathering, described as research or audit, was seen as necessary in order to resist managerial gatekeeping regimes and to ‘shut people up.’

“I think more and more in the NHS, as we become cash-strapped... it’s difficult for organisations to justify big expenditure... and so therefore you have got to have evidence about why you’re doing something, even though you might know it’s the right thing to do” (I2M1, infusion pumps, manager, emphasis added).

Int: “But if you already know that... why are you doing the trial?”

“Because, basically, we’re not allowed to not do it...one of the deals with our PCT was that we have this trial in place” (P10D1, robot, surgeon).

There was a view that with the introduction of GP commissioning, EBM/HTA forms of evidentiality were going to be more routinely and widely called for.
Clinical factors

The level of clinical uncertainty and risk involved was important in determining the required level of formal evidence. Where the anticipated effect of the technology was substantial, they could be detected through observational research, eliminating the need for an RCT. For example, some informants believed that while an RCT was necessary for the robot’s use in bladder cancer (because there were doubts over cancer clearance and operative morbidity), it was not necessary in prostatectomy where benefits were more or less established through routine use and observational evidence.

Treatments of last resort, like the use of cells in severe burns, also allowed the evidential bar to be set ‘reasonably low.’

Int: “Can you say how cost effective it is?”

“I don’t think we can...I mean, most of the patients that it’s used on are 50+ percent burnt...If we were going to move into lower burn areas, sort of 30 percent, 20 percent, then I think it would be more important to do this” (TGI2, cells, company representative).

The need to evaluate the level of clinical safety and effectiveness could, for some technologies, conflict with whole-service evaluation:

“If it’s some medical procedure where you’re cutting somebody open and there are very, very clear safety considerations, then you want very, very clear evidence of effectiveness. If...the technology is incidental, and actually, it’s really about organisational change... trying to hold that to the same level of evidence standards that you do for drugs, I think is actually detrimental. I mean, first of all because you can’t get that evidence, I think. And then secondly, you know, everybody is sort of waiting for the gold standard RCT trial evidence, and holding back, and it actually constrains change and innovation” (EGA1, telemonitoring, academic).

Technology factors

The scale and clinical market of a technology might affect the extent and form of evidence mobilised by decision-makers. Component technologies, for example those seen as one item in a surgical ‘armamentarium’ - used infrequently and for narrowly defined populations - were unlikely to gather enough momentum for an expensive RCT.

The extent of the technology’s novelty was also a factor: the greater the novelty, the greater the need for ‘high level’ or at least more robust evidence. Minor, incremental adjustments did not necessitate the same level of evaluation. This was illustrated by NICE’s decision not to appraise robotic prostatectomy as it was not considered different enough from laparoscopic prostatectomy (NICE, 2006b).
The informants thus used a discriminating, proportionate approach in assessing the place of high-level HTA evidence in technology adoption, based on the need and justification for such evidence. The level of cost, clinical risk and novelty of the technology and the scale of its adoption were criteria used in determining the need for high-level evidence. Furthermore, such evidence could be seen to have a political function in resisting gatekeeping.

The informants also had views about how best new technologies might be evaluated and we outline these below.

7.2 Technologies-in-flux and evaluation

The emerging picture of how technologies became recognised in the NHS, how they might or might not enter practice and be formally evaluated was one of *market-led innovation and haphazard evaluation*. There was a view that much new technology resulted from profit-oriented ‘tweaks’ on current technology that was ‘a bit smarter, a bit quicker… And here it is, in your face, buy it!’ This was acknowledged even by some sections of the industry.

“It’s almost: “well, we’re going to miniaturise it, because we can!” When in fact the miniaturisation doesn’t convey any real benefit” (HUS-I-2, ultrasound, company representative).

What some would call the early ‘rush to market’ of the technology was often accompanied by uncoordinated, small-scale studies of variable rigour that failed to confirm or reject the technology’s (cost)effectiveness. The disconnect between adoption and evaluation meant that many technologies partially or minimally diffused, always subject to doubt or scepticism by some sections of the clinical community, sometimes being eventually discredited.

“Is the evidence there? In lots and lots and lots of disjointed papers over the last 30 years, which I don’t believe is what we in today’s NHS require; we need an absolutely conclusive “yes, this works and if you don’t use it, you won’t be doing the best for your patient’” (T2H1, cells, manager).

“Some things have come and been done by loads of surgeons for back pain… and have been proven to be a waste of time” (S1D1, spinal fusion, surgeon).

7.2.1 Doing the ‘right research’

Conducting the ‘right research’ was seen as essential for appropriate adoption. There was a view that at national HTA level, some ‘re-thinking’ was needed to align technology evaluation with the needs of the NHS. In particular, evidence from the controlled environment of RCTs and statistical pooling of data in meta-analyses and systematic reviews had to be complemented and in some cases substituted with more pragmatic and realistic designs that tracked the performance of the technology in the real
world of NHS service delivery, the technology’s effects ‘across the system’ and assessed the implications of the adoption process. This type of research would not have a narrow focus on clinical effectiveness but, for example, show whether the robot was an appropriate technology for a district general hospital as opposed to a teaching hospital, identify which sub-groups and populations would benefit the most from telehealth or clarify how a handheld ultrasound scanner might fit in pathways and workflow and produce savings. This approach was seen as especially valuable for service/system embedded technologies and those with unclear scope and market. Here, there was a need to examine aspects such as funding, stakeholder incentives and organisational impact (note, – CHF: chronic/congestive heart failure).

“I think RCTs are appropriate in certain circumstances, you know, when you’ve got a very, very specific intervention that you’re testing, and it’s quite a sort of closed system... [for example] ECG for patients with CHF with no other co-morbidities and you’re evaluating that against the usual form of care...But... let’s call it remote care of people... the actual innovation is so unbounded and sort of open, woolly, you know, ill-defined actually, and there are multiple objectives usually; the... group of users almost invariably has many different conditions or needs, and of course... the health policies in the context are changing. So in those circumstances, a sort of RCT is actually not the best approach” (EGA1, ECG telemonitoring, academic).

RCTs also often happened once the technology had already diffused.

“But half of me then says, “well, so what?” Because these technologies are the future and you know, at the end of the day, robots are going to happen anyway... I think the case for the [RCT] is less now than it was five years ago“ (P2D2, robot, surgeon, involved in pilot RCT).

Some of the surgeons involved in this pilot RCT referred to scientific curiosity and excitement as one reason for their participation.

“To be honest, I would like an RCT just for my own...because it would be the first RCT in any surgical modality” (P10D1, robot, surgeon).

A piecemeal approach at national level, coupled with a focus on conducting RCTs could lead to fragmentation and duplication of the research effort. One clinical academic working in anticoagulation had rejected a call for a new RCT because it would be a ‘waste of money;’ instead, he was conducting an ‘adoption study’ that took the data from studies previously amalgamated in a systematic review, re-analysed them at individual patient level, with the aim of identifying subgroups of the patient population where the case for adoption was stronger and more specific than from the original systematic review (with an indication that patients with artificial heart valves was one such group). It also examined the mechanisms that might contribute to the
technology ‘working’ or ‘not working.’ This informant believed that the findings from this study would be the tipping-point for a step-change to wide scale adoption of the technology.

However, in contrast, there were difficulties associated with pragmatic evaluation: funding was difficult to secure and it required that the technology was adopted relatively widely before it could be evaluated using realistic designs. Equipoise inevitably became problematic.

“You know, playing around with the 100 treatment episodes, you develop the technique...you will have ironed out any problems in terms of infrastructure... But the next stage is actually much harder, to then say, “now that we’ve done that, let’s stop doing what we have done for the last 100 cases, and go back to what we used to do and compare the two.” Now, most people will say, “Oh no. This is clearly better (I think); so we can’t go back to the old ways!”’” (T8D1, cells, surgeon).

Pragmatic research also typically took the form of small-scale, less rigorous studies undertaken for example by individual PCTs, with questionable validity and generalisability, as in the case of telehealth (Section 6.1.4).

**Research design**

As the above analysis shows, the difficulties associated with formally evaluating emerging – and evolving – technologies were widely acknowledged by the informants. In this subsection we note a variety of factors specifically related to research design and research environment in the technology adoption space that informants highlighted.

- Failed study; we give an example of a failed attempt to conduct a formal controlled study on sprayed cultured keratinocytes for burns in Appendix 8.
- Frequent modification of the technology made evaluation difficult (robot, spinal implant).
- Ill-defined outcome measures and complications (surgical technologies; wound healing rate a ‘naïve’ measure for cells, reduction in scar area and pain would be more appropriate).
- Case-selection bias (cells).
- Learning curve/operator factor (especially surgical technologies).
- Small referent population (spinal implant, cells, coagulometer, all niche technologies).

Equipoise was a problem mainly but not exclusively for RCTs, as evidenced by the feasibility RCT on the robot: of the target 75 patients in the first year, only 32 had been recruited. Surgeon and patient preference for robotic surgery was reported to be the reason. At one hospital, a large volume of data was collected to audit a new set of infusion pumps but
analysis was never conducted as a consensus view had developed that the pumps were a ‘good thing.’

Confounding (component or system-embedded technologies) was a problem for example for cells, spinal implant and ECG telemonitoring (when used in conjunction with other remote-care modalities).

The timing paradox meant that the technology could become embedded or obsolete by the time long-term evidence was available. This was a possibility for the coagulometer with the emergence of new drugs.

Evidential context and the transferability of evidence was an issue. Evidence for cells in acute burns might not be applicable in chronic wounds and vice versa; robotic data from high-volume US hospitals might not hold in low-volume NHS hospitals; spinal implant results in the US, where growth-stimulating BMP was used widely for grafting, might not apply in the UK where BMP was little used.

Evaluations: ongoing, planned, suggested

Although many of our informants were clinicians and managers and not academics/researchers, there were suggestions for and reports of planned/ongoing evaluations. Some suggestions are included in Appendix 9. Many of these designs reflected the principle of ‘good enough’ evaluation in conditions that made RCTs unfeasible. They had pragmatic designs, with the following features:

- baseline disease specification
- protocols for indications and procedures for the technology’s use
- comparison (within patient; between similar/risk-stratified patients/cohorts; between hospitals)
- specification of outcomes of interest
- use of validated measurement tools.

Some informants suggested that greater use could be made of registries, although the difficulty of consistent reporting and the tension between data volume and specificity were recognised. For some of the technologies – cells and spinal implant – companies had instituted data collection systems that enabled the documentation and auditing of outcomes; at least in one case, this was reported to be rarely used by surgeons.

Research environment: There was some scepticism about the research environment in health care due to structural/political factors. Commercial interests, i.e. the need to recoup expenditure and make profit, were cited as hindering evaluation, as were career interests, i.e. the need to publish scientific articles for career progression, encouraging short-term studies. Funding was perceived as a barrier, both for NHS-initiated research and for product evaluations by small companies (Appendix 10). Despite much rhetoric around the need for RCTs, informants reported difficulty in securing funds for RCTs, for example for a robot RCT. Infrastructure could be a
problem, as in the case of burns care where the absence of an ‘academic base’ or research centre was seen to impede research and technology evaluation (although three new research centres were being planned in 2012).

7.3 Summary

What counted as evidence in the adoption space was a composite, diverse stock of information from scientific, practice based and industry/promotional sources, in some contrast to the understanding of evidence in the EBM/HTA paradigm. Many informants employed a dual discourse that accommodated both perspectives, but, on the whole, used what we term ‘evidence-for-confidence,’ combining practice and reasoning with HTA evidence (where available) to make adoption decisions. We posited this against ‘evidence-for-policy,’ deriving from high-level HTA evidence. While the informants could see a place for this type of evidence in technology adoption, this was a graduated approach with only some technologies in some contexts seen as requiring high-level evidence, depending on costs, scale of investment and clinical risk. Clinicians’ and managers’ orientation to evidence-for-confidence had some resonance in academics’ calls for ‘pragmatic’ research focusing on the adoption space workings of the technology rather than narrow clinical/technological effectiveness, especially for systemic technologies. The difficulties arising from the evolving and global nature of technologies and the structural aspects of the research environment were acknowledged and a wish expressed for better alignment of technology emergence, adoption and evaluation.

We now turn to the question of how adopters of technologies accomplished and organised early use.
8 Early use and diffusion

This chapter considers our data from the point of view of the acquisition and early use of the technologies and provides insights into the relevance of training, clinical application and usership, routinisation, and how risks are managed in adoption. (Procurement is considered in Section 6.4). It also examines the concept of diffusion and how this figures in the adoption space.

8.1 Training and learning

Training is an obvious initial step in bringing technologies into use, both as an operational requirement and as a strategy in managing and limiting risks. When the introduction of new technology creates a new kind of usership, which applies to some of our cases, training becomes a large undertaking. A number of training issues affecting adoption emerged from the study:

- training provision for early, innovative use
- accreditation
- appropriate organisational models of training provision: competition and uncertainty
- companies’ role in identifying local training needs and extent of NHS adopters’ reliance on this
- the interface between NHS-organised and company and third-party (e.g. university-based) training
- users’ v companies’ control over training and use of the technology
- learning curves.

The issue of adoption for training purposes (rather than training for adoption) is discussed in Section 6.1.5.

We present a summary and key examples of problematic issues.

Company role in training

Training in the use of the product was frequently part of the contract agreement between the NHS adopter/user and the producer/distributor. Table 6 summarises the position for each technology, together with costs where available, whether the training was mandatory, and the form of company-provided training. Unsurprisingly we found a great deal of vendor flexibility in providing training to suit potential users.

Different types of training

There is a clear distinction between technical training (showing how the device or product works) and clinical training (interpreting results, practical techniques, etc). There are, clearly, limits to technology producers’ legal
liability (assuming they are not qualified or authorised to provide medical services) and many company informants were careful to point to the limits of the training they offered. As shown in Table 6, the availability and requirement for formal accreditation varied by technology.

‘Early’ training, timing

We frequently found lack of clarity about training in potentially risky early phases of adoption, when no formal training infrastructure had been put in place and staff had to learn on the job. Trial and error and dependence on serendipitous, personal networking and relationships was to the fore. Ideally, training would take place just before the technology is implemented, but availability of training and availability of users did not necessarily coincide. Being able to release staff for training, or find/fund replacements, can prove unexpectedly problematic – although this can be accommodated by flexible vendors.

Training can evolve over time as the market matures and the technology becomes more widespread. Initially there was no industry training for the robot and mentors were obtained from the US and Europe, but since approximately 2005 the vendor offers a structured programme. UK-based mentors are now available and one adoption site was considering setting up as a training centre.

Training models and the ‘market’ for training

The degree of centralisation/coordination of training and the fact that there is a commercial market for such services, emerged as issues.

In the case of the robot we found reluctance of the manufacturer to let go of training when consultants wanted to take over and to set up an NHS training centre: a demonstration centre idea was under discussion and a ‘buddy programme’ was being planned. In another example from the NPT coagulometer case study, a PCT accepted increasingly flexible pathways for service providers to demonstrate competence. This change was attributed both to the achievement of “sufficient accredited practitioners” (policy document) and to GP resistance to a regime perceived as excessively time-demanding. Also, we noted tension (funding was withdrawn) between the manufacturer and a self-appointed ‘national’ centre for training the trainers (nurses) in self-monitoring.

Learning curve

Adopters will have different levels of relevant experience and confidence and their training needs and learning curve speeds vary. Relevance of related skills could be disputed: for example, some surgeons considered robotic surgery to be very similar to laparoscopic methods:

“Most of the people who’ve got a robot would already immediately consider themselves an expert in the field and not require training...[they’re] already laparoscopic experts in their field, and they’re doing the same operation, they’re just using a different tool” (P8D1, robot, surgeon).
Table 6. Summary of company training

<table>
<thead>
<tr>
<th>Technology</th>
<th>Included in contract?</th>
<th>Cost</th>
<th>Mandatory?</th>
<th>Form</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion pumps (DERS)</td>
<td>Y</td>
<td>Included</td>
<td>Y</td>
<td>Industry trains users or trains the trainers. Ongoing support with error log interpretation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECG telemonitoring</td>
<td>Y</td>
<td>For extra training</td>
<td>N</td>
<td>Industry trains users (professionals &amp; patients) or trains the trainers.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Highly variable. Device use may be intuitive. No training on ECG interpretation.</td>
<td></td>
</tr>
<tr>
<td>Robot (since approx 2005)</td>
<td>No</td>
<td>£7000 (vendor)</td>
<td>Y (vendor)</td>
<td>Overseas 2-day course (live pigs), cadavers, dry lab work, observations, mentoring. Mandatory vendor accreditation if user wants to be a 'robotic surgeon.' Proctoring first 'few' cases.</td>
<td></td>
</tr>
<tr>
<td>Coagulometer</td>
<td>Y</td>
<td>£1500 (university)</td>
<td>Y (NPSA guidance – service providers must prove competence)</td>
<td>Industry training by site visit. University course. Locally organised provision. Flexible approaches (nationally) to demonstrating competence.</td>
<td></td>
</tr>
<tr>
<td>Spine implant</td>
<td>Y</td>
<td>No cost</td>
<td>Y (vendor)</td>
<td>1-day course for surgeons. Industry presence at first 10 cases. Hand-holding in theatre for nurses.</td>
<td></td>
</tr>
<tr>
<td>Cultured cells</td>
<td>Y</td>
<td>Included</td>
<td>Y (vendor)</td>
<td>Industry presence at first case. Hand-holding to ensure good practice.</td>
<td></td>
</tr>
<tr>
<td>Hand-held ultrasound</td>
<td>Y</td>
<td>Included</td>
<td>N</td>
<td>Online tutorials, user guide etc; links to educational organisations</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Introducted in 2012 (toward end of research)</td>
<td></td>
</tr>
</tbody>
</table>

* NPSA - National Patient Safety Agency

Which is not a view supported by industry:

“You know, we have this all the time where a surgeon will say, "Oh, I’m skilled, I’ve done some laparoscopic surgery for many
years, 30 years or whatever it might be, I don’t need any training, I’m just going to hop on!” And we won’t support that” (PI3, robot, company representative).

Two issues were particularly relevant to the robot’s adoption. First, there was no consensus over what constituted the robotic learning curve (i.e. how many cases). Second, informants referred to different learning curves for different outcomes, progressively more difficult and requiring longer periods of use, e.g. competence in using the robot, shorter operating time, complete cancer removal, nerve sparing, fewer complications.

Such considerations imply a degree of risk in integrating adopted technologies into practice that may not be to the fore in case-building for adoption decisions.

8.2 Usership: tailoring and extending the use of technologies

Adopting new technologies requires that existing practices, structures and pathways be flexible and in some cases replaceable. The early use period presents two distinct but related issues. First, the uptake, introduction and use of technologies by the range of involved users. Second, market-construction through the interaction of producer companies, the NHS users/customers, and others.

In our original proposal for this research we suggested that one key dimension along which technology adoption processes might vary was the ‘configurability’ or ‘discreteness’ of technologies. In other words, the extent to which the nature of the technology itself, as either standalone and easily aligned into existing practices, or as complex and requiring adaptation by users into their working practices and systems, would shape adoption decisions and processes. Our data suggest that, in fact, all the technologies display some features of configurability or flexibility in their application. Furthermore, some of the technologies were promoted, and sometimes resisted, on the basis that initial use in well-defined and controlled circumstances could be extended to further specialties or care settings. Technologies can thus be both ‘tailored’ to local circumstances and preferences, and ‘extended’ to new applications.

The somewhat opposing dynamics of tailoring and extending can be illustrated in terms of clinical case selection, the technical configurability/flexibility of the technology, and the boundary-crossing capability of the technology (e.g. multi-speciality, multi-hospital departments, secondary-primary sector).

Clinical case selection: It is acknowledged that clinical users vary slightly in their discretionary practice with technology-assisted procedures. Our data suggest that the early use of technologies, like their adoption, was shaped by their identities: tailoring and extending were intricately bound up with risk, justification (cost-effectiveness) and utility identities. In the case of the
surgical technologies, tailoring and extending took the form of careful, tentative case selection, ensuring that the technology’s very early use was restricted to a clearly defined group of patients. For the robot and spinal implant, these were the best prospect cases that were expected to present no unanticipated problems during the procedure and to do well. This ‘cherry picking,’ as one informant described it, was followed by gradual and careful extension to more complex/worse prognosis patients as confidence grew. Further extension involved the use of the technology for new indications and even in other specialties.

Interestingly, for cells, early selection was centred on worst prospect cases, very severe burns where cell use represented one more or a last attempt at salvage. This expensive technology was not needed and therefore not justified in less severe cases that were expected to resolve either on their own or with less expensive treatments. Extension scenarios for cells were more limited; however, we learnt that some surgeons had plans to incorporate cells into routine treatment protocols, potentially widening its applicability, rather than using it as a treatment of last resort.

Risk was also the central concern in case selection for self-monitoring by coagulometer, with only patients judged (by the clinician) to be ‘competent’ and ‘responsible’ seen as able to manage a risky monitoring regime. This discourse was shared by PCT staff responsible for service development. Examples of suitable users were typically: younger people, professionals, university professors, haematologists. While the rationality of case selection practices in the surgical technologies are less open/available to scrutiny by lay commentators, both the rationality and the acceptability of selection criteria for more organisational, systemic forms of technology use can be contested. Thus, the restriction of self-monitoring to patients judged competent could be seen as an instance of stereotyping and was indeed resisted by user/patient campaigners. It was also not replicated in other countries where the technology was seen as widely applicable and had diffused much more extensively (Section 5.4).

Utility was also a consideration in tailoring early use. The spinal implant was seen as especially useful for obese patients and those who had had unsuccessful open surgery; the robot’s claimed task dexterity was seen as more useful in complex surgery; self-monitoring was thought to expand the menu of available options for patients on warfarin treatment.

Perceived organisational risk (disorganisation/conflict) associated with service-embedded, systemic technologies like near patient testing with coagulometer and smart infusion pumps, meant that initially, self-contained sectors (one or two general practices or hospitals and catchment areas, or one or two hospital departments) were selected, the service being extended more widely later.

When the technology’s clinical market and usership were less well defined in its early career (as was the case with the ultrasound) the scope of specification of use, rather than tailoring, was a central concern. Cardiac care has been the primary candidate ‘home’ for this technology but
extension of application by users could be relatively swift and, like the robot, further **boundary-crossing** extension into different specialties and settings was likely.

“His experiences were very much cardiology in the beginning, but because he’s used to looking at ultrasound and using echo, he’s now started to use it for abdominal, looking at very simple things like gallstones, dilated kidneys, bladder retention” (HUS-I-1, ultrasound, company representative).

In the case of the CRP point-of-care test (not adopted in the NHS) an appropriate approach to its potential application was envisaged:

“I can see this fitting into an integrated pathway, where you are trying to identify those patients at highest risk of complications and admissions” (CGD6, CRP, clinician).

Similarly, telemonitoring ECG would expand the range of management options available:

“We’re also talking to one cardiac company where they have a cardiac medication that they give to patients. Now they’re very interested in having our device to be issued with the medication in order to monitor the patient as well, to make sure that the compliance with the medication is good” (EGI2, telemonitoring, industry).

**Flexibility of technology.** We found different types of configurability/flexibility in the way the technologies were implemented and how the designing of their use was envisaged. We summarise some of these here:

- The robot could be set up in different ways and with different sets of instrumentation.
- Cells varied in the size of sheets and some practitioners’ preference for the spray version.
- Infusion pump users (clinical engineers, pharmacists) had to provide drug parameters for the software functions, which varied from site to site, and department to department.
- The ECG component of telemonitoring units was simply one option available to users.

In some cases, this flexibility in product options was the direct result of feedback between users and producers, as in cells, possibly making use of the product more likely. In others (e.g. smart infusion pumps), such flexibility appeared as a requirement (to tailor the technology to local systems) and was seen as a complicating factor making adoption more of a challenge.

As in the case of training, the extent of company influence and control on usage of a technology in practice could be substantial. This was most
obvious where a company representative would be present in the operating theatre for spinal implant procedures, and in the case of one smart pump provider who collated and analysed the hospital’s error logs to produce reports. In the latter case, although this removed the burden from the users it was not done in a timely enough manner for the reports to be useful for changing practice.

In summary, therefore, we found that initial case selection was typically narrow and closely linked to the technology’s risk, cost-effectiveness and utility identities. Generally, initial use was a low-risk approach and modes of application were readily aligned with existing practices, structures and pathways, with later, more ambitious expectations and plans to extend use. The technical configurability of a technology could be adoption-promoting or adoption-inhibiting depending on the context, that is, how its flexible features interacted with the perceived needs, objectives and existing practices and the organisation of users.

The following sections consider the types of risk that arose and how they were dealt with in technology adoption.

8.3 Routine application and risk strategies

In the two previous sections of this chapter we considered training and case selection – both activities that can be seen as being oriented to patient safety and minimising risk in the context of early adoption. Here, we focus on other elements of risk strategy and ‘routinising’ technologies.

Standardising application: organising use

The move to routine application of technologies was addressed partly through the development and deployment of protocols, standards and guidelines. Here, we noted again a difference between relatively stand-alone and service embedded, systemic technologies. In the latter case, adoption involved not just technology but technology-embedded-in-service, with a multi-disciplinary, sector-crossing professional and/or lay (clinician/technician/manager/commissioner/patient) usership. As a result, its use required a high level of organising and the management of diffused risks, a requirement that could only be achieved through alignment with and legitimation through a number of pre-existing or tailor-made service specifications, protocols, universal standards, (external) quality control procedures, policies, etc.

For example, NPT anticoagulation monitoring services responded to guidance from the NPSA and the NPT technology itself was approached in terms of standards and operating procedures:

“There was also an agreement about the use of near patient testing equipment and the computer dosage software system. So, again, trying to ensure that there was consistency of systems... we agreed a sort of standard operating procedure across primary
and secondary care, so that both sectors were clear about roles and responsibilities” (A2M2, coagulometer, commissioner).

Building of protocols typically involved stakeholders from different parts of the ‘system’ and were labour-intensive and time-consuming. The selection of protocols and specifications was challenging and necessitated networking with NHS peers, as noted in Section 6.3.1.

Sometimes, the technology itself could play a part in creating standardised practices (HRV - heart rate variability):

“What the HRV does, it actually provides the means to a non cardiac trained nurse, to be able to observe when a change has occurred outside of the typical range for that patient. And when they see this, they will then have a reporting process” (EGI1, ECG telemonitoring, company representative).

In this type of adoption, several types of risk could be tackled simultaneously through organisational strategies:

“The standardisation was the safety angle. The centralisation is the financial and management angle; you’ll save money by centralising” (IGI1, infusion pumps, company representative).

By contrast, stand-alone technologies used by individual clinicians in a self-contained and episodic manner, such as the robot and the spinal implant, went through slower, less well delineated routinisation processes. Here, early individual trial and error gradually evolved into more collaborative, consensus and standards-developing action within the clinical community. Sometimes, if the technology represented a radical change to practice, the need for standardisation was more urgent, as in the case of a new magnetic growing rod used in the treatment of scoliosis.

“There’s no guidelines on the actual technique itself as to whether you should have two rods, one rod; whether you should have hooks... there’s no real protocol in terms of how often you should get them up to have the extensions, how much should you extend them by... We had a discussion about this in the BSS [British Scoliosis Society] meeting last year and nobody could say, really, when you should do it and by how many millimetres you should do it each time” (S2D2, spinal surgeon).

A number of surgeons were planning to organise a user-group ‘think-tank’ with assistance from the technology’s UK distributor, to which the most experienced user in the world was to be invited, with a view to developing a protocol.

In the case of the robot, however, it had taken around eight years from its introduction to the UK for the first ‘master-class’ to be initiated with a similar function of ‘comparing and contrasting techniques’ and learning from the expert. The organiser had a keen interest in how the robot was used by different surgeons.
"And traditionally, a lot of the surgeons... were using the fourth [robotic] arm on their left hand... their non-dominant hand, so we switched it over to the right side of the patient and now we actually control it by the surgeon’s dominant hand... much better” (P10D1, robot, surgeon).

The robot’s identity as a low-risk, easy-to-learn technology (another form of laparoscopic surgery) may have contributed to the slower development of such initiatives.

As described, much of adopters’ strategies for anticipating and dealing with issues of risk were provided for by training, initial tailored use, some degree of ‘hand-holding’ by industry and standardising protocols and practice. We also found other perhaps less obvious means by which potential risks were handled. For example, patient safety concerns could lead to the institution of ultra-cautious patient pathways in the initial phase:

“So, creating infrastructure: having the nurses trained, theatres, wards, ITU - we use an ITU instead of a high dependency unit. Having all of that in place probably won’t be necessary...on the [Hospital] model, patients went to fast track recovery for 24 hours; now they go back to the ward” (P1D1, robot, surgeon).

Clinical governance structures and procedures in some instances included new product/technology safety committees that oversaw the technologies’ introduction and required early audit data, allowing monitoring of early use of a technology.

### 8.4 Monitoring use and gathering evidence

Arrangements for collecting data on new technology use were highly variable both within and between technologies. They ranged from nothing (beyond established routine procedures), to stringent and mandatory procedures, which may be defined locally or nationally, or under regulatory reporting systems. Established procedures facilitating monitoring as part of routine data collection include regular clinical audit meetings, clinical incident reporting, established registries/databases run by professional organisations (e.g. cancer surgery or serious burns), and local departmental arrangements (e.g. surgical infection rates). Data collection was carried out for multiple purposes:

- to seek to establish effectiveness for what we have termed ‘evidence-for-confidence’
- other forms of feedback to improve care procedures
- as risk management
- to control use for example for cost control
- for publication
- as part of an established audit or review procedure.
The types of data collected varied widely, ranging from small numbers of clinical case outcomes to large scale adverse event monitoring and service cost data.

Here, we focus on key issues that arose from the case study data.

8.4.1 Monitoring of use: issues

Monitoring of costs

Technological services such as telemonitoring and diagnostic tests or aids (CRP, coagulometer and the handheld ultrasound) are subject to PCT performance monitoring and reporting. PCTs carry out financial monitoring, for example for the number of prescriptions of the coagulometer’s testing strips. This was described as both to control the frequency of testing and to ensure that providers are correctly claiming enhanced payments for enough patients. In such cases the extent and form of such oversight was a managerial or commissioner responsibility, and as such subject to variation in local systems.

Resources for monitoring use

Even if there was willingness to collect and submit data it may not happen because of needs for extra manpower and time:

"The outcome tool that we offer, we’ve invested thousands in that, and most surgeons go, “Oh, yeah, that’s really good!” and then we go and we train them on it and they have to do 30 seconds extra work per patient, that’s when it falls down!...we can fund the tool but we can’t then fund a person as well" (SI1-2, spinal fusion, company representative).

"It’s all very well setting this up in the first place, but then how do you analyse the data that it produces? Because these pumps are going to generate a lot of information... So you’ve then got to have a new bureaucracy” (I1H1, infusion pumps, equipment manager).

Quality of clinical data

Unsurprisingly, we found instances where technology outcomes were deemed difficult to quantify or standardise (e.g. wound healing) or required significant patient involvement (questionnaires - robot), thus reducing the likelihood of completion. There were many instances of uncertainty over what data and outcomes to collect, standardisability, and appropriate timescales for monitoring.

Thus questions are directly raised about the appropriateness of evidence in a relatively close-knit interpersonal innovation culture such as the burns community. Conversely, where formal research was carried out, this could conflict with clinical goals, because such research requires more rigorous
procedures, restricts patient use and takes time away from clinical practice (e.g. robot, in one site).

**Industry-adopter links**

Early use of a technology, and monitoring of that use, often involved collaborative working between industry and a small group of users and may form part of the product development process. The role of reporting practices during early use, alerting the clinical community and also industry to potential problems, was illustrated for example by design modifications of the spinal implant. The use of this implant was revised to include posterior screws for greater stability and a rod with a tendency to become displaced was redesigned.

Data collected in the early phase are often used by industry as promotional material and/or presented (infrequently, published) by the adopters. We found instances of it being difficult to get data transferred from users to industry (spinal implant and cells – voluntary arrangements), but also difficulty getting information from industry to users (infusion pumps – at one site frequency of data feedback was not built into the contract).

“I think he had been contacted by the company as well to see if we could provide them with any more detailed information of who, what, where, why and when we’d been using their product on” (T1D3, cells, surgeon).

“We have agreements with the PCT that, for our purposes, we can use anonymised data to use it to develop new approaches” (EGI1, telemonitoring, company representative).

Thus we found in examining interaction between industry and NHS adopters numerous examples of uncertainty and possibilities for monitoring of early use, frequently under negotiation or unfulfilled.

Like training (Section 8.1) and protocols (Section 8.3), early monitoring of use can be crucial to stabilising a technology’s identity amongst its users and NHS organisation, practices and pathways. However we found, with some exceptions, that the monitoring of early use (acquiring and using appropriate data) is highly problematic. Issues raised directly by informants and our analysis included:

- labour costs and funding of data collection
- monitoring for financial control
- uncertainty about what constituted appropriate monitoring data
- co-production of data between industry and NHS users and mutual communication of data
- lack of standardisation of clinical outcome measures.

Problematic issues include the well-known dilemmas of evaluation of the early clinical outcomes of interventional technologies, expressed in terms of calls for registries and the like, and illustrating the practical and resourcing
difficulties with these. Further, we observed for several of the technologies that the industry role in facilitating the collection of data was limited, although this was less the case for those in which data services could be part of the technology package itself (infusion pumps, ECG/telemonitoring). It appeared that there might be scope for relatively small injections of resources or development of communication mechanisms between companies and adopters to improve early data collection processes, data co-ordination across sites, and feedback. We also noted frustration amongst clinical adopters who were able to present small scale results in meetings, but were not able to cross the line into journal publication. This evidence, regarded as weak in conventional HTA/EBM hierarchy terms, might nevertheless constitute appropriate ‘evidence-for-confidence’ and could inform adoption decisions within relatively short timeframes.

8.5 Diffusion

Adoption and diffusion as terms are often used in a single phrase (see also Chapter 3) and it is difficult to separate them conceptually. For our purposes we use the term adoption to refer primarily to a decision-making process, albeit one that might not be definitive, while diffusion refers to the patterned spreading of uptake of a technology at particular settings or amongst particular users or communities of practice. It is immediately clear that it is impossible to draw a clear line between the two concepts, since diffusion amongst aggregates of new users requires adoption decisions and arrangements to be made at some level.

Based on our data, we can identify three aspects of diffusion as it relates to the adoption process:

1. actual diffusion, diffusion rates or non-diffusion of technologies
2. formal diffusion plans
3. imagined ‘diffusion scenarios.’

We briefly explore these aspects in this section, from the perspective of the NHS.

In order to advance our understanding of the adoption space, it is useful to assess how formal diffusion plans as well as looser diffusion scenarios mobilised by stakeholders are linked to actual levels and rates of diffusion of technologies. Actual diffusion is a consequence of aggregate adoption decision-making processes that include organised planning as well as less organised ‘diffusion scenarios’ that are built up and enacted by those involved in the adoption space. Discrepancy between actual diffusion and diffusion plans is the rule rather than the exception. Formal planning and informal expectations about diffusion are produced by both companies and NHS stakeholders. Planned diffusion within an NHS organisation or across provider organisations is often referred to colloquially as ‘roll-out.’ Our data provide evidence of relevant actors’ commitments to particular technologies and related services, which have shaped the process of adoption and diffusion as intended (diffusion plans), and instances of the absence of such
'successful' diffusion. These various sorts of commitments to planned or envisaged diffusion are evident in the 'identities' discussed in Chapter 5.

Considering actual diffusion, it is thus worth gauging in broad terms the rational scope for (further) diffusion of our case study technologies and the reasons for this. Our suggestions on this, while data-informed, can only provide an impressionistic picture of overall diffusion of each technology.

The extent to which diffusion happens as a spontaneous, naturally-occurring process and to what extent it is or can be controlled in some way is a key issue. While this is partly a matter for policy, our data show that the identity of technologies amongst users and key decision-makers renders successful planning either more or less achievable. In some technologies, for example cells, the concept of 'diffusion' appears of limited relevance because of the low numbers and the on-demand nature of production, though this could change if it became more widely accepted in the burns armamentarium. The concept makes more sense in our other case studies. For example, diffusion of the NPT coagulometer can be planned/achieved on a large scale as a matter of policy/service reorganisation. In terms of 'roll-out' of NPT-based services in the study, it was often historical relationships that paved the way for early diffusion in a locality. It is interesting to note the different possibilities for 'rolling-out' afforded by the same technology in different contexts: while rolling out is perfectly feasible for NPT coagulometer, the same drivers do not apply to self-monitoring, partly because diffusion depends on an adoption decision by individual GPs and patients themselves and partly because of the manufacturer’s promotion direct to patients. In this case, the technology can merely be ‘allowed’ and ‘encouraged’ indirectly.

“We’re allowing it because it’s in the spec, by including it, we’re encouraging it, we need to make sure practices are aware, and make sure it’s safe for patients. We’re looking at a predicted increase of 14 percent of patients on warfarin” (A1M1, coagulometer, commissioner).

On the other hand, in the case of the robot, many informants spoke about how a potential for planned diffusion at NHS level had been subverted by the very strong drivers of market-led and trust-based acquisition of the technology, resulting in a skewed diffusion by 2011 with concentration in London and the South East, one in the north and none in Scotland, Wales and Northern Ireland. Apart from service delivery and equity implications, one result was acquisition by district general hospitals with low clinical volume, with further implications for safety and clinical and cost effectiveness; many robots in these settings were infrequently used.

“I think the NHS have always thought that this type of technology would be adopted by the sort of leading cancer centres and I think the original idea was looking at maybe six or seven centres in the UK would have this technology, and they would be the centres of excellence for cancer care... And I think we’ve all been surprised at how great an adoption of this type of technology has occurred;
there’s 21 systems in the UK at the moment” (PI1, robot, company representative).

The geographical factor also appeared in the diffusion of smart infusion pumps, where the market perception was that there was higher uptake of dose reduction software in the South of England than the North.

In surgical technologies such as the spinal implant or cells, word of mouth was considered the primary method for credible diffusion. This applies to many of the technologies and we discuss this in Section 7.1.

“So I really do think that who’s using it... the anecdotal thing is very valuable. And anecdote and expert opinion has probably had more effect on spinal surgery than any RCT has!” (S3D1, spinal implant, surgeon).

In some cases the disparity between diffusion scenarios (generally not formal or organised enough to be called ‘plans’) and adoption practice was enormous, as was the case with the much-hyped ultrasound scanner. As noted in Section 5.4, its identity as an ‘electronic stethoscope’ and an ‘amazing’ development, contrasted with the real constraints on its wide diffusion presented by absence of a training infrastructure, an ambiguous utility identity and its disruptive potential. Which of its multiple identities will become dominant over time is very difficult to predict.

An important factor in diffusion (of awareness of the product, at least) with cells and other specialist burns products was the mobility of the specialist workforce between centres in a relatively close-knit community, several of whose members, for example, had worked with the same surgeon-innovator in Australia as part of their training. Such processes also applied to the robot.

The importance of diffusion scenarios in building technology identity was also evident in the case of telemonitoring technology. Here the time period over which diffusion might be assessed was emphasised, an issue also important to questions of evidence and evaluation (see Chapter 7).

“Time is very important in determining the effectiveness: over how long are you looking at it? What are your assumptions about how quickly you’re going to see effects and so on? And conventional modelling doesn’t pick that up” (EGA1, telemonitoring, academic).

It is also possible for actual diffusion to outpace rational adoption plans, leading to supply-induced demand:

"To give you an example of a project locally: they wanted to demonstrate the benefits of telemonitoring, quite rightly, and they therefore needed to be able to get numbers, and...getting numbers is sometimes difficult! So there was encouragement...to find people to recruit to the service. Now that’s not a mainstream service; that’s trying to get bums on seats” (EGA2, telemonitoring, academic).
The proportion of telemonitoring units that included an ECG function was said to be in the region of 1-2 percent. However, whether this was actually used was determined by the clinician user in some cases. Thus the extent of actual diffusion, even where a technological service has been ‘adopted’, may be impossible to know.

Unsurprisingly, examples abound of technologies being adopted in spite of rational EBM/HTA evidence:

“So, I think even without evidence things are now happening actually.” (EGA1, telemonitoring, academic)

In summary, our findings suggest that while expectations and scenarios about diffusion are important, they are not influential unless they are enacted in decision-making processes in the adoption space. The concept of ‘diffusion’ itself implies a mass produced product, so a technology such as cells does not comfortably fit this sort of concept. Likewise the knowledge-intensive, highly specialised and mediated nature of healthcare systems militates against its value. Nevertheless it is applicable to some of the technologies that we have studied. We note that companies have a wide variety of business strategies, which sometimes encompass apparently ‘low’ diffusion in the NHS. As one would expect, many of the obstacles to ‘implementation’ of ‘adopted’ technologies concern the organisational and professional boundary matters discussed elsewhere in this report.

Our case studies furnish examples of the stakeholders’ diffusion scenarios or expectations failing to be mobilised (robot) and planned diffusion succeeding (NPT anticoagulation monitoring). The scope for rational planning of diffusion appears to differ to some extent by technology (Table 7) in the context of universal health care delivery systems such as the NHS, because of the nature of the technology and its clinical/evidential context. Diffusion of cells and the spinal implant are unlikely ever to be successfully planned, whereas planning by PCTs/hospitals is in principle more viable in ECG telemonitoring, CRP, the ultrasound scanner and smart infusion pumps. The robot presents a high-cost technology where planned diffusion at a national level could perhaps be a more rational strategy. Scenario methods and modelling of diffusion assumptions during adoption planning are areas that are likely to reward further development toward strategies for building appropriate adoption.

8.6 Summary

This chapter illustrates the great complexity of considerations about managing initial adoption of technologies, establishing acceptable standards, monitoring early introduction, and issues of diffusion in the adoption space of different technologies. Overall we found a cautious approach being taken by NHS actors, balancing needs to tailor technologies to local circumstances against ambitions to innovate and extend technologies into new, potentially riskier applications and service configurations.
<table>
<thead>
<tr>
<th>Technology</th>
<th>Diffusion stage/level</th>
<th>Further (rational) scope in NHS?</th>
<th>Main factors and identity issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coagulometer</td>
<td>medium but slow</td>
<td>Much wider; more focus on more specific patient groups</td>
<td>Especially NPT incentives; hospital clinic model under pressure of volume. Identity related to system re-organisation; devolution to primary care. Planning at local level. Introduction of new drugs.</td>
</tr>
<tr>
<td>Cells</td>
<td>low</td>
<td>Not much</td>
<td>Competitor products, rarity and complexity of cases; regulatory issues; effectiveness identity uncertain and clinician determined. Diffusion difficult to plan.</td>
</tr>
<tr>
<td>Spinal implant</td>
<td>low</td>
<td>Not much</td>
<td>Specialist field out of favour; clinical risks seen as important; restriction to a very specific clinical indication and constrained by contested identities. Diffusion difficult to plan.</td>
</tr>
<tr>
<td>CRP</td>
<td>not adopted</td>
<td>Could be introduced</td>
<td>Clinical rationale; national HTA interest. Potential policy alignment; reduce hospital referrals, antibiotic resistance. Weak evidential identity in UK/NHS. No planning.</td>
</tr>
<tr>
<td>ECG tele-monitoring</td>
<td>very little</td>
<td>Much wider</td>
<td>Broader telehealth impetus growing though ECG ‘not most interesting part;’ favourable reimbursement; embedding in other tele systems. Likely policy alignment (3 Million Lives, etc). Positive ‘political’ identity (scenarios) conflicts with service complexity.</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>very early</td>
<td>Much wider</td>
<td>Negotiation into patient pathways required; need to stabilise clinical role – weak_complex core identity. ‘Early’ stage. Multiple diffusion scenarios.</td>
</tr>
</tbody>
</table>
9 Main conceptual conclusions

In this chapter, we first summarise the main findings of the study. We then bring together the different strands of our analysis to build a coherent conceptual account of how device technologies are adopted in the NHS, illustrating this through a summary of the ‘careers’ (Blume, 1992) of some of the technologies. We also show how this account links to our original research questions. We outline the strengths and limitations of the study. Finally, we place our account in the context of policy and suggest directions for further work.

9.1 Summary of findings

9.1.1 Technology identities

In seeking rational technology adoption, there is now a policy impetus to ascertain the ‘value proposition’ of technologies, i.e. their clinical outcomes; their role in the patient experience, the timeliness and safety of care and the reduction of inequalities; and their impact on productivity and cost reduction (DH, 2011, p 11). Our research shows that value propositions are closely associated with technology identities that circulate in the adoption space: the ascertaining of a technology’s value is not entirely a rational, ‘evidence based,’ process but is subject to socially mediated processes and socio-technical and socio-political forces. While many influences were identified in the study, the powerful role of the industry in identity construction was noteworthy, in particular where the technology had potential for high public visibility and public attractiveness, as with the robot. In other cases, identities arising from practitioner beliefs and practices successfully resisted industry-constructed ones, as in the case of the coagulometer for self-monitoring. This technology acquired identities as high-risk (patient incompetence) and high requirement (needing reimbursement) in particular, because both the risks and the requirements were perceived as beyond the control of those acting as gatekeepers to adoption, i.e. GPs/PCTs. These identities designated it as a niche technology and limited its wide diffusion.

The unfavourable identities of self-monitoring persisted despite relatively conclusive evidence of its effectiveness (the only one of our technologies to have this kind of evidence base). Clinical effectiveness identities for all the other technologies were contested, but there was an adoption-relevant bottom line: the technology had to be at least as effective as the current alternatives (so that patients were not disadvantaged). A belief in superior effectiveness was generally not given as the main reason for adoption. Exceptions were anticoagulation near patient testing and smart infusion pumps where the main underlying reason for adoption appeared to be the promise of more effective practice/service. Other shapers of adoption were identities relating to the technology’s role:
• in boosting institutional image and income (robot)
• as a tool in the surgical armamentarium (spinal implant, cultured cells)
• as a tool to expand clinical/diagnostic repertoires (ultrasound, ECG telemonitoring)
• in responding to patient demand (self-monitoring).

Whether a technology was embedded in a secure clinical rationale, i.e. whether the intervention it made possible was seen as needed, was also relevant in establishing the technology’s underlying clinical value. Finally, technologies’ future value, in terms of technological advances and cost-effectiveness, helped designate them as desirable/feasible but these identities were highly speculative in nature.

Inevitably, the perceived unavoidable requirements imposed by technologies also shape their value propositions. Such ‘requirements’ largely flow from the technology’s function, design and use, but in the adoption space such material constraints become transformed, becoming less or more significant and also change over time. With relatively self-contained clinical technologies, such as the robot, spinal implant and cultured cells, a central question was the extent to which the technology required an intellectual leap by the practitioner in terms of clinical routines or risks. In this regard the spinal implant was a ‘high-requirement’ technology (novel surgical approach, risk of bowel perforation), limiting its diffusion. With the more service-embedded, systemic technologies like the coagulometer (near patient testing), infusion pumps and ECG telemonitoring, organisational requirements were more salient. Adoption of these technologies - effectively service reorganisations – was likely to have been limited by the potential for organisational upheaval. ECG telemonitoring in particular had a high functional requirement (NHS/non-NHS organisational structures for data communication and interpretation and for action) that was not easy to fulfil.

User training, a common requirement for all the technologies, was generally successfully managed; but the early history of the robot and the adoption of the ultrasound device demonstrated that this too could be a limiting factor, especially during early emergence. The ultrasound scanner’s adoption was constrained by the unusual requirement for ‘basic’ imaging training for users as well as device-specific training, an undertaking the company did not consider possible at the time.

The requirement for funding and for PCT/commissioner reimbursement of revenue costs also limited technologies’ adoption, but not universally. Many adopting individuals and organisations found ways round this requirement, notably by mobilising value-demonstrating identities and through a willingness to take financial risks. The exception was CRP testing, not adopted in the UK reportedly because of an expectation that PCTs would not reimburse its use, although a weak clinical rationale (unnecessary test) and absence of policy alignment were also likely to be factors.
Typology of technologies

One study objective was to develop a typology of technologies. While we have noted and documented many similarities and differences between the technologies along a number of important dimensions, we have not produced a typology. We have found that adoption pathways were shaped by multiple interacting technology identities that did not display broad patterns or afford categorisation. It is, of course, possible to approach any categorisation from a number of perspectives and points of reference, for example ‘technology-as-technology’ (the technology’s material and use-related sociotechnical attributes) or ‘technology-in-development’ (the sociotechnical processes that explain its genesis and journey to commercialisation). The type of classification that is of interest to NIHR Health Services and Delivery Research Programme (HS&DR) and to the NHS concerns, on the other hand, ‘technology-as-organisational-project,’ that is, its adoptability in the local context. We identified two dimensions along which it was feasible to classify technologies in terms of the organisational impact of adoption.

One was the identity relating to organisational requirements. There was a clear differentiation between, on the one hand, technologies that required service changes, new skills acquisition, new types of relationships between professionals or between professionals and patients, etc, and on the other, those that could relatively unproblematically slot into existing arrangements. This can be understood as a distinction between stand-alone technologies and service-embedded technologies, with important implications for adoption.

The second dimension concerned the type of adoption that technologies made possible – or afforded. While some could only be adopted at scale or at a corporate level involving large numbers of multi-disciplinary stakeholders, relatively formal procedures and large-scale financial investment, others could enter use through ad hoc decisions by individual clinicians, while still others followed an intermediate path between these two opposites. The type of adoption also had implications for trialability – use in a limited number of contexts, for a limited number of conditions or for limited periods – and subsequent reversal of adoption.

These two criteria, the technology’s disorganising/re-organising potential and adoption type, may provide a rough guide of adoptability and indicate key issues to decision-makers.

Although we were not able to produce a full typology, the five-component ‘technology identity’ construct can, we believe, function as an action-guiding theoretical concept by methodically directing decision-makers’ attention to key issues/variables. We have developed a preliminary version of a decision tool designed to enable this which we intend to develop fully in future work (Section 9.6).
9.1.2 NHS know-how

Many managers – and clinicians – did not appear to be familiar with or skilled in seeking, obtaining, appraising and synthesising knowledge/information about the technology. Managers relied largely on clinicians to ascertain the clinical effectiveness of the technology and clinicians used ‘evidence-for-confidence’ where high-level comparative effectiveness evidence did not figure prominently (and in many cases was not available). Importantly, clinicians provided advice and information on the clinical value of the technology as part of the adoption process, once they had expressed an interest in acquiring it. The use of formal evidence was especially problematic where there was a multiplicity of publications with variable rigour as in the case of the robot. Effort was made to use information/evidence critically; informal tests of trustworthiness were used such as the country of origin of evidence and the clinical standing of the champion clinician(s). There was awareness of the potential for bias in industry-provided information. However, skills needed to undertake independent scrutiny, such as critical appraisal of evidence, economic analysis and forecasting, application of evidence to local scenarios and modelling, were either absent or under-used. These shortcomings were most obvious when adoption required more formal processes such as the preparation of a business case, leading to reliance on industry (see below).

9.1.3 NHS adoption processes

Technology adoption was essentially a political process, reflecting the successful mobilisation of some technology identities at the expense of others, through persuasion by the most powerful/loudest voices. Micro-decisions by individual or groups of clinicians were not open to organisational review; higher-level processes involving committees and trust boards were also relatively opaque in that ‘background’ undocumented and unreferenced work often predetermined the outcome of more visible formal processes. There was a haphazard approach to stakeholder participation; as a result, those with potentially useful skills, perspectives and experiences were not routinely or systematically involved. Trialling was common. While in theory this represented a rational approach to adoption, dysfunctional trialling, with technologies being adopted through the back-door, was also common.

It was very clear that while potential adopters wished for extensive information about the technology, its workings and its anticipated impact, it was not easy to access this. Considerable (personal) effort and improvisation was needed and informal networking proved invaluable for this. But this type of information retrieval produced information of variable quality and applicability. The extent of industry involvement in NHS decision making (e.g. business case content) was surprising but explained by the dearth of both skills and reliable/accessible information. In particular, mid-level managers expressed a desire for mechanisms for benchmarking and
more standardised and easily accessible NHS-produced information and templates.

A holistic approach - a broad and forward looking assessment of the technology’s organisational impact coupled with financial planning - was not the norm. As would be expected, systemic technologies requiring reorganisation were more likely to be subjected to this kind of scrutiny; others were generally not. This was an important omission in the case of the robot, a relatively self-contained technology but one requiring considerable expenditure/capital investment and therefore likely to have a significant impact on organisational budgets and financial viability.

The relative power of PCTs - or clinical commissioning groups (CCGs) from 2013 - in technology adoption requires attention. Our data suggest that this power was only meaningfully wielded for technologies adopted in primary care. There was a view that GP commissioners in the restructured NHS would exert more power and influence over secondary care adoption decisions. There was, however, a counter view that industry would find it easier to persuade GP commissioners of the value of their products.

9.1.4 Early use and ‘diffusion’

The data showed that the period of early use was critical in a number of ways and that self-organising practices, actions and interactions in the adoption space determined how risks were managed and shaped the technology’s future use and diffusion.

Technical training for users, on the whole, was the responsibility of industry and was well organised. However, two types of problem were evident, in particular with technologies requiring advanced skills, for example the robot and ultrasound device. First, the training infrastructure for these was absent in the very early period, creating a risky lacuna. Second, there was a distinction between becoming competent in the use of these technologies and becoming expert, with no consensus on when the transition happened. More generally, training was often part of the sales package and outside professional/regulatory mechanisms. While this system worked well, in some cases (e.g. the robot and ultrasound device) more coordinated and professionally embedded arrangements and some form of standard accreditation, similar to the training model for the coagulometer, may be more optimal. The monopoly of the robot’s manufacturer in the provision of training prevented the development of NHS-led/provided training designed to meet service needs.

A meticulous routine of tailoring and cautious, risk-limiting case selection demonstrated how professionalised practices were directed at safe introduction of new technologies. As use was extended and became more embedded in practice, the need to benchmark, document and standardise use and to develop protocols became clear. Here, however, we noted the tendency for systemic ‘technologies-as-service’ to benefit from earlier and more consistent attention compared to stand-alone technologies and the
importance of systematic and coordinated monitoring, data gathering and reporting. Monitoring of early use and appropriate data collection were highly problematic issues.

‘Diffusion’ emerged as a contingent and fuzzy notion that had limited utility in some niche technologies (e.g. cultured cells) and took different forms in others. Diffusion was technology-specific and could occur:

- at a local or national level
- through an increase in the number of users or through boundary-crossing into clinical specialties and healthcare settings
- in a spontaneous or planned manner.

The importance of identifying those technologies that both permitted and required planning was clear, as was ensuring that planned diffusion did not outpace efforts to ascertain the technology’s value. Above all, the study spotlighted the gap between imagined and actual diffusion with implications for horizon scanning and policy making e.g. through scenario methods.

### 9.2 The adoption process map

Bringing our findings together, we have developed an explanatory process map (Figure 4) of spontaneous device technology adoption that sets out key actors, practices, interactions and mechanisms that shape spontaneous adoption decisions. The map represents the complexity, embeddedness and denseness of technology adoption and includes cognitive, psychological and social aspects and both structural and agentic shaping. It makes it clear that all relationships between actors and zones can be recursive and mutually constitutive.

The map begins by acknowledging the role of macro factors and social structures as well as health and technology policies in adoption. We have placed the world of policy and the rationality it represents conceptually outside the sociotechnical zone, although policy is of course a social and socially mediated domain. This separation is needed to accentuate the fundamental difference between how technology adoption might or ought to happen and how it does happen. Also influential in adoption are:

- NHS financial arrangements
- device regulatory frameworks
- social hierarchies and power distributions between professional groups, organisations and health sectors
- HTA outputs and the rational adoption discourses that accompany these
- formal needs assessment and various health related policies (e.g. QIPP, patient self-management, patient safety).
Figure 4. Technology adoption process map

ADPTION SPACE

MACRO/STRUCTURAL
- Economy
- Payment by results
- Industry size/model/market penetration
- Commercial competition
- Private health care market
- Regulation
- Power relations/hierarchies

POLICY/RATIONAL
- EBM/HTA evidence
- Epidemiology/needs assessment
- Rational discourses
- Health/clinical policy
- Resource allocation
- NHS trust budgets

SOCIO-TECHNICAL: ACTORS & OUTPUTS

NHS organisation  
Industry  
Material technologies  
Evidence-for-confidence

Professionals (clinicians, managers)  
Professional/lay organisations  
Patients  
Media/internet

Technology Identities
- Plausibility/Visibility/Distinctiveness
- Clinical market/usership
- (Cost)effectiveness
- Risk
- Utility
- Future

Organisational adoption processes
- Adoption types/Trialling
- Passage points/Power
- Politics/Innovator

Organisational adoption know-how
- Bureaucratic know-how
- Industry involvement
- Networking

Adoption/non-adoption  
Early use

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The relationship between these factors and the adoption of a technology is problematic and nonlinear. These factors influence adoption, sometimes as identifiable constraints/facilitators, but more often by inhering in and influencing the beliefs, behaviours, relations, interactions, concepts and conditions that the actors, including the material technology, co-create (as suggested by the theory of structuration). They thus dissolve into the sociotechnical zone, the dynamic heart of the map.

In the sociotechnical zone, multiple actors are implicated in adoption-relevant processes and behaviours:

- Human actors (clinicians, managers, patients, academics, company representatives) hold beliefs, attitudes and expectations and engage in practices and interactions.
- Organisations make their mark through particular management styles and missions.
- The technology and associated technologies contribute through their material (unavoidable) properties including the financial costs incurred.
- The industry promotes the technology using strategically designed and tightly controlled scripts that penetrate each actor group.
- The media and the internet contribute a portfolio of technology ‘stories’ that transmit particular knowledges about the technology.
- Evidence-for-confidence (combining these knowledges with HTA outputs) is mobilised in technology-relevant practices, interactions and documents.

The reactivity between the actors produces three kinds of outputs, conceptual, processual and evidential, that we posit are the key to understanding how technology adoption occurs:

- constructed technology identities
- organisational adoption processes
- organisational know-how.

Identities are constructed around the core material properties of the technology but also represent the local assessments, understandings and expectations of the human actors; they translate diverse inputs into succinct, heuristic, meaning-laden and transportable ideas about the technology. The concept of technology identities transcends the narrow focus on NHS organisations in the technology adoption/innovation literature which necessarily tells a partial story. The concepts utilised here and the analytic focus on the technology itself lay bare the networked nature of technology adoption and the presence of extra-organisational forces that nevertheless influence organisational behaviours. This does not mean, however, that organisational processes do not have a formative role. Trialling – the opportunity to ‘try and see’ - appears to play a vital role in decisions. Organisational routines and passage points as well as the relative
power of care sectors, providers and commissioners feed into a highly political process of adoption with conspicuous involvement of industry. In these processes, particular technology identities come to the fore, shaping decisions. In short, the process map suggests that technology adoption/non-adoption results from intricate relations between structural and agentic elements and socially mediated action by multiple actors, framed by a multitude of expectations and agendas.

The continued adoption/diffusion of the technology can have a recursive impact by feeding back into the adoption space. For example, the more widely a technology is adopted, the more credible it can become, strengthening its identity as safe and clinically effective, even when no new HTA evidence has been produced. It is crucial to note that the different conceptual domains and actors in the adoption space are in continual recursive inter-relations: everything is potentially influenced and defined by everything else. Although this statement is too general to be useful, it reminds us of the plasticity and interpretability of what might initially appear as clearly defined and static phenomena.

The process map is best illustrated through specific technology examples, as below.

### 9.2.1 Spinal implant

Low back pain has a high prevalence but the effectiveness of fusion is contested with many spinal surgeons not undertaking any surgical intervention (epidemiology). This device was therefore of no utility/relevance to large numbers of spinal surgeons (utility). NICE guidelines (2009) advised a ‘package of care’ that included physical and psychological interventions applied over several months before referral for fusion surgery (health policy), further limiting its utility. The US manufacturer had originally failed to persuade the current UK distributor to market their product (industry market penetration); a contract with an alternative distributor was terminated after signing up just one user (in private practice). The current distributor was approached once again and this time accepted, achieving more success (market penetration/visibility). The implant surgery could only be performed at two levels on the spine, (material technology), making it a niche technology (scope). Soon after the product entered the market, the majority of private health insurers designated it an unproven, experimental procedure with inadequate evidence (EBM/HTA evidence) and refused to pay for it (private healthcare market). It was therefore no longer a source of private income for spinal surgeons (utility).

The novel surgical approach, near the sacral bone, was unfamiliar to many spinal surgeons who needed to learn new skills in handling the relevant anatomy (requirement – clinical adjustment); related to this, the risk of bowel perforation and infection was an issue and there had been one or two reports of serious injury in the UK (requirement – risk adjustment). Furthermore, there were several other minimally invasive fusion...
technologies available and surgeons interested in this type of surgery could chose one that best suited their own ‘hands’ (distinctiveness).

At the organisational level this implant, an expensive form of fusion (costs), was one of the technologies that was increasingly coming under the managerial radar, with corporate procedures of adoption, such as committee approval or a tendering process (passage point). The inclusion of it in tenders, along with other spinal products, reduced its distinctiveness as an innovative technology (distinctiveness). However, in some cases, the clinicians could circumvent these managerial processes and obtain the technology (power/politics). This partly depended on whether the relevant surgeon or someone else acted as an innovator (innovator).

The economic downturn (economy) meant that the distributor re-focused marketing efforts, with more emphasis on those products it designated as ‘cost-effective,’ priced to compete with alternatives on the market (industry marketing, cost-effectiveness). Nevertheless, surgeons were exposed to the technology at conferences where successful results were reported and witnessed the procedure at training sessions (clinical effectiveness). Some used or were interested in using the spinal implant because it could be one ‘tool’ in their ‘toolbox’ for the foreseeable future (future role), appropriate for a small number of patients who presented with a particular combination of features (scope/utility).

9.2.2 Coagulometer

Self-monitoring by patients on long term oral anticoagulation therapy (OAT - warfarin) accords with general principles of promoting self-care and patient empowerment and NICE guidance on stroke (NICE 2006c; health policy). Over one million patients are on OAT in the UK at any one time (epidemiology). Estimates of the numbers undertaking self-monitoring are unknown, current estimates between 20,000-30,000 are plausible (market penetration).

Self-monitoring using this device has to be understood within the context of anticoagulation service delivery (organisational adjustment), in which there is a trend toward near-patient, primary/community-based provision, supported by incentives in GP Enhanced Service provisions (resource allocation). During this research the company marketing strategy (industry) became more proactive with direct-to-patient marketing (visibility), especially under threat of new drugs that would not require patient monitoring (NICE 2012a,b; future, competition), and the company had started identifying patient groups that they believed would be most likely to stick with the technology once they had adopted it (industry, clinical market). The company also got the device listed in the ITAPP list of innovative technologies for NHS consideration (industry; policy; visibility) – though listed as requiring further ‘evidence’ for wide adoption. Use of the technology requires manual dexterity, fingerpricking, a testing strip inserted into the handheld device, reading the digital figure produced, and communicating this to a health professional (usability, training). Usually
patients have to both request (innovator) and acquire the device themselves at a cost of £300-£400 (economy, passage point).

NHS stakeholders generally accepted the published HTA effectiveness evidence (EBM/HTA evidence/rational discourse, effectiveness identity), but were very cautious about service risk and patient selection. Better educated, younger, working patients were generally selected (risk) and senior NHS staff tended to stereotype local populations as ‘undemanding’ (informal needs assessment, utility) in our study sites. In one study site, perceived as successful in introducing NPT and self-monitoring, the decision to de-commission hospital clinic-based provision had acted as the turning-point for reconfiguring the service (passage-point, organisational adjustment). In this site a close relationship had developed between a specialist nurse and the patient organisation (lay organisations - patients) active in the field, resulting in a core of self-monitoring patients at one community provider (innovator). An initial set of coagulometers had been obtained from a concluded clinical trial and were re-used (bureaucratic know-how; networking). This group of patients was largely taken over by a GP innovator when the service was re-organised, though the champion role of this GP was seen as somewhat counterproductive by the PCT because it unbalanced overall GP provision in the locality (organisational adjustment, politics- conflict). It was notable at this site that the adoption project was led by a person who combined GP and commissioner roles (sociotechnical actor). Diffusion scenarios (future identity) varied massively between the commissioner scepticism mentioned above, through local enthusiasm and industry market strategy, to a high-profile clinical academic making a case that 50 percent of the long-term anticoagulating population could adopt self-monitoring (compared to current 1 to 2% maximum). This was based on an ‘adoption study’ producing EBM/HTA evidence (rational discourse). Thus the future adoption of the coagulometer could be seen to hinge on relationships between a strongly held, practice and commissioner-based risk identity, a strengthening rational evidence base, industry marketing, and the perceived utility accorded self-monitoring in whole-services of anticoagulation provision. Behind this lie macro factors of the new device-threatening drug and pressures for increased levels of stroke prevention activity which would increase the eligible population still further.

9.2.3 Cells

The cell sheets were originally designed to overcome the disadvantages of cultured epithelial autografts (CEAs) used in severe burns. However, by the time the product was available, use of CEAs had essentially ceased and the cell sheets were competing with cultured cells in a spray formulation produced by hospital laboratories (material technology, competition). The company responded to user feedback by also providing a spray version, although this loses the innovation that was inherent in the sheets and users now see the manufacturer as simply another provider of cultured cells (distinctiveness). A chequered history also means that many users are
confused about the companies' identities (industry, visibility), although most are only concerned about the product.

Severe burns are rare (epidemiology) and treatment is provided in a small number of specialist centres and funded on a regional basis (NHS organisation; NHS trust budgets). Such cases are expensive to treat so that high cost treatments are not out of character (material technologies and costs; clinical market). Cases are also unpredictable, highly individual and urgent (clinical market) so decisions are made quickly, repeatedly and on an ad hoc basis (adoption types). This patient population combined with the small number of consultants, who have considerable procurement freedom (professional groups; power relations), previously removed other professional groups from adoption decision processes. However, a recent drive by the manufacturer towards SLAs (industry model) and tighter NHS budgetary controls (economy) is resulting in a move towards more formal adoption processes, e.g. tendering (adoption type, passage points), that involve a wider range of professionals (professional groups). The recent resurgence of a similar and cheaper product provides added competition (competition).

The regulatory regime at the time of product launch provided this technology with a relatively unhindered release onto the market (regulation). The European ATMP regulations now prevent other tissue engineered/cell therapy technologies from being made available without obtaining a marketing authorisation, however this product remains available under grandparenting arrangements and because the UK allows the use of unlicensed medicines for individual patients (regulation).

Published evidence exists for the use of cultured cells/skin in wound healing and there are case studies of chronic wounds from early evaluation work with this product (EBM/HTA evidence, evidence-for-confidence). It is extremely difficult to produce high quality evidence in severe burns (EBM/HTA evidence, clinical market). Given the complexity of both patients and the treatment even established adopters are equivocal about the clinical benefit of cultured cells (utility). Chronic wounds as a market for autologous cells is currently impractical as competitor products are very cheap (competition; material technologies and costs) and the users and patients are not suited to such a delicate and expensive product (clinical market; patients; professional groups; usership). There has been some misunderstanding and misuse of the product leading to poor perceptions of its effectiveness locally (material technologies; training).

In summary then, it is clear that adoption decisions and pathways are strongly socially mediated in the detailed ways shown above. They are shaped by the actions and interactions of numerous sociotechnical actors, framed by macro structures and conditions, and influenced to varying degrees by policy. It is clear that the nature of the technology itself also is significant. As technologies make their journey through the adoption space to different settings and through time, these sociotechnical workings influence technologies’ desirability, acceptability, feasibility and adoptability.
9.3 The adoption space model

Here, we distil the main sociotechnical elements of the adoption process map to present a more parsimonious adoption space model (Figure 5). We propose that adoption/non-adoption are the outcome of three inter-related processes:

- The co-construction of technology identities
- Organisational arrangements for decision-making
- Relevant organisational know-how and evidence use.

The goal of our model is to explain how naturally-occurring (not managed) adoption happens. It does this by crystallising key social processes and cognitive patterns in the multi-actor adoption space.

Figure 5. The adoption space model

The technology identity construct is essential to understanding adoption. Technology identity is a dense, highly composite phenomenon. Each identity, to varying extent, incorporates diverse influences and issues and carries the imprints of macro and meso social structuring. The notion of identity subsumes more conventional technology adoption discourses around ‘users, contexts, technologies’ (Fitzgerald et al, 2002; Fitzgibbon et al, 2010) by combining all three under its remit and in doing this, it reflects the way actors in the adoption space talk – and probably think – about technology and its adoption. It is important for policy to be cognisant of these ‘everyday’ conceptualisations if it is to exert an improved degree of influence and control (See 9.5) in the field of adoption.
Whether technologies are acquired by individuals with no organisational sanctioning or must negotiate some type of organisational passage point, adoption decision-making necessitates the use of locally available/accessed evidence and know-how to assess whether adoption is locally appropriate. Organisational arrangements and know-how therefore play a crucial mediating role in adoption. It is during these processes of assembling, examining and weighting evidence that particular identities or a cluster of identities gain legitimacy and result in adoption or non-adoption.

Actual adoption and early use feed back into these processes, in particular identity construction, by revising prior views and beliefs, in the study mainly in the direction of greater belief in the technology’s utility and safety.

We have shown the rich and varied nature of ‘local technology assessment,’ expressed as constructed technology identities, in sharp contrast to centrally organised health technology assessment and the provision of guidance, notably by NICE. A broader and more varied constellation of considerations and evidence are implicated in a local adoption or non-adoption decision than is the norm in cost-effectiveness and cost-utility analyses. In effect, the same technology is the subject of myriad local assessments. Unlike pharmaceuticals, the health-related and economic consequences of devices depend substantially on how they are used: the skill of the primary user, the presence and skills of the wider team, the nature and size of the patient market, the frequency of use, the location of use, the interaction with other technologies within and outside the NHS and so on. These matters can hardly be determined by centrally produced, de-contextualised and probability based assessments of cost-effectiveness; even a technology shown to be highly cost-effective through well-conducted RCTs may not be used in a cost-effective or safe manner at a local hospital. Because the safety, cost-effectiveness and utility of devices are intricately bound with their local usage, the assessment of the appropriateness of their adoption must also be a local project. Clinicians and managers face a formidable task here. We have set out how technology identities are co-constructed within a dispersed, dynamic, structurally differentiated adoption space, where industry enjoys a strong position and deploys a variety of marketing methods. The task of the local NHS is to discursively move the technology from the adoption space to within its own jurisdiction in order to assess whether various identities relating to the technology’s innovativeness, cost-effectiveness, utility, risks and requirements hold within the local context and its contingencies. If conducted effectively, this process may result in the revision of certain identities, with implications for the adoption decision.

Thus, on the basis of our substantial body of data and our grounded conceptual analysis, we propose an original conceptualisation of appropriateness in technology adoption decision-making that recognises the distributed (local) nature of technology adoption decisions:

Using relevant local expertise to conduct impartial, holistic, systematic and forward-looking scrutiny of all types of available
evidence on the attributes, anticipated accomplishments/impacts and actual consequences (post adoption) of the technology in order to reach decisions that best accommodate the interests of the local health economy and patients and to review and revise these decisions as necessary.

Our findings indicate that decision making (at both individual and collective levels) can be undocumented and political and that evidence of variable quality is used, sometimes uncritically. These processes provide little opportunity for checking, verifying, challenging and if necessary revising technologies’ identity profiles.

**Figure 6. Towards appropriate adoption**

![Figure 6 Diagram](image)

Again based on our data and our analysis, we propose that three mechanisms are needed in order to improve local assessment and to render technology adoption more locally appropriate (Figure 6):

1. **Critical reflexivity.** Decision-makers (clinicians, managers, commissioners) would benefit from a critically reflexive approach when assessing the validity of the technology’s various identities. This entails an awareness of, among others, how identities are
constructed, as detailed in this research, including the role of industry, the source and quality of the evidence used in identity construction, the role of (own) enthusiasm, clinical norms and beliefs about patients in shaping views on the technology.

2. Transparent and auditable processes. The deliberation, assessment and decision-making processes, in their organisational contexts, could be more systematically documented in order to enable scrutiny and review of the sources, evidence and rationales used and to enhance accountability.

3. Post-adoption monitoring and evidence gathering. Because the mode of use fundamentally impacts on safety, cost-effectiveness and utility, NHS organisations need to monitor adopted technologies’ use in sufficient detail in order to determine whether the anticipated benefits are being realised.

The strength of using critical reflexivity (Cunliffe, 2002) is two-fold. First, it builds on the logic of the adoption space and actors’ indigenous cognitive and sociotechnical orientations in engendering change, rather than attempting to superimpose a different paradigm, for example of HTA. In positing critical reflexivity as a solution, we acknowledge the power of technology identities and offer a way of bringing about a change in perspective that works with, not against, this construct. Second, critical reflexivity is a sustainable strategy, directed at capacity building as well as episodic impact, so that it can be deployed in many technology adoption contexts over time as well as in other decision-making contexts. As an output from our study and in order to operationalise the aim of rendering technology adoption more locally appropriate, we suggest the development of a decision aid, the ADOPT Profile decision tool (see 9.6). We intend to fully develop the tool through future work. To sum up, the model we have developed is an empirically grounded conceptualisation that brings new insights into the study of device technology adoption in the NHS. As well as contributing to our understanding of how adoption/non-adoption decisions are made on the ground, it offers a platform from which empirically feasible improvements may be identified and interventions designed.

9.4 Strengths and weaknesses of the study

The inclusion of eight different technologies in this study has provided a diverse and very rich dataset and has allowed us to develop analytic lines and reach conclusions with some confidence. The partially prospective, qualitative design of the study enabled us to gain an understanding of the naturally occurring processes of adoption. The theoretical framework of the adoption space was a useful starting point and ensured a comprehensive, holistic approach that paid attention to all the relevant actors and issues. The ethnographic interviews allowed informants to share their views openly and the inclusion of documents and websites provided insight into alternative discourses. Grounded theory analysis enabled the construction

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of empirically secure abstractions and conceptual analyses that render the findings more transferable.

We were not, however, able to carry out much classical ‘ethnography,’ as explained in Section 2.4. This kind of rich data may have unearthed issues that we were not able to capture. Additionally, we collected less data for some main technologies due to problems with access and the diffuse and nebulous nature of adoption. Similarly, either clinicians or managers were under-represented in some technologies. These shortcomings may have skewed the data to some extent. The data collected for the rapid appraisal technologies, while providing valuable information for some aspects of adoption, were not designed for a complete analysis of adoption.

Our analysis led to a radical re-conceptualisation of technology adoption and its study, by postulating that socially constructed technology identities centrally influence adoption decisions. This is a departure from conventional distinctions between technology, user and context attributes and suggests that all are implicated in constituting the adoption-relevant identities of technologies. As this is an emergent conceptual schema, our research questions were formulated without the benefit of this type of understanding. Nevertheless, the identities concept and its components, together with the other strands of analysis (evidence in the adoption space and organisational adoption processes and know-how) explicate the mechanisms that underpin our original research questions:

- alignment of factors that determine adoption pathways
- the tension between promotion (industry/enthusiasts) and gatekeeping
- what constitutes ‘appropriate’ adoption
- whether and how intervention may be possible.

As explained above (Section 9.1), we were unable to devise a full ‘typology’ of technologies, though we identified two key distinctions (standalone/embedded; adoption types). We were also unable to elaborate on the evaluation of technologies, because there was negligible evaluative activity at the user sites we engaged with (with the exception of the robot which was the subject of a feasibility RCT), although there were a few examples, included here in the appendices.

Our study was limited to England and there are references throughout this report to PCTs, which are peculiar to the NHS in England. However, the commissioning and reimbursement functions of PCTs are also a feature of other parts of the NHS, through different organisational structures. We are confident, therefore, that our findings relating to the role of commissioners in technology adoption will be useful throughout the NHS. Also, the structure of NHS England is in the process of major reconfiguration (Health and Social Care Act, Great Britain, 2012). We point to potential implications of the new organisation for our findings in Section 9.6.1 below. Despite its limitations, we believe that our study makes a valuable and original
contribution to the body of knowledge on health technology adoption. It is likely to have high transferability for two reasons. First, the diverse sample of technologies represents and covers:

- primary and secondary care
- treatment, diagnosis and monitoring
- high and low costs
- doctor, nurse and patient users.

Additionally, while most of the technologies were not directly endorsed by policy, one – local anticoagulation services using the coagulometer – was an example of a policy-endorsed technology. Generic telemonitoring has also recently been endorsed by the government following the WSD trial with the 3 Million Lives campaign and the DALLAS programme. Second, our analysis has been conceptual and theoretical, designed to elicit underlying mechanisms (i.e. identity construction; informal and political adoption processes; use of ‘evidence-for-confidence’) that are likely to be replicated in other NHS and technology contexts, although the empirical details of these contexts may differ. Of course, this can only be confirmed through future studies.

9.5 Study findings in the context of policy

In policy discourses, technology has had a dual presence: as a significant driver of health care costs and as an efficiency tool driving down costs. In the UK, in 2012, technology has come to be represented largely as a cost-saving force in healthcare, when it presents as innovation. Innovation is defined as:

“An idea, service or product, new to the NHS or applied in a way that is new to the NHS, which significantly improves the quality of health and care wherever it is applied” (DH, 2011, p 9).

The industry is expected to ‘partner’ a process with the NHS and government departments in pursuit of innovating technology, designing high-value, low-cost products and reversing the trend to supply ‘incremental, cost-additive’ products. In the light of our research, we identify two potential difficulties with these expectations. First, our data indicate (and confirm pre-existing understanding) that the conception and development of many technologies fall into the ‘incremental, cost-additive’ category, with manufacturers interested in, as one informant put it, ‘tweaking’ existing technologies in order to increase profits, with little regard for epidemiological or service delivery needs. Many technologies are produced by large multinationals with global markets, further limiting the relevance of NHS-specific technological objectives (although we note the current discourse of ‘disruptive’ innovation). Technologies continue to be sold to the NHS by commercial entities with the objective of making profits and through a sales force that uses scripts of certainty and belief in the value of the technology and with a low awareness/appreciation of robust
comparative effectiveness research. Second, ascertaining what constitutes the right kind of innovation remains difficult. Expanding benefits beyond clinical outcomes by embracing the wider notion of value may be helpful, but makes evaluation even more complex. The tension between probability based, de-contextualised evidence, or ‘evidence-for-policy,’ and pragmatic, contextual, small-scale evidence (e.g. observation, interactional exchange of information, case studies), or ‘evidence-for-confidence,’ must be attended to. Often, the impact (and value) of a new technology only becomes known post-adoption/implementation (Robert et al, 1999). The construction of technology identities further complicates this endeavour as traditional technology evaluations have not been designed to identify this kind of information. A more mixed approach to ‘evidence’ may be necessary. Finally, the proposition that technology costs may be ‘reprofiled’ and met from ‘downstream revenue savings’ needs to be considered in view of organisations’ limited capacity to produce actual cash savings from technologies, as indicated in this research.

9.6 Practice and policy relevance of the study

As well as contributing to the scholarly literature on device technology adoption, our study has practical relevance and can contribute ideas to the policy project of reforming the innovation process in the NHS. The detailed adoption process map we provide can be used as a template to assess the value/promise of individual technologies. The different types of technology (stand alone; service embedded) and of adoption (ad hoc/individual; intermediate; macro/corporate) that we delineate can guide the adoption process, informing service and budgetary planning. Fundamentally, the model that we put forward can make a significant contribution to shaping wide-ranging cultural, educational and organisational change in attaining the desired outcome of appropriate adoption. The novel understanding of appropriateness that we introduce differs from the policy drive for accelerated adoption and diffusion (DH, 2011). We have shown that the notion of acceleration, while relevant in those few cases where the universally uniform application of a technology is both possible and desirable, is unsuitable for and can contribute little to the majority of technologies and adoption scenarios. One reason for this is the plurality, ambiguity and inadequacy of the available evidence on technologies’ true contribution to healthcare, so that a strong consensus on their value remains elusive. Another is the highly context-dependent and contingent nature of technology use, so that a claim for universal value is difficult to sustain. We therefore propose a shift from a preoccupation with the speed of adoption decision-making at the local level to its quality. In recognition of the importance of local decision-making, we plan to translate our findings into a practice-relevant decision tool to help local NHS decision-makers undertake more independent, holistic, rational and realistic assessment of candidate technologies and to render adoption more appropriate. The ADOPT profile tool will be theoretically underpinned by the pedagogical view that reflexivity is an effective mechanism for sustained cognitive and
behavioural learning and change (Cunliffe, 2002). We envisage that the tool will operationalise six inter-related mechanisms (subject to testing):

1. Enabling decision-makers to understand the interpreted nature of beliefs/expectations relevant to the technology, to link these with sources/types of evidence/information used, to seek alternative evidence as necessary and to revise/reformulate their ideas (a transferable managerial skill).

2. Systematic consideration of all relevant issues/factors.

3. Upstream engagement of relevant stakeholders.

4. Transparent, auditable organisational processes.

5. Improved assessment of the technology.

6. Improved post-adoption monitoring and data gathering.

In addition to the proposed ADOPT Profile tool, we have identified inputs that may contribute to the appropriateness of technology adoption in the NHS. Some of these also feature in the DH Innovation Health and Wealth report (2011).

**Adoption**

- Transparent/documentated formal organisational processes (including, for example, multi-disciplinary ‘modelling’ exercises)
- Systematic sharing of evidence and good practice
- Centrally produced NHS templates/business cases
- Training for middle/top management and clinicians on technology adoption/innovation skills
- NHS trust based or centrally provided - industry-independent - ‘consultancy’ services on technology adoption (e.g. knowledge brokers, resource centres (Williams et al, 2008))
- Greater role for commissioners in technology adoption (primary, community and secondary care).

**Technology evaluation**

- Pragmatic RCTs (Vickers and Scardino, 2009; Relton et al, 2010)
- Wider use of good quality observational data (Rawlins, 2008)
- An observational studies register to ensure greater ‘reliability, credibility, and transparency of observational epidemiology studies’ (Swaen et al, 2011)
- Greater use of clinical registries and possibility of using electronic clinical records (Varela-Lema et al, 2012)
• Better coding, improved post market surveillance and systematic data collection during early use (Campbell, 2012).

9.6.1 The New NHS England

At the time of writing this report NHS England was undergoing major restructuring resulting from the Health and Social Care Act (Great Britain, 2012). Following the ‘go-live’ deadline of April 2013 it will probably take some time for the new arrangements to ‘bed in’ and have a significant effect on technology adoption decision-making processes. During our data collection we attempted to gain some insight from our participants regarding the anticipated impact of these changes, but at that time (2011) there was little known about how the new structures might work in practice. As we prepared the report for publication, the picture became somewhat clearer.

Two elements of the changes may impact on device technology adoption and diffusion:

• the change from PCTs to Clinical Commissioning Groups (CCGs) and the move to clinician-led commissioning
• the creation of Academic Healthcare Science Networks (AHSNs).

CCGs have a duty to ‘promote innovation in the provision of health services’ and ‘promote research on matters relevant to the health service, and the use of evidence obtained from research’ (DH, 2012a). But it is unclear whether and how they may alter the way or the speed with which technologies are adopted or not adopted. Some participants thought that GP commissioners in the restructured NHS would exert more power and influence over secondary care adoption decisions. There was, however, a counter view that industry would find it easier to persuade GP commissioners of the value of their products than they had experienced up till now with non-clinical managers.

Potentially of more significance are the AHSNs. These collaborations between the NHS, academia and industry are tasked with ‘identifying, adopting and spreading innovation and best practice’ at scale and pace. It is envisaged that every NHS organisation will be part of an AHSN and that both service and technology innovations will be included in their remit. One role of AHSNs of direct relevance to this research is:

“Supporting knowledge exchange networks to provide for rapid evaluation and early adoption of new innovations under tight surveillance and monitoring” (DH, 2012b).

However, as evidenced in some examples in this research, it should be noted that ‘early adoption’ is not necessarily the same as appropriate adoption.
In addition, the draft CQUIN (Commissioning for QUality and INnovation) guidance 2013/14 (NHS Commissioning Board, 2012) requires that NHS service providers demonstrate compliance with the six High Impact Innovations (as appropriate) listed in the IHW report in order to pre-qualify for quality payments (DH, 2011). These include the 3 Million Lives campaign (telehealth), intra-operative fluid management technologies and digital initiatives to reduce unnecessary face to face contact.

9.7 Suggestions for future research

This study has provided original insights and analyses on technology adoption. Future research can take these forward by confirming, revising and developing them and by making them more transferable. We suggest some ideas that can inform this work.

- Development and evaluation of the ADOPT Profile tool indicated above.
- Case studies focusing on a smaller number of theoretically sampled technologies and using more ethnographic (embedded) designs that test the adoption process map put forward in this study, in particular the recursive and instrumental role played by technology identities and requirements. Further exploration of the integration of approaches from Science & Technology Studies, HSR and organisational analysis are likely to be valuable here.
- Intervention studies to develop further and test the ADOPT Profile tool, in particular as a predictive assessment of technologies’ adoptability and value
- Intervention studies to develop and test the suggested NHS-specific organisational inputs listed above (under Adoption)
- Research on developing appropriate curricula for technology adoption training.

In conclusion, this research has spotlighted to date ill-understood sociotechnical processes that influence how new technologies enter the NHS at micro and meso levels. Some technologies are the subject of attention from central bodies such as NICE and expertly produced national guidance is available on their adoptability. Many more are introduced to NHS staff by commercial vendors active in a profit-oriented market and local assessment and decision-making are required. These decisions encompass multiple considerations aside from EBM concepts like cost-effectiveness and considerable information and know-how are needed. This research and its outputs will make a contribution in this respect.
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Engel, M. F., Palinga, F. P., Hoepelmana, A. I. M., van der Meer, V., & Oosterheerta, J. J. (2012). Evaluating the evidence for the implementation of C-reactive protein measurement in adult patients with suspected lower


### Appendix 1 Sample topic guides

#### NHS informant

<table>
<thead>
<tr>
<th>Topic</th>
<th>Topic</th>
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</thead>
<tbody>
<tr>
<td>The history (awareness) &amp; views</td>
<td>Awareness of/views on evidence base</td>
</tr>
<tr>
<td>How revolutionary / incremental</td>
<td>Safety/concerns</td>
</tr>
<tr>
<td>Advantages/Disadvantages of the technology (for patient/doctor/trust)</td>
<td>Training</td>
</tr>
<tr>
<td>Have the views changed over time</td>
<td>Anticipated issues around use/logistics</td>
</tr>
<tr>
<td>The Trust (non)adoption story and processes</td>
<td>Litigation and liability</td>
</tr>
<tr>
<td>Business case</td>
<td>Audit?</td>
</tr>
<tr>
<td>Trust &amp; PCT views</td>
<td>Need for RCT?</td>
</tr>
<tr>
<td>Funding</td>
<td>Ideal evaluation</td>
</tr>
<tr>
<td>Mode of use</td>
<td>NICE guidance</td>
</tr>
<tr>
<td>Expected throughput</td>
<td>The future of technology in local/national context</td>
</tr>
<tr>
<td>Private practice income</td>
<td>Ideal diffusion/role of policy</td>
</tr>
<tr>
<td>Use of evidence</td>
<td>Is technology needed</td>
</tr>
<tr>
<td>Cost-effective?</td>
<td>Impact on epidemiology of condition – intervention thresholds</td>
</tr>
<tr>
<td>Clinically effective?</td>
<td>Slow or fast uptake in UK</td>
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#### Industry informant

<table>
<thead>
<tr>
<th>Topic</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition of technology</td>
<td>Scope for adaptability</td>
</tr>
<tr>
<td>Competitor products</td>
<td>Used across specialties?</td>
</tr>
<tr>
<td>Advantages/Disadvantages</td>
<td>NHS politics</td>
</tr>
<tr>
<td>Risks</td>
<td>Litigation/liability</td>
</tr>
<tr>
<td>Need for technology</td>
<td>Training – how/where/cost</td>
</tr>
<tr>
<td>Costs – direct/indirect</td>
<td>Regulation</td>
</tr>
<tr>
<td>First NHS use - where/how</td>
<td>Clinically effective?</td>
</tr>
<tr>
<td>Current NHS use (diffusion)</td>
<td>Cost effective?</td>
</tr>
<tr>
<td>Fast/slow diffusion (compared with other countries?)</td>
<td>Optimal throughput</td>
</tr>
<tr>
<td>How clinicians hear about technology</td>
<td>Awareness of/views on evidence base</td>
</tr>
<tr>
<td>Who approaches who and says what</td>
<td>NHS audit –company involvement</td>
</tr>
<tr>
<td>Trust purchasing arrangements</td>
<td>Need for RCT?</td>
</tr>
<tr>
<td>Company input to business cases</td>
<td>NICE guidance</td>
</tr>
<tr>
<td>Funding sources</td>
<td>Company profile</td>
</tr>
<tr>
<td>Purchase or lease</td>
<td>Vision/future plans for technology</td>
</tr>
<tr>
<td>NHS decision-making</td>
<td>Business strategy</td>
</tr>
<tr>
<td>PCT role</td>
<td>Marketing strategy/activity</td>
</tr>
<tr>
<td>Variation in trust processes</td>
<td>Direct contact with patients/patient demand</td>
</tr>
<tr>
<td>CEP / NHS PASA involved</td>
<td>Impact on epidemiology of condition – intervention thresholds</td>
</tr>
<tr>
<td>Private sector use</td>
<td>Slow or fast uptake in UK</td>
</tr>
<tr>
<td>Issues around use</td>
<td></td>
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<tr>
<td>Used singly or dependent on other technology/service</td>
<td></td>
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</table>
Appendix 2 Conferences and meetings attended by the PATH team

- Academia, industry and the NHS: collaboration and innovation, London, 27 November 2009
- KTN Technologies for Wound Care Product Design & Intelligent Use, London, 28 Jan 2010
- Launch excellence (industry), London, 8 March 2010
- London Regenerative Medicine Network, 8 April 2010
- British Burn Association Annual Scientific Meeting, E. Sussex, 21-23 April 2010
- Britspine (spinal surgeons), Liverpool, 29-30 April 2010.
- BAUS (British Association of Urological Surgeons), Manchester, 21-24 June 2010
- Meeting organised for NHS managers by manufacturer to introduce product, Manchester, 24 June 2010
- Birmingham International Burns Congress, 6 September 2010
- Procurement in the NHS, Manchester, 15 September 2010
- British Burn Association Annual Scientific Meeting, Salisbury, 23-25 March 2011
- Whole System Demonstrator Action Network Update Meeting, Hull, 30 June 2011
- Institute of Physics and Engineering in Medicine: Selecting Medical Equipment, York, 13 September 2011
- Kings Fund, International Congress on Telehealth and Telecare, (virtual/online attendance), 6-8 March 2012
Appendix 3 Coding frame

A-'innovator' as facilitator
A-(learned?) innovativeness
A-aborted
A-backtracking
A-business case
A-business case-realistic?
A-by default
A-by national policy
A-by patient
A-by trying/evaluation
A-costs considered?
A-creativity
A-dec making-clinician
A-dec making-NHS
A-dec making-patient
A-dec making-risks and benefits
A-decision-stakeholders
A-distrustful of I
A-driver-alignment of interests
A-driver-dysfunctional service
A-E-reliance on clinicians
A-enthusiast
A-evidence considered?
A-evidence not enough
A-formal models/templates
A-history
A-I-'helping' NHS dec-making
A-implementation
A-incentives?
A-individual narrative
A-infrastructure needed
A-local supply
A-need for personal experience
A-patient consultation
A-politics/power/relationships
A-private sector
A-procurement-models
A-routinisation
A-scale of local uptake
A-sustainability
A-T comparisons
A-taking financial risks
A-tariff
A-teething problems
A-timescale
A-whole system approach
A-workload
A/D-pattern
A/D-roles and structures
D-Approp-mode of use
D-Approp-NHS-wide planning
D-Approp-trial & error
D-awareness of T
D-centralised v distributed services
D-desire/wonder
D-first NHS use
D-Inappropriate
D-increased belief in technology
D-international comparison
D-media
D-natural NHS trajectory
D-patient demand
D-peer opinion/recommendation
D-scale of diffusion
D-turning point
D-workforce mobility
D UK-slow?
E-access
E-assessment of E
E-awareness
E-C-effic-NHS data
E-C-effect-disinvestment
E-C-effect-inefficient use
E-C-effect-volume
E-Clin-effect-volume
E-clinical uncertainty
E-context specific
E-discounting/countering negatives
E-EBM/HTA discourse
E-effectiveness-established
E-effectiveness-knowledge/ theorising
E-effectiveness-not established
E-effectiveness-observation/experience
E-evidence-ignored
E-evidentiality-context dependent
E-how used/presented
E-ideal study
E-international differences
E-NICE's role
E-non-EBM/HTA discourse
E-of what
E-RCT-desirable/needed
E-RCT-equipoise?
E-RCT-learning curve problem
E-RCT-not desirable/needed
E-RCT-not for everything
E-RCT-predicting results
E-RCT/study-difficulties
E-RCT/study ongoing
E-planned
E-timespan-too long
E-v I profits
E-v patient care
E-what counts as evidence
E-who pays for it
Exp-C-effectiveness-'likely'
Exp-C-effectiveness-'unlikely'
Exp-exponential benefits
Exp-hesitant about T
Exp-optimal service
Exp-private patients
Exp-projection-niche market
Exp-projection-routinisation
Exp-reput/kudos/income-small hospitals
Exp-reputation/kudos/income
Exp-vision-general
Exp-vision-local
G-practice/policy
H-commercial difficulties
H-dysfunctional service
H-econ conditions
H-finance/PCT
H-lack of private income
H-market penetration
H-NHS policy/bureaucracy

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Atlas codes for higher-order theme: Technology identities

A-history
A-(learned?) innovativeness??
A-dec making-risks and benefits
A-enthusiast
A-individual narrative
A-need for personal experience
A-T comparisons
D-awareness of T
D-desire/wonder
D-increased belief in technology
D-peer opinion/recommendation
E-awareness??
E-EBM/HTA discourse ??
E-effectiveness-established
E-effectiveness-knowledge/theorising
E-effectiveness-not established
E-effectiveness-observation/experience
E-evidence-ignored
E-non-EBM/HTA discourse
E-what counts as evidence
Exp-C-effectiveness-'likely'

T-market size-unpredictable
T-means & is science
T-multiple purposes
T-neg consequences
T-profitable for user? (GP)
T-revolutionary
T-shapes user identity
T-standards/quality control
T-superseded
T-value of intervention
T-versions
T Disadv-not easy to use
T use-adaptability/configurability
T use-case selection

T use-clinical guideline/protocol
T use-dependent on ICT/info flow
T use-description
T use-evidence gathering
T use-I support needed
T use-knowledge/skills/team/logistics
T use-learning curve definition
T use-monitoring/revising
T use-multiple spec
T use-own level of experience
T use-patient behaviour
T use-single spec
T use-standardisation

T use-T-human symbiosis
T use-T induced use
T use-user feedback
Training-formal accreditation
Training-funding
Training-how/where
Training-impact on junior grades
Training-less difficult T young docs?
Training-patient training
Training-shortcomings
Training-variation
Users-patient-rationale for T
Users-profile

H-producer capacity ??
H-provider variations ??
H-resistance/politics??
H-safety/value not demonstrated
H-sustainability ??
H-tougher regulation ??
H-user forgetting
N-T awareness
R-high risk
R-loss of clinical control
R-loss of financial control
R-low risk
R-of T
T-Adv-achieves clinical goal
T-Adv-as revision surgery
T-Adv-boosts clin confidence
T-Adv-context/condition dependent
T-Adv-cost savings
T-Adv-disadv of comp/alternat
T-Adv-easy to learn
T-Adv-easy to use
T-Adv-for whom/when
T-Adv-increased volume
T-Adv-little/exaggerated
T-Adv-no advantage
T-Adv-patient convenience
T-Adv-patient expectations

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T-Adv-quicker recovery/shorter stay
T-Adv-reduce negative consequences
T-Adv-safer healthcare
T-Adv-task-dexterity
T-Adv-task-ergonomics
T-Adv-task-speed
T-Adv-user dependent
T-as leveller of clin plyg field
T-as mediator of clin consultation
T-as patient educator
T-as service re-organiser
T-costs
T-description by user -
T-Disadv-costs
T-Disadv-difficult to learn
T-Disadv-increases
uncertainty
T-Disadv-not easy to use
T-Disadv-patient
inconvenience
T-Disadv-task slower
T-incremental step
T-it's a service, not just T??
T-market size
T-market size-
unpredictable??
T-means & is science
T-misunderstanding the T
T-multiple purposes
T-profitable for user? (GP)
T-revolutionary
T-value of intervention
Users-patient-rationale for
T
Users-profile ??
We would like to invite you to take part in the PATH study. Before deciding whether to take part, please take time to read this information sheet which outlines the study and what participation will involve. If you have any questions, please contact the named researchers.

What is the purpose of the PATH study?
The PATH study aims to discover the underlying dynamics of technology adoption by using qualitative research methods to produce case studies of different medical devices and procedures in the process of adoption. The study will produce a conceptual model that explains why and how different technologies follow different adoption trajectories and will attempt to identify good adoption and evaluation practice. It is a key policy objective to ensure that only new health technologies that are cost-effective are used routinely in the NHS and that those found not to be cost-effective are discarded. This is difficult because studies have shown that practitioners do not commonly change their practice in line with published scientific evidence and do not, for example, adopt a technology that has been shown to be cost-effective. However, practitioners do adopt new technologies ‘spontaneously,’ as a result of entrepreneurialism, by trial and error, and in interaction with other stakeholders. Understanding the mechanisms of spontaneous adoption can provide important insights which the NHS can use to better plan and manage the adoption of tested, cost-effective technologies.

Why have I been invited?
You are invited to take part in the PATH study because you are employed at [NHS Trust/PCT/GP practice], one of our case study sites and your work involves, directly or indirectly, the purchase, use or evaluation of [technology], one of our case study technologies.

Do I have to take part?
It is entirely up to you whether you want to take part in the study. If you decide to take part, you will keep this information sheet and sign a consent form. You will be free to withdraw from the study, from an interview or from a discussion session at
any time without giving a reason. You can also decline to answer any specific interview questions without giving a reason.

**What do I have to do if I take part?**

We may invite you to take part in any or all of the following research activities:

- We may invite you to attend one or more interviews to discuss your perspective on the technology and its use locally. One of these may be a face-to-face in-depth interview lasting about one hour; others are likely to be shorter face-to-face or telephone interviews. All interviews will be audio-recorded. Time taken for interviews will not normally exceed three hours over the study period (for key individuals). The topics covered will include: the onset of the use of the technology; decision-making about the technology and the involvement of others; training; views on the usefulness of the technology, risks, opportunities and evaluation.

- We may invite you to participate in group discussions about the technology together with colleagues also involved with the technology, to be led by a member of the research team and audio-recorded.

- We may observe meetings at your organisation held as part of your routine work or convened specially to discuss the technology. We may take notes during our observation or audio record the proceedings of the meeting.

- We may periodically contact you by email or telephone for updates on key events, etc, concerning the use of the technology.

- We may request copies of documents that are relevant to the purchase, use and evaluation of the technology.

**Will my taking part in the study be kept confidential?**

All data collected from you during the course of the research will be anonymised so that you cannot be recognised. Your name will be removed from recorded data (interviews and meetings) and transcripts will be labeled with a unique identifying code. The key to the codes (that links named individuals with their data) will be stored on secure university computers and only members of the PATH research team and authorized university personnel will have access to this. Anonymised data will also be kept on secure university computers and in locked cabinets. We will pay special attention to maintaining the confidentiality of your data at all times; information and views you provide will never be divulged to or discussed with others at your organisation or those at other study sites.

**What are the possible disadvantages and risks of taking part?**

There are no physical risks in this study. If you agree to take part, it is possible that you will experience some intrusion and inconvenience (e.g. making time for interviews and discussions or having meetings recorded or observed). If you experience serious inconvenience or discomfort, the researchers will be happy to discuss this with you and will discontinue data collection if necessary.

**What are the possible benefits of taking part?**

There are no physical benefits in this study. Participating in the study may increase your job satisfaction by providing an opportunity to reflect on and take stock of personal and organisational practices and possibly to initiate desirable changes.
What if there is a problem?
The research team will be happy to discuss your concerns and will endeavor to resolve these. But if you wish to complain formally, or have concerns with any aspect of the way that you have been approached or treated during the course of this study, the usual National Health Service complaints mechanisms should be available to you.

What will happen to the results of the study?
A final report of the study findings will be given to the study funder and a summary will be sent to each participant. The findings will be published in peer reviewed scientific journals and lay publications; in these, we may use anonymised quotations from your interviews or meetings attended by you.

Who is organising and funding the research?
The PATH study is funded by the National Institute for Health Research Evaluation Trials and Studies Coordinating Centre (NETSCC) Service Delivery and Organisation (SDO) programme. The study sponsor is King’s College London (KCL). The study is conducted jointly by KCL and Cardiff University.

Who has reviewed the study?
This study has been reviewed by the National Hospital for Neurology and Neurosurgery and the Institute of Neurology Joint Research Ethics Committee.

Further information and contact details

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Many thanks for taking the time to read this information sheet.
Appendix 5 Consent form

PATH
Pathways to adoption of technology in healthcare
Participant Consent Form
(Version 2 - 23/07/09)

Participant identification code:

Please initial each statement

1. I confirm that I have read and understand the Information Sheet (Version 2 dated 23/07/09) for the above study.

2. I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily.

3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and also that I am free to withdraw from an interview and to decline to answer any interview questions at any time without giving any reason.

4. I agree to have my interviews and meetings that I attend to be audio-recorded.

5. I agree to have anonymised sections of my interview or meeting data to be included in publications resulting from the research.

6. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from Cardiff University and King’s College London, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

7. I agree to take part in the PATH study.

Any information you give us will be kept strictly confidential and your name will not be linked to it. Please sign below if you agree to participate in the PATH study.

__________________________________________
Name of participant

__________________________________________
Signature

___________
Date

__________________________________________
Name of researcher

__________________________________________
Signature

___________
Date

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Appendix 6 Concepts and meanings

**Adoption**

The processes involved in making the decision to use the technology. The decision-making can be at different levels: individual, organisational, regional, national. It can be informal or formal and transient or permanent. Distinct from routinisation and implementation.

**Adoption work**

Individual and/or collective actions and interactions aimed at enabling adoption of the technology at a specific setting. These can include political/strategic persuasion, forming alliances with stakeholders, evidence collection and demonstration, organising encounters with the technology, committee work, preparation of business cases, liaising with companies, contract preparation and negotiation, etc.

**Early use**

The immediate period following a decision to use the technology, characterised by a degree of trial and error and discovery about the technology. Distinct from routine or established use.

**Routinisation**

The period during which and the naturally-occurring processes through which the technology becomes part of routine practice, with continuity and more or less stable modes of use. Distinct from implementation.

**Implementation**

Processes involved in operationalising a decision to adopt and routinise the technology in an organised manner at a specific setting. Involves a degree of managerial (top-down) use of authority and a long-term perspective. Distinct from naturally occurring routinisation; however, many processes required for implementation mirror those in routinisation.

**Diffusion**

The number of individuals or organisations that have adopted the technology (i.e. are using the technology) at any one time and change in this over time. The speed with which the technology is adopted across the country.
Promotion

Discourses and activities undertaken by enthusiasts (industry, clinicians, managers, patients, policy-makers) aimed at creating a positive image for the technology, rendering it desirable and feasible and rendering its adoption more likely. Includes: highly visible and positive media coverage, user stories with happy endings, strategic use of scientific literature, marketing; patient demand; endorsement by government/professional organisations; etc.

Gatekeeping

Discourses and activities usually undertaken by NHS management (hospital and commissioner) or clinical engineering departments aimed at regulating the adoption of technology. Includes: declining to meet the costs of acquisition or continued use (e.g. funds for purchasing/leasing, reimbursement for treatment episodes), introducing formal structures or procedures for adoption, bringing managerial power to bear on clinical or patient-led impetus for adoption, formulating policies that designate the technology ‘low priority,’ etc.

Evidence

Information relating to the technology’s use, clinical and cost effectiveness, risks, utility and impact and referred to as a basis for technology-directed views and actions. Here, evidence is defined from the perspective of the informants, i.e. what they believe constitutes evidence and what they report using as evidence. Therefore, evidence here includes high-level HTA evidence (RCTs and meta analyses of RCTs), low-level evidence (case-series), anecdote, conversations, personal experience, etc. The type of evidence is indicated where necessary.

Evaluation

Activities designed to produce evidence (in the broad sense used here) on the technology’s use, clinical and/or cost effectiveness, risks, utility and impact. Evaluation in this broad sense can range from formal HTA type activities, through somewhat formal research, to informal ‘try and see,’ and from the systematic use of data to canvassing of opinions.
Appendix 7 Formal approaches to trialling

Example 1 – User scoring in the tender process

User scoring of competing products is becoming more prevalent in both local and national procurement processes. One participant described their process when undertaking hospital-wide replacement of infusion pumps, a process managed by the Trust’s Clinical Engineering department.

A user group was set up involving mostly nursing staff from all the major hospital areas. Companies were invited to demonstrate their products to this group from which a shortlist of five were selected to go forward to formal trials. The five pumps were trialled simultaneously in five clinical areas for two weeks each and then rotated around, so that each area used each pump. Companies provided user training. Every user completed an evaluation form each time a pump was used, the results were consolidated and the pumps were allocated clinical and technical scores. If the device is found to be unsuitable during the trials it may be withdrawn.

This evaluation was conducted in parallel to the procurement tender, i.e. the companies’ detailed responses to the Trust’s equipment specifications. The scoring was then used in conjunction with the tender information to select the most appropriate alternative.

Example 2 – Local development of formal evaluations

At one site individual initiative and a local culture of scientific rigour had produced an environment in which relatively formal evaluations were part of the departmental routine. All new products were subject to the same two-stage process. First two or three patients were selected as case studies for ‘proof of concept’ trialling. If the product was found to be reasonably promising it would progress to a 10-patient structured evaluation where multiple parameters were measured, e.g. time to healing, nursing time, ease of application/removal, patient pain. A cost benefit analysis was part of the evaluation and results were saved for future comparison with other products. These evaluations took part in the burns/plastic surgery department which had developed a leading role in the Trust in terms of product approval for procurement. Structured feedback was also provided to the manufacturers, some of whom responded positively.

Example 3 – Serendipitous use of academic assistance

One telemonitoring site benefited from the academic connections of one of their Community Matrons. Two of her cardiac rehabilitation MSc students were looking for a subject for their dissertation at about the time that the PCT/local authority were piloting ECG telemonitoring. The students worked at selecting a control group to match to the patients trialling the technology
and collected data on admissions and mean blood pressure. Their report also detailed two case studies. The scientific rigour is not high, but the use of control groups is probably uncommon in less formally run pilots.

Example 4 – Independent audit?

One telemonitoring industry representative described a small pilot which was independently audited:

“A complete audit, and again this is generally not done...there’s lot of hidden costs...it’s probably the most accurate estimation of cost savings that’s been published, I think.” (EGI1, telemonitoring, company representative)

Published information available doesn’t quite support this statement. The pilot first year report does contain quite detailed and thorough information about the costs of setting up the pilot – this is often a neglected area when adopters are keen to demonstrate the success of their endeavour. However, this does indicate that a degree of rigour in evaluating pilots of healthcare technology is still a matter for surprise and note.
Appendix 8 Failed attempt at a controlled trial

A consultant with a special interest in research and development provided an example of the difficulties in producing high quality evidence for healthcare technology in general, and in cultured cells in burns care in particular. They started work as a consultant at a specialist burns treatment centre when a trial had just begun. The trial was intended to investigate the efficacy of sprayed cultured keratinocytes (from a hospital laboratory) in severe burns. The patients would act as their own controls; part of their injury was treated with skin graft plus cells and part with only skin graft.

There were several factors which contributed to the trial's failure:

- Patients/clinical market: Patients with severe burns are rare, complex and very sick. Several months may pass without any patients with severe burns being admitted at a specialist centre (and surviving).

- Selection criteria: In order for patients to act as their own controls the burn wound needed to be sufficiently large and continuous with an even depth of injury. Selection criteria must be rigorous to ensure appropriate comparisons, however this also reduces the number of suitable patients even further.

- Outcome measures: Wound healing is difficult to quantify and compare; photographic evidence is required. Scar quality should be assessed over several months, or preferably years, but patients are often out-of-area in regional services and are difficult to follow-up after discharge. Process measures (e.g. dressing changes or nursing time) are often required alongside clinical and patient reported outcomes (e.g. pain, satisfaction).

- Research infrastructure: Recruitment and good data collection require significant manpower and other resources. The study did not have appropriate dedicated clinical man-hours or support staff. Data collection suffered as a result.

- Culture: All staff (including laboratory staff) need to be aware of the trial and assess each patient for suitability. A protocol for identifying and recruiting patients should be established and followed.

- Politics of multicentre trials: To overcome the problem of recruitment other treatment centres were asked to collaborate. However, one centre's research was not another centre's priority and differences in attitude, treatment and data collection methods impaired the usefulness of the additional facilities.

"What it demonstrated to me was that it is actually really difficult to set up this kind of trial...it's taken...about eight years for me to think about doing the same thing again." (T8D1, cells, surgeon)
Appendix 9 Suggestions for technology evaluation

We were interested in the use of 'evidence' in adoption decisions. Participants often talked about the difficulties of producing high quality evidence for healthcare technologies so we asked them to suggest better models/methods for evaluations.

Pragmatism

In some cases (potential) users have to accept that RCTs are just not possible or not practical. Pragmatic approaches would find alternative means to assess effectiveness; retrospective and observational models could be employed both within and across centres if suitable data were collected prospectively. Where RCTs are not available and presented data often consists of case studies, the most useful approach is likely to be somewhere in the middle:

"It’s better than "we’ve treated 100 patients and we think they did really well!" (T8D1, cells, surgeon)

"It’s worthy! In the absence of a randomised control trial, it’s probably the best thing to do." (P4D1, robot, surgeon)

Patient selection

Ideally patients and conditions should be comparable between cohorts. RCTs use strict selection criteria and then compare patient characteristics to demonstrate this. If historical data is available on large numbers of patients (e.g. in audit or registry databases) then control groups can be selected to match intervention groups as closely as possible. Alternatively, prospective, non-randomised studies could use risk stratification tools to match patients. But pragmatism is still important:

"You want to get standardised patients and you're just not going to get that" (T8D1, cells, surgeon)

There also seems to be realisation (in coagulation self-testing and telemonitoring) that patients do not benefit equally from standardised interventions and that research is needed to better understand how to select patients.

"We've got about 300 individuals...and we're looking at the predictors of success and failure...what makes it work well and what makes it go badly" (A2CA1, coagulometer, academic)
Outcomes

Published studies are often difficult to compare or aggregate due to variable use of outcome measures. Amongst participants there was more discussion about the usefulness of certain outcome measures than about standardisation of measurement methods. For example, one surgeon listed erectile function as a desirable outcome, whereas another dismissed this as a function of the surgical technique (nerve sparing) which would be dependent on patient characteristics. Some outcome measures require long-term follow-up and/or significant patient co-operation, reducing the likelihood of compliance. Surrogate markers can partially overcome this:

"positive margins are a surrogate marker of future relapse, and actually half the patients who have positive margins, never get a relapse" (P4D1, robot, surgeon)

User bias

Where user technique plays a significant role in effectiveness bias can be introduced by the use of enthusiasts or experts. Users should be able to demonstrate that their competence with a new technology is comparable to the established technique. One surgeon suggested strict criteria to select suitable participants:

"I would ask for an audit, an independent audit of [their] most recent 30 consecutive cases. Very specific criteria and I will make a judgement on that...length of surgery, length of in-patient stay, bleeding, PSA...urinary leaks. (P7D1, robot, surgeon)

Another suggested that using multi-centre studies (and therefore more users) would be better than a single centre trial in order to compensate for his bias as an experienced enthusiast.

Registries

Registries were suggested as an alternative to individually organised studies. These were often associated with industry or professional organisations, with variable success. Compliance was a big issue but could be improved by:

- making them mandatory, e.g. as a condition of sale or by professional agreement
- having suitable manpower resources to overcome the extra (perceived) workload for clinicians
- having financial resources to administer it, e.g. the NHS pays for each patient registered (cf. QoF)
- making it quick & simple

"In hip and knee surgery, it’s pretty black and white; their pain source has gone away, generally, and it’s just at what point does
it wear out and need another one? With spinal surgery, it’s just so much more complicated." (SI1, spinal implant, company representative)

**Service delivery models**

Where the technology is associated with substantial (and variable) changes in service organisation and user roles it is difficult to study the effects of the technology in isolation. Also, having a whole-system approach to evaluation can elucidate wider impacts. In the case of telemonitoring, the variability in both business models and implementation was particularly high.

"modelling can help you at least understand how the costs and benefits fall across the wider system...So it might be, like many health care changes, the bit that makes the investment isn’t necessarily the one that gets the benefit!" (EGA1, telemonitoring, academic)

In the case of DERS, there is the suggestion that smart pumps in isolation are of limited effectiveness. One sceptic suggested that the only appropriate method for assessing these technologies would be as an integrated, hospital-wide system and to compare incidents across the whole medication process with another hospital. An enthusiast, wanted comparisons with and without drug libraries, but also with integration to other systems.

One participant responded to a written question regarding how to design evaluations that could be conducted at a higher level than at each individual trust:

- National clear generic specification.
- Framework agreement of equipment that meet the specification
- Clear evidence for/against the technologies provided as a simple summary with details available as appendices.
- Devolved local decision-making on evidence and product selection
- Local decisions and reasons for them sent back to regional/national centre. (GGE2, generic, equipment manager)
Appendix 10  SME difficulties with evaluations

It is a platitude to say that new drugs cost millions of pounds to develop and test. Clinical trials for medications are well-defined and long, those for medical devices much less so. However, an amendment to the European Medical Devices Directive came into force in 2010 which increased and clarified such requirements for manufacturers:

“You have to do a clinical evaluation of a device. And in general it's got to be based on clinical data, but it can be either an evaluation of relevant scientific literature, or it can be a critical evaluation of a clinical investigation. Or it can be a mixture of both” (GGH1, generic, equipment manager)

With particular reference to tissue-engineered and stem-cell technologies, the Advanced Therapy Medicinal Products Regulations also require clinical evaluations before a European marketing authorisation can be obtained.

Most medical technologies are created by Small and Medium Enterprises (SMEs, less than 250 employees); 99 percent of medtech companies in the UK are SMEs and 60 percent are micro-companies (<10 employees) (BIS Strength & Opportunity, 2011). In comparison, only 11 percent of pharmaceutical companies are SMEs. Such companies can rely heavily on grants and venture capital investment to fund product development and they generally lack the financial capital to fund large scale trials of their products:

“The logical thing to have done next would have been to have secured a decent amount of funding, to have used the experience of what we'd gained from the first study on diabetic ulcers to set up a bigger study with some real funding behind it, which we didn’t have, to do a bigger clinical single blind study, and to also try and see if we could engage with a cost effectiveness study at the same time. So we did take a look-see on what would be involved, and we realised that we didn’t have the resource to do it, and we would have liked to have done it. But you can’t do a cost effectiveness study based on 18 patients and no money...To do a cost effectiveness study, you would probably be talking of 2-300 patients.” (TGI3, cells, academic)

To get from the level of proof of concept and case studies to more rigorous evaluations and wide scale diffusion many medtech manufacturers end up selling their intellectual property to big pharma or technology companies.

This issue was particularly relevant to the company making cultured cell products. The manufacturer had a chequered commercial history; including grant and venture capital funding, several distribution companies, administration and name changes. The collaboration with venture capitalists (VCs) was not successful as the investors had different priorities to the technology developers:
“Venture capital fund managers want their money back in three to five years. Now there have been many, many studies published that show the average time for profitability of something in the medical device area is 28 years. So, the fact that we had ours working clinically in a small number of patients is at least 15 years away from making it an economic success.” (TGI3, cells, academic)

“They’d had VCs going, well, you’ve got to get to market as quickly as possible, and basically you’d paid for massive expansion. So you had a viable business in the background...but it was encumbered with this huge overhead of R&D expenses and marketing expenses, and executives and non-executive directors, and all the stuff that you always get in a venture-funded start-up.” (TGI2, cells, company representative)

A lack of available funding and difficult management structures were not the only impediments to developing larger and better clinical trials. Clinicians’ time and enthusiasm are required to rigorously evaluate a new technology. ‘Opinion leaders’ and ‘clinical champions’ with time for this are apparently becoming rarer. Many of our clinical participants complained about their lack of time for research roles.

The developers of these products perceived a gap for SMEs. They were able to ‘fund’ early case studies, essentially providing free product in exchange for free clinician time. But were unable to produce or find funding for higher quality evidence:

“You can’t expect to have...to do a cost analysis when you’ve barely got the money to do six patients. So, it’s...it’s how you bridge that gap, but it’s a really big gap.” (TGI3, cells, academic)

It was felt that the NHS had a perception about ‘how things are done properly’, that a new technology should appear on the market with big trial evidence behind it, as pharmaceuticals currently do.

“It’s either it’s prudent and accepted, in which case you can charge for it. Or, it’s not prudent, in which case everything’s a trial and in that case, nobody pays a bean for it. And that makes it difficult for small companies like ours.” (TGI2, cells, company representative)

There was a suggestion that the NHS should do more to provide ‘a culture that protects it while it gathers credibility’. This could happen by accepting technologies with promising, but low level evidence, and agreeing to part-fund the evaluations by not expecting free product:

“And in that gap...there’s highly likely to be benefit to the NHS from treating those patients. Is there a way in which the NHS could contribute to the company for...in exchange for that benefit?” “I’m aware that there are grants available...“Small companies don’t want grants, they want sales.” You want to be able to sell your products and from those sales develop the revenues that means you can stay in your business. You don’t
want to have to be leaping through hoops to get grants to do things, because they’re unpredictable, they’re short term, they’re all sorts of things.” (TGI2, cells, company representative)

“I think the NHS could help adoption if they were prepared to adopt things on a contingent basis earlier, and actually pay for the products, rather than necessarily going through the NIHR or whatever it is, and giving grants to people to do things, because it’s a much less attractive and less helpful way of funding that type of activity.” [TGI2]