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User-led Innovation in the UK National Health Service

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A thesis submitted to The Open University in partial fulfilment of the requirements of the degree of Doctor of Philosophy

Faculty of Mathematics, Computing and Technology

October 2009

Submission date: 24 March 2009
Date of award: 26 October 2009

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Abstract

Healthcare services are delivered to patients using complex technology systems. Many innovative healthcare technologies are produced by industrial suppliers; however, healthcare staff are also active innovators of the technologies that they use in their own work. By assuming the role of user-innovators, they can create new technologies, procedures, processes and service-designs that improve and support healthcare provision. The focus of the research reported in this thesis is the phenomenon of user-led innovation of healthcare technology in the UK National Health Service (NHS).

Exploratory research was carried out to develop a detailed understanding of user-led innovation within the NHS based on the perspectives of user-innovators. This thesis presents the results of the research in the form of four interpretive case studies, that contribute to an understanding of the enabling and inhibiting factors affecting user-led innovation. Each case presents an overview of the process of user-led innovation which was followed and the context in which it occurred.

Several distinctive characteristics of user-led innovation are identified and a generic activity model of the user-led innovation process is described. Evaluation in user-led innovation processes is highlighted to have multiple purposes, beyond objective technology assessment. It is shown to support the on-going social-construction of user-developed technologies but also highlights the role of evaluation as a resource for exercising political influence within the innovation process.

User led innovation is established as a theoretically useful and coherently defined mode of innovation, distinct from the lead user or open innovation paradigms. The major contribution of the thesis is an integrated model of healthcare technology systems that emphasises the role of proto-institutions as critical products of user-led innovation. The thesis concludes that in order to maximise the benefit of user-led innovation in the NHS, innovation policy and practice should be broadened to recognise the role of proto-institutions as a valuable product of user-led innovation.

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Glossary

BEP	Biotech exploitation platform
BPS	British Pain Society
CfH	Connections for Health programme (formerly the NHS National Programme for IT)
CLP	Congenital cleft lip and or palate
COREC	Central Office for Research Ethics Committees
CSAG	Clinical Standards Advisory Group
CT	Clinical trial
DoH	Department of Health, UK
EBM	Evidence-based Medicine
ERDA	European regional development agency
IP	Intellectual property
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NIII	NHS Institute for Innovation and Improvement
OECD	Organisation for Economic Co-operation and Development
PASA	NHS Purchasing and Supply Agency
PMS	Pain Management Service
PSRE	Public sector research establishments
QoL	Quality of Life
RDA	Regional development agency
SCOT	Social Construction of Technology
TTO	Technology transfer office
UTTO	University Technology Transfer Office

Statement of published work

This thesis includes a material published in the following papers:

Savory, C. 2006. Does the UTTO model of technology transfer fit public sector healthcare services? *International Journal of Innovation and Technology Management* 3 (2):171-187.

———. 2006. Knowledge Translation Capability and Public-Sector Innovation Processes. Paper read at *International Conference on Organizational Learning, Knowledge and Capabilities*, 20th - 22nd March 2006, 20th - 22nd March 2006, at University of Warwick, Coventry, UK.

———. 2006. Translating knowledge to build technological competence. *Management Decision* 44 (8):1052-1075.

———. 2007. Continuous user-lead innovation and the development of a proto-institution of healthcare delivery services. Paper read at *8th International CINet Conference 2007: Continuous innovation - Opportunities and challenges*, 7-11 September 2007, at Gothenburg, Sweden.

———. 2009. Building knowledge translation capability into public-sector innovation processes *Technology Analysis & Strategic Management* 21 (2):149-171.

Acknowledgements

In writing this thesis, I have received generous support from many individuals. I owe enormous thanks to my supervisor John Hughes and colleague Joyce Fortune, who have both given invaluable support and advice during this research. I would also like to thank my other colleagues and friends without whose help and encouragement this thesis would never have been finished, especially: Ivan Horrocks, Chris Bissell, Magnus Ramage, Kevin Gowans and Max O'Driscoll. Finally, thank you to my family for putting up with me during this research.

Chapter 1: An introduction to the thesis

1.1 Introduction

This chapter gives an introduction to the research reported in this thesis and an overview of its structure. The focus of the research undertaken is the phenomenon of user-led innovation of healthcare technology in the UK National Health Service (NHS). The research was required in order to address an imbalance in the existing literature on user participation in technological innovation, which is heavily biased towards industrial contexts. This imbalance in the literature creates a practical problem for NHS managers and policy makers when attempting to improve the scale and scope of user-led innovation in the NHS. This has created a research problem around the need to identify and analyse patterns of user-led innovation within the NHS, and understand the drivers and constraints that predispose them to be successful or to fail. The research aimed to contribute to knowledge of the phenomenon of user-led innovation and to:

- extend the existing understanding of the characteristics of user-led innovation;
- define and analyse the processes followed by user-innovators working in the NHS, in order to develop their innovations;
- identify the enabling and inhibiting factors affecting progress of user-led innovation;
- identify the extent to which the NHS provides a supportive context for user-led innovation to occur.

User-led innovation of healthcare technology in the NHS occurs in a complex, organisational context. For this reason, it was most appropriate for the research to adopt a case-study approach. This thesis presents and reviews four cases of user-led innovation in order to develop an improved understanding of user-led innovation in the NHS, its processes and the nature of the technologies that it creates.

This chapter introduces and justifies the area of research, setting out the research aims, objectives and research questions. The final section of the chapter provides an outline of the structure of the thesis.

1.2 An introduction to the issues surrounding user-led innovation in the NHS

The literature on technology users' roles in the innovation process has focused mainly on the manufacturing and consumer goods industries (Thomke and von Hippel 2002). As a result the models do not automatically apply to user-led innovation of healthcare technologies. However, the role of users in the innovation of healthcare technology has a long history.

Since ancient times surgeons have taken the role of both designer and user of surgical instruments (Kirkup 2006) and clinicians have been responsible for innovation in the design of healthcare service delivery (Lettl 2005; Lettl, Herstatt, and Gemuenden 2006). The combination of these roles stems from their inventive and innovative personalities, combined with a context in which there is a high problem pressure and a lack of availability of relevant competences and resources. The ability of healthcare staff to develop technological innovations continues to be demonstrated in innovation competitions, run within the NHS, where many innovations have been developed by doctors, nurses, managers and auxiliary staff, often without the formal involvement of NHS senior management and only rarely as a response to central initiatives (NHS Innovations 2004).

The role of NHS staff in leading innovation has been placed firmly on the political agenda (Darzi 2008:59), with clinicians and other NHS staff being encouraged to lead the improvements in healthcare. This recent emphasis on staff-led innovation is not new. Since early times, the development of healthcare technologies has often been driven by those delivering treatment and not simply the product of scientific discover.

However, since the early 1990s the performance of the NHS in managing innovation has become a concern to the UK government. The NHS has been identified as possessing a weak capability to innovate. The NHS's ability to exploit the ideas and inventions that it develops has become a focus of attention (Baker 1999; Office of Science and Technology 2000; Culyer 1994; DoH 2002, 2002,

1998). But on a broader scale, the capability to reconfigure itself for the 21st Century (UK Government 2000) has also been raised as a priority. Criticism of the NHS's ability to manage innovation has developed into both an organisational and political issue. In particular, its failure to adopt new healthcare technologies and practices has received attention:

> But the NHS does not always make best use of innovation. ... Despite some excellent work taking place locally, there remains some reluctance within the NHS to adopt new products and processes. (Darzi 2007:40)

There are several issues that have affected the ability of the NHS to innovate. These issues are related to the nature of user-led innovation, complexity of healthcare technologies and the structural characteristics of the NHS.

User-led innovation

Several significant challenges face the NHS in supporting and managing user-led innovation. There is no widely accepted understanding of the phenomenon of user-led innovation that is applicable to the NHS, making it difficult to identify how best to develop supportive organisational settings. The lack of clarity leads to gaps in understanding of how user-led innovation processes are structured; or the impact of management interventions on their progress. User-led innovation is a bottom-up phenomenon and operates very differently to the top-down initiatives that represent the normal modes of change in the NHS. It also represents a different mode of innovation to many other sectors where innovation is the product of team working, rather than the efforts of a single individual. Finally, the lack of understanding of user-led innovation means that policy makers and managers have little guidance on its potential enablers and barriers.

These issues are compounded by the difficulty in gaining data about user-led innovation within NHS organisations. A difficulty is that until a user-led innovation has reached some level of success, it is unlikely to gain visibility within the parent organisation. Support for innovation activity is under resourced in the NHS and as a result many innovative ideas may never be formally recognised or supported. They may then go unnoticed or simply fail to be developed due to lack of resources. This means that it is difficult to understand the scope, scale or potential benefits of user-led innovation activity in the NHS.

Complexity of healthcare technology innovations

Much of the work on user-participation in innovation has concentrated on the hard technologies, such as physical devices or software. In contrast, within a healthcare context, innovation needs to focus on soft technologies such as procedures, processes and service designs. In fact, it is plausible that operationally focused staff would be in a strong position to pursue innovation of both the hard and soft technologies that they use. This represents a potential strength of user-led innovation to develop new technologies that fit an existing organisational context, or for staff to innovate hard and soft technologies in parallel.

The innovation of healthcare technology systems can be driven by a number of factors including:

- Translation of research-based knowledge into clinical practice (Davis et al. 2003);
- Invention by users and recombination of existing technologies (Hargadon 2003);
- Shifts in the paradigm underpinning treatment, for example a shift from a bio-medical to bio-psychosocial model of care (Engel 1977);
- Shifts in the location of healthcare delivery, in particular the shift from secondary to primary care contexts;
- Shifts in the user-groups for which technologies are aimed. Thus, a technology may undergo innovation that allows its use to shift from specialist staff to generalist staff, to carers, and to patients (Christensen, Bohmer, and Kenagy 2000).

This range of factors suggests that a challenge when managing user-led innovation is maintaining a holistic view of the whole technology system that is subject to change.

Structural characteristics of the NHS

Several structural characteristics of the NHS impact on the potential effectiveness of user-led innovation. The NHS is an organisation with significant knowledge resources including a high proportion of well educated specialist staff. The operational requirements of the NHS mean that there is expertise in scientific and management disciplines. Overall, these knowledge resources create a potential for innovation activity. Unfortunately, the NHS has a firmly established functional organisation structure, based around specialist areas. This has resulted in a tendency for

knowledge to reside within knowledge "silos", the boundaries between specialist areas often acting to reduce sharing of knowledge across disciplines.

The ability to drive innovation and change in the NHS depends on staff possessing significant organisational power. This power is needed both to access necessary resources and to effect change. Distribution of power within the NHS is based on organisational position and the possession of specialist knowledge; both senior NHS managers and senior clinicians can exert significant power. This situation suggests that senior clinicians are well placed to drive innovation and change. Conversely, less senior NHS staff attempting to effect innovation, may lack the power needed to address organisational inertia.

A major structural constraint on user-led innovation in the NHS is the overriding ethic held by NHS staff to provide patient care. These values influence the prioritisation of activities, giving short term clinical problems higher priority than longer term activities, such as innovation.

Finally, the NHS is a singularly large, complex, high-budget, influential institution, with political and economic sensitivities surrounding it. In practice, the NHS is a loose confederation of organisations working both co-operative and un-co-operatively together to provide patient care to the UK population. In 2006, it had a budget of £84 million and employed 1.3 million people. As the Audit Commission points out:

> It comprises some 600 different organisations, each with its own responsibilities and operating to different sets of financial rules and incentives. They interact with each other and also contract with independent providers ranging from GPs to private hospitals. (Audit Commission 2006:2)

1.2.1 Definitions

This research has adopted a number of specific definitions.

- Hard healthcare technology: considered as the physical artefacts that support healthcare technology systems (e.g. pharmaceuticals, medical devices, and the physical facilities that provide the context for healthcare technology systems).

- Soft healthcare technology - practices, protocols, processes and formal service designs that structure the provision of healthcare, often in conjunction with hard technologies.
- Healthcare technology: A healthcare technology is any technology for which the purpose is the maintenance or restoration of human health. This research makes the assumption that healthcare technologies are usually used as part of a wider healthcare technology system and rarely in isolation. This definition is discussed further in Chapter 2. Healthcare technologies can have a number of purposes:
  - Diagnostic: used in diagnosing a healthcare condition.
  - Therapeutic: used in treating a healthcare condition.
  - Assistive: used to support patients with a healthcare condition.
  - Operational: used in the operational management of healthcare.
  - Informatic: used to mange information relating to healthcare.
- Users: This relates to the individual or teams responsible for applying a technology rather than those benefiting from the application of the technology. For example, the user of a medical device is the individual who applies the device, and is not necessarily the individual to whom it is applied. For many healthcare technologies, the users will be clinicians and other staff in professions related to medicine. In an instance where a healthcare technology is "self-applied", the user is also the patient.
- Innovation: The whole process of developing a novel idea or invention through to gaining value from the invention either directly through financial returns e.g. royalty fees, or in the context of healthcare the improvement in efficiency or effectiveness of a healthcare process.
- User-led innovation: an innovation that is driven by a user-innovator. In contrast to a research-led or supplier-led innovation. A detailed discussion of user-led innovation is given in Chapter 2.
- Research-led innovation: innovation resulting from a formal research project with the clearly articulated purpose to invent a new healthcare technology.

- Supplier-led innovation; an innovation driven predominantly by a technology supplier in response to a perceived commercial opportunity.
- User-innovator: technology user who innovates a technology that they use in their normal work.
- Innovation team: the team led by a user-innovator involved in a user-led innovation project.

1.3 Research aims and objectives

1.3.1 Research aims

The overall aim of this research is to explore the phenomenon of user-led innovation in the NHS. To achieve this overall aim the following subsidiary aims were addressed: produce an in-depth understanding of the characteristics of user-led innovation in the NHS; identify the processes that user-innovators follow in order to develop their innovations; establish the enabling and inhibiting factors affecting progress of user-led innovation; and evaluate the extent to which the NHS provides a supportive context for user-led innovation to occur.

1.3.2 Research objectives

Objectives of the research were to:

- Review the literature that underpins an understanding of the phenomenon of user-led innovation the NHS.
- Set out an appropriate methodology that will enable rigorous investigation of user-led innovation in the NHS.
- Carry out an exploratory study into the innovation support provided by NHS innovation hubs.
- Identify and investigate four NHS sites, in order to develop distinctive case studies of user-led innovation based on the perspectives of user-innovators.
- Use the case study findings to establish the enabling and inhibiting factors affecting user-led innovation.

- Based on the case study findings and theory within the existing literature, synthesise models that aid understanding of the nature and process of user-led innovation.

1.3.3 Research questions

The research sought to answer four exploratory questions on the nature of user-led innovation in the NHS. The questions were:

- What are the characteristics of user-led innovation projects in the NHS in terms of: their purpose, the people involved and the criteria used for judging success?
- How do user-innovators in the NHS manage and structure the innovation process?
- What is the nature of the technology created through user-led innovation in the NHS?
- How and for what purpose do user-innovators evaluate their innovations as they are developed?

1.4 Outline of the thesis

The thesis consists of further nine chapters. A brief overview of each chapter is provided below.

Chapter Two: Literature review

This chapter focuses on the key concepts that underpin an understanding of the phenomenon of user-led innovation in the NHS. It reviews and synthesises the literature underpins this research providing a theoretical perspective on: the nature of healthcare technology systems, user-led innovation, and the NHS as a context for user-led innovation.

Chapter Three: Methodology

Presents an overview of the methodology adopted in the research; it explains and justifies the research design adopted for the research.

Chapter Four: Exploratory study

Reports on the findings of an exploratory study into the formal support provided to user-innovators in the NHS. It reviews both the UK government policy on NHS innovation and the practical support given to NHS staff by the NHS innovation hubs.

Chapter Five: Case Study 1 - Leg Ulcer Telemedicine System (LUTM)

This case reviews the development of a leg ulcer telemedicine system created by a vascular surgeon working in a general NHS hospital in the Birmingham. The telemedicine system underpinned a significant change in service design and the implementation of a shared-care model of leg ulcer treatment.

Chapter Six: Case Study 2 - Electronic Pelvic Floor Assessment Questionnaire (ePAQ)

This case reviews the development of ePAQ, an electronic questionnaire created for use in a uro-gynaecology outpatient clinic. The development of the innovation from an early stage to creation of a spin-out company, in parallel with its evolution from paper-based to web-based questionnaire is described. The ePAQ system has had a significant impact on the effectiveness of the clinical interview between consultant and patient when diagnosing uro-gynaecological disorders.

Chapter Seven: Case Study 3 - Cleft lip and palate study model (CLP)

This case examines the role of a change in process in the creation of plaster study models used to audit the effectiveness of cleft lip and palate. The case highlights the process of user-led innovation within a department of a teaching hospital, but also in relation to the wider issue of treatment audit across centres within the UK.

Chapter Eight: Case Study 4 - Pain management Service (PMS)

This case outlines the innovation in the process re-design of a pain management. The services was based within an acute hospital and served five primary care trusts. The innovation in service design was based around the implementation of a bi-psychosocial model of pain. The case examines how the innovation developed from a crisis in service provision to becoming embedded within national care guidelines and a model of best practice.

Chapter: Nine: Research Questions Revisited

This chapter provides a review of the research findings in relation to the research questions identified at the start of the research.

Chapter Ten: Conclusions

The conclusion sets out the main contributions made by this thesis to development of a theory of user-led innovation and its implications. Finally, the chapter sets out areas for further research.

The references section and appendices is presented at the end of the thesis.

Chapter 2: Literature Review

2.1 Introduction

This chapter reviews the literature that underpins an understanding of the phenomenon of user-led innovation in the UK National Health Service. The chapter is split into sections that each address an aspect of the subject area.

The first section reviews the technology literature in order to develop a better understanding of the scope of the technology concept within the healthcare sector. The review considers perspectives from technology studies, social theory and institution theory literature. The second section develops a definition and establishes the characteristics of user-led innovation that distinguish it from other modes of innovation. The third section reviews the organisational learning and knowledge management literature to develop an understanding of the problem of knowledge translation, a critical process for ensuring that user-led innovation can draw on multi-disciplinary knowledge from within and external to the organisation. The final section assesses the NHS as a context for user-led innovation. The section evaluates how culture, organisational structure and policy supports and retards user-led innovation.

2.2 Healthcare technology systems

Healthcare, and the healthcare services provided by the NHS in particular, are inherently complex. There are three related reasons for this. First, the remit of the NHS means that it has to provide an extremely broad range of services, from minor treatments delivered by a GP, to treatments delivered by multi-disciplinary teams. For example, in the case of cancer treatment, effective treatment relies on co-operation between oncologists, surgeons and radiographers, with each group applying their own specialist technologies. Second, to meet the individual requirements of patients, all of these services have to be customised, to a greater or lesser extent, for each patient treated. A central tenet of the UK NHS is that the patient care should be tailored to an individual's needs (UK

Government 2000:17). Consequently, there is a tension when designing healthcare processes between providing either standardised or customised services. Standardisation has the potential to reduce costs, reduce involvement of specialist staff, increase scope for application of quality assurance and implement evidence-based practices. In contrast, customised services will ensure that patients are given highly specific treatments, based on direct contact with specialist staff. The optimum balance for the NHS is to be able to provide services that enable mass-customisation. Finally, organising the technical, human and organisational resources necessary to respond to these demands creates further complexity. Consequently, when discussing innovation of healthcare, it is almost impossible to separate the technical, social and organisational dimensions of healthcare provision.

To develop an understanding of healthcare innovation it is necessary to apply a working definition of a healthcare technology system. Since such systems are not limited to the physical artefacts used for diagnosis, therapy or the operation of healthcare services. Healthcare technology systems also involve the knowledge and capabilities built up by individuals and organisations over time. This section argues, therefore, that the study of healthcare technology innovation must be sensitive to both technical development and wider socio-technical issues.

The concept of healthcare technology relates to an eclectic range of technologies, from sticking plasters to systems concerned with the treatment of cancer. The problem in understanding healthcare technologies and their innovation, is that a successful technology is not simply defined by a specific physical artefact. Individual technical artefacts can have multiple diagnostic and therapeutic purposes. For example, in the case of image-guided therapy the technology has the ability to diagnose a tumour and then apply therapeutic radiation (Yanof and Kuhn 2006:140). More critically, different groups of users can apply technology differently, while addressing the same problem.

> With some image-guided applications, the clinical protocols and technical methods are under varying stages of clinical investigation. There may be multiple approaches to achieve the same therapeutic objectives and have they can have complex trade-offs. Clinical protocols and use of technology may vary between, or even within

> institutions, and always depend on the presentation of each patient. (Yanof and Kuhn 2006:146)

This demonstrates the extent to which human systems influence the use of technological artefacts. In this example, human agency in the form of critical and reflective practice allow the optimisation of a treatment. Therefore, healthcare technologies are implemented into, and become an embedded and integral part of complex systems for maintaining the health of humans. Human agency is not the only factor however in shaping technology. Social structures will also influence the use of technology. Institutionalised regulation of healthcare has created jurisdictional, moral and administrative governance structures (Webster 2007:134), that impact on how technology is used. While these social structures may be highly formalised, it is also evident that highly localised structures influence use of healthcare technology, for example, patient safety sub-cultures (Ginsberg et al. 2006:103). The use of technology is therefore a product of the relationship between, and interaction of, structure(s) and human agency. These relationships are discussed in more detail later in the section. This section will set out the conceptual basis on which the research defines healthcare technology and the implication for its innovation.

2.2.1 Defining technology

Before addressing the nature of a healthcare technology, it is useful to consider how general definitions of technology impact on an understanding of healthcare technology. The overwhelming conclusion of reviews that list definitions of technology (Roberts and Grabowski 1996; Howells 2004; Orlikowski 1992) is that technology is a complex concept. Many definitions provide only partial descriptions, a problem in even using the term "technology" is its multiple meanings. Souitas suggested the use of an OECD 'Oslo Manual' definition of technology, that suggests it can be:

> ...interpreted broadly as the whole complex of knowledge, skills, routines, competence, equipment, and engineering practice. (Souitaris 2003:513)

However, the OECD in a later edition of the Oslo Manual, suggest that the word technological is too problematic to use in relation to the study of innovation as:

> ...the word raises a concern that many service sector firms would interpret technological to mean 'using high-technology plant and equipment', and thus not applicable to many of their product and process innovations (OECD and EUROSTAT 2005:17).

Despite this ambiguity, there is consensus that technology is concerned with solving problems through the application of knowledge:

> ...the total knowledge and skills available to any human society for industry, art, science, etc. (1994:1583)
>
> Any tool or technique: any product or process, any physical equipment or method of doing or making by which human capability is extended. (Schon 1967)

Technological knowledge and modes of enquiry are very distinct from, for example, scientific knowledge and scientific method. The latter is concerned with discovery of fundamental physical truth, while the former is concerned with developing solutions to problems encountered by humans.

> ...technological knowledge is knowledge of how to do or make things, whereas the basic sciences have a more general form of knowing. (Layton 1987:603)

Thus technological knowledge is not simply the practical application of scientific knowledge; as witnessed by the way technological knowledge precedes scientific knowledge. For example, the invention of the steam engine and design of aerofoil profiles both preceded scientific explanation of their operation (Vincenti 1990).

Ellul raises the concern that humans have little control over the path of technological development and that there is a deterministic quality to technology: "human beings have to adapt to it and accept total change" (Ellul and Bromiley 1989:136). Technological determinism suggests that creation or use of technology will lead to inevitable social change, however this may be a flawed view of the relationship between technology and society (Edgerton 1999). When new technologies are implemented there is no guarantee that they will be adopted or their use will impose a specific social order (Barley 1986). It is however useful to recognise that technological trajectory is not easily reversible, for example American society's dependence on the internal combustion engine.

This suggests that the problems created by a current technology are the sources of future technological solutions (Kranzberg 1986). Thus dependence on the internal combustion engine has driven development of bio-fuels.

A contrasting view to technological determinism, is the view that technology is socially constructed and shaped by human interaction (Bijker, Hughes, and Pinch 1987; Bijker 1995; Pinch and Bijker 1984; Bijker and Law 1992; Garud and Rappa 1994). Several studies have to the body of work on social construction of technology (SCOT). Bijker highlights how the development of technologies, such as the bicycle, bakelite and fluorescent lighting, is profoundly affected by how the meanings associated with a technology develop in an on-going process of social construction, in which frames of reference on a technology are created by relevant groups of users. Through a process of interpretive flexibility the meanings associated with a technology evolve until finally forming rhetorical closure (Bijker 1995; Bijker, Hughes, and Pinch 1987).

Heidegger suggested that technology provides a distinct mind-set, beyond a set of tools (Heidegger 1977). Thus, a technological world-view has a fundamental influence on the way people act by "enframing" or "throwing" them in technology (Ihde 1993; Borgmann 1984). This means that they view the world through technology, rather than seeing technology as simply tools with which to act on the world. Though Heidegger warned about the de-humanising effect of technology, his overarching message is that a technological caste of mind can benefit humanity. Teich (2003) made a similar point:

> The tools themselves are not the technology; it is the use to which they have been put that marks them out as a technology, and it is people who do the putting to some use for some purpose. (Teich 2003:12)

Technology is therefore not neutral and will impact on the intentions and purposes of people who interact with it (Kranzberg 1986).

Winner explores technology's lack of neutrality and suggests it has an explicit political role. Using large technological systems as examples, he suggests a theory of technological politics in which technologies will "demand" or shape social structures (Winner 1985:27). First, the nature of a specific technology cam settle "... an issue in a particular community". Secondly, technologies

may require or be "strongly compatible with particular kinds of political relationship". This view is echoed in critical theories of technology in which technology is viewed as hegemonic and supports the interests of particular social groups (Feenberg 2002). This view of technology draws on Gramsci's view of hegemony, suggesting that opposition to an established technology can fly in the face of common sense, or prevailing popular and practical beliefs (Kirkpatrick 2008:75). This highlights the extent to which technology can create bases of power that serve the interests of a specific social or gender groups (Cockburn 1981).

2.2.2 Hard and soft technologies

The discussion so far demonstrates that a working understanding of technology must encompass several dimensions. Mitchum, for example, identified technology as having four dimensions: knowledge, activity, objects and volition (Mitcham 1994). This definition maintains a useful distinction between components of technology based on tangible artefacts; and those based on technological knowledge, systems of activity and human decision-making in relation to technology application. The distinction between artefacts and the more intangible aspects of technology has been categorised as hard and soft technology respectively (Swamidass and Nair 2004). Soft technology has been more specifically defined as:

> ...systems of thought, practice and action that facilitate the achievement of explicit aims. (Bessant and Francis 2005)

Soft technologies therefore include systems of thought that enable the application of hard technology, but also those that enable improvement and change in the application of a hard technology. The distinction between hard and soft technologies is useful as it highlights an ontological separation between technologies that are physical and those that are knowledge-based. This distinction is appropriate to healthcare technology. Within healthcare, hard technologies include devices, drugs, facilities etc. Furthermore, and significantly, within the EU medical devices directive (*Directive 2007/47/EC of the European Parliament* 2007) this distinction has been recognised. Hence medical device technology encompasses hard technologies; thus a hard healthcare technology can be seen as including pharmaceutical technologies and:

> ... any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software necessary for its proper application intended by the manufacturer to be used for medical purposes for human beings for the purpose of:
>
> - diagnosis, prevention, monitoring, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
> - investigation, replacement or modification of the anatomy or of a physiological process,
> - control of conception,
> - and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; (*Directive 2007/47/EC of the European Parliament* 2007:23)

Soft healthcare technologies include the practices, procedures and services designs used in patient care. These soft technologies would therefore also include knowledge embodied in processes and procedures used to support patient care - e.g. surgical procedures, care plans and protocols. Good examples of this would be: procedures for carrying out specific key-hole surgery; recommended care protocols, for example treatment of leg ulcers(RCN 1998); service design (Moffatt et al. 1992), national level care guidelines based on health economics (NICE 2005); and, at an operational level, application of improvement strategies, such as Lean or 6-Sigma (Eldridge NE et al. 2006).

The implication of the above discussion for the study of healthcare technologies is that it is not simply the physical artefact that must be considered. These artefacts are tied into processes for delivering care, analogous to manufacturing production systems based on jobbing, flow and mass customisation processes. The layout of these processes is subject to innovation, as is their management and control. So for example, a surgeon will use a physical artefact, within a surgical

procedure (a process), which in turn is within broader system for managing the flow of the patient through the healthcare service (a management and control system).

2.2.3 Socio-technical views of technology

The distinction between hard and soft technologies highlights the need for including the social dimension of technology when discussing healthcare technology systems. Technology must therefore be viewed in the context of a socio-technical system (Trist 1981), with technological solutions encompassing both machines and social machinery (Teich 2003:14). Central to this understanding of technology is the recognition that the choice of individuals to understand, use and apply technology is separate from the physical artefacts of technology. Hence the role of technology is subject to processes of social construction (Orlikowski 1992).

Of particular significance is the argument that the socially constructed nature of technology has a fundamental impact on its innovation. In a study of the development of cochlear implants, it was found that for two independently developed devices, the perceived purpose of the device affected the final design and evaluation (Garud and Rappa 1994). The difference in the two devices was explained by the contrasting sets of assumptions built into the teams' respective cognitive frames. Similarly, within the NHS the meanings and assumptions associated with healthcare technology systems, for example treatment centres, have also been shown to be subject to multiple interpretations between government, strategic health authorities and front-line clinical staff (Pope et al. 2006).

The SCOT perspective is recognised as providing a valid perspective on technology, consequently it is generally accepted that technology cannot be treated as a given. Instead it is an equivoque open to several possible or plausible interpretations (Weick 2001:148).This suggests that implementation of technology cannot be viewed in a deterministic fashion. The role of individuals in making choices about the use of technology must be recognised; technology cannot and should not be treated as a "black box" (Jones 1999:125). Therefore, a coherent perspective of technology must recognise the relationship between human agency and technology; and conversely the extent to which human agency shapes technology. For example, Orlikowski argues for a narrow definition of technology but emphasises the strong relationship with both human agency and social structures:

> In defining my concept of technology, I restrict its scope to material artefacts (various configurations of hardware and software). I wish to sustain a distinction...between the material nature of technology and the human activities that design or use these artefacts...[and] facilitates my framing of the role of technology in terms of a mutual interaction between human agents and technology, and hence as both structural and socially constructed. (Orlikowski 1992:403)

Orlikowski notes the limits of using a single construct for technology when attempting to analyse the relationships between humans and technical components:

> ...even as we gain in generalisability, we have lost the ability to ask questions about how artefacts interact with human agents. By aggregating task, technique, knowledge, and tools into a single construct – technology – interaction among these constituting components and with humans is ignored. For example, we cannot examine how different assumptions, knowledge, and techniques can be embedded in different kinds of artefacts or practices, and how these have differential consequences for human action and cognition. (Orlikowski 1992:399)

This is a significant point in relation to healthcare technology showing it cannot be defined only in terms of artefacts; much of the power of modern healthcare is in the skills, techniques, practices, contexts and methods of organisation. Most importantly, the reflexive nature of the healthcare professions means that even clearly defined healthcare processes are subject to customisation for each patient. It is these factors that increase the complexity of healthcare technology and its innovation.

A healthcare technology system therefore comprises two significant technological sub-systems:

- Hard technology - considered as the physical artefacts that support healthcare technology systems (e.g. pharmaceuticals, medical devices, and the physical facilities that provide the setting for healthcare technology systems)
- Soft technology - including the practices, protocols, processes and formal service designs that structure the provision of healthcare, often in conjunction with hard technologies.

The distinction between these two sub-systems is important, as hard and soft technologies are ontologically distinct. The four modes of reality suggested by Fleetwood (Fleetwood 2004) are useful in understanding the distinction between hard and soft technology. Hard technology can be regarded as a synthesis of the materially, ideally and socially real. In addition to their material existence independent of individuals or communities, hard technologies are mediated by a limited range of interpretations that apply to the technology. Hence, a heart-lung machine is clearly a materially real entity; however, mediated by accepted interpretations that it has a specific purpose within specific surgical procedures. In contrast, soft technologies are social entities and have no physical existence. Instead, they are better understood as socially real and have "not one iota of materiality" (Fleetwood 2004:201). Soft technologies are distinct from physical machinery and are closer in their mode of existence to skills, rules, social structures and institutions.

By making this distinction between hard and soft technologies, it is possible to analyse a healthcare technology system without running the risk of aggregating the interaction between physical artefacts and human interaction. The above discussion highlights that hard and soft technologies are not simply two ends of a spectrum. They are two distinct types of technological entity. Technological systems will to a greater or lesser extent include both classes of technology.

The implication of understanding healthcare technology in these terms is that it is necessary to understand the role of human agency in healthcare technology systems and consequently how structural factors enable or inhibit human action

Orlikowski's rationale for narrowly defining technology in terms of only physical artefacts was that she was concerned to highlight the interaction between human agency, social structures and technology. This was done through application of structuration theory (Giddens 1984). Structuration theory attempts to fill a perceived gap in social theory by explaining the duality of structure and agency, emphasising the:

> ...reciprocal interaction of human actors and organisation structure. The central idea is that human actors or agents are both enabled and constrained by structures, yet these structures are the result of previous actions by agents.(Sarason 1995)

Structuration theory has however been described more as a meta-theory (Weaver and Gioia 1994) and does not directly address technology, however its utility is that:

> …it tells us what sort of things are out there in the world, not what is happening to or between them. (Craib 1992:108)

Orlikowski has however led the application of structuration theory specifically to the study of technology (Orlikowski 1992; Orlikowski 2000). She highlights that structuration theory is helpful in four ways to understanding technology. It addresses:

- the extent to which human agency impacts upon technology use and purpose, suggesting that technology is a product of human agency;
- the extent to which technology acts as a structural influence on human agency;
- the influence of other social structures on the use of technology;
- the impact of technology on social structures.

The relationship between technology, social structures and human agency is summarised in Figure 2.1.

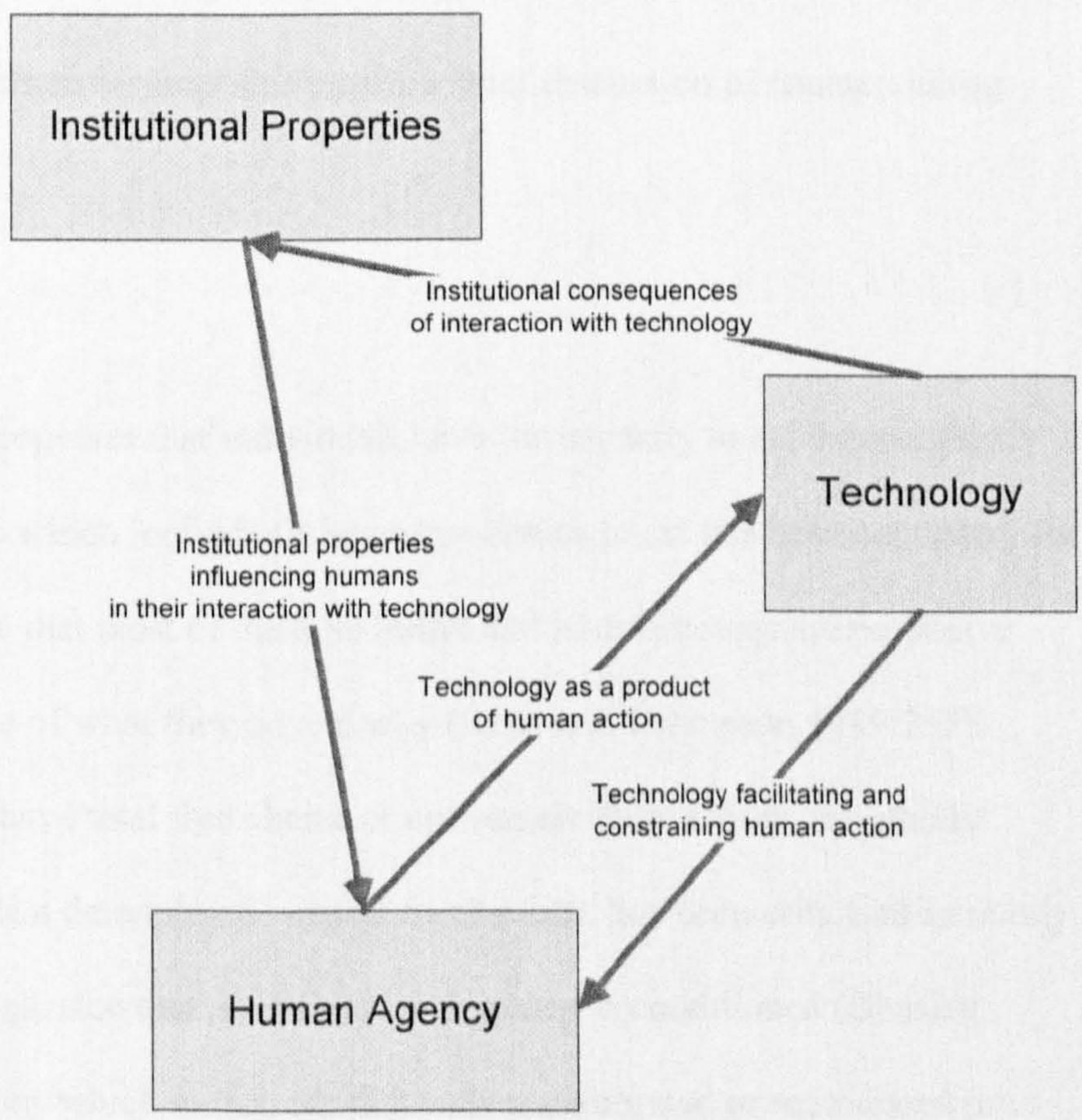


Figure 2.1: Orlikowski's structurational model of technology (Orlikowski 1992)

Orlikowski's model highlights that the socially constructed roles and meanings associated with a technology are subject to interpretive flexibility (Orlikowski 1992; Pinch and Bijker 1984). It also models the process through which technology and its users undergo a mutual adjustment over time (Leonard-Barton 1988). In the context of healthcare technology systems this iteration between the scope and role of technology has been demonstrated in the case of specific medical technologies during their development and use, for example, cochlear implants (Garud and Rappa 1994), cataract surgery (Mina et al. 2004; Metcalfe, James, and Mina 2005). The fundamental point to note here is therefore that the agency of developers and users of technology inevitably impact on both soft and hard technology.

When applying Orlikowski's model to healthcare technology several problems emerge which are rooted in the assumptions that underpin structuration theory:

- social structures are only instantiated as a result of ongoing human agency
- they have no independent existence;
- human actors exert free choice in what they do; and,
- past events have little impact on the ongoing process of structuration.

In order to address the problems these assumptions create, a brief discussion of countervailing views of agency is necessary.

2.2.4 Human agency

The concept of human agency recognises that individuals have the capacity to act independently of their social context. The extent to which individuals have free choice to act has been contested; for example, Giddens' takes the view that most of the time individual human beings are purposive actors, acting with full knowledge of what they do and why (Held and Thompson 1989:253). However, to suggest individuals have total free choice or conversely their actions are wholly controlled by social structures, via a deterministic causal mechanism, has been criticised as overly simplistic. Instead, it has been suggested that an individual's agency is conditioned (Bhaskar 1989:94) by wider social structures, which in turn are themselves elaborated or reproduced over time (Archer 1995:157; 2003:3).

An individual's actions can be disaggregated into three elements of agency: iterational, projective and practical-evaluative (Emirbayer and Mische 1998). These elements are of particular relevance to understand how agency relates to technology. The iterational element is concerned with theories of practice and reflects the reactivation of past patterns of thought and action, routinely or habitually incorporated in practical activity (Emirbayer and Mische 1998:971). The projective element in contrast can be viewed in terms of strategic thought applied to use of the technology through generation of possible future trajectories of action. Finally, the practical-evaluative element is concerned with the capacity to make practical judgement in response to non-routine, evolving situations. In relation to technology, this can be compared to craft skill. Human agency in relation to technology can therefore be separated into three areas. Where technology is used on a habitual, unconscious basis; where strategic choices about its future use are made; and where, using acquired skill, technology is applied in new ways in response to a new situation. These three elements of agency underpin the development of capability to use hard technology.

The healthcare sector is one that has grown progressively over several hundred years. The way the sector operates at any time is a product of not just human agency but structural influences built into the healthcare technology system. For example, the use of hospital buildings built in the early twentieth century for twenty-first century healthcare, places a significant constraint on the layout of service provision. Similarly, the adoption of new procedures is dependent on strong, clinically backed evidence and economic tests of efficacy. No individual actor can legitimately act outside these norms of practice. The existing range of technologies available in the sector also limits the extent to which a new technology may be implemented. Any new technology must fit into the existing technological architecture or have the resources available to replace existing architectures of healthcare. The service design of healthcare is another structural constraint on healthcare technology innovation. The introduction of new technologies may require radical reconfiguration of a service, including changing location, layout, facilities, job roles ands skill requirements.

As discussed above the extent of choice available to human actors is constrained. This is particularly the case when examining professional roles in healthcare. The strong professional identity of healthcare professionals is a major constraint on the way that they act. This identity is built into the professions at the level of training, professional codes of conduct and even in

legislation. For example, doctors who have taken the Hippocratic Oath have their freedom to act in extreme circumstances greatly constrained, for example in the area of palliative care. While such actors have the choice as to whether to enter the profession, or not, the rules of the game are such that if someone wants to have a healthcare career within the NHS they must follow accepted patterns of behaviour in the way they pursue their career.

The limits to how an individual is either able to make choices or is constrained in how they act with regard to technology, suggests that extension of Orlikowski's structurational model of technology to healthcare technology requires further clarification of the nature of both human agency and institutions. Human agency needs to be considered to enable a better understanding of how soft technologies are developed and maintained in relation to hard technologies. The nature of institutions needs consideration, as several institutions exist within the healthcare sector that enable or inhibit the creation and implementation of hard and soft technology.

Conflation of agency and structure

A number of scholars have been critical of structuration theory's conflation of structure and agency (Archer 1995:132; Bhaskar 1989:36; Willmott 1997; Archer 2003:2). Barley and Tolbert summarise these concerns about conflating structure with action:

> Conflation concerns the problem of reducing structure to action (or vice versa) and the difficulty of documenting the existence of an institution apart from activity. Unless institutions and actions are analytically as well as phenomenologically distinct, it is difficult to understand how one can be said to affect the other. (Barley and Tolbert 1997:99).

Other writers have suggested that for both agency and structure there is a clear distinction. Carter and New suggest that:

> ...each [structures and agents] possess distinct properties and powers in their own right (often referred to as sui generic properties and powers). (Carter and New 2004:5)

Based on this discussion it is critical to note that social structures are ontologically distinct from human agency.

Impact of the historical development of technology

Giddens' account of structuration theory also underplays the role of time in the process of structuration. The current configuration of a technology is deeply coupled to its historical development. During a technology's development contemporary assumptions, values and knowledge are embedded into the technology itself. Even many years later, these embedded factors will continue to influence human activities. When considering the relative roles of both hard and soft technology it is important to recognise the historical basis on which their trajectories are built (Clark 1985). Technology is however capable of embodying accepted ways of working, for example in the design of computer software. Orlikowski suggests that:

> Technology is built and used within certain social and historical circumstances and its form and functioning will bear the imprint of these conditions. (Orlikowski 1992:411)

This is very well illustrated in the way in that technology systems embody legacy elements that are the result of influence by organisational structures and technology users. It was observed during World War Two that artillery crews would pause for several seconds before firing motorized weapons. It reportedly required a veteran to explain that this pause was for "holding the horses" (Morison 1966), this was a routine that had been vital in the past but had been followed unquestionably, despite the phasing out of horses in the artillery. In his example, though the hard technology had evolved, the soft technology still embodied practices from many years earlier. Similarly, the continued use of the QWERTY keyboard in the face of improved designs has been argued to be due to the establishment of the soft technology of touch typing technique (Gould 1997).

In healthcare, this is a central consideration as hard technology, such as devices and even facilities, impacts on how patient treatment can occur. Thus, any new technology must fit within the existing infrastructure of hard and soft technologies. For example, in implementing new angioplasty techniques for treating heart attacks there is a need for changing both the skills of staff and the infrastructure in which they operate (Department of Health 2008; Nugent 2008). Similarly, the established soft technologies involved in healthcare are often deeply embedded in institutions associated with specific professions and professional healthcare education. For example, it was

reported that endovascular techniques for treating intra-cranial aneurisms were slow to be adopted until neurovascular surgeons training was changed, stroke units evolved and evaluation of the technology accepted by the profession; all these factors representing structural barriers to the new technology (Wilson 2006). Similar institutional factors have been suggested as affecting adoption of minimal invasive surgery techniques for hernia repair (Darzi and Mackay 2002). This implies that any action taken by healthcare workers in relation to technology is conditioned by the history of both hard technology and associated institutions. It is for this reason that an analysis of healthcare technology must include related institutions and must also explicitly recognise the temporal linkage between structure and agency (Archer 1995:65).

Institutions

The discussion so far demonstrates that systems of healthcare technology consist of social structures, human agents, and hard and soft technologies. To support an understanding of the structural elements of a technology system it is useful to utilise the concept of institutions:

> ...multifaceted, durable social structures, made up of symbolic elements, social activities and material resources. (Scott 2001:40)

Technology has a significant temporal component and so in building a model of a healthcare technology system it is useful to recognise the role of institutions in this development over time. In common with technology, institutions are social structures that retain aspects of this history:

> ...institutions are accretions of past practices and understandings that set conditions on action. Unless an institution exists prior to action, it is difficult to understand how it can affect behaviour and how one can examine its implications for action or speak of action's subsequent affects on the institution. (Barley and Tolbert 1997)

Institutions attain a high degree of resilience over time (Scott 2001:48) and so even where a technology was developed in the distant past, its impact can be carried within an institution. The nature of institutions is such that they:

> are relatively resistant to change...tend to be transmitted across generations (Scott 2001:49).

Interaction with technology can act to reinforce structural properties over time. This suggests that in using a technology individuals will often unconsciously be reinforcing institutions through their interaction with technology. This is

> ...often not reflected on by users, who are generally unaware of their role in either affirming or disrupting an institutional role status quo. (Orlikowski 1992:411)

The adoption of an institutional perspective on technology also highlights the legal, moral and cultural elements that interact with technology. It is for these reasons that this research adopts institutions as the principle social structure of interest in this research.

Institutions have an existence separate from human agency and can be defined as:

> ...social entities characterised by their self-regulating nature...[comprising] relatively widely diffused practices, technologies, or rules.(Lawrence, Hardy, and Phillips 2002)

Institutions operate on a basis of not just shared norms and values, but also shared knowledge and belief systems (Scott 2001:39). Institutions include formal organisations, such as an individual hospital, to entities that act across several organisations such as professions. An institution may not relate directly to any formal organisation. An example of this is evidence-based medicine. This is a coherent set of practices, technologies and rules, that is not linked solely to one formal organisation. However, as an institution it creates forces that influence many aspects of the medical practice. Finally, communities of practice represent an important category of institution (Orr 1996). Unlike professional bodies, a community of practice lacks formal structure, or even formal recognition (Brown and Duguid 1991). Within healthcare however, the strength of communities of practice, for example around a specific clinical service, are of relevance to the process through which services innovate.

Pillars and carriers of institution

It is useful to apply a model of institution that links the various elements of institution and the mechanisms through which they are carried. Scott presents a review of institutional theory and then develops a comprehensive model of the elements and carriers of an institution (Scott 2001). He identifies three pillars to institutions: regulatory, normative and cultural-cognitive.

Each of the three elements of institution are embedded in organisations via various carriers (Jepperson 1991:150). Scott suggests four categories of carrier: symbolic systems, relational systems, routines and artefacts. Table 2.1 illustrates the typical pillars and carriers that underpin institutions.

Table 2.1: Pillars and carriers of institutions (Scott 2001:77)

Pillars / Carriers	Regulative	Normative	Cultural-cognitive
Symbolic Systems	Rules, laws	Values, expectations	Categories, typifications, schema
Relational systems	Governance, power systems	Regimes, authority systems	Structural isomorphism
Routines	Protocols, operation procedures	Jobs, roles, duty	Scripts
Artefacts/objects	Comply to specifications	Comply to convention	Possessing symbolic value

All four carriers underpin an understanding of how institutions impact upon healthcare. Healthcare is an area in which symbolic systems are common and include: rules and laws used to regulate healthcare practices; values and expectations of professional practice; and shared cognitive frames held by staff working in healthcare. Similarly, the relational systems in healthcare are also important carriers. Governance systems, such as those for primary and acute healthcare services, are pervasive in the sector, while authority systems in healthcare are dominated by those possessing specialist knowledge. This has resulted in authority being gained not just through formal governance systems but also through possession of specialist knowledge (Rushmer et al. 2004). Many organisational routines in healthcare are based around standardised protocols and operating procedures, such as those defined by regulatory bodies. The expected norms of professionalism often define the scope and content of healthcare workers' jobs and roles. Hard and soft technologies are ubiquitous and critical components of healthcare services and as such is an important category of artefact to consider when looking at the relation between innovation and institutions.

Scott's model of institution highlights the potential for varying levels of analysis (Scott 2001:83). These could range from a world system through to the level of an organisational sub-system. Thus, the influence of institutions can be considered at both the macro and micro level; the potential for recognising institutional forces acting at multiple levels may also need to be considered. For

example, within public healthcare technology systems there is a need to recognise forces exerted by high level institutions such as governments and regulatory bodies. Conversely, even at a micro-level there will be strong institutional forces perhaps created at a very local level within a single organisation such as a hospital. Institutions may therefore take very different forms depending upon the level of analysis.

For example, Table 2.2 illustrates an institutional analysis of the organ transplant technology systems within an organ replacement service (Stahl, Vacanti, and Gazelle 2007). This shows the institutional structures that impose regulative, normative and cultural-cognitive influences on the operation and development of associated services.

Table 2.2: Pillars and carriers of institution: as applied to organ transplant technology systems, adapted from (Scott 2001:77)

Pillars / Carriers	Regulative	Normative	Cultural-cognitive
Symbolic Systems	Legal controls on organ transplant and replacement technologies and their use.	Ethical codes of conduct for organ replacement.	Accepted knowledge-base for organ replacement technologies considered suitable for human use.
Relational systems	Professional/legal codes of practice.	Accepted models of governance for organ transplant services.	
Routines	Standardised procedures for organ transplant services.	Established job roles and skill-sets of staff involved in transplant services.	Local communities of practice within organ transplant services.
Artefacts/objects	Medical technologies meeting requirements set by regulatory authorities.	Organs for transplant that match agreed and accepted standards.	Evidence base underpinning use of organ replacement technologies.

Proto-institutions

An institutional analysis can also consider the evolution of institutions over time. The extent of acceptance and influence of institutions develops over time. It has been suggested that institutions in their early stages of evolution can be viewed as proto-institutions:

> practices, technologies and rules that are only narrowly diffused and only weakly entrenched, but that have the potential to become widely institutionalised (Lawrence, Hardy, and Phillips 2002).

This is an important concept in relation to healthcare technologies as it provides a means of understanding the structural qualities of healthcare technology systems and process through which

they become accepted. For emerging healthcare technologies a proto-institution will be representative of the structures that support the technology and allow it to be implemented within an organisation. Diffusion of the technology will be contingent on diffusion of the proto-institution.

2.2.5 Institutions and hard and soft technology

Technologies are not neutral in their relationship with either institutions or human agency. Barley's study of the implementation of MRI scanners demonstrated that despite the relatively fixed functionality of MRI scanners, the effects of both structure and human agency led to very different implementations of the same technology, in two apparently similar settings (Barley 1986). This suggests that to understand the innovation process of a healthcare technology system it is important to be clear about the status of soft technology encompassing the knowledge, skills, routines and processes that develop from users' interaction with technology, conditioned by institutional context.

For this research, both technological competence and capabilities are used to define the scope of soft technology (Boisot 1998:5; Savory 2006). Technological competences are concerned with enabling the use of a hard technology to a required level of performance. These relate to single-loop levels of learning (Argyris 1976) and include:

- Explicit, codified knowledge associated with the technology, its design and operation.
- Procedural knowledge and competence in the actual implementation of the technology (Zander 1995)
- Embodied knowledge, skill and expertise held predominantly by individual gained through use and experience of a hard technology (Blackler 1995; Zuboff 1988:36)
- Tacit knowledge held by communities using and applying technology (Orr 1996; Wenger 1998)

In contrast, technological capabilities embody double-loop learning in order to developing strategic skill in applying, improving and integrating technology. Technological capability includes:

- Dynamic capabilities required to select adopt and abandon technology (Eisenhardt and Martin 2000; Helfat and Peteraf 2003; Kogut and Zander 1992; Teece, Pisano, and Shuen 1997; Leonard 1995).
- Performance improvement capabilities, organisational process to support the on-going improvement of the technology and its application (Pisano 1996; Pisano, Bohmer, and Edmondson 2001)

A soft technology over time will take on institutional properties. For example, this is illustrated in the way continuous improvement (CI) programmes becomes established within organisations (Bessant, Caffyn, and Gallagher 2001). In the early stages, CI is a set of piecemeal, poorly coordinated activities. In contrast, a mature CI capability is embedded within the whole organisation's structure and culture.

It is particularly useful to consider soft technologies in institutional terms when studying their innovation. Soft technology can exist at various stages of institutionalisation. For a newly developed soft technology a very low level of institutionalisation will have occurred. The institutional features of such a soft technology are embryonic and can best be viewed as a proto-institution. Over time the soft technology will diffuse more widely, with its institutional structures becoming more established, accepted and adopted.

This has been demonstrated in healthcare areas such as cataract surgery and hip replacement (Metcalfe and Pickstone 2006). In these cases, soft technologies developed around the new hard technologies of replacement lenses and implantable hip joints. Early on these developed as proto-institutions, having limited organisational prominence. It was only over of time that they became more widely institutionalised. In the case of cataract surgery, it was necessary for resistance from existing institutions to be overcome, before the new technology was fully diffused and institutionalised. Some elements of the proto-institution develop into major institutional structures. For example, a proto-institution of cataract surgery included a small group known as the International intra-Ocular Club, this eventually developed into an important professional group for cataract surgeons, the European Society of Cataract and Refractive Surgeons.

Soft technologies represent a fourth sub-system within healthcare technology systems. They are the product of human agency, change over time and though their widespread institutionalisation lead to institutional change. In short, soft technologies are the technological competences and capabilities built up around hard technology.

2.2.6 Section summary

This section has drawn on three streams in the research literature: technology studies, social theory concerned with the relationship between structure and human agency; and institutional theory. It concludes that in understanding healthcare technology it is important to recognise the socially constructed element of technology, especially in terms of a specific technology's accepted meaning and purpose. The frame of reference adopted by a group of users on a technology is therefore crucial not only to it use, but also its ongoing development. Thus innovation of healthcare technologies is not a purely objective process. The section highlights the scope of healthcare technology to be beyond just hard technologies such as medical devices. The development of technology is also concerned with soft technologies, the competences and capabilities that enable effective use had technologies. The section considers the role of institutional structures in relation to technology and recognises the extent to which institutional structures support the use of the technology and its development. The implication of this section is that technology forms an intrinsic component of institutions. Finally, the section concludes that during innovation of healthcare technologies, proto-institutions are created that represent the critical elements of institution necessary for effective implementation of a technology.

The following section reviews the literature in order to produce a working definition of user-led innovation.

2.3 User-led Innovation in the healthcare sector

This section uses the innovation literature to develop a working definition of user-led innovation that is applicable to the healthcare sector. The section concludes by defining user-led innovation in the context of the healthcare sector, describing the typical characteristics of user-led innovation projects and defining key terms associated with this definition.

2.3.1 Defining innovation

Broad based definitions of innovation highlight the breadth of the innovation concept and differentiate it from other processes, such as invention. Schumpeter defines innovation in terms of the actions required to introduce a new or qualitative change in a product; or new pattern of organisation such as a production process (Schumpeter 1934). This definition assumes the main unit of analysis to be the firm, rather than industry sector, and the innovation process to include activities from invention through to the production of a new product or implementation of the new process. It does not specifically relate to public-sector organisations. More recently, the OECD have defined the term innovation as:

> ...the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations. (OECD and EUROSTAT 2005:47)

The OECD definition mirrors that of Schumpeter but in common with Rogers, stresses that the novelty of the product or process is assumed at the level of the firm or individual, rather than to an industrial sector or the world (Rogers 2003:12). The definition does not preclude its application to public-sector organisations providing services. An innovative product or process may already be in existence in the context of some other organisation. The OECD definition takes a pluralist view of what constitutes an innovation including changes to products, processes, marketing methods and organisational methods. This definition provides a useful framework for looking at innovation in the NHS as in many cases the innovation will often be a combination of product, process and organisational structure.

The emphasis of both these definitions is on the implementation of the novel ideas. This implies that an invention, will not be classified as an innovation until it has been successfully implemented. However to study innovation processes it is important to recognise that an invention that is yet to be implemented might be viewed as a nascent innovation. The timescale may mean that the invention will be perhaps several years from becoming recognised as an innovation. Conversely, nascent innovations, such as patented technologies that are never commercialised, may in time be

recognised as failed innovations. Failed innovations are still instructive about the innovation process and the actors that play a part in that process.

The concept of innovation has however become overloaded and can refer to both to both outcome and process. It is important to be able to characterise innovation in terms of products or processes; as well as the process through which these are developed.

2.3.2 Innovation as an outcome

The first characterisation of an innovation is as an outcome. Innovations can range from the relatively minor, representing incremental improvements, or can be radical new breakthroughs, including new technologies (Freeman 1974). At an industry level a distinction has been drawn between continuous and discontinuous innovation (Tushman and Anderson 1986; Moore 2005; Bessant 2005). Continuous innovations improve, while preserving, the current way of doing things, in contrast discontinuous innovation result in disruption to the *status quo*. For continuous innovation organisational learning is a central to the innovation process allowing steady improvement of products or process; often with established organisations well placed to drive the innovation process. In contrast, disruptive, dis-continuous or break-through innovations are often associated with new-entrant firms, while established firms are severely challenged (Christensen 2000). Types of technological innovation can be seen as lying along a continuum between incremental and radical change. In the case of products, incremental innovation is likely to occur at the level of individual components, while more radical innovation will tend to take place at an architectural level (Henderson and Clark 1990).

The distinction between continuous versus discontinuous perspective is useful for product or process innovations, but within a healthcare context, innovation is rarely based around a single artefact or process. Innovation in the delivery of health services is better viewed as a process of technological innovation that focuses on a technology system rather than a single technology. Lettl *et al* point out that radical innovation is multi-dimensional phenomenon linking technology, market, organisational change and environmental alterations (Lettl, Herstatt, and Gemuenden 2006). Drejer highlights that a feature of service innovation is the interplay of organisational, external relationship, formalisation and *ad hoc* innovation (Drejer 2004). Tether does however

warn that service innovation can be more subtle often proceeding incrementally and through less obvious means including human skills and or inter-organisational co-operation (Tether 2004).

Within a healthcare setting interpretation of what constitutes an innovation has resulted in the development of various categories. At a crude level, distinction is made between technological innovation and service improvements (HITF 2004). In a review of innovation studies, four categories of innovation were identified: organisational practices (comprising service and climate innovations); new organisation structures; new technologies; and new roles (Lansisalmi et al. 2006). The review found it surprising that only 13% focused on new technology. The review authors however may be missing the point about the nature of healthcare technology. The concept of the technology complex (Fleck and Howells 2001) illustrates that the distinction between technological and organisational innovation is blurred. From this perspective focusing on either technical innovation or organisational innovation, is likely to give only a partial view.

Bower has discussed the distinction between embodied (e.g. pharmaceutical products, medical devices) and disembodied (e.g. surgical procedures) innovations in the context of health care (Bower 2003). She highlights that where both embodied and disembodied innovations combine, complex innovations are the result; resulting in changes at the artefact level and the professional practice level of the technology. Metcalfe *et al.* reinforce this point and note that:

> ...no innovation takes place or diffuses in isolation and the determinants of success for new medical procedures often reside on the development of complementary techniques, drugs and devices. (Metcalfe, James, and Mina 2005)

Christensen has highlighted how innovation in hard technologies has enabled their use by less specialised staff (Christensen, Bohmer, and Kenagy 2000), this has been suggested as having a disruptive impact on existing healthcare technologies. Christensen cites several examples ranging from open heart surgery requiring specialist surgeons to relatively simple procedures, such as patients' self-management of diabetes, that have undergone such innovation. These innovations have led to both changes in the required performance of hard technology and the user group concerned with implementing it. He cites four main levels of use for health technology: medical specialists; primary care staff and GPs; nursing staff; and patients. For each of these levels of use,

hard technologies are created to satisfy the wider needs of the soft technology operated by the user group. Thus, for medical specialists diagnostic devices are likely to be highly accurate, precise and provide a sophisticated user-interface; while for self-care situations the corresponding device is likely to have simple interface with minimal instrumentation, for example heart defibrillators designed for use by laypeople (Little and Katzman 2006:489). The trajectory of innovation will vary for both hard and soft technologies, according to the user group at which it is targeted.

2.3.3 Process models

The second characterisation of innovation is as a process. Since it was recognised that the innovation process could not be treated as a black box (Rosenberg 1982), various process models of innovation have been developed. In reviewing these models several authors have linked these to generations of model (Hobday 2005; Forrest 1991; Marinnova and Philliore 2003; Rothwell 1992), with each generation having a distinct emphasis. First and second generations were concerned with viewing technological innovation in terms of either a technology push (Bush 1945)or pull (Kamien and Schwartz 1975). Third-generation models recognise the close coupling of innovation activities, through a logically sequential, though not rigidly continuous interaction between research and customer demand (Rothwell and Zegveld 1985:50). Fourth-generation models concerned the iterative process of interaction and collaboration between technology suppliers and customers (Kline and Rosenberg 1986; Rogers 2003; Rothwell and Zegveld 1985).

The most sophisticated process models however were concerned with increased strategic and technological integration (Rothwell 1994). The integration of the processes has lead to the recognition of the role of national systems of innovation (Lundvall 1992; Howells 1999; Freeman 1995); evolutionary models (Metcalfe 1995; Metcalfe, James, and Mina 2005; Mina et al. 2004; Tether and Metcalfe 2003) and distributed models (Coombs, Harvey, and Tether 2003; von Hippel 2007).

Linear

The merit of linear models of innovation is in simplicity of description. For this reason, stakeholders in innovation projects may accept it as a reliable model of what is involved in

innovation, creating a blind-spot to the true complexity of the process. This is reflected in Rogers' six-phase model of diffusion, which, he is careful to note, is affected by serendipitous events and so should be used as a:

> ...general guide to the process from which many innovations will deviate (Rogers 2003:158)

It is also worth noting that linear innovation processes often result from application of clearly defined innovation strategies. For example, linear processes have been applied in areas such as: new product development (Cooper 2000; Cooper, Edgett, and Kleinschmidt 2000); information systems planning and development (Ward and Daniel 2006; Ward 1990); and the pharmaceuticals industry (Northrup 2005:54).

Linear models have however been generally discredited as lacking sophistication. In particular, the issue of parallel and recursive activities means that the process is better characterised as a nonlinear, dynamic system than a simple linear model:

> When innovation work begins, the process does not unfold in a simple linear sequence of stages and sub-stages, Instead, it proliferates into complex bundles of innovation ideas and divergent pathways of activities by different organizational units...the process diverges into multiple, parallel, and interdependent paths of activities. (Van de Ven 1999:10)

Criticism has been targeted at the normative and deterministic character of process models of innovation. The use of linear models is however widespread as a means of proving a basic blueprint for technological innovation activities. It has been suggested that linear models have continued to guide public policy, principally because they lend themselves to easy statistical measurement; at best representing:

> ...a theoretical construction of industrialists, consultants, and business schools, seconded by economists. (Godin 2006)

Distributed innovation systems

More relevant to user-led innovation is the recognition of its distributed and systemic nature. It has been identified that innovations are created by innovation systems rather than discrete processes (Edquist 2001). The national and regional systems of innovation literature adopt a macro view of innovation processes and highlight the importance of an infrastructure of institutions to support innovation (Freeman 1995; Freeman 1987; Lundvall 1992). Within industrial sectors, sectoral systems of innovation are based around networks of relationships (Malerba 2004) or technological fields (Carlsson et al. 2002). Metcalfe *et al* highlight that in the case of the healthcare sector:

> ...the changing private vs. public nature of the institutions involved in the innovation process reflects a fundamental aspect of science-industry collaborations...institutions involved in the delivery of health services also appear to be fundamental components of the innovation system.

Coombes *et al* highlight however that innovations often need to draw expertise from across different sectors or technical disciplines; and so even the use of industrial sectors defined by SIC or patent classes may define unsatisfactory boundaries or units of analysis (Coombs, Harvey, and Tether 2003:1146).

The distributed models of innovation highlight the iterative and non-deterministic quality of innovation processes; with the actions of individuals and institutions in the process being unpredictable.

2.3.4 Barriers to innovation

The barriers to innovation can be categorised as either internal or external factors (Piatier 1984). External factors include market and government related barriers; but also technical, social and inter-organisational barriers. Internal barriers include people related, structural and strategy related barriers. It has however been noted that studying the barriers to innovation is intrinsically difficult as failed or disappeared innovators and their innovations are often not counted (Hadjimanolis 2003:569).

The innovation barriers research has been concerned with innovation at a relatively high level. In contrast, users involved in healthcare innovation may face several specific barriers. Lettl suggests that two significant barriers are cognitive barriers (barrier of not knowing) and a lack of willingness (barrier of not wanting) impede users from generally taking part in innovation of radical new health technologies (Lettl 2005:170). It is not unreasonable to also assume that even for incremental innovations, both a lack of either technical knowledge or motivation will impede innovation processes. Organisational context has been noted as a source of significant barriers. For nursing staff developing innovations, it has been suggested that there is a need for:

> ...strong consistent leadership that 'clears the way' for creativity...an effective innovation pipeline...incorporating systematic processes in order for innovations to be delivered...[and the right] behavioural traits and collective mindsets. (Hughes 2006:100).

Other factors affecting the potential for users to be involved in innovation is the close proximity of interdisciplinary know-how and also resources of time, funds and people (Lettl, Herstatt, and Gemuenden 2006:259).

2.3.5 Technology transfer

Universities have been identified as significant and vital institutions within national innovation systems (Nelson 1990). The role of universities is however not purely as a source of innovation in isolation, but as a member of a triple-helix of relationships, spanning universities, government and industry (Etzkowitz and Leydesdorff 2000). The recognition of the importance of IP developed within universities and other public sector research establishments (PSRE), has led to efforts to manage the IP more effectively and to gain revenues for the PSREs. In the USA, this led to the Bayh-Dohl Act of 1981, that enabled universities to own and profit from IP (Mowery, Sampat, and Ziedonis 2002; Nelson 2001). Similarly in the UK increased efforts have been put into technology transfer from PSREs (Baker 1999; Office of Science and Technology 2000; DTI 2004). The result of these measures has been that university technology transfer offices (UTTO) have been created in many universities, with the prime purpose to:

> ...facilitate technological diffusion through the licensing to industry of inventions or intellectual property resulting from university research. (Siegel, Waldman, and Link 2003)

This emphasis on identifying and commercialising new technologies can be viewed as underpinning a purely technology push approach to innovation. Even within a university context, this has not been seen by all writers as always beneficial with the overall returns from the exploitation of university IP being disappointing (Colyvas et al. 2002). The result however has been that there are now explicit mechanisms through which PSREs are able to exploit IP through patenting, licensing and creation of spin-out companies. It has been noted that patents have no intrinsic value until a suitable business model has also been identified (Chesbrough 2003:161). The evaluation of the success of UTTOs in technology transfer has however been highlighted as problematic (Bozeman 2000) due to the difficulty of identifying appropriate measures of the impact of transfers.

Table 2.3: Distinction between innovation in Universities/PSREs and NHS Organisations (Savory 2006)

	University/PSRE	**NHS Organisation**
Context	Research and invention is primary purpose Development of published work improves professional status Experimental and risk tolerant	Operational focus with invention a byproduct of practice Innovation is problem oriented Highly regulated and risk averse
Evaluation criteria for innovation	Quantity of patents and licenses Improved technical human capital Prestige and reputation Political kudos	Improved operational efficiency Improved quality of care Value of income stream from technology licenses
Technology	Hard technologies	Closely coupled hard and soft technologies
Proximity of R&D effort to context of use	Distant Multidisciplinary teams drawn from specialist research staff	Close to the context of use Operationally focused individuals and teams
Mechanisms for diffusion and adoption of technology	Market mechanisms	Diffusion of soft technology

The creation of technology transfer offices has also taken place in the UK NHS. However, Savory has suggested that treating the NHS as simply another public sector research establishment, without recognizing its unique characteristics and distinct differences from universities and research institutes (see Table 2.3), can lead to the use of a sub-optimal model of innovation management (Savory 2006). The implication of this is that the un-critical application of the UTTO model undermines the development of a systemic approach to NHS innovation management.

2.3.6 Closed and open innovation

A alternative perspective has been proposed that highlights the shift from a closed to an open innovation paradigm (Chesbrough 2003). This shift signals a rejection of the assumption that innovation stems from an organisation's internal R&D process; the predominant model of innovation practised by large corporations in the 20th Century. Instead, it is suggested that organisations recognise that the ideas and technologies that underpin its products are as just as likely to be found outside an organisations as within. The principal cause for this shift in paradigm is that in comparison with the early 20th Century, knowledge is now more widely distributed. Knowledge to underpin innovation is no longer created only within an internal R&D organisation, staffed by the main experts in a specialist field. The open innovation paradigm acknowledges a change in the emphasis in how innovation occurs. It is now common for organisations to seek suitable knowledge and technology from external sources.

This has had an impact on the importance of intellectual property (IP) and the mechanisms used for managing and exploiting it. It is now common for companies to explicitly search externally for potentially useful knowledge and technology and where appropriate to negotiate the purchase or licensing of relevant IP, for example Proctor and Gamble's "Connect and Develop" strategy (Sakkab 2002). The paradigm emphasises the need to match up an organisations' own IP with complementary assets from other sources (Teece 2000:p135; 1986; Teece 1998).

The open innovation perspective has much in common with Mode-2 knowledge creation (Gibbons et al. 1994; Nowotny, Scott, and Gibbons 2001; Nowotny, Scott, and Gibbons 2003). Mode-2 knowledge creation emphasises that new knowledge, and consequently potential innovation, can be created outside the domain of traditional scientific research.

The growth of the 'knowledge' industries has not only led to an increase in 'knowledge' workers and a proliferation of sites of 'knowledge production, but has also tended to erode the demarcation between traditional 'knowledge institutions such as universities and research institutes and other kinds of organisations. Novel 'knowledge' institutions are arising – in small and medium-sized high-technology

> companies...management consultancies and think-tanks...corporate universities. (Nowotny, Scott, and Gibbons 2001:15)

The Mode-2 perspective highlights the scope for different forms of knowledge production, highlighting the scope for knowledge workers to engage in innovation activity, in particular technology users as participants and leaders of the innovation process.

A second aspect of the shift towards open innovation has been the increased democratisation of innovation. This shift recognises that the source of ideas underpinning innovation can also be from an organisation's customers. This has been seen as a shift from supplier-centred to user-centred innovation in which lead-users are important contributors to the innovation process (Hippel 2005:122). This highlights the distinction between innovation in which users rather than technology suppliers are active in the innovation process (Voss 1984). For example, GE Plastics were proactive in gaining important insights into new products through collaborative development with key customers seen as lead-users of their technologies (Thomke and von Hippel 2002). This was achieved through a combination of knowledge sharing and the provision of tools for the customer to use. This has shifted the emphasis of innovation study from one where R&D is the primary focus, to one where involvement of lead-users, either individually or in groups, has been made. Hippel highlights that lead-users are a distinct group from suppliers as users hope to benefit from the use of an innovation rather than gaining a benefit from selling the innovation (von Hippel 2007). Examples of where users have taken on lead-user roles include: the fields of scientific instruments (Hippel 1988), sports goods (Luthje 2004; Franke and Shah 2003) and surgical equipment (Lettl 2005).

Figure 2.2 shows how the nature of innovation has shifted from the closed to open innovation paradigm. The result of this shift has been an increase, not only in the absorption of knowledge and technology from outside the organisation, but also the increased participation and control by technology users in the innovation process. The extreme situation is represented by user-led innovation, where users take on the prominent role in defining and managing the development of innovation.

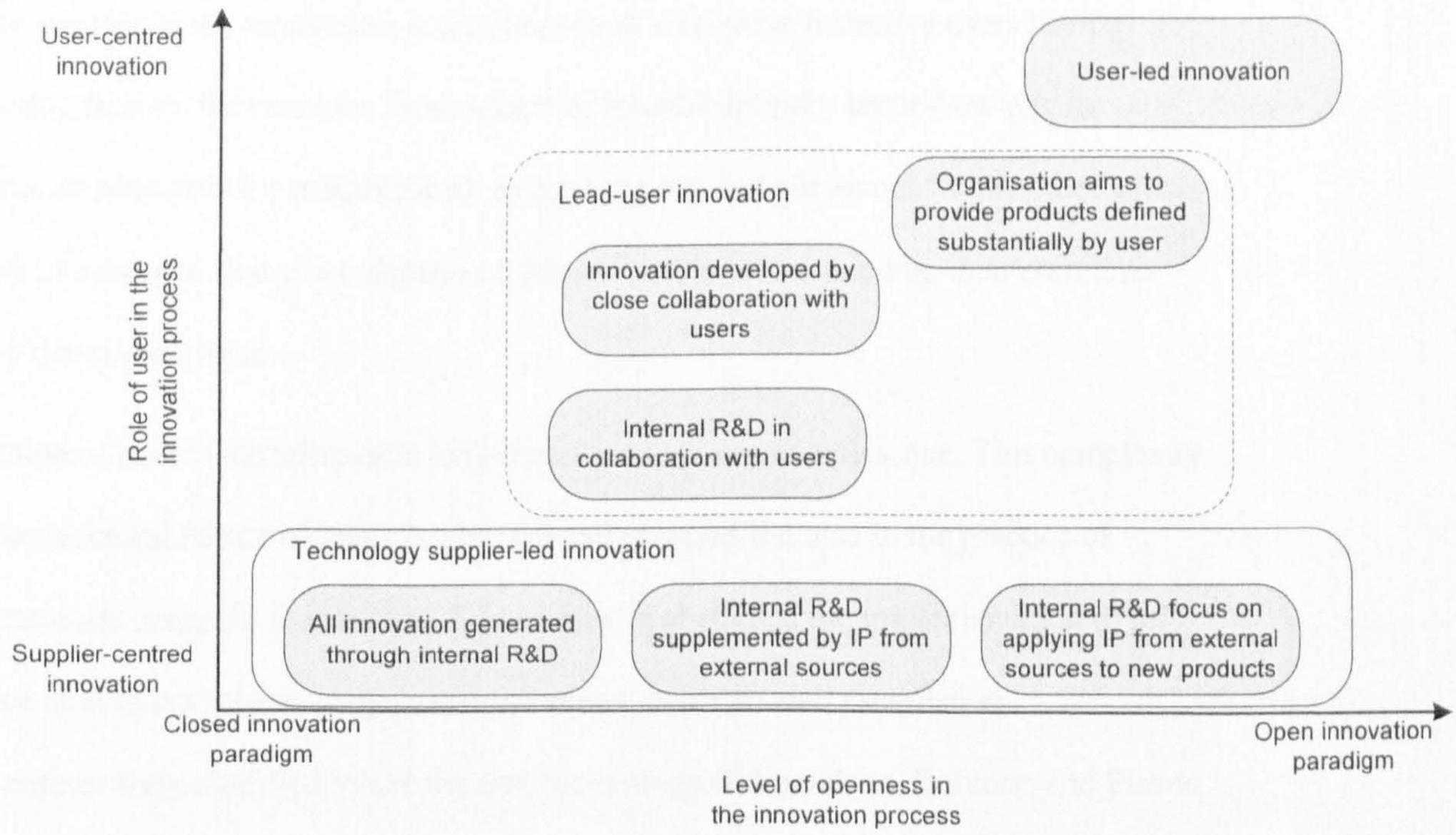


Figure 2.2: Differentiating supplier-led, lead-user and user-led innovation

The open paradigm is important as it represents the basis on which over several centuries much innovation in healthcare has developed. This is most clearly identified in the case of innovation of surgical tools and techniques, where as the principal users, surgeons have often led the innovation process. The open innovation paradigm also highlights the limitations of expecting innovation activity to take place within a single organisation. The challenge in user-led innovation is to ensure that innovations developed by users have timely input from other specialists, in order to ensure successful innovation. In the context of healthcare this implies that even where a user, such as a clinician, invents and develops an innovation, there may be a point where the project needs to be augmented with other technical and business skills. User-led innovation can be a powerful mechanism for allowing the "voice of the user" to be embedded in the innovation process, however, there will be a point where the "voice of the engineer" or "voice of the business specialist" needs to established.

2.3.7 Role of users in healthcare innovation

In healthcare technology, Lettl has suggested that surgeons take on the role of originators, developers, entrepreneurs and marketers. The entrepreneurial role is characterised as: high problem pressure, user as inventor, high degree of innovativeness, missing competences and resources. These factors leading to the innovator selecting, forming and co-ordinating an innovation network

(Lettl 2005). The context of the innovation is also important with some inventive users having access to supporting factors, for example, close access to interdisciplinary know-how e.g. in teaching hospitals, or resources for research such as time, money and personnel. While other users with lower levels of access to resources, depend on intrinsic motivation spending their own time and resources on developing ideas.

The implementation of novel technologies in health care settings is a complex one. This complexity lies not just in the technical nature of many healthcare technologies but also in the practice of healthcare professionals using the technology. Edmondson *et* al studied the implementation of an innovative device used in open-heart surgery and the extent to which well established organisational routines were modified to use the new technology (Edmondson, Bohmer, and Pisano 2001). The study concluded that crucial to the implementation was the role of surgical staff as leaders in changing the way operating theatre teams worked together. Authority structures, psychological safety and team stability were all found to affect the ability of a team to develop the new organisational routines needed to support technology implementation. This example of healthcare innovation highlights the need to consider the organisational aspects of technology in particular the organisational routines built up around existing and new technology; and the way that certain routine need to be disrupted or unlearned (Orlikowski 2000).

It is common for clinicians to be closely involved with technological innovation either in isolation from the wider healthcare industry or in some form of partnership, for example with manufacturers of medical devices. User-led innovation in healthcare is likely to take a very different form to other sectors due to the complex institutional framework in which healthcare products must be developed and implemented.

User-led innovation in the healthcare sector

Some examples of user-led innovation in healthcare have been presented in the literature (Hughes 2006; Lettl 2005; Lettl, Herstatt, and Gemuenden 2006; Metcalfe and Pickstone 2006). Unfortunately many examples of user involvement are based around lead-user involvement or other forms of participation in supplier-led innovation, (for example, (Shah and Robinson 2006, 2007).)

Metcalfe *et al* describe an example of a major innovation in healthcare, the development of intra-ocular lenses (OLC) to treat cataract (Metcalfe, James, and Mina 2005). This case recognises the extent to which user-led innovation can underpin significant healthcare innovations; the development of effective cataract treatment. The innovation

> ...radically transformed the conception, design and delivery of a major medical service, the removal of cataracts combined with their replacement by a functioning lens. (Metcalfe, James, and Mina 2005:4)

The study highlighted how the clinicians concerned did not simply invent a potential solution, the original surgeon and the subsequent network of other clinicians, acted to complete the innovation process by addressing many procedural, organisational and institutional issues. The subsequent innovation process

> ...was achieved by the creativity of individual inventors combined with the transnational medical-industrial complex that has changed radically the innovation system in this field of ophthalmic medicine. A procedure originally based around pioneering 'hero-surgeons' deploying 'craft technique', has evolved into a 'routine, quasi factory' procedure capable of being effected in a local medical centre by clinician nursing staff, whose education and training has correspondingly changed. This indeed is a fundamental transformation of a service activity and its skill base. (Metcalfe, James, and Mina 2005:4)

Their work highlights that user-led innovation is concerned with not just changes in technology but also the technological capability required to makes use of technology, often in the face of professional hostility. This can entail radical change of organisations and institutions.

Innovation diffusion in healthcare

An integral part of the innovation process is diffusion to adopters of the innovation. Only through diffusion can an invention be effective in terms of profit or less tangible benefits such as general good to humanity. Innovation diffusion is critical part of the overall innovation process and relies

on four crucial elements: the innovation, communication channels, time and social systems (Rogers 2003:11).

Adoption rate can be affected by an innovation's characteristics, including: relative advantage; compatibility, complexity, trialability; and observability (Rogers 2003:15). But also, the characteristic of the adopter, with early adopters having very different characteristics to laggards of technology (Rogers 2003:283). Within a healthcare context other specific factors affect adoption including: existence of homphilious groups; the pace of innovation/re-innovation; norms, roles; and social networks (Cain and Mittman 2002).

The adoption of healthcare innovations can be problematic. It has long been recognised that a major factor in adoption in healthcare technology is not the:

> ...performance characteristics but the way in which various actors in the organisational system assess its likely impact on them and their perogatives. (Kimberly and Evanisko 1981)

A major source of this resistance are the boundaries between professional groups that may operate using distinct knowledge bases and research cultures. These can make the transfer of innovations across multi-professional organisations, such as hospitals, very problematic (Ferlie et al. 2005). In the context of health devices, it has also been suggested that critical factors affecting adoption are the subjective expected value of the device and the level of evidence provided to support its effectiveness (Roback et al. 2007).

In a systematic review of literature on healthcare innovation adoption it was acknowledged that interpersonal influence and opinion leadership were critical to adoption, but acknowledge that it was unclear how clinical and nonclinical social networks served as channels for the social influence and the reinvention and embedding of complex service innovations (Greenhalgh et al. 2004).

Structuration theory and technological innovation

In the area of innovation some application of structuration has been attempted with respect to the innovation process (Jones, Edwards, and Beckinsale 2000) and to the relationship between organisation identity and innovation (Nag, Corley, and Gioia 2003). The application of

structuration theory to innovation studies is limited, with little or no explicit use of structuration theory, for example, Giddens is not directly referenced in several key works (Hippel 2005; Rogers 2003; Rothwell 1994; Tidd and Hull 2003) on user or service oriented innovation.

The advantages of taking a structuration view of innovation over either an individualist or a structural view of innovation have been noted (Slappendel 1996). Slappendel emphasises that much innovation research has either focused on the individual or has been concerned with structural influences on innovation. She suggests that innovation research should take an 'interactive process perspective' of innovation, that recognises both the deterministic and volunteristic aspects of social systems'; recognising the 'various levels of analysis and clarifying the connections' between action and structure; link action and structure with 'different phases in a temporal sequence'; applying theories of the action-structure relationship, such as structuration theory. This highlights the need to recognise the link between structure and agency within the user-led innovation process.

2.3.8 Section summary

Based on the discussion in the section, his research defines user-led innovation in the context of the healthcare sector in terms of the following characteristics:

- The innovation is instigated by the users of a healthcare technology. These users take on the role of user-innovators and may be clinicians, staff in professionals allied to medicine or staff responsible for the operation of healthcare organisations.
- The innovation occurs within the context of a healthcare technology system comprising both hard and soft components.
- The innovation is a response to a problem perceived by the users in the course of their work. The problem, in turn, creates an opportunity for the user to develop a viable solution.
- User-led innovation projects are controlled predominantly by the users instigating them. Industrial partners and other stakeholders may be enrolled into the project but the majority of power in decision-making lies with the user-innovators.
- User-led innovation projects may sometimes need to address institutional change as a part of their development.

- User-led innovation takes place within an open innovation network of staff, or may be the work of a limited group of staff. User-led innovations may be developed at a very local level, however these innovations may rely on the wider network for knowledge, resources and innovations.

Based on this definition several terms are suggested as useful for describing user-led innovation projects.

User: the user of a healthcare technology. This may be a healthcare worker but may also be a carer or a patient.

User-innovators: A user-innovator is a user who takes a prominent role in developing a healthcare technology innovation.

Innovation team: User-led innovators may form teams that use staff from within and external to the organisation support the innovation project. Team members may not be direct users of the technology.

Industrial partners: As part of the technology transfer process associated with user-led innovation, industrial partners such as device manufacturers may be enrolled into the innovation team.

Invention: User-led innovation will be based on ideas or inventions by the user-innovator.

Product: The result of a user-led innovation process may result in a new product such as a device or new service design.

2.4 Innovation as a process for knowledge translation

It has long been recognised that the invention of new technologies is not simply the preserve of specialists, working within the bounds of their own specialism. Adam Smith noted that it is the case that inventions can be the combination of previously disconnected bodies of knowledge.

> All the improvements in machinery, however, have by no means been the inventions of those who had occasion to use the machines. Many improvements have been made by the ingenuity of the makers of the machines, when to make them became the business of a peculiar trade; and some by that of those who are called philosophers or

> men of speculation, whose trade it is not to do any thing, but to observe every thing; and who, upon that account, are often capable of combining together the powers of the most distant and dissimilar objects. (Smith 1981:76)

By making this point, Smith is highlighting that a significant challenge for inventors and innovators is to absorb knowledge from other specialisms and to apply them in their own. This is not simply a challenge for individual "philosophers or men of speculation", it is also a problem at the level of the organisation. It is now accepted that innovation will inevitably involve combining previously separate technologies and bodies of knowledge, innovation as a process of *bricolage* (Garud and Karnøe 2001:23). The ability to absorb and apply knowledge is therefore a prerequisite for an organisation that seeks to facilitate technological innovation. Conversely, to gain value from innovation, especially with respect to a user-led innovation, it is necessary to facilitate the subsequent diffusion of knowledge from the organisation, in order to ensure the diffusion of the innovation to other contexts.

An organisation's ability to apply knowledge from outside has been termed absorptive capacity (Cohen and Levinthal 1990; Zahra and George 2002), or hybridisation (Howells 2004; Howells 1997). In the healthcare sector, knowledge translation is a term used for describing the transformation of research knowledge into practical healthcare situations (Davis et al. 2003). Knowledge translation is a useful term in relation to the study of user-led innovation as it encapsulates the processes required for knowledge to be generalised or diffused away from an original context; transferred between contexts; and then re-applied in a new context. The capability to translate knowledge is however not easily defined by organisational procedures. In contrast, the absorption of knowledge can be seen as critical and dynamic organisational capability, representing complex organisational learning. This suggests that an organisation's ability to absorb, re-create and subsequently diffuse knowledge associated with technological innovation can be viewed as a knowledge translation capability (Savory 2006, 2006, 2009).

The section will review the key concepts from the knowledge management literature relevant to knowledge translation. It then sets up discusses the problem faced by user-led innovation in order to both absorb and diffuse knowledge relating to technological innovation.

2.4.1 Knowledge translation: the knowledge management problem

The ability to combine an organisation's internally developed knowledge with externally sourced knowledge has been described as a combinative capability (Kogut and Zander 2003, 1992). This capability is concerned with combining knowledge into organisational and technological opportunities from: the organisation's existing information and know-how; internal learning e.g. reorganising, accidents and experiments; and external learning e.g. acquisitions, joint ventures, new people. In their account of combinative capability, Kogut and Zander highlight the inherent difficulty in transferring knowledge and emphasise the need to codify knowledge so that it can be applied to new contexts. However, despite the scope for codifying knowledge it was recognised that knowledge is built on prior knowledge, making the adoption of proximate technologies easier for organisations than those that are completely foreign to an organisation. This preference for technologies closer to the familiar, reinforces the path dependence of capability development. The theory of combinative capabilities is a useful starting point for considering how technological capability is built from the translation of existing knowledge. However, Kogut and Zander raised the question of what social fabric needed to exist in order to support the learning of a new capability.

Absorbing knowledge

The process of absorbing knowledge requires both the transformation of imported knowledge and reconfiguration with internally generated expertise leading to the organisation developing:

> ...highly elaborate and structured knowledge tailored to its concept of innovation...social and cognitive and change is fundamentally qualitative and incremental in nature. (Howells 1997)

Leonard highlights the need for a mutual adaption between technology and the user (Leonard-Barton 1988). This is based on the need to combine the knowledge associated with the technology and the knowledge existing with the users. On a wider scale, at the level of an industry or society in general, this mutual adaption can be seen in terms of changes to technological frames or transformations through an actor-network (Bijker 1995). Actor-network theory in particular stresses that the various stakeholders using a technology will each modify or hybridise knowledge

as the technology is applied and re-applied (Law 1999). This highlights that the absorption of knowledge is based on re-creation of knowledge and so a translation capability must be concerned with knowledge creation as well as knowledge transfer. Leonard has set out a useful framework for considering the development of technological capabilities based on the activities of problem solving; implementing and integrating, experimentation and importing knowledge (Leonard 1995:8). These four activities provide a useful basis for understanding the key activities required to import and re-configure knowledge.

Transferring knowledge

While there is a point at which knowledge translation involves re-creation of knowledge, several mechanisms for transferring knowledge also need to be supported. These mechanisms are based on the need to transfer abstracted, codified or tacit forms of knowledge.

Boisot described the transformation knowledge undergoes as it is moved from its original domain to a new situation using the I-space model (Boisot 1998). He highlighted abstraction, codification and diffusion as three potential processes for supporting knowledge transfer. His model provides a basis for understanding knowledge translation.

Abstraction: Abstraction is concerned with the extent to which knowledge is situated in a specific context. While tied to a very specific, concrete situation knowledge has a low level of abstraction. Through processes of abstraction however, knowledge can be transformed so that it has a more general application. For example, within the car industry, knowledge of car suspension dynamics can be abstracted away from the context of Formula 1 racing into general principles. General principles regarding suspension dynamics are valuable as the knowledge they encapsulate is in a form that can then be applied into a new local context e.g. saloon cars through a process of assimilation into a new context. Abstracted knowledge has therefore been stripped of detail that is only relevant to a specific context. The role of abstracted knowledge in knowledge translation is critical. Abstract knowledge provides the:

> ...ability to represent phenomenon in terms of a limited number of 'essential' elements, rather than in terms of their 'concrete' features. (Arora and Gambardella 1994)

Therefore, the ability to abstract knowledge from its original context enables the stickiness (Szulanski 2000, 1996; von Hippel 1994) of technological knowledge to be reduced. Typical examples of abstracted knowledge include scientific laws, generalised heuristics and best practices such as clinical care guidelines.

Codification: Boisot identifies knowledge codification as a process that supports the process of knowledge abstraction. This process is concerned with the extent to which knowledge is made explicit (Nonaka and Takeuchi 1995; Polanyi 1958). Typical examples of codified knowledge would be drawings, technical specifications, patents, text books and mathematical formulae. Codified knowledge exists separately from the human actors who create the knowledge. Codified knowledge is therefore knowledge that has been separated from tacit understanding and placed into a form that can be accessed by others. Access to codified knowledge is of course contingent on possession of relevant skills, hence to access a mathematical model of car suspension dynamics mathematical ability is required. The embedding of knowledge in hard and soft technologies, for example design knowledge embedded within CAD software (Blackler 1995) can also be seen as a knowledge codification mechanism. Knowledge abstraction clearly depends on effective processes of codification.

Knowledge diffusion: Diffusion is the third process identified by Boisot to explain knowledge transfer. Diffusion is concerned with the extent to which knowledge transfers away from it original context. While abstraction and codification can aid the process of diffusion, it is still plausible that abstracted and codified knowledge remains only in its original context. An example of this might be where knowledge is kept secret for commercial purposes. In the context of innovation, however, knowledge diffusion is necessary either as a source of knowledge for inventors or as a mechanism for enabling the diffusion of subsequent innovations. Thus publishing a book, filing a patent or presenting information at an academic conference are all mechanisms for diffusing abstracted and codified knowledge to new situations. Unfortunately, for effective transfer, diffusion processes must also address tacitly held knowledge.

The extent to which tacit knowledge is capable of being transferred has been the subject of much discussion. At one extreme the view is that by definition, tacit knowledge cannot be made explicit

(Polanyi 1958). Others have taken the view that it is possible for tacit understanding to be re-created by others. For example, the process of socialisation, for example through apprenticeship enables tacit understanding to be shared (Nonaka and Takeuchi 1995). The social linkages between people within and external to an organisation will also enable knowledge conversion. Communities of practice are can be viewed as the prime unit of analysis when considering the informal structures that support organisational learning (Wenger 1998). They are relevant to an understanding of a knowledge translation capability as they will inevitably be a source and destination for translated knowledge. A KTC must be able to span several communities of practice within and outside an organisation to be effective. The main strength of communities of practice as a unit as analysis, is their emphasis on situated learning, this in turn allows the development of localised, specialist knowledge. This has been suggested as a key source of innovation (Lave and Wenger 1991; Tyre and von Hippel 1997).

The linkages between individuals, teams, departments or divisions are central to the transfer of knowledge within organisations. These links can vary between strong, formal relationships; and weak, highly informal relationships. Though intuitively it can seem that strong links will be most effective for sharing knowledge, both strong and weak links have been found to have strengths (Hansen 1999). Strong linkages are most effective for transfer of complex knowledge, though are relatively costly to maintain. Weak linkages however are more effective for transferring simple forms of knowledge and can be maintained for lower cost, for example, less need for frequent contact or reciprocal arrangements. Strong links can inhibit wide searches for information by restricting searches to established communication channels (Henderson and Clark 1990). It has also been suggested that loose inter-personal ties are least likely to transfer redundant knowledge i.e. knowledge already accessible to a group (Granovetter 1973). The implication for a knowledge translation capability is that an optimum situation is to have strong ties where there is a clear need, while organisational support for promoting weak ties is also needed, for example knowledge mapping, databases on intranets etc.

2.4.2 Section summary

This section has discussed the relevance of Boisot's learning cycle to knowledge translation and highlights the problems faced by individuals, groups and organisations in developing an effective knowledge translation capability. Savory has discussed the basis of a knowledge translation capability and highlighted the need for effective processes to:

- strategically scan for the existence of relevant knowledge outside the organisation;
- maintain internal and external linkages for transferring knowledge;
- absorb knowledge from outside the organisation;
- and, diffuse knowledge out of the organisation. (Savory 2006)

This suggests that a challenge facing user-led-innovation projects and the user-innovators leading them, is the development of effective knowledge translation mechanisms to support user-led innovation, as illustrated in Figure 2.3.

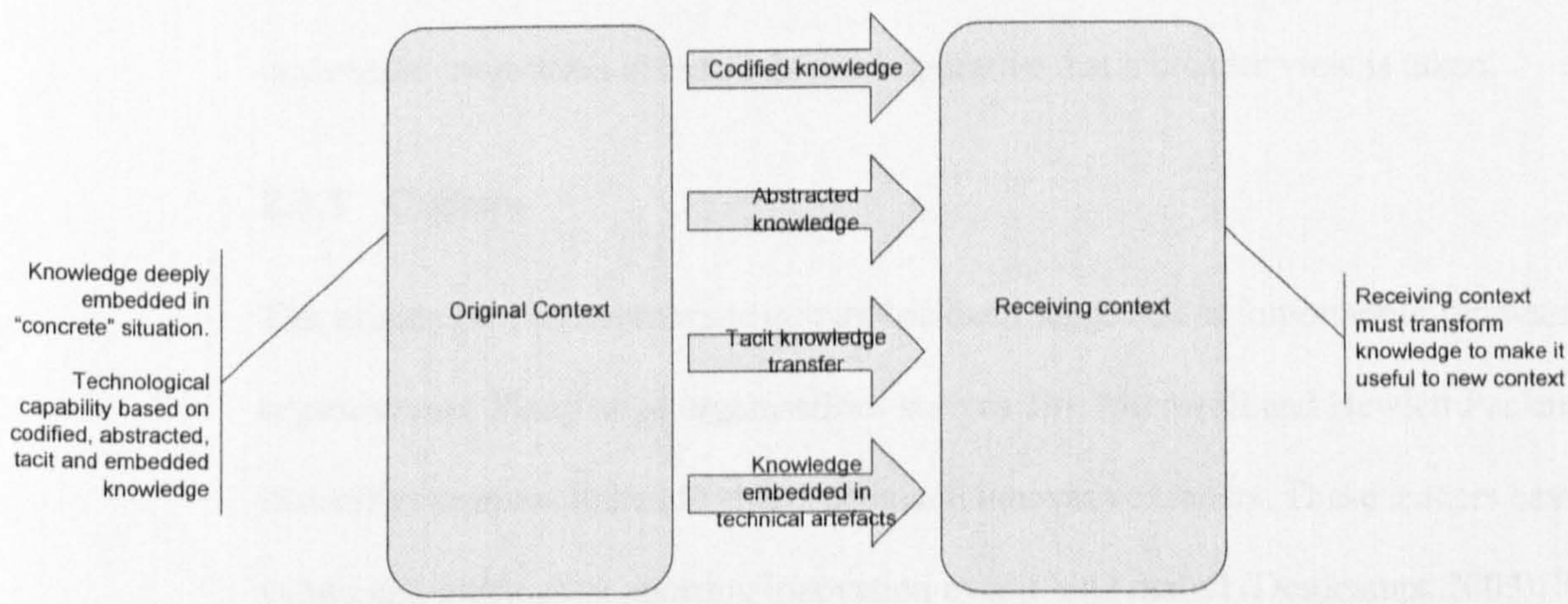


Figure 2.3: The knowledge translation problem

2.5 The NHS as a context for user-led innovation

The nature of innovation in any organisation is complex. In the case of the NHS and its hospitals, innovation can take many forms making it a particularly complex context for innovation. One source of this complexity is the range of specialist groups and the diversity of services that are provided. It is suggested that to understand innovation in hospitals it is best to treat hospitals as healthcare technology system hubs providing complex services; rather than more simple

organisations delivering production functions, based on collections of technological and bio-pharmacological capacities and or information systems (Djellal and Gallouj 2005). Treating a hospital as a healthcare technology system hub allows the complex interrelationships to be recognised. It would be easy to see hospital innovation simply in terms of medical innovation of hard technologies, including biomedical/bio-pharmacological substances and medical devices; or soft technologies such as care protocols, diagnostic or therapeutic strategies. Similarly, innovation goes beyond the application of information technologies to healthcare. Within their own model of hospital innovation, Djellal and Gallouj stress the innovation of services as the main unit of analysis, rather than a specific technology. They suggest that innovation results in the extension, specialisation, intensification or recombination of a service's constituent technologies. These changes to a service will result at the component and architectural levels of technology (Henderson and Clark 1990). By maintaining a focus on the service however, a link is maintained between the technology and its implemented use in the organisation. The implication of this is that while it is useful for pharmaceutical companies, medical device manufacturers and even universities to consider medical innovations from the perspective of specific hard and soft technologies, to understand innovation in hospitals it is imperative that a broader view is taken.

2.5.1 Culture

The existence of an appropriate culture has been suggested as important to innovative organisations. Many large organisations such as 3M, Microsoft and Hewlett Packard have innovative cultures linked to charismatic and innovative leaders. These leaders have influenced values and practices supporting innovation over a long period (Deschamps 2003). The presence of an innovation culture may be a pre-requisite to encouraging technological innovation in the NHS. This raises the question of whether the NHS does have an innovative culture? Any attempt at characterising the culture of the NHS is prone to generalisations simply because of the size and diversity of the organisation. Several observations can, however, be made.

The primary base of power in the NHS is medical knowledge, and because of this doctors in particular hold significant power (Worthington 2004). This places them in a position to set strategic direction or set agendas. Other healthcare professionals such as nurses and paramedics hold lower

levels of power and influence, these groups do however have power to block or resist change. The powerful position of doctors leads to scientific method being the primary process for validating knowledge. This has implications for technological innovation as evaluation of technology tends to be based on a search for scientific fact. This may be limiting as epistemologies based in the social sciences carry less credence (Jones 2001). Thus despite the need to recognise the socio-technical dimension of technology, NHS decision-making is underpinned by a knowledge validation process based on a positivist epistemology. Though alternative epistemologies have been used in clinical settings (Reason and Bradbury 2000), they remain marginal. This strong positivist worldview is illustrated by a statement from a senior manager at the NHS Modernisation Agency, who commented that information needed to be presented to clinicians:

> ...in a format that is easily understood and statistically valid, which appeals to doctors. (Rogers, Silvestor, and Copeland 2004)

It is revealing from this statement that in order to drive improvements to organisational rather than medical operations, NHS decision making requires scientific levels of proof. As increasingly recognised in the management literature, this may lead to a myopia in which only the measurable is managed, or even believed.

The cultural propensity for scientific knowledge leads to initiatives being led by scientific method. For example, the NHS has since the early 1990s placed emphasis on evidence-based clinical practice. This approach to clinical practice is concerned that where research data is available it should drive clinical practice. There have also been moves to develop evidence-based policy in the NHS. Both these initiatives are an attempt to transfer scientifically validated knowledge into clinical practice and policy making. While there has been some criticism of evidence-based policy on the grounds that research results are often too context specific to be widely generalised (Black 2001). Evidence based policy in the NHS has attracted specific criticism on the grounds that policy requires a more pluralist and diverse approach and to recognise that policy often requires compromises between competing view-points (Marmot 2004). Evidence based initiatives are an example of the predominantly positivist culture in the NHS rooted in the dominant views of the medical profession.

While emphasis on scientific knowledge and the division of the organisation on functional specialisms has allowed the enhancement of patient care through practitioners gaining specialist skills; innovation has been impeded by rigidity; pecking orders; strict demarcation; tribalisism between staff; and departmental silos (Rushmer et al. 2004). While the source of many innovations may be the combination of diverse disciplines, the NHS's predominantly functionally based structure acts against such innovation.

The NHS has a strong culture of professional autonomy because of the NHS's structure based on functional specialisms (Worthington 2004). This structure should provide an effective setting for innovation to occur, as professional staff have some control and discretion in how they approach their work. There are, however, a number of factors that may stop individuals pursuing certain innovations. There is an increasing requirement for new practices to be rigorously tested prior to being approved by regulatory authorities at national and regional levels. This carries with it a significant bureaucratic overhead that can potentially retard innovative activities. While there are parallels between the culture of hospitals and universities in terms of levels of professional autonomy, the main purpose of healthcare organisations is the delivery of patient care. The operational demands made on staff means there is little time to spend on innovative activities.

In order to develop a thriving innovation context in the NHS, account needs to be taken of its culture. As outlined above the NHS's culture is complex and heterogeneous; complex because of the web of power relationships; heterogeneous because of the diversity of disciplines and roles. In addition to its size, the NHS also experiences a high rate of change initiated mainly by central government. Perhaps the most acute driver of change is technology. The rate of technological change has implications for the organisation in terms of both resourcing new technology and the development of skills to use it. The past twenty years have seen a succession of initiatives in the NHS, these have resulted in change fatigue becoming endemic in staff. For these reasons, an approach to managing innovation in the NHS must be sensitive to the diverse cultures and recognise that for an organisation experiencing rapid change any solutions are likely to be only transitory.

2.5.2 Structure

Until the 1990s, the NHS was organised as a single, large professional bureaucracy (Harrison and Wood 1999; Mintzberg 1993). Since then there have been a number of structural changes to its operation that have both enhanced and constrained potential for technological innovation. As part of the NHS and Community Care Act 1990 an internal market was formed within the NHS. This made an explicit split in the NHS between purchasers and providers of health services. During the 1990s, this was developed into a system of primary and secondary care trusts. Though the emphasis on an internal market was abandoned, as it failed to integrate the NHS or promote widespread partnerships (Greener 2004), the system of trusts has continued to develop. Primary care trusts remain as commissioners of services from acute trusts. While the element of competition between trusts has been reduced, there is still a strong internal cost accounting structure. This has an impact on innovation as while service delivery crosses boundaries e.g. between primary and acute trusts, investment in new technology takes place at the trust level. This has an effect that where investment in innovative technology is born by a primary trust, the most significant impact on efficiency and effectiveness may be gained by acute trusts.

The centralised purchasing function that existed in the NHS before the 1990s has continued to operate, though in a modified form. In 1991 the purchasing function was reorganised as a special health authority called NHS Supplies. The aim of the authority was to achieve best value for money for the NHS. In April 2000 NHS Supplies was developed into the NHS Purchasing and Supply Agency (PASA), an executive agency of the Department of Health. PASA acts as a strategic advisor to the NHS on procurement. The agency oversees a complex supply chain to the NHS that includes pharmaceuticals, equipment and consumables. The impact of purchasing policy impacts on the diffusion of innovation into the NHS. While efforts are made to ensure that purchasing decisions are made at an appropriate level, the agency has a role in assessing individual products for use in the NHS PASA operate a list of approved products for use in the NHS. This list is based on providing value for money but has become a *de facto* standard for approval of products used in the NHS. Even for products based on innovations originating within the NHS, the acceptance of the product onto the PASA list is a major step in gaining widespread NHS use. The latest development has been the move to privatise PASA. This development will not however ameliorate the problem

of a single agency acting as the main gatekeeper for the new technology adopted by the NHS. Marketing of new technology into the NHS will still be problematic, even for those technologies developed initially within the service.

While NHS purchasing policy has been concerned with the most effective approaches to purchasing technologies used in the NHS, there has also been a move to ensure their cost effectiveness. The National Institute for Clinical Excellence (NICE) was set up in 1999 with the aim of national guidance on economic use of resources in relation to patient care. Initial criticism of NICE suggested that it did not assess new technologies in a completely objective manner and it was suggested that:

> NICE has effectively become an advocacy mechanism by which lobbies of specialists and their supporters in the pharmaceutical industry extract more public money from the NHS. Instead of challenging the pharmaceutical industry to show value for money, NICE has become their "golden goose." (Cookson, McDaid, and Maynard 2001)

It is suggested that one of the main purposes of NICE is now to ration the use of health technologies in the NHS (Maynard, Bloor, and Freemantle 2004). This is based on the need for the NHS to contain spending on new technologies and balance effectiveness and cost. As such NICE is a primary gatekeeper, arbitrating on the adoption of new technologies. Successful diffusion will depend on explicitly satisfying an objective assessment of a technology's performance. The main basis of this objective assessment being based upon value for money, measured specifically in terms of cost of quality adjusted life year (QALY) (Raftery 2006). However, success may also be dependent on gaining the backing of powerful groups of clinicians, patients or health industry organisations.

Changes in the role of managers, creation of trusts and the development of agencies such as NICE and PASA are not the only changes that impact on NHS innovation. They do however demonstrate that the range of changes that are going on in the NHS can, when combined, have unforeseen consequences for promoting or stopping innovative activity.

2.5.3 Policy

The organisational context in which innovation occurs in the NHS is strongly affected by policy. Like any public sector organisation, these policies are driven not just by the organisation itself but also the political forces of government. There have been a number of policy initiatives that have lead to change in the NHS, though not always with the specific aim of generating an innovative culture. Key reports and policies included:

- "Supporting research and development in the NHS". (Culyer 1994);
- " Policy framework for the management of intellectual property within the NHS arising from research & development". (DoH 1998)
- "Creating knowledge creating wealth: Realising the economic potential of public sector research establishments. A report by John Baker to the Minister for Science and the Financial Secretary to the Treasury" (Baker 1999);
- "The Government response to the Baker Report: 'Creating Knowledge, Creating Wealth: Realising the economic potential of public sector research establishments'" (Office of Science and Technology 2000);
- "The NHS Plan, A plan for investment, a plan for reform" (UK Government 2000);
- "The NHS as an innovative organisation, a framework and guidance on the management of intellectual property" (DoH 2002);
- "Better health through partnership: a programme for action" (HITF 2004);
- "Agenda for Change - Final Agreement" (DoH 2004).

There had been a number of explicit efforts to improve the rate of innovation in the NHS. These can be seen as furthering one of two potential goals. The first goal has been to capture and protect commercially valuable intellectual property produced within the NHS, and then to exploit it through licensing or the creation of spin-off companies. The second has been to operate a culture of process re-design and continuous improvement within the NHS, so that innovations developed in one part of the NHS are shared throughout the service. The aim of supporting and exploiting NHS

innovations can be seen as either to produce healthcare products for the global healthcare market or to diffuse them within its own internal market.

The drive to protect and exploit IP produced within the NHS can be seen as part of a broader move to commercialise IP developed in all public sector research establishments (PSRE). Suggestions for improved flexibility in the management of R&D in the NHS were set out in the early 1990s. The Culyer report highlighted that R&D occurred needed to be seen as a core activity throughout the NHS and not just in teaching hospitals (Culyer 1994). The Baker report also set out a rationale for why and how increased commercialisation of NHS R&D could occur (Baker 1999; Office of Science and Technology 2000). A number of other subsequent initiatives were then made to manage IP in the NHS better (DoH 2002; DTI 2004; HITF 2004). The emphasis of these initiatives was on establishing a clear process for identifying, protecting and exploiting IP. The ultimate aim of these initiatives is to establish income streams from innovations originating in the NHS. This income could then be used to improve patient care.

The move to generate innovation that acts to re-design NHS processes or contributes to continuous improvement can be seen as part of a modernising agenda. The general focus of this drive has been on the identification and promulgation of best practices. The NHS Modernisation Agency was proposed in 2000 to support change management, mirroring similar initiatives in the private sector (UK Government 2000). It had a role in promoting continuous improvement of services. The agency was not however charged with managing innovation in technologies such as medical devices.

The policies on NHS innovation were clearly demarcated between innovation of services and innovation of technology. There was no apparent recognition that the two are linked. This division was articulated in the DoH guidance in management of intellectual property in the NHS:

> An innovation can be used to improve the health service in one of two ways. First, after suitable evaluation, it could be freely disseminated across the NHS by knowledge management processes. Second, the evaluation may show that it is best treated as an invention... It may not be clear until after evaluation which path an innovation should follow. NHS bodies will need to have in place a management process to comply with

Research Governance responsibilities, with an identified lead person able to respond professionally to employees. The formal audit process carried out by NHS bodies to review their R&D outputs, commonly called 'technology audit', may also identify IP that is a 'good practice' innovation which needs to be evaluated and disseminated freely when appropriate. Plans are being put in place to capture these innovations which have no commercial value but the potential to improve health and to save expenditure by the NHS. (DoH 2002)

This two pronged approach to innovation resulted in service improvement becoming the preserve of the modernisation agency, while commercially valuable innovations were the preserve of a separate agency (Savory 2006). NHS Innovations, was responsible for overseeing the creation of a number of technology transfer offices, known as NHS innovations hubs (DoH 2002) to support the protection and commercialisation of NHS IP. In 2005 the two agencies were brought into the same body, the NHS Institute for Innovation and Improvement (NHS Institute for Innovation and Improvement 2005) but the separation of service and technology innovation was maintained.

2.5.4 Section summary

This section has reviewed the NHS as a potential context for innovation by considering its culture, structure and the policy frameworks under which it operates. It has then considered the historical development of what became the overriding model of innovation within the NHS, based on the technology transfer processes. The section highlights that the NHS context may be poorly served by the uncritical use of established models of technology transfer because of their over-emphasis on hard technology; understating the need to manage innovation of soft technologies. For a further discussion of these issues, see also Savory (2006).

2.6 Chapter summary

This chapter has reviewed the literature relating to user-led innovation in the NHS. The existing literature on user-led innovation was limited and though the wider innovation literature has some relevance, the review highlights the need to address two specific questions about the nature of user-led innovation and the processes through which it occurs:

- What are the characteristics of user-led innovation projects in the NHS in terms of: their purpose, the people involved and the criteria used for judging success?
- How do user-innovators in the NHS manage and structure the innovation process?

The chapter also highlighted the complex nature of healthcare technology, raising questions about the nature of the technologies produced through user-led innovation processes and the extent to which hard and soft technologies are affected. This suggested the third research question:

- What is the nature of the technology created through user-led innovation in the NHS?

Finally, the assessment and validation of new healthcare technologies is an essential part of the healthcare technology innovation process. In order to be adopted by the NHS, or other healthcare systems, it is necessary that technologies created through user-led innovation are shown to be effective. Ultimately, the adoption and implementation of new technologies created through user-led innovation processes depends upon successful validation. This leads to the fourth research question:

- How and for what purpose do user-innovators evaluate their innovations as they are developed?

The following chapter describes the methodology and its rationale, developed to investigate the four research questions.

Chapter 3: Methodology

3.1 Introduction

User-led innovation in the NHS is a new area of study. The role of users in innovation have been the focus of research in other areas, such as new product development, but the theoretical basis for understanding user-led innovation is still being developed. This research was exploratory and aimed to build a theoretical foundation to aid understanding of user-led innovation in the complex context of the NHS. A major challenge in the research was to build an understanding of how the micro-level processes that enable innovation of healthcare technology systems were related to macro level factors, such as healthcare policy, professional bodies and the wider healthcare industry. The methodological approach taken in the research had to be appropriate for exploratory research into a complex socio-technical system. This chapter discusses the rationale for the choice of methodological approach and then presents an overview of the adopted research design.

An overview of the research design is shown in Figure 3.1. The figure shows the relationship between the preliminary research stages and the main research in which four case studies of user-led innovation were developed.

3.2 Methodological framework

The area of user-led innovation in the NHS is characterised as novel and an expanding area of research. For this reason, it was important that during the course of the research, the methodology adopted must be adequately flexible and capable of evolution. The research did not set out to prove a specific *a priori* theory or hypothesis established from the start. Instead, the research was concerned with exploring specific research questions and then through analytical generalisation (Gill and Johnson 1997:120; Yin 2003:32), develop theory that would aid the explanation. This suggested the use of an inductive or grounded approach; an approach benefiting from flexibility

and a potential to provide both explanations and new insights (Easterby-Smith, Thorpe, and Lowe 2002:47).

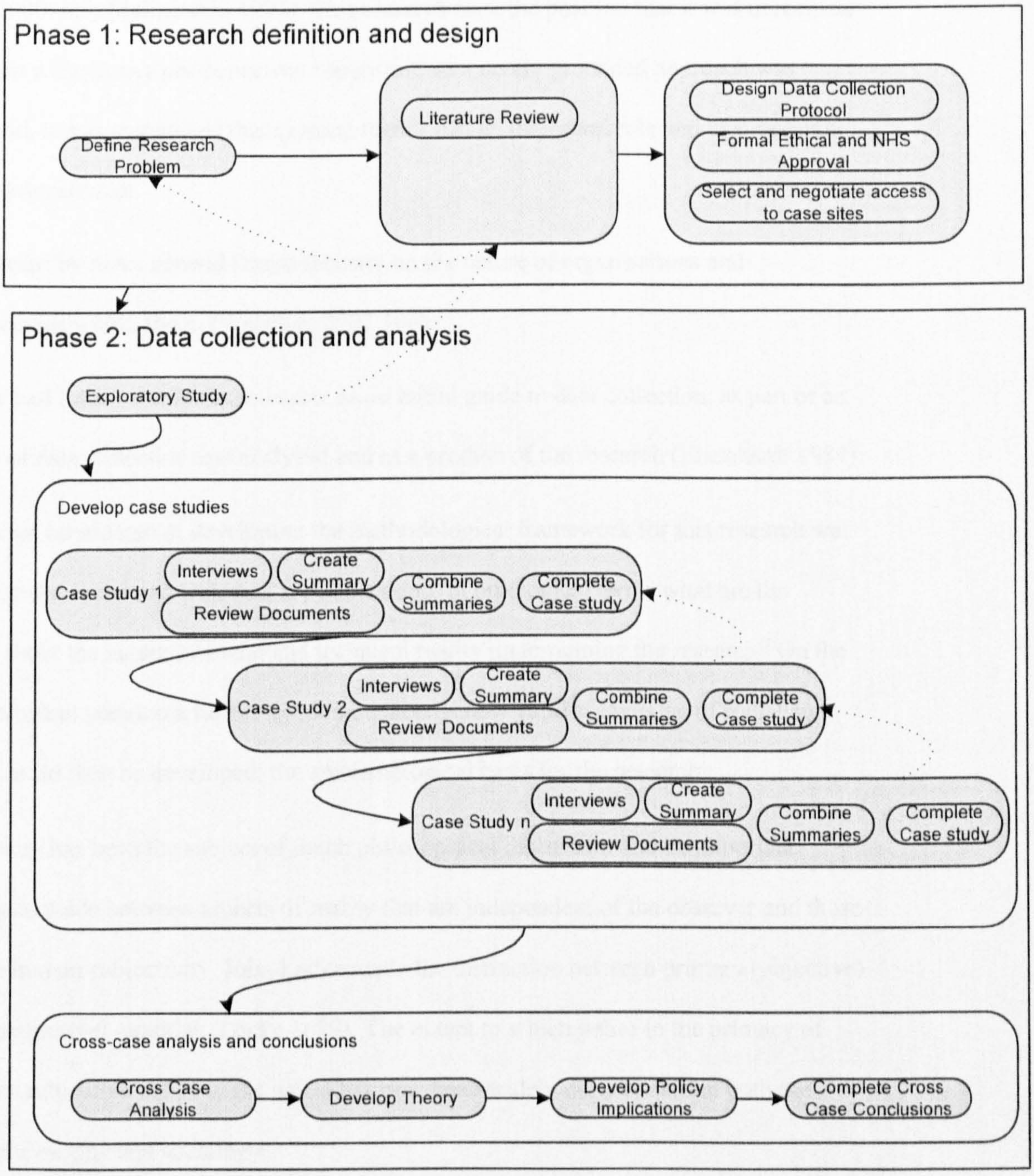


Figure 3.1: Overall design of the research process

The role of existing theory to the research was however still important. Some relevant theory had been developed; however, its application to user-led innovation in the context of public-sector healthcare was in its early stages and limited. Within the research literature there has been some disagreement about whether researchers should either enter the research process without theoretical preconceptions; or whether the researcher needs to start with a clear theoretical framework. Within grounded theory (Glaser Barney and Strauss Anselm 1967), an emphasis is put on the discovery of theory as a product of the analysis of field data, researchers being discouraged from engaging with

the existing theory base prior to commencing fieldwork. Malinowski has however suggested the difference between being burdened with preconceived ideas and arriving with an idea of what to look for (Stake 2000:449; Malinowski 1922). This research took the position that it was unrealistic to enter a situation without any pre-conceived theory and so a purely grounded approach was unrealistic. Instead, it was recognised that existing theory had an important role and that research on micro phenomena should:

> ...be informed by more general macro theories on the nature of organisations and social processes within them. (Walsham 2002:106)

Theory therefore had three roles in the research: as an initial guide to data collection; as part of an iterative process of data collection and analysis; and as a product of the research (Eisenhardt 1989).

An important factor considered in developing the methodological framework for this research was the basis on which the social and technical are understood; in ontological terms what are the assumed beliefs about the nature of social and technical reality underpinning the research? On the basis of this ontological position a further question concerns how valid knowledge of social and technical reality could then be developed; the epistemological basis for the research.

The nature of reality has been the subject of much philosophical discussion and an important distinction has been made between aspects of reality that are independent of the observer and those that are based on human subjectivity. John Locke made the distinction between primary (objective) and secondary (subjective) qualities (Locke 1689). The extent to which belief in the primacy of either objective or subjective views of the world has now been widely debated within both the general field of philosophy and sociology.

Table 3.1 Alternative stances on knowledge and reality, adapted from (Walsham 2002:104).

Epistemology: Positivism	**Ontology: External realism**
Facts and values distinct and scientific knowledge consists only of facts	Reality exists independently of our construction of it.
Non-positivism	Internal realism
Facts and values intertwined; both are involved in scientific knowledge.	Reality-for-us is an inter-subjective construction of the shared human apparatus
Normativism	Subjective idealism
Scientific knowledge is ideological and inevitably conductive to particular sets of social ends.	Each person constructs his or her own reality

It has also been the subject of discussion in specific fields concerned with researching socio-technical systems, such as information systems. Walsham notes that it is important for researchers to be clear and explicit about the philosophical stance they assume in their research, suggesting that both an ontological and epistemological stances need to be explicitly stated, see Table. 3.1 (Walsham 2002:104).

It was noted in the previous chapter that healthcare technology systems have both objective and subjective elements. For this reason, it was believed that this research would be limited by adopting either a purely external realist or purely internal realist position. Instead, a position was adopted that recognised both the objective and subjective dimensions of reality, a position adopted within critical realist research (Carter and New 2004). Fleetwood highlights that four categories of reality are of relevance the:

- materially real: relating to entities that exist independently of individual and communities;
- ideally real: relating to conceptual entities;
- socially real: relating to social practices;
- and artefactually real: relating to entities created by human action. (Fleetwood 2004: 32-35)

This ontological perspective complements approaches adopted in the study of information systems information systems research, in which it has been recognised that three distinct types of knowledge are relevant (Lyytinen and Klein 1985). These are based on the work of Habermas who identified three knowledge interests: technical, practical and emancipatory (Burrell 1994);(Habermas 1971). Technical interests are based upon a scientific knowledge, practical interests based on historical-hermeneutic sciences and emancipatory interests on critical theory. Each of these interests has been the focus of positivist, interpretive and critical approaches to research. Within information systems it has been suggested that an over emphasis on positivist research methodology can lead to partial view of the phenomenon studied. Orlikowshi and Barroudi suggest that:

> The quest for universal laws leads to a disregard for historical and contextual conditions as possible triggers of events or influences on human action. The design and use of information technology in organisations, in particular, intrinsically embedded in social contexts, marked by time, locale, politics, and culture. Neglecting these influences may reveal an incomplete picture of IS phenomena. (Orlikowski and Baroudi 2002:63)

From this position any research into user-led innovation must recognise that to gain a full understanding of the phenomena multiple lenses are needed, that make the researcher sensitive to not simply process and structure, but other issues including meaning and power relationships (Flood 1999:94).

3.3 Case Study Methodology

The main approach used for guiding this research has been a case study methodology. This section will outline the rationale for adopting a case study methodology and critically review potential problems with its use in relation to user-led innovation in the NHS.

3.3.1 Role of case study research

A case study can be described as:

> an empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident. (Yin 2003:13).

Yin supplements this definition with the comment that case study is a research strategy that covers the logic of design, data collection techniques, and specific approaches to data analysis.

Benbasat *et al* have suggested case study research strategies have the following characteristics (Benbasat, Goldstein, and Mead 2002:82).

- The phenomenon of interest is examined in a natural setting.
- Data are collected by multiple means.
- One or few entities (person, group, or organization) are examined.

- The complexity of the unit is studied intensively.
- Case studies are more suitable for the exploration, classification and hypothesis development stages of the knowledge building process, the investigator should have a receptive attitude towards exploration.
- No experimental controls or manipulation are involved.
- The investigator may not specify the set of independent and dependent variables in advance.
- The results derived depend heavily on the integrative powers of the investigator.
- Changes in site selection and data collection methods could take place as the investigator develops new hypotheses.
- Case research is useful in the study of 'why' and 'how' questions because these deal with operational links to be traced over time rather than with frequency or incidence.
- The focus is on contemporary events.

Case study research is important when the phenomenon can not be studied out of context for, example through experimental methods (Yin 2003:13). The research needs to focus on a specific instance of a phenomenon and the various interactive processes that affect it (Bell 1993:8), or for "sticky, practice-based problems where the experiences of the actors are important and the context of action is critical" (Benbasat, Goldstein, and Mead 2002:80). The case study approach allows the researcher to adopt a holistic view of the context and to "...retain the holistic and meaningful characteristics of real-life events" (Yin 2003:2). In addition to where the phenomenon is closely coupled to its context, it has been suggested that case research is beneficial where the research and associated theory is exploratory and in its early, formative stages (Roethlisberger and Lombard 1977). Case studies are important where research in the area is still exploratory and needs to focus on "...understanding the dynamics present within single settings" (Eisenhardt 1989). Much exploratory research in the fields of information systems and innovation studies has been done using case study methods (Walsham 2001; Suchman 1987; Bessant 1993; Howells 2004; Jones 2001; Leonard 1995). The method has allowed data to be considered from a wide range of sources including interviews and documentation.

An important issue in case study research is the extent to which the findings of a case can be generalised. Case study research does not follow a sampling logic, as in statistical generalisation, where the research seeks to generalise from a sample to the wider population. Instead, case research is concerned with analytic generalisation as distinct from statistical generalisation (Yin 2003:32). Analytic generalisation represents the process of generalising from empirical descriptions to theory and has received the attention of several social science and information systems researchers (Eisenhardt 1989; Glaser Barney and Strauss Anselm 1967; Klein and Myers 1999; Lee and Baskerville 2003; Strauss and Corbin 1998; Walsham 1995, 2002; Yin 2003). Walsham highlights the potential of four categories of generalisation that may be gained from case studies: development of concepts; generation of theory; drawing of specific implications; and contribution of rich insight (Walsham 2002:110).

3.3.2 Multiple case methods

An important strategy for selecting cases in order to support the generalisation of case findings to theory is the adoption of a theoretical sampling approach to case selection. In contrast to statistical sampling; the aim of a theoretical sampling strategy is to:

> ...replicate previous cases or extend emergent theory, or they may be chosen to fill theoretical categories and provide examples of polar types. (Eisenhardt 1989)

In replicating cases, the emphasis is on theoretical replication where the events reported in the case provide support to an emerging theory. The emerging theory may "...predict similar results ... or predict contrasting results but for predictable reasons" (Yin 2003:47). An issue to consider when identifying a case study site is the extent to which the site is either typical or unusual in its characteristics. This is important because the type of site selected will impact on how the findings of the case are generalised. For this reason, the choice of site is not restricted to only the typical. Yin suggests that when selecting case sites for single case studies, it is appropriate to apply one of several different rationales: the critical case, extreme or unique cases; representative or typical cases; revelatory cases; and longitudinal cases (Yin 2003:40). This highlights that case study research can focus on not just the typical but also the particular. In a similar approach, Stake suggests that cases can be categorised into three types: intrinsic cases where the primary aim is

better understanding of that particular case; instrumental cases where the purpose is to gain insight into an issue or redraw a generalisation; and a collective case study in which an instrumental case is extended to multiple cases (Stake 2000:437). The value of studying particular cases is that it gives the opportunity to gain a deep understanding of what is "...perceived to be the case's own issues , contexts and interpretations" (Stake 2000). One possible selection strategy can be to compare successful and unsuccessful user-led innovation projects. This strategy is however difficult to operationalise. First of all, the distinction between success and failure is not always clear. Criteria for project failure and success can be viewed as based on multiple factors, many of which will be subjective and dependent on the view point of the observer(s) (Fortune and Peters 2005:14). This makes the judgement of whether an innovation is a success or failure difficult to make, until the project has been studied in some depth. Secondly, the problem of identifying user-led innovations in the NHS is more difficult when trying to identify failed innovation projects. There are likely to be great many projects that have failed at an early stage, or anonymously after a period of development. Similarly, there are likely to be many that at a local level have been successful but remain unpublicised, as they have not diffused away from their original area of development. Finally, degree of success achieved is based on a variety of criteria e.g. sales of a commercially produced device, cost savings within the NHS, improvements in quality of patient care.

Detailed case study research creates the opportunity to gain a deep understanding of the phenomenon, through the development of thick description that supports understanding of the "...subtleties of changing interpretation" (Walsham 2002:103). Taking an approach that is open to the idiosyncrasies of a particular case, results in an increased scope for emergent issues to arise, grounded in the data collected (Strauss and Corbin 1998). Use of research methods, such as surveys, would not be as effective in allowing the detail of the innovation process to be understood.

A potential strategy for developing a rich understanding of a phenomenon, such as an innovation process, is to adopt a process theory based approach. This emphasises patterns in events, in contrast to variance theory in which explanations are based on causal relationships between independent and dependent variables (Mohr 1982). Based on this, narrative strategies of qualitative process research (Langley 1999) can be used to construct from data a story that emphasises the chronology of events, as well as the concepts, understanding and ultimately theory linked to the data collected

(Ferlie et al. 2005; Golden-Biddle and Locke 1997). Such a strategy is potentially problematic due to the fluid characteristics of process phenomena (Pettigrew 1992), and the difficulty in isolating units of analysis in an unambiguous way (Langley 1999). Thus in researching a process, it is necessary to recognise the relevance of both variables and events. For example, with an innovation process there will be a number of events triggered by actors that are seen as significant, however, contextual variables such as the prevailing norms and values will also impact on the process. Such a strategy does risk "death by data asphyxiation" (Pettigrew 1990) due to large data sets required, in turn leading to the problem of distinguishing between relevant and irrelevant data (Miles and Huberman 1994). It is also made more complex due to the possible non-linearity of an innovation process (Van De Ven 1992).

An important part of the development of a rich description is the iteration between theorising and observation. This has been described as an interplay between researcher and data:

> Analysis begins with the first interview and observation, which leads to the next interview or observation, followed by more analysis, more interviews or fieldwork, and so on. It is the analysis that drives the data collection. Therefore, there is an interplay between the researcher and the research act. Because this interplay requires an immersion in the data, by the end of the inquiry, the researcher is shaped by the data, just as the data is shaped by the researcher. (Strauss and Corbin 1998:42)

The rational for using a multiple case approach, over a single case approach, was that it would be difficult to identify a single case that adequately addressed the research problem. The research problem recognised that the activities underpinning user-led innovation are wide ranging and so taking a multiple case approach was more likely to yield a broader perspective on the phenomenon.

The problem addressed in this research lacked any existing or well formulated theory but suggested that user-led innovations are not extreme events, but relatively common. However, the research proposition suggests that user-led innovations are varied and do not follow precise processes. This suggested that a single case would be less sensitive to the variety of ways that user-led innovations develop.

In contrast, a multiple case research design provided broader basis for investigating user-led innovation. The cases developed would be vital for identifying differences as well as similarities between innovation projects. Multiple cases have potential to inform the prediction of similar results; and the prediction of dissimilar results, but for predictable reasons (Yin 2003:47).

3.3.3 Triangulation of data

An important benefit of adopting a multi-case research design is that the development of multiple viewpoints on specific phenomenon are developed. For a research design where all cases share similar context, for example the NHS, the cases provide specific perspectives on common areas of interest. In this way, perspectives on major institutions will yield a range of insights into their inter-relationship. This could be viewed as a form of data triangulation (Denzin 1978) in which multiple sources of data are used to develop a converging line of enquiry (Yin 2003:99). The use of several data sources within each case (various informants, documents etc.) allow details of a specific case to be triangulated. This is an important strategy as in developing an understanding of when and why decisions were made, it is useful to be able to compare accounts in both interviews and documentary evidence.

It should be noted however that where a participant's account does not triangulate with another source e.g. an account given in a publication, it does not immediately mean that either account is false. The differences in the accounts of events provided to researchers may be incomplete due to: time constraints in data collection; complexity of events; limits of the research participants' memories; differences between written and oral communication conventions; or participants' reticence to supply a full account. It is also plausible that the perspective of participants changes over time. While triangulation is a useful tool, it is important to recognise its limitations, especially where assessment of a truth is based on repeatability of an observation across several sources.

This suggests that research can adopt an interpretive position on the nature of fact. Stake highlights that while much qualitative research is concerned with using multiple perceptions to clarify meaning and to verify the repeatability of an observation, another important function if to clarify meaning by identifying different ways the phenomenon is being seen (Stake 2000:443). This is a position advocated in information systems research where Walsham notes that:

> ...I take an interpretive study to mean that multiple perspectives are provided by participants, and thus that the interesting data study cannot be 'triangulated' to provide a 'true' interpretation, since whose truth should be chosen? The interpretive researcher filters participants' statements and actions through a lens of his or her own subjectivity, and then produces a 'story' about the events that have occurred and some reasons for them. The purpose of the story, again, is not to tell 'the truth' about the case study but to tell a 'truth', namely the researcher's own thoughts and ideas concerning the phenomena at issue. (Walsham 2001:7)

This shows that the concept of triangulation has been dismissed in interpretive research, as an interpretive approach is based on different assumptions to positivist approaches, making triangulation simply not possible (Orlikowski and Baroudi 2002:67). The role of multiple cases should therefore be seen as allowing a range of perspectives to be developed, on a range of phenomena, rather than simply as a basis for triangulation data.

3.3.4 Sources of evidence

A benefit of a case study approach is the opportunity to combine data from several information sources. Yin defines six categories of information source relevant to case study research: interviews, documentation, archival records, direct observations, participant observations and physical artefacts (Yin 2003:86). The case approach therefore has a substantial benefit and relevance when investigating phenomena such as user-led innovation projects.

The use of interviews has a central role as it provides potential for several important forms of evidence. Interviews are important in developing a narrative of how a project progressed. They are useful for gaining participants' perspectives on issues and themes within the research. In the case of research that reviews a project, the interview is an opportunity for participants to reflect upon the actions of themselves and others. For members of staff involved in user-led innovation, an interview with a researcher may be the first time that they have been actively questioned about their involvement in a project. The participant may experience the interview in a range of ways including seeing the interview as:

- time and space to reflect deeply;

- an opportunity to present a revised and generally positive view of the project;
- intimidating and potentially problematic if the participant says the wrong thing;
- surprising that an outsider is interested in their role in the project;
- an opportunity to provide a candid view to an outsider.

The researcher's perception of the participant's view of the interview may change the way the interview is conducted. This may take the form of coaxing a participant to talk, to reining in an overly verbose participant. However, it is not possible for the researcher to understand fully the way the participant experiences the interview; however, it is likely the researcher will gain clues from the participant's body language and the way that they answer questions.

Recruiting key members of staff to the research is central to its success and the extent to which it is achieved will have an impact on the perspectives portrayed of the case site. Gaining access can be viewed as a process requiring negotiation and renegotiation (Burgess 1984). The negotiation of access will take place through a mixture of formal and informal processes.

The use of project documentation is a valuable source of data for building case studies of user-led innovation. Within the healthcare sector, it is common practice for research to be published. For many innovative projects, aspects of the projects have been periodically described in published accounts. For example, it is common for clinicians to publish accounts in academic journals as well as more professionally oriented journals such as the British Medical Journal. The accounts given of projects are vital for several reasons. First, they provide narratives of stages of the innovation. Second, they record perspectives and views held by project members on the role and function of a specific aspect of the innovation. Finally, they provide an important perspective on the background to the source of knowledge underpinning an innovation. It is common for a research article to acknowledge the work of other research groups explicitly in similar and allied areas. This can provide a useful viewpoint on where an innovation lies in relation to an overall technological trajectory.

3.3.5 Critical review of case study strategies

A case study methodology was adopted for this research as it provided the most appropriate strategy investigating the research problem, however such a strategy could be criticised as having some inherent weaknesses. The key criticisms that can be made against a case study methodology is that they: lack scientific rigour, provide a poor basis for scientific generalisation, are time consuming and result in lengthy documents. However, the preceding discussion has addressed each of these criticisms as alternative approaches such as survey or experimental methods have limited application to the research problem.

The use of a survey based approach was discounted for two reasons. First, the research was exploratory and placed emphasis on rich detail and understanding the context in which innovations occur. A survey would have been unlikely to give this level of insight. Second, the development of a sampling frame for user-led innovation in the NHS would be problematic. The occurrence of user-led projects is difficult to ascertain due to their lack of visibility, even within their own organisations. Even if a sample was identified, it would be difficult to define precisely the full population to which the sample related.

Experimental approaches were also discounted, primarily, because it would be impossible to separate a user-led innovation project from its context. It would be unrealistic for example to define two projects, one as experiment and the other as control. The exploratory nature of the research meant that it was not possible to define an innovation experiment in terms of a small number of causal relationships. It was also noted that even if a survey was devised, the findings of such a survey would have little utility in building theory of user-led innovation.

The case studies developed in this research were based on a retrospective review of each user-led innovation project. The length of time available for the research meant that it was not possible to carry out a single, longitudinal case study of a specific project. Even if time was available, it would also be difficult to identify user-led innovation projects due to their typically fuzzy early stages.

Walsham notes that the mode of interaction of the researcher with a case study site can take several forms (Walsham 2006). He suggests a continuum between an outside researcher and an involved researcher. He characterises the outside researcher as neutral to the situation. The involved

researcher is closely related to the case site, indeed, to the point of consciously and explicitly acting to change the situation being studied, as may be the case within an action research project. For this research, the researcher was to maintain a neutral position in relation to the context of all the case sites and had contact only through the interviews with participants.

Overall, the decision to adopt a research strategy based on multiple case studies was underpinned by the following advantages. The development of rich accounts of the progress of the various projects would allow deeper insights to be developed, than would be the case if quantitative approaches were adopted. The development of multiple cases would be valuable in allowing multiple perspectives to be taken of the phenomenon of user-led innovation, both within and across cases. The adoption of an interpretive approach to the case studies also encourages the recognition of emergent themes in the research, strengthening the opportunity for theorising.

3.4 The Research design

This section will describe the approach taken to the research and detail how the case study material was collected, analysed and presented.

The design of the multiple case study method adopted for this research drew on Yin's case study method (Yin 2003:50). The design was based on three phases concerned with: research definition and design; preparation, data collection and analysis; and finally cross-case analysis and conclusion. In common with Yin's model the research design incorporated feed-forward and feed-back loops that allows the experience gained from each case study to be fed into other parts of the research. The overall design of the research is shown in Figure 3.1.

During the conduct of an individual case study, it is inevitable that the researcher will gain insights into the research problem. Such insights needed to be recognised and so three mechanisms were embedded in the design. First, through a feed-forward loop the conduct of subsequent case studies could be altered. This meant that during subsequent cases the researcher could focus on any emergent themes. Second, in the light of a new insight, previous case studies would be reviewed and the interpretation of the data from interviews or documents adjusted. Finally, new insights into the research problem could lead to adjustments to the research design.

3.4.1 Research definition and design

The initial phase of the research design was concerned with preparation for the research, within practical constraints. When selecting a suitable research method a number of constraints needed to be considered. The constraints were linked to two areas: the difficulty of researching innovation projects generally and researching innovation projects specifically in the NHS.

User-led innovation projects have a number of characteristics that create difficulties for researchers. The first of these is that it is difficult to identify user-led innovation projects early in their development. By their nature, they are bottom-up projects which will often take place with little formal support. They can be invisible in the organisations in which they develop. They are therefore not likely to be identifiable until they reached a level of maturity or have developed external linkages, for example to industrial partners, sources of funding. For many user-led innovations in the NHS, it was only when entering innovation competitions that they became visible to the NHS organisation itself, or observers from the outside. A second factor affecting the visibility of user-led innovation projects is the extent to which they are kept confidential. Many projects are kept secret in order to protect commercial interests and intellectual property rights. This can make it difficult to identify projects or even gain participation of project teams in research. Only when the period of secrecy has passed would it be possible to gain access. Unfortunately, by the time the project becomes public many of the interesting early stage project processes have come to an end.

Within these constraints, several objectives were set for case study design.

- build narratives of how innovation projects took place in the NHS;
- develop models of the actual processes followed that would allow an interactive process perspective to be taken to viewing the case studies (Slappendel 1996);
- develop a model of the perspectives taken by NHS staff to the innovation process (Souitaris 2003:524);
- identify emergent issues that impact on the NHS innovation process.

Based on these objectives Phase 1 of the research established three units of analysis on which to base the research design. The phase then included a literature review and an exploratory study. The

phase was complete once the data collection protocol had been defined, ethical approval gained, formal access to NHS staff agreed and case sites selected.

Units of Analysis

The emphasis of the research was on individual user-led innovation projects, however, understanding the broader context of government and NHS policy was critical. For this reason, three levels of analysis were identified for the research (see Figure 3.2). The first level (Level 1) was concerned with NHS policy and is tightly coupled to government policy. Possible data sources included both NHS and government documents. The second level (Level 2) was related to the management of innovation within the NHS, particularly in terms of the innovation management services that are made available for managing innovation projects. These services may be provided from within the NHS (e.g. the NHS based innovation hubs), by UTTOs or by private companies offering innovation management services e.g. private NHS Innovation hubs. The third level (Level 3) was concerned with specific innovation projects carried out in the NHS.

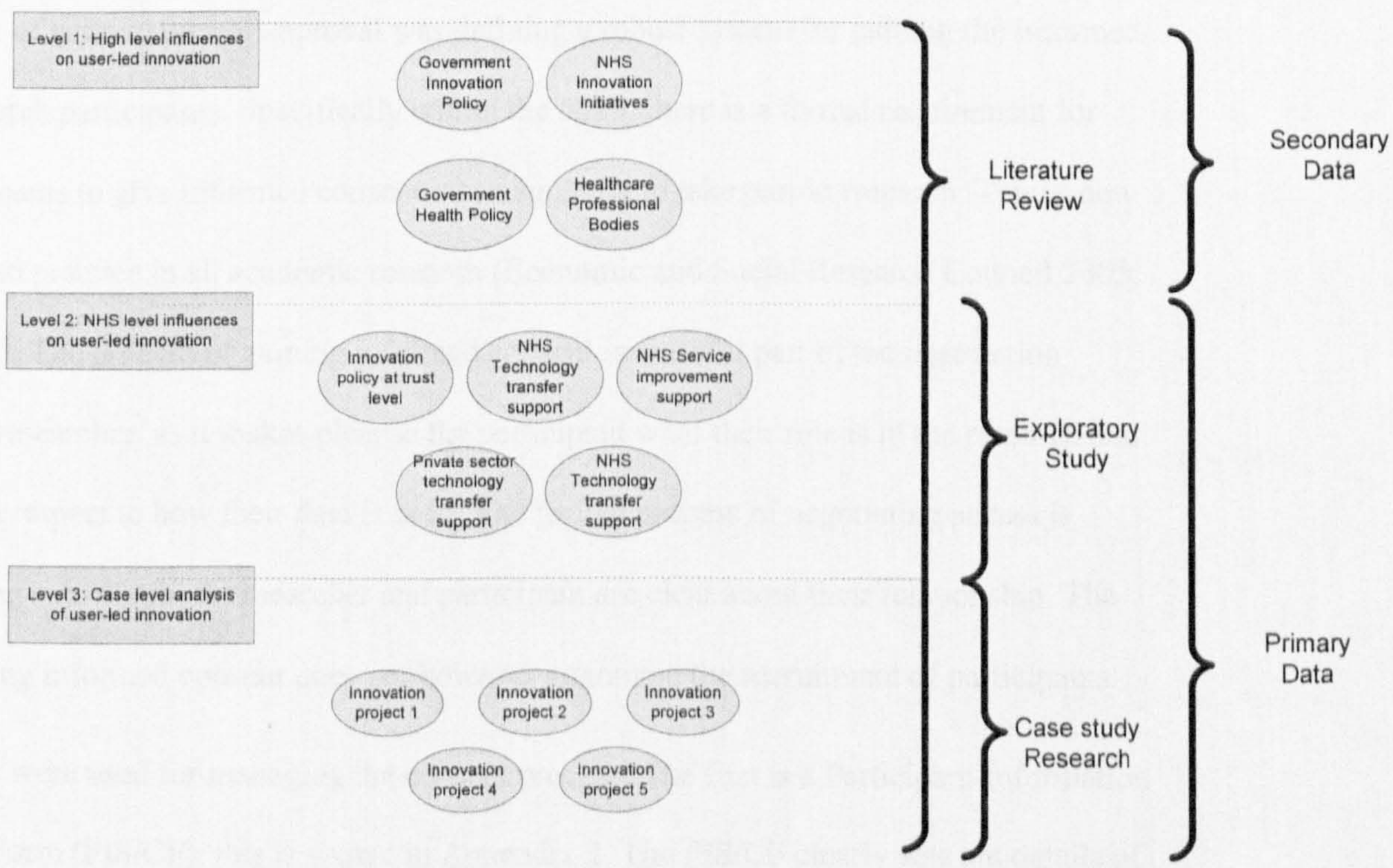


Figure 3.2: Levels of analysis used within the data collection

The three levels of analysis guide the data collection relating to the cases studies. All the individual case studies will be based on primary data collected at Level 3. The collection of relevant data at Level 1 and Level 2 will however help provide contextual information relevant to the individual cases. The research was therefore based on a multiple case study design, with the individual cases

contributing an understanding of innovation processes in the NHS. For each case, the unit of analysis is the innovation project however for the overall study the unit of analysis is innovation processes in the NHS.

Ethical and research approval

The proposed fieldwork for the research was to involve the interviewing of NHS staff. For this reason under the terms expected for the management and governance of research within the NHS two parallel processes were followed in order to gain ethical and R&D approval. Ethical approval for research is required for any research carried out with participation of patients of NHS staff or on NHS premises. The process for gaining ethical approval is defined by the NHS Central Office for Research Ethics Committees (COREC). The process for gaining approval was set out in a set of operating procedures (COREC 2004) based on defined governance arrangements (COREC 2001). Ethical approval for this research was granted by the Eastern MREC (multi-centre research ethics committee) based in Cambridgeshire.

An integral part of gaining ethical approval was defining a robust system for gaining the informed consent of research participants. Specifically within the NHS, there is a formal requirement for research participants to give informed consent when agreeing to take part in research. This is now also seen as good practice in all academic research (Economic and Social Research Council 2005; Oates 2002:213). The process of gaining informed consent is a useful part of the negotiation process for the researcher, as it makes clear to the participant what their role is in the research and their rights with respect to how their data is used. The formal process of negotiating access is crucial in making sure that both researcher and participant are clear about their relationship. The process of gaining informed consent does not however guarantee the recruitment of participants.

Two documents were used for managing the consent process. The first is a Participant Information Sheet/Consent Form (PIS/CF), this is shown in Appendix 2. The PIS/CF clearly sets out details of the project. The participant completes the PIS/CF to record specific points of consent. The use of the PIS/CF was valuable as it ensured that all participants were fully aware of the basis on which they participated. The second part of the consent process was for participants to approve a summary of their interview. This was done using the Participant Interview Summary Approval

Form (see Appendix 3). This was used to record that the participant had read and approved the interview summary. This confirmed that all data in the summary could be published and placed in the public domain.

In addition to gaining ethical approval, local R&D approval had to be gained from each NHS trust in which participants were to be recruited. This was in accordance with the research governance procedures in the NHS. Approval processes were defined by each NHS trust and were not consistent across all trusts, but typically involved the researcher submitting the standard NHS R&D Form to the R&D department of the relevant trust.

Exploratory Study

An important part of Phase 1 of the research was the completion of an exploratory study that had a number of objectives. First, to identify key issues related to the management of innovation in the NHS, as understood by staff responsible for supporting innovation activity. Second, through the development of relationships with innovation managers in the NHS it would be possible to understand the networks of relationships and the mechanisms available for gaining access to innovation projects. Third, it would be possible to identify potential cases suitable for more detailed case study work. Finally, through the initial contact with NHS innovation managers it would be possible for the researcher to be acclimatised to the culture of innovation in the NHS.

The exploratory study was based on unstructured interviews with staff involved with innovation management in the NHS. Six NHS innovation managers were interviewed. All the managers worked for innovation hubs supporting the NHS. Two of the managers worked for innovation hubs set up as limited companies, independent of the NHS, but contracting services to NHS trusts. Four of the managers worked for hubs that were integral to the NHS. Interviews were unstructured but were focused on several themes:

- The role of innovation hubs in the NHS
- Significance of user-led innovation
- The process used for managing user-led innovations
- Extent to which the NHS has an innovation culture

- Problems encountered in the NHS when developing innovations

In addition to the interviews with innovation managers, additional information was also gained through informal contact with NHS trust R&D managers and attendance at healthcare innovation related conferences and events.

The informal contact with NHS innovation staff was a very useful part of the exploratory study. Several benefits were gained that supported the subsequent research. First, the researcher was able to gain a clearer view of the key concerns that technology transfer managers in the NHS have regarding management of innovation. In particular the main problems that they perceived in managing innovation and how their normal mode of operation addressed these issues. Second, the researcher was able to gain a better understanding of the language used within NHS innovation management and key concepts that guided technology transfer practices. Third, through the informal conversations during the workshop the researcher was able to gain a view of the work of the managers, via their comments and anecdotes. Fourth, the exploratory study was instrumental in building a base of contacts for further research, including invitations to NHS innovation conferences. In particular, the exploratory study yielded several suggestions for potential case study sites. Two of which were ultimately followed up in the main study.

An unexpected outcome form the exploratory study was that the researcher became known within the community of NHS innovation hubs. Despite the size of the NHS, the relatively small number of innovation hubs means that the community of NHS technology transfer managers is relatively small. By engaging with this community early on in the research, the researcher was able to make contact with staff from six NHS innovation hubs. The exploratory study helped the researcher build positive relationships with the hub managers; which in turn reduced problems in gaining access to case sites.

Data collection protocol

For the main study, the data collection followed the protocol given ethical approval by COREC. All interviews with the project participants followed a semi-structured format. The interview schedule is shown in Appendix 1. The schedule was designed to ensure that interviews covered main issues around how the innovation started and developed. It sought to gain the participants

perspective on the innovation project and identify factors that affected the project. An important outcome of the interview was to gain a narrative view of how the project proceeded from the participant's point of view.

Selecting Cases

The primary selection criteria for cases studied in the project was that they were recognised as having achieved some level of success. This in line with the assumption that:

> A common feature of an innovation is that it must have been implemented. (OECD and EUROSTAT 2005:47)

This implies that where activity fails to result in an implemented change, it is not an innovation. Therefore, selecting cases that have achieved some success enables identification of innovations; avoiding selection of cases sites that, though involving scientific or technological progress, are not cases of innovation. It is however possible for innovation activities to be pursued by an individual or team that fail to result in an innovation.

While it may also be useful to consider cases that have been unsuccessful in creating an innovation, as noted earlier in this chapter, the identification of failed innovation projects is problematic. The subjective and observer-dependent nature of failure means that it is difficult to categorise a case as either successful or unsuccessful. This is problem is made more acute in the broad range of potential parameters that may be used in assessing innovation success, beyond simply whether an innovation is implemented.

For these reasons, an initial screening considered only projects that had received some recognition, for example by winning or receiving a commendation when entered into national or regional healthcare innovation competitions. This was a useful criterion for identifying innovation projects that shared similar characteristics. Projects passing this criterion were likely to have been either locally implemented or have reached a critical point where the underlying concept of the innovation have been proved to work (i.e. reached proof of concept). This criterion was also a proxy for projects in which the innovation team had reached a point of wishing to gain wider networks of relationships with industrial partners or groups within the healthcare community. The

result of selecting the case sites in this way was that the selected cases can be seen as typical examples of successful projects, potentially improving the generalisability of the research (Gomm, Hammersley, and Foster 2000:79).

In addition, a number of secondary criteria were used for identifying potential innovation projects for the study.

- The project should be a user-led innovation project, driven by one or a team of NHS staff, though not necessarily from the same NHS organisation.
- The innovation should be based in problems identified by the user-innovator (practice-based) rather than the result of a direct R&D initiative.
- It should have been developed primarily in a hospital rather than some other institution e.g. a university.
- Involve a degree of NHS service re-design rather than only being concerned with development of a hard technology e.g. a medical device.
- The project involved innovation of both hard and soft technologies and was not purely an organisational innovation.

The final selection of cases was based on two comparative dimensions. The first dimension was the scope of the innovation. The project had the potential to lie on a continuum between those that had an impact limited to a single element of a care process, while the other had an impact on the whole care process. The second dimension was concerned with extent to which the IP associated with the innovation had a potential commercial value. Using these two dimensions, four comparative case sites were identified. These are illustrated in Figure 3.3.

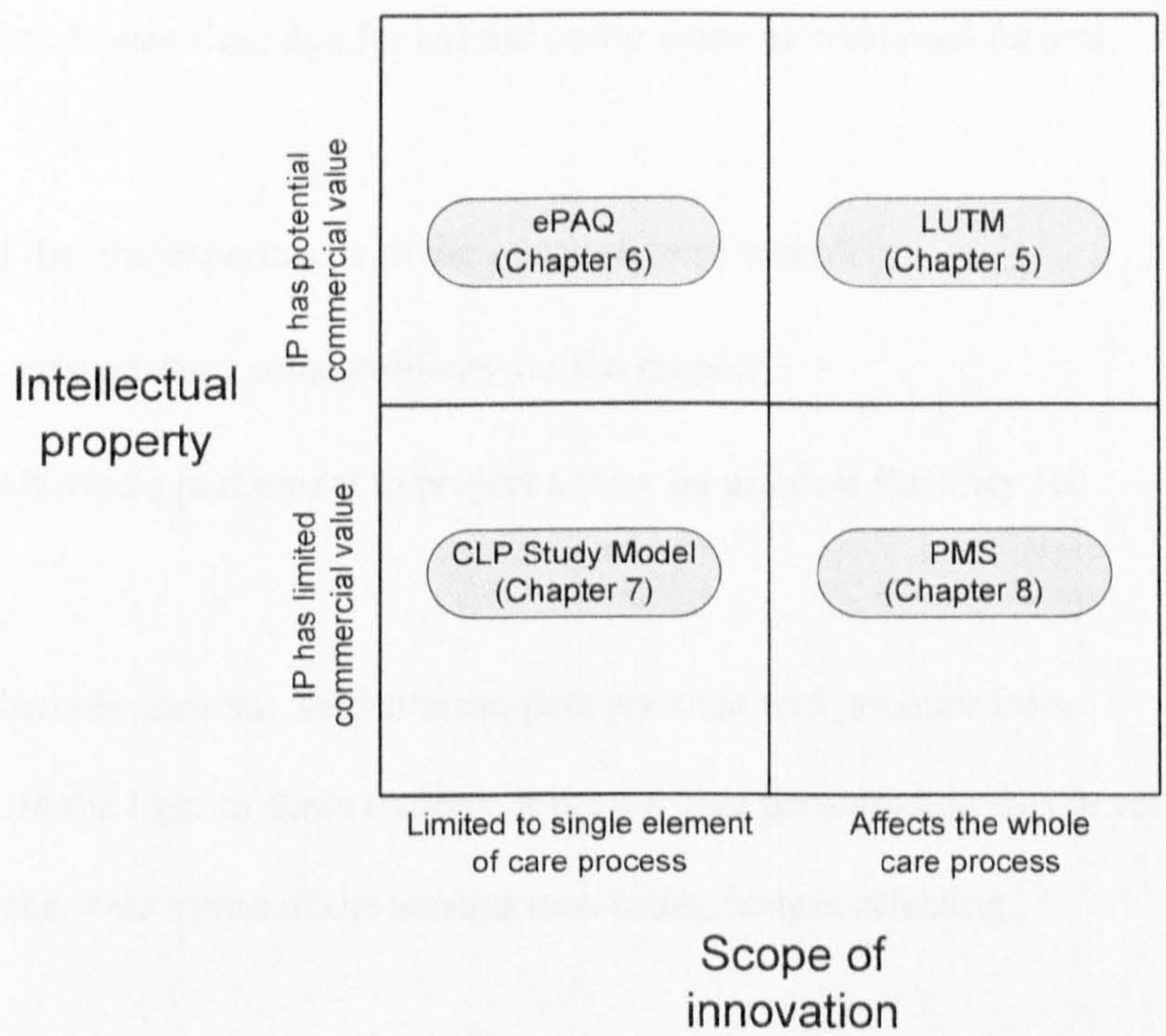


Figure 3.3: Case selection matrix

Gaining access and recruiting participants

Once a potential case site had been identified, formal R&D approval from the trust was sought before formally contacting potential participants. The first participant recruited for each case site was the user-innovator. The user-innovator then identified other staff who had been involved in the project.

Co-ordinating recruitment of participants to the research posed several challenges. First, convincing the user-innovators of the value of the research. Second, identifying other staff with relevant experience of the project, these members of staff may have had smaller, less prominent or very specific roles in the project. Yet, these participants could provide valuable insights into the project. As the research unfolded, it was sometimes necessary to extend participation progressively. This was often because potential participants were suggested during interviews, to illuminate specific aspects of the case. A challenge for the researcher was recognising the point where extending participation in the research would no longer be beneficial to the research.

At an informal level, negotiation of access depended on participants satisfying themselves that participation was worth while and served their own interests. NHS staff, and consultants in particular, have little slack time and so fitting in an hour long interview was not always easy. The informal contact with the researcher when negotiating access did help satisfy participants that the

research served their own interests. It was clear that for several participants motivational factors included:

- Feeling it was important that the experiences of their project were recorded;
- Belief that participation may produce some publicity for the project;
- Talking to a researcher allowed a participant to project a view on an issue that they felt strongly about.

Other motives for participating include altruism, self-interest, peer pressure and pressure from senior members of project team. In the light of these reasons, it is clear that participation was never free of bias, however, the researcher was aware of the various motivating factors affecting participants.

The problems in gaining access to relevant NHS staff at the case sites were significant. The projects studied had typically taken place over several years, and so it was common for some of the participants in the project to have changed jobs, or even left the organisation. The local R&D approval process would typically take from six weeks to several months to complete. Due to this delay, it was not unusual for contact with the user-innovator to be lost; often taking several weeks to regain contact and then arrange interviews with participants. Under these circumstances, though a more comprehensive study could be potentially done by the inclusion of a wider range of participants, the problems in gaining access would have imposed significantly greater delays in carrying out the research. For this reason, for all the case studies, participants were drawn from staff associated with projects for which a realistic chance of gaining access existed. The researcher is satisfied that in all the cases, a satisfactory range of relevant staff involved in the projects were recruited to the research.

The interviews associated with each case were done usually over the period of a few weeks. The five sets of case site interviews were done over a period of eighteen months. The timing of each set of case interviews was dependent on when the case site was identified and then the speed at which access was negotiated.

Interviews for the research were carried out at the sites where the participants worked. It was common for several participants to be interviewed in a day, when they worked on the same site.

The limited availability of members of staff meant that on several occasions interviews were based over a period of weeks.

3.4.2 Data collection

The primary source of data was collected through interviews with user-innovators and other staff who had worked on the projects. The conduct of the interviews followed the protocol discussed earlier in this chapter. The interview schedule proved to be the primary structure for each interview. However, due to the differences between projects and the different roles of participants it was common for the interview to address specific questions to varying degrees of detail. As the research progressed the range of topics discussed within the interview also evolved. In particular, the researcher supplemented the question on the interview schedule with questions relating to themes that emerged during the fieldwork. These themes included:

- Extent to which innovation was in response to clinical or economic problems.
- Explanation of how the project team formed and evolved.
- Sources of funding for the project.
- Role of innovation and technology transfer support initiatives e.g. innovation hubs.
- Extent to which innovation activities are an integral part of participant's role.
- Manner in which the innovation has been evaluated.
- Impact of NHS governance on the project.
- Impact of the project on design of service delivery.
- Assessment of how and to what extent diffusion of innovation has occurred.

The addition of these themes is a result of the iteration between data collection and theory building taken in the research. As the researcher gained a greater understanding of the phenomenon of user-led innovation in the NHS, research questions were modified and awareness of relevant issues deepened.

Interviews were planned to take place during a period of approximately forty five minutes. In the event interviews ranged in length from between thirty five minutes to two hours. It was generally

the case that once participants started to talk about their involvement in projects they were enthusiastic to discuss their involvement.

Most of the interviews with research participants were recorded using a small digital, voice recorder. Of the eighteen interviews, three were not recorded; instead the interviewer made contemporaneous notes, which were then written up more fully straight after the interview.

Secondary sources of data were also identified that provided additional data for each case. For most of the cases, the innovation team had usually produced a range of publications in academic, medical and professional journals that outlined aspects of the innovation projects. In addition, other publications were often available that provided detail of the historical development and context of the innovation. For example, for the innovation described in Chapter 5, there were several publications that detailed the development of leg ulcer treatment during the 1990s and the adoption of shared-care models.

3.4.3 Data analysis

Analysis of the data collected in the main study was analysed in two stages. The first was at the level of the individual case study. The four cases were then considered together in a cross-case analysis. Data analysis was based on three complementary processes: induction, deduction and "inspiration" (Langley 1999).

Inductive processes were used to develop theory from the data collected in the cases. This involved reducing and then displaying the data in some form, followed by drawing conclusion on the data (Miles and Huberman 1994:11). The initial stage was the development of project narratives (Stake 2000:439), These provided a provide a focused description of the case from the perspective of the researcher, though based on the aggregation of the perspectives of the participants. In addition to the project narratives, other techniques were used to enable the analysis. Cognitive maps were useful for mapping the perspective of participants on their innovation projects (Eden 1988; Eden and Ackermann 2004; Huff 1990; Swan 1997). Process maps were used for establishing phases in the projects, key activities and decision points. Influence diagrams were used where appropriate for establishing the inter-relationships between issues within cases. Finally, force-field diagrams were used to summarise the key enabling and inhibiting factors affecting the projects (Lewin 1951).

The literature review carried out to underpin the investigation of the research questions, led to the synthesis of the theoretical models discussed in Chapter 2. These models were used in a deductive fashion in analysing the case studies. Through comparison, it was possible to recognise how the reality of the cases matched with the synthesised model. The discussions both individual cases and the four cases together was informed by this process of compassion.

The final analysis process was based around the researcher becoming immersed in the research data (Strauss and Corbin 1998:47) and the recognition that analysis can lead to sudden insights. Critical insights do not necessarily flow from only codified patterns of analysis and the roots of such insight may be the result of inspiration, insight and creativity (Langley 1999; Potter 2002:85).

Case level analysis

Data from the interviews was analysed through several stages. The purpose of the stages was to analyse systematically data from individual interviews, through the development of themes and issues, backed up where necessary with verbatim quotations. The summaries of all the case interviews were then aggregated, before being developed into the final case study. This process is shown in Figure 3.4.

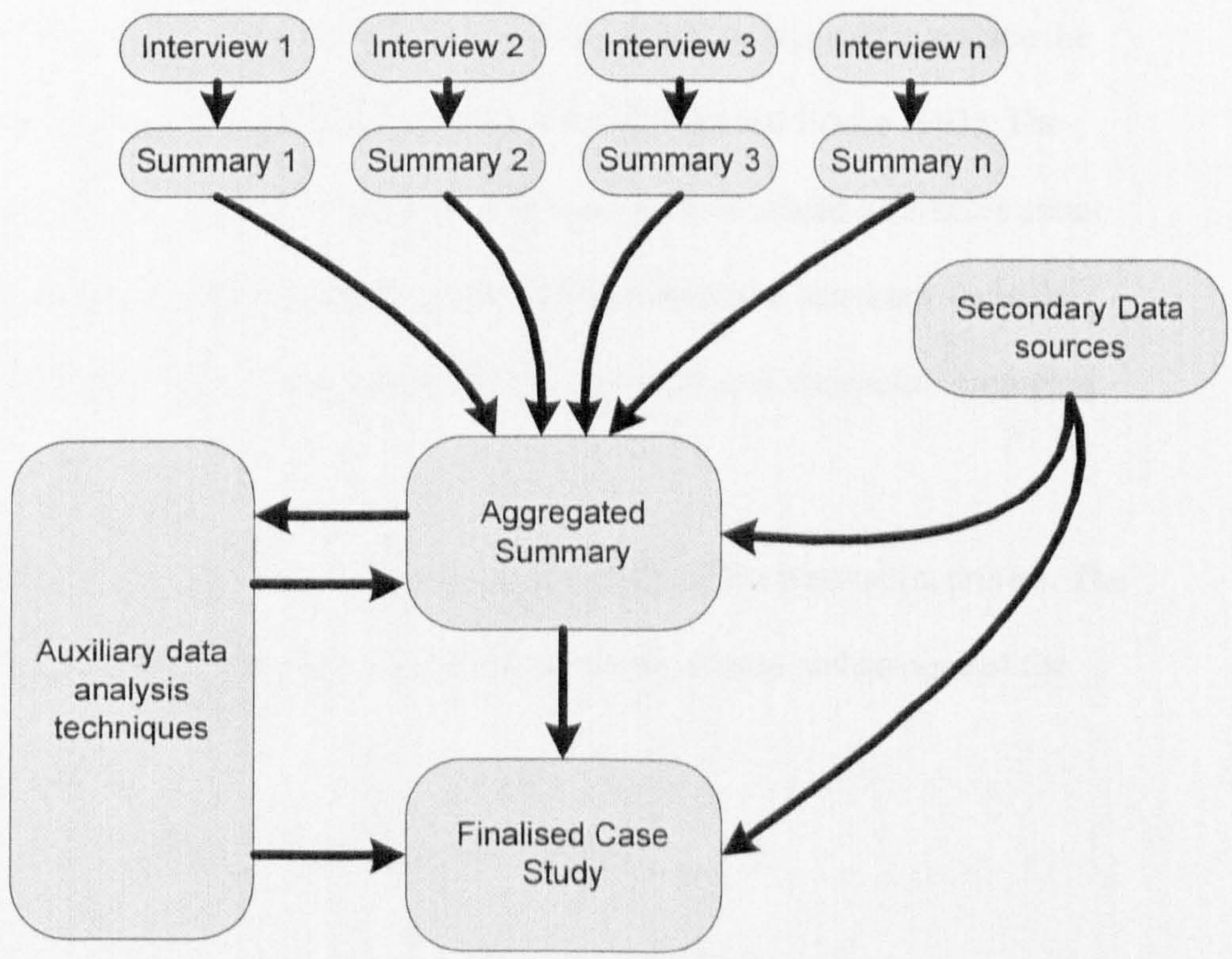


Figure 3.4: Development of interview data into completed case study

The first stage was to convert data held in interview notes or recordings into an initial summary. The interview summary provides a written account of the content of the interview. Its purpose was to present only the views and perspectives of the participant to which it related. No additional analysis was included; however, the researcher ordered the summary around themes and issues raised in the interview or of interest to the researcher. The researcher would also include any queries or additional questions raised in reviewing the interview. For this reason, the summary was not simply a transcript of the interview. It represented the data that the researcher perceived as being useful to the research. Once the summary had been produced, it was returned to the participant who then had the opportunity to add, amend or remove material from the summary, before authorizing the summary to be used within the research. Participants would also be given the opportunity to answer additional questions or supply supplementary information. Once the participant had approved a finalised version of the summary, it could be used in the next stage of the analysis process.

The second stage of the analysis process involved aggregating all the interview summaries into a single summary. This aimed to allow data relating to common themes to be combined, while maintaining any multiple perspectives identified within the case. Quotations from participant interviews were retained in the single summary to provide a link with base data and introduce the voice of the research participant into the final case study (Golden-Biddle and Locke 1993). The summary also incorporated material from secondary data sources, such as published articles about aspects of the innovation project. An important part of the aggregation of the summaries was the use of various analysis techniques that allowed the ordering of concepts and viewpoints emerging from the analysis.

The final stage of the analysis was to develop a completed case study of the innovation project. The final case study provided a comprehensive account of the innovation process and comprised the following sections:

- Background to the technological context of the innovation
- Overview of the innovation
- Identification and mapping of the innovation process followed

- Discussion of the innovation process followed
- Discussion of the organisational context of the innovation
- Key emergent themes and issues raised by the innovation project

Once the case study of the innovation project was complete, the themes raised could then be used within the cross-case analysis.

3.4.4 Cross case analysis and conclusion

The cross case analysis used a similar analytical framework to the analysis of the individual cases. Figure 3.5 summarises the way three streams of analysis contributed to the research.

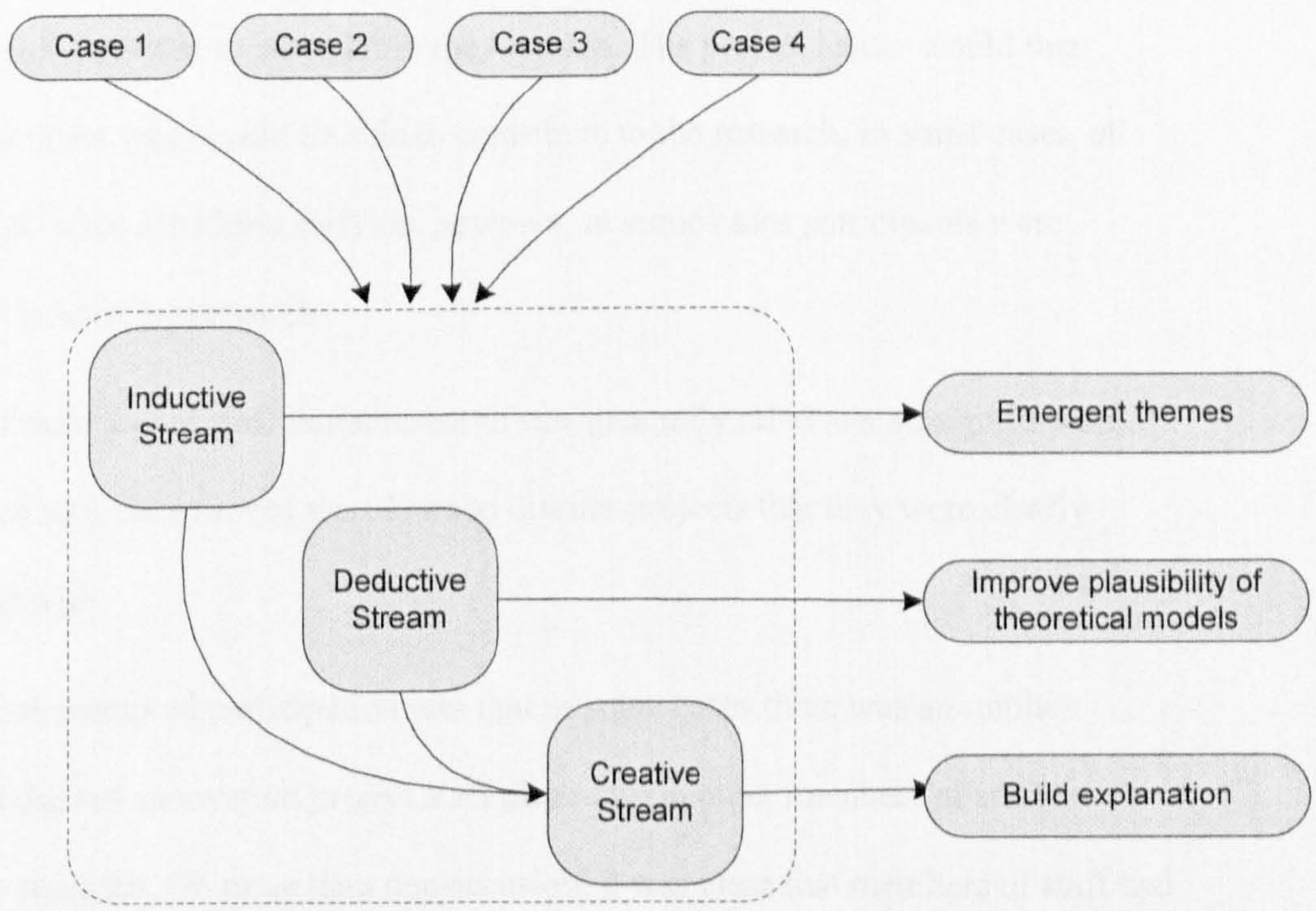


Figure 3.5: Process of cross-case analysis

The inductive process of analysis continued by combining the emergent themes raised in each case. This served to identify commonality between the cases, but also highlighted their differences. This phase of analysis was particularly relevant to the exploratory questions set at the start of the research relating to the nature of user-led innovation and the processes that it follows.

The deductive stream of analysis continued through the consideration of the extent to which the theoretical models reviewed in Chapter 2 provided a plausible explanation of the four cases.

The creative stream of analysis was vital in extending the analysis to the building of explanations (Yin 2003), based on the case data. This was of particular relevance in relation to the development of the role of proto-institutions in the innovation diffusion process.

3.5 Reflection on process

The following section discusses some issues raised within the research process.

Gaining participation of the innovation team

Participants were recruited to the research on the basis of their involvement in specific innovation projects. Once an innovation project had been identified as a potential case study, the leader of the project was contacted and requested to take part in the research. The project leader would then nominate other staff members who would be able to contribute to the research. In some cases, all relevant members of staff were identified early on, however, in some cases participants were identified and recruited later in the research.

Getting participation of members of staff in the research was generally relatively straightforward. Many of the members of staff interviewed were keen to discuss projects that they were clearly proud of being involved with.

A less obvious factor that prompted participation was that in some cases there was an implicit expectation by some of the key innovation project staff placed upon other members of staff to become involved in the research. On more than one occasion, it was clear that members of staff had agreed to participate because a senior member of staff had suggested that they had a duty to take part. For a least two of the case studies, the researcher felt that an important motive for participating in the research was to gain further publicity for the respective innovation project. More generally, it was common for key members of innovation projects to exert an expectation on other staff to participate.

Gaining participation of relevant members of staff was in some cases problematic. The problem for several of the case studies was that due to the fact that the innovation activity had occurred over a number of years it was common for some of the potential participants to have left the organisation

or even moved to a different country. Unfortunately, due to the constraints of cost and time placed on the research, it was not possible recruit staff who had subsequently moved to other institutions.

Sequence of interviews

The difficulty of arranging and coordinating interviews, meant that it was not possible to maintain a consistent pattern of interview sequences for each case site. During the research, the interviews for each specific case, did not follow a consistent sequence. For some cases, interviews took place first with key members of staff followed by secondary members of staff; other cases involved the interview of secondary staff first, followed by the key members of staff. One of the cases involved the interviewing of someone who at the time, the researcher perceived to be a key member of staff, but was in fact less influential in the case study.

A second problem in sequencing interviews was that it was not always possible to identify all the suitable staff at an early stage. It was common for participants during interviews to suggest other members of staff who were relevant to the case study. For some of the case studies this meant that the list of the research participants increased as the research progressed.

The interview sequence was important because the researcher would gain an understanding of the project during the course of interviews. This meant that the interviewer had to be aware that their own initial impression of the project, gained from an early interview, did not overly dominate or influence their understanding of subsequent interviews.

For the reasons set out above, it was not always possible to sequence interviews using a specific logic. However, several sequences could have been considered:

- interview key members of staff first, followed by staff who had a more secondary role within the project;
- interview secondary members of staff first followed by the key members of staff involved in the project;
- interview staff, based on their involvement chronologically in the project.

On reflection, the researcher felt that there was often value in interviewing secondary staff before interviewing the key members of staff. This was because it was common for secondary staff to give

detailed accounts of the sequence of events at specific stages of the projects; while key members of staff had forgotten much of this specific detail. By interviewing the secondary staff first, it was easier to cross-check accounts.

Recording of interviews

Several advantages to recording the interviews were identified. First, by recording the interview, the interviewer was able to maintain a more conversational style, without the interruption of having to make extensive notes. The interviewer was also able to concentrate more on the line of questioning during the interview, this was a great advantage given the semi-structured format of the interviews. Second, the interviewer was able to analyse participants' comments more carefully when listening to a recording of the interview. This meant that certain nuances of speech or the use of specific terms by participants, were reliably recorded making them available for later analysis. Third, during a long account of the project given by a participant, it is not always appropriate to interrupt the participant. This means that it is difficult to clarify exactly what was said at the time of the interview. The availability of good quality recording of an interview allows the participant's words to be carefully scrutinised. This was also invaluable when taking verbatim quotes.

The recording of interviews has been criticised by other researchers (Walsham and Sahay 1999). In particular, the suggestion that by recording an interview, the participant is made self-conscious of what he or she says. This can lead to reluctance to comment on sensitive issues or political situations.

It was not felt by the researcher that either of these two issues had a significant impact on the interviews. All participants in the research were given the option not to be recorded during the interview, with only two participants opting not to be recorded. The researcher felt that for all the other participants, recording of interviews was seen as inconsequential, or even normal. Several participants when asked whether they were unwilling to consent to being recorded commented that they expected the researcher to record the interview. This is a reflection that within the healthcare sector and clinical research in particular, recording of interviews is common place. The researcher believes that for many participants, though initially aware of the recording process, after only a few minutes they were oblivious to the recording. This was probably helped by the voice recorder being

small and discreet. For many of the interviews, the researcher was surprised at how candid many of the participant's comments were. The researcher felt that despite recording the interviews, participants still felt free to comment about even delicate political situations within innovation projects. The impression given by many of the consultants interviewed during the study was that they were unconcerned about expressing their views. However, for more junior staff it was impossible to judge fully the extent to which they felt free to express their views.

A potential problem with recording the interviews was the time needed to analyse them. It was common for analysis to take a significant amount of time and though much detail was gathered, some of this detail was not always relevant.

Participants' revisionist accounts of the process

This research could not be carried out by using longitudinal case study methods. The nature of the projects was such that early stages were carried out in an unofficial manner. In many cases, the NHS trust with which they were associated was not even aware of their existence.

The approach taken in the research was is to identify innovation projects that have reached a specific point in their progress and to take a snapshot view of the project and the perspectives of the innovation team members. This provides less opportunity to identify how views of the team have developed over time. It also risks producing revisionist accounts of the events affecting the project. Unfortunately, for the case sites chosen there was no practical means of carrying out a longitudinal case study, except perhaps for the later stages of the project. Potential differences in the way participants recollect significant events during the project can however be ameliorated by triangulation between participants' accounts.

The risk of revisionism in the accounts given by participants is a real one and is the most difficult one to reconcile. It is inevitable that in building case studies from participants' recollections of projects that the participants will emphasise, under emphasise or even disregard certain events. For these case studies, however, the researcher has set out to identify the factors affecting user-led innovation in the NHS. But this reason, the use of what may be revisionist accounts of projects is still legitimate. Part of the function of the case study interviews was to allow participants to reflect on their projects, often for the first time in any formal way.

It was obvious that for many of the team members, the opportunity to review a project with an external observer was often seen as both novel and useful. It was clear that for many of the participants, it was the first opportunity they had ever had to reflect on their project and discuss the decisions that they made. It was not unusual for participants, at the end of an interview that had far exceeded their planned timescale, to comment that they had found the interview enjoyable, interesting and useful. The use of snapshot views has a value as it enables participants to reflect on long term developments of a project. The identification and explanation of critical events and processes is of particular value for both researcher and participant. Several participants commented at the end of their interviews, that it had been an enjoyable process, and it was clear to the researcher that the participants were often very careful organising their thoughts and making sense of how the project progressed.

For these reasons, the accounts given by participants must be treated as revisionist views. By incorporating hindsight to their understanding of events during the projects, the accounts have significance in that they give not simply a narrative of events, but a critical appraisal, in which the participants are actively making judgements about the factors that enabled or hindered the progress of their projects. The cases therefore give a valuable perspective on the projects.

Withdrawal of participants

A crucial factor in developing the case studies was the willingness of individual projects to be scrutinised. For one case study, this external scrutiny did cause a problem. The innovation project was at a crucial stage where it wished to gain industrial partners to develop the project further. The project team took part in interviews with the researcher, however, over the following few months the team decided to withhold their consent to have their interview data used in any published work. The reason given for this was that it compromised the project during a difficult period of negotiation with external partners. For this reason, the case study was not used in this research. The example does however highlight the difficulty of gaining data regarding projects at sensitive points in their development. This creates a difficulty for researching such projects. While the sensitivity of various commercial issues may diminish over time, it is unlikely that participants will maintain a consistent view of events, with the risk that when reflecting back on such periods participants will

provide revised interpretations and perspectives on events, actions and even values. The case in question was withdrawn from this research, however, it is hoped that once the commercial sensitivity issues have been ameliorated by the passage of time then study of the case can be continued and subsequent research findings published.

3.6 Summary

This chapter has provided a rationale for adopting an interpretive, multiple case study research methodology. It has outlined the research design and described its implementation. The principal concern in developing this methodology was to ensure that the research enabled the exploratory study of the phenomenon of user-led innovation. The methodology adopted a theoretical sampling strategy as it represented a systematic research framework, yet maintained a level of flexibility in order to be sensitive to the emergence of unforeseen factors within specific case studies. The following five chapters report the findings of the exploratory study and the four case studies.

Chapter 4: NHS Innovation Hubs and Support for User-led Innovation

This chapter presents the findings of the exploratory study. It explains, from the perspective of NHS innovation managers, how high-level policy initiatives have to a greater or lesser extent conditioned the formal support available to NHS user-innovators. First, the chapter outlines the policy frameworks that affected NHS innovation support and development of the innovation hubs. The chapter then presents two distinctive examples of innovation hubs, Trustech and Medipex. These are used to show how specific hubs addressed the challenge of supporting innovation projects. This evidence provides a view of the practical support given to NHS user-innovators and the perceived challenges to successful management of user-led innovation.

The exploratory study set out to explore issues around user-led innovation in the NHS at NHS policy level and organisation wide support. Its focus was on the services available to support innovation in the NHS, in particular the NHS innovation hubs. These represented the formal mechanisms available to NHS staff for supporting innovation activity. The basis on which this support operated was important as this represented part of the context in which NHS innovators pursued their projects. The study also gave insight into the paradigm in which staff responsible for innovation support operated.

The findings presented in this chapter are based on data collected in face to face and telephone interviews with hub managers. These followed a semi-structured format using a common set of guiding questions (see Appendix 4 for the interview schedule). Additional data was collected through contact with hub staff at NHS innovation hub events.

The informants for the exploratory study comprised:

- CEOs of four NHS innovation hubs;
- technology transfer managers from five NHS innovation hubs;
- two NHS trust R&D managers;

- a clinician responsible for founding a major healthcare innovation awards competition (Medical Futures) and conferences aimed at supporting medical innovation;
- and, press releases and media articles.

The two hubs are distinctive examples for a number of reasons. Both were well established but constituted in different ways. Their difference was in part, due to their development from existing technology transfer organisations being a funded body and a private company respectively. One hub was created as an integral part of the NHS, and the second as a limited company. These two contrasting hubs provide a useful basis for understanding the challenges experienced by all NHS innovation hubs.

The views of the managers were important as the NHS innovation hubs represent the official mechanism for managing intellectual property and technological innovation within the NHS. The hubs were set up as a result of the recognition that advisor organisations were needed to support innovation in the NHS (DoH 2002:15).

4.1 Innovation in the NHS: The context

At the start of the research in 2005, the NHS was in a state of flux about how to support innovation. A series of policies had been implemented in the NHS over the previous decade that impacted on how innovation was to be managed. However, the formal management of innovation and associated IP was still relatively unstructured. Technology transfer out of the NHS was already happening, but support for innovation varied greatly from trust to trust. It was common within teaching hospitals for technology transfer services to be provided by university–based technology transfer offices (UTTO). These were often well developed and resourced. For example, Addenbooke's hospital in Cambridge, had a close relationship with Cambridge University's UTTO, Cambridge Enterprise. Similarly, the Oxford Radcliffe Hospitals NHS Trust had a similar relationship with ISIS, Oxford University's UTTO. Technology transfer services were also provided in some specific areas, such as biotechnology, by public and private sector organisations. In other examples of innovation projects, individual NHS staff members managed their own projects, negotiating directly with private sector partners. Some of these self-managed projects had been commercially successful.

4.2 Purpose and development of the NHS innovation hubs

4.2.1 Innovation in the NHS

Several underlying assumptions about the nature of innovation underpinned the foundations of the innovation hubs. The management framework for managing IP in the NHS (DoH 2002:11) differentiated between "good practice" innovations and inventions that represented significant IP. Good practice innovations required evaluation and dissemination freely within the NHS through knowledge management processes. The assumption was that these had no commercial value but had the potential to improve health services and save expenditure by the NHS. Significant IP generated from NHS based research or through the delivery of patient care, was the main focus for the hubs and was to be exploited on a commercial basis.

It was this distinction between innovation of practices and inventions that defined the work of the hubs. The assumption was that a judgement could be made between treating an innovation as a "best practice" or treating it as an invention. The preferred route for best practice innovations was referral to the NHS Modernisation Agency. NHS innovation hubs were then expected to handle IP associated with significant inventions. This type of IP was to be exploited in three potential ways:

- outright sale of the IP to an existing company;
- licensing or assigning the IP to an existing company in return for fees and royalties;
- licensing or assigning the IP to a spin-out company set up specifically to exploit the IP in return for fees, royalties and shares. (DoH 2002:15)

The ultimate aim of exploiting innovations was two fold. First, improvements in patient care gained from widespread diffusion of service innovations, i.e. through the diffusion of "best practice". Secondly, generating financial revenues from the commercial exploitation of IP. Figure 4.1 shows the range of ways in which IP in the NHS could be developed further in order to gain value from the innovation.

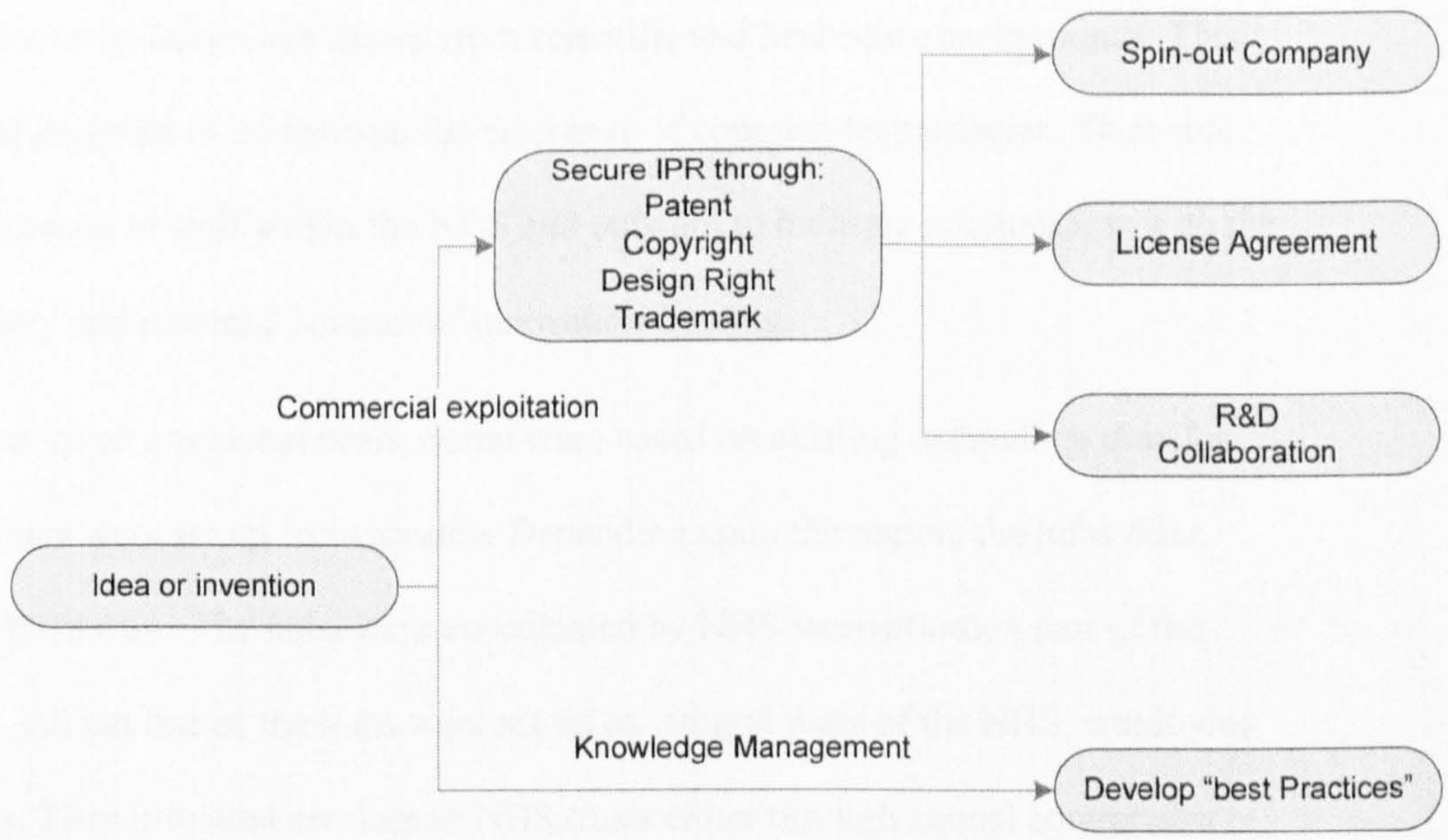


Figure 4.1: Innovation development paths

4.2.2 Mission and aims of the hubs

When the hubs were devised, the DoH proposed a formal list of the services that needed to be provided including:

- Identification of IP through technology audits;
- Training for NHS employees in the importance and understanding of IP;
- Evaluating IP and initiating additional R&D to produce evidence of clinical application;
- Registering the IP;
- Commissioning the product info prototypes;
- Advising on and exploiting the IP through licensing or through the setting up of companies;
- Collaborating with universities and other third parties in the exploitation of IP generated jointly with trusts. (DoH 2002:15)

4.2.3 Creation of the hubs

The hubs were established between 2001 and 2004. Those created early on tended to develop from established advisor organisations. Several of the later hubs developed as new organisations drawing their staff from either UTTOs or private sector technology transfer companies.

Most of the staff employed by hubs were drawn from scientific and healthcare backgrounds. This gave them the required expertise to understand the relevance of complex technologies. Their role required them to face inward to staff within the NHS and outward to building relationships with the wider healthcare industry and potential sources of innovation funding.

The NHS hubs were set up on a regional basis. Some were based on existing technology transfer organisations while others were set up from scratch. Depending upon the region, the hubs often served more than one NHS trust. The hubs were coordinated by NHS Innovations, a part of the Department of Health. All but one of the hubs were set up as integral parts of the NHS, employing staff on NHS contracts. They provided services to NHS trusts either through annual contracts or providing specific services.

4.2.4 Funding

The hubs were funded from several sources as shown in Table 4.1.

Table 4.1: Sources of funding for NHS Innovation Hubs 2003/2004 Source: (NHS Innovations 2004)

Hub	Employees (FTE)	Number of trusts served	Grant Funding					
			PSRE	DoH	Other	ERDF	RDA	BEP
North	7	2	●	●	●	●	●	
North West (Trustech)	8	4	●	●			●	●
Yorkshire and Humberside (Medipex)	5	3	●	●				
East Midlands	5	2	●	●			●	
West Midlands	3	3	●	●				
London West	3	1	●	●			●	●
London North Central	2	1	●	●			●	
London East	4	1	●	●			●	
London South	1	1	●	●			●	
East*		3						
South East*		5						
South West*		3						

*The East, South East and South West hubs were still to be formally created in 2004.

The hubs operated in a competitive market for technology transfer services where inventors had a level of freedom to choose from whom they drew advice and services. From the perspective of the hubs, there was an inequality in funding as compared to other technology transfer companies. This

was most significant in the number of staff available to them. As new entrants to this market, they had to compete with established technology transfer companies possessing reputations and greater resources. The hubs were operating from a weaker position.

Hubs were able to gain an additional stream of income raised by providing various services to NHS trusts. Royalty income from successful projects provided a small but potentially longer term source of finance. So it was a priority for hubs to pursue projects that had significant long term commercial value. This made activities such as licensing and creation of spin-out companies, in which they would have a direct financial interest, a critical area of activity for ensuring their long term viability

A major concern for the hubs was their long-term funding. They were able to access some short term, start-up funding, but the expectation was that they would become self-funding over time. However, most hubs believed it would be challenging to become completely self-funding in the medium term because of the long lead time required to establish and gain income from innovative technologies. Many of the technologies managed by the hubs were still at an early stage of development and were unlikely to provide significant revenues for several years.

A major source of the hubs' income was grant funding. These were for limited periods of time and had to be bid for on a periodic basis. Application for grants required significant effort and staff time, but only provided medium term certainty for the hubs. Their behaviour would therefore be driven by the terms of grant schemes.

A further complication to becoming self-funding was the difficulty in gaining income from service improvement. There were no clearly defined mechanisms for allowing the hub to generate income from these types of innovation. This was exacerbated by the difficulty in quantitatively assessing the benefits of service improvement, often dispersed over several parts of the NHS.

4.2.5 Service provision

Two categories of services were provided by the hubs. The first was concerned with identifying and exploiting IP as and when presented to a hub. These services were instrumental in nature and aimed principally to exploit any innovations identified through "pearl-searching" strategies. These

activities mirrored those provided by other university and private-sector technology transfer companies.

- Innovation Auditing
- Providing financial support for activities such as proof of concept via an internal development fund
- Support for gaining IP protection;
- Guidance on regulatory approval processes;
- Accessing prototyping and industrial design expertise.
- Product Development
- Advice when gaining access to finance
- Advice when choosing industrial partners
- Advise inventors on potential sources of grants from external bodies

The second category was concerned with proactively generating a culture and environment conducive to innovation. Typical services in this category included:

- Networking
- Management Support
- Seminars/Workshops & Conferences
- Innovation Advice & Information
- Providing common points of contact
- Matchmaking with potential partners external to the NHS

4.2.6 Identifying innovation projects

The hubs developed several ways of identifying potential innovations on which to focus their support. The aim was to identify innovation projects early on, so that they could be offered support, advice or access to funding.

First and most importantly was undertaking of innovation audits. This was one of the key IP activities identified by the DoH as requiring the support of hubs (DoH 2002:15). During an

innovation audit, hub staff assessed commercially viable ideas and inventions in NHS organisations.

Second, innovations were identified by holding regional innovation competitions. These enabled hubs to "flush" out a relatively large number of innovations that would not otherwise be identified. The annual competitions run by each hub typically attracted one hundred and fifty entries, of which 70%-80% were classified as service improvement innovations, with a small proportion relating to devices.

The third activity was raising the awareness of NHS staff to the importance of innovations and existence of innovation support services. Emphasis was placed on highlighting the benefits and importance of protecting NHS IP. Typical activities to support this was through leaflets, workshops and other information dissemination activities. The mature hubs found that after two or three years of awareness raising activity they built up a reputation for their work. This resulted in an increase in the number of inventions presented to the hubs from word of mouth recommendation. As a result the hubs received contacts from NHS staff who had developed innovations, but felt that that they were not getting support from their managers. The hubs believed that the process of raising awareness was crucial to their success and NHS innovation in general. Hubs were acutely aware that the large majority of staff in the associated NHS trusts were unaware of the how to progress an innovation or the support available to do this. In contrast, staff who had experienced hub services were generally enthusiastic and felt that they had been well supported.

The hubs were concerned about giving clear guidance on how staff should act to protect IP, so that its value was not lost to the NHS. Typical guidance provided to staff with an idea or invention that they considered novel was based on:

- contacting a senior manger, the NHS trust R&D department or innovation hub, to discuss protection of the IP and how to proceed;
- ensuring that a confidentiality agreement was in place prior to holding discussions with third parties.

It was emphasised to staff that they should not discuss the idea with external organisations, collaborators or colleagues, until the idea was properly protected. They were directed not to publish any details of their ideas in academic journals or at conferences.

Some hubs found that the identification of innovation through technology audits proved to be inefficient in identifying important IP in the NHS. Instead, it was found more fruitful to use informal networks and contacts. First contact with inventors was often the result of asking a general question "who are the most innovative people around here?" Through subsequent discussions, both the innovations and innovators would be identified by word of mouth allowing access networks of inventors and projects. Innovators would sometimes reveal other projects that they were working on and suggest other staff you involved in other innovation projects.

The financial potential of innovations was assessed by calculating their market value, based on the opinion of hub staff and external advisors e.g. from the NHS and industry. Inventions were assessed in terms of their novelty and the status of any associated IP, including relationships with existing patents or licences.

Finally, the hubs were aware that a number of innovations were not presented to them because the NHS staff involved would work directly with private organisations. This created a risk that IPR was not being correctly assigned to the NHS. It was unclear how the hubs could resolve this problem without the risk of destroying motivation to innovate or even driving innovation underground.

4.3 Trustech and Medipex: Two established NHS innovation hubs

Two established and successful NHS innovation hubs, Trustech and Medipex, were included in the exploratory study. At the time of the exploratory study in 2005 many of the other hubs had only just been or were yet to be established. Though sharing similar aims, the two hubs contrasted in that Trustech was established as an integral part of the NHS, while Medipex was a private company.

4.3.1 Backgrounds

Trustech

Trustech was one of the first hubs to be created. Based in Manchester, it had its origins in an organisation called ManIP, which supported technology transfer of biotech and general healthcare technologies. This was set up to provide innovation support and management services, to both universities and NHS trusts in the North West of England. ManIP was primarily supported by funding from the DTI's Biotech Exploitation Platform Challenge (BEP). This was a technology transfer scheme launched in 1996 that aimed to bring:

> ...together universities, research organisations, NHS Trusts and other organisations to create a network ... provide specialist advice in developing and managing IP... protect and exploit research outputs and [provide a] platform for packaging complementary technologies in bioscience. (Barnes 2000)

As a BEP organisation, ManIP's main function was to carry out technology audits to identify promising new technologies. Once these were selected, ManIP advised on protection of associated IPR and supported the innovation through a conventional technology transfer process.

ManIP developed from a BEP to formally become in 2001 the NHS innovation hub Trustech. It employed several of ManIP's staff and became a fully integrated part of the NHS, employing nine staff drawn from a range of relevant specialisms.

Medipex

Medipex Ltd was based in Leeds and served as the NHS innovation hub for Yorkshire and Humberside. It was the first NHS innovation hub set up as a limited company and unlike other hubs that grew from BEPs had its roots in a company, Medilink Ltd. Medilink provided a number of services to the healthcare industry including SME's. These included support for protecting IPR, technology transfer and market access services to medical technology businesses across Yorkshire. Medipex was created as the result of an agreement to form a consortium with the Sheffield and Leeds NHS trusts. Medipex operated with fewer sources of funding than other NHS based hubs

being financed by PSRE stage 1 funding and some Department of Health funding. It did not receive funding from other sources, such as regional development agencies (NHS Innovations 2004).

The hub was set up with a strong private sector ethos drawing staff from private rather than public sector backgrounds. The board of directors was made up of people with predominantly private sector experience in the healthcare industry, particularly with technology start-ups and spin-off companies. The board also had non-executive directors drawn from each of the trusts in the consortium. Several factors informed the decision to create the hub as a limited company. Primarily it was believed that by staying separate from the NHS it could resist the NHS's tendency to form rigid bureaucracies. This would allow it to remain a small, autonomous, innovative organisation and engender staff loyalty. Private company status carried greater freedom to set up spin-off companies. Medipex believed its independence from the NHS gave it a greater private sector focus, enabling it to understand and interact with the wider healthcare industry and markets. It believed itself to be more market focused than other agencies, such as university technology transfer companies.

4.3.2 Missions, aims and services provided

The mission and aims of Trustech and Medipex were very similar. For example, Trustech's mission was to provide innovation management services to north-west NHS trusts and universities underpinned by five aims:

- Promote awareness of the value of IP
- Identify, protect and develop innovation
- Generate revenue for self-sustainability
- Become recognised as a regional centre
- Integrate with regional and national organisations (Deed 2002)

The emphasis of the first two aims was on technology transfer out of the NHS, with the aim of exploiting IP. The last two however, exemplify the importance perceived by the hub in becoming visible both within the NHS and external to the NHS. In particular, the need for the hub to develop

trusted relationships between the NHS and the wider healthcare industry on a regional, national and global scale.

The focus of both hubs was on the commercial exploitation of innovations rather than service improvement innovations. The hubs tended to pass service improvement innovations on to other agencies, such as the NHS Modernisation Agency. Service improvements represented a large proportion of the innovations presented to the hubs, making up approximately eighty percent of those presented.

Both hubs provided similar services, offered on a contractual basis and included the following.

- General advice and raising awareness about IP management for NHS staff.
- Innovation Auditing: Identification, assessment and exploitation of IP.
- Training and education about protecting and exploiting IP
- Advice on construction of IP exploitation strategies.
- Advice on sources and ways of accessing funding
- Access to expert legal, financial and commercial advice
- Evaluation of IP and initiation of further R&D.
- Provision of proof of concept funding.
- Commissioning of prototypes.
- Identification of potential commercial partners.
- Management Support to NHS trusts, for example, assistance in management of IP portfolios.
- Creating a common point of contact and support networking between NHS and private sector organisations.

Providing these services was the main source of income for the hubs, apart from any external funding from DoH or development agencies.

4.3.3 Technology transfer processes followed by the hubs

The technology transfer processes followed by both hubs were not rigid and the processes were customised for each project based on each innovation's characteristics. Despite this variation, it was evident that the processes operated by the two hubs did share some common features.

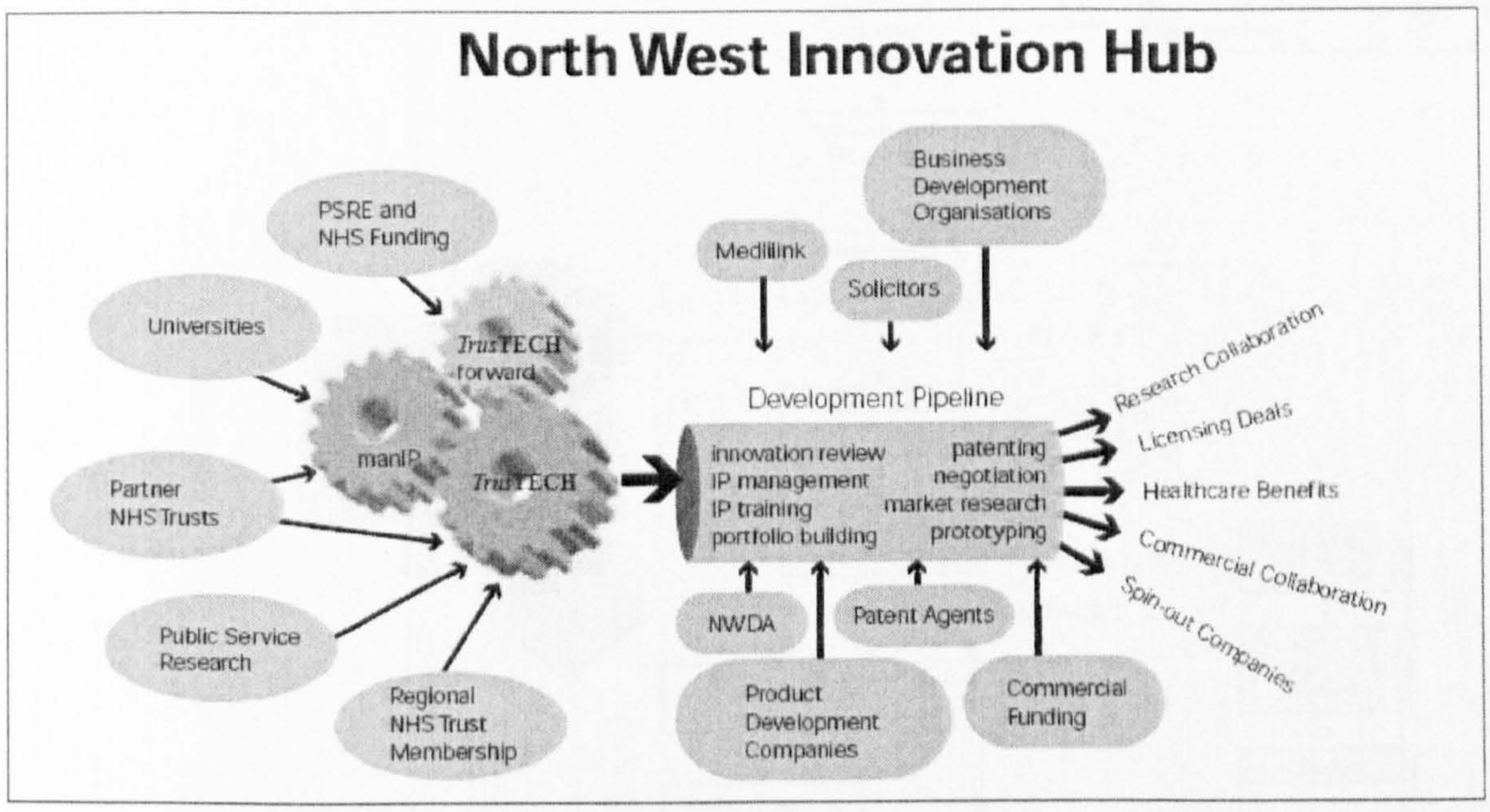


Figure 4.2 Trustech commercial exploitation process (Deed 2002)

Figure 4.2 gives an overview of the processes and relationships that Trustech sought to develop. Its commercial exploitation process illustrates its role as a relationship builder between innovators, investors, development support organisations, industrial partners and ultimately customers. The process was structured around a development pipeline, though this was demonstrated more explicitly in the process operated by Medipex.

Medipex's presented the process model shown in Figure 4.3 as an illustrative model of the exploitation process based upon an innovation pipeline. However, it does give more detail of the relevant stages and activities underpinning technology exploitation; though Medipex acknowledged that it was not comprehensive and understated the iterative nature of the process. The process was based upon three stage gates that acted as decision points for reviewing the progression of the project. Each of the three stage gate reviews were carried out by a dedicated committee, focusing on finance, project appraisal and marketing respectively. Each review was concerned with the extent to which the project had captured, assessed and developed IP and whether it continued to

present a benefit to the NHS. All the committees aimed to provide supportive and constructive criticism to the project team.

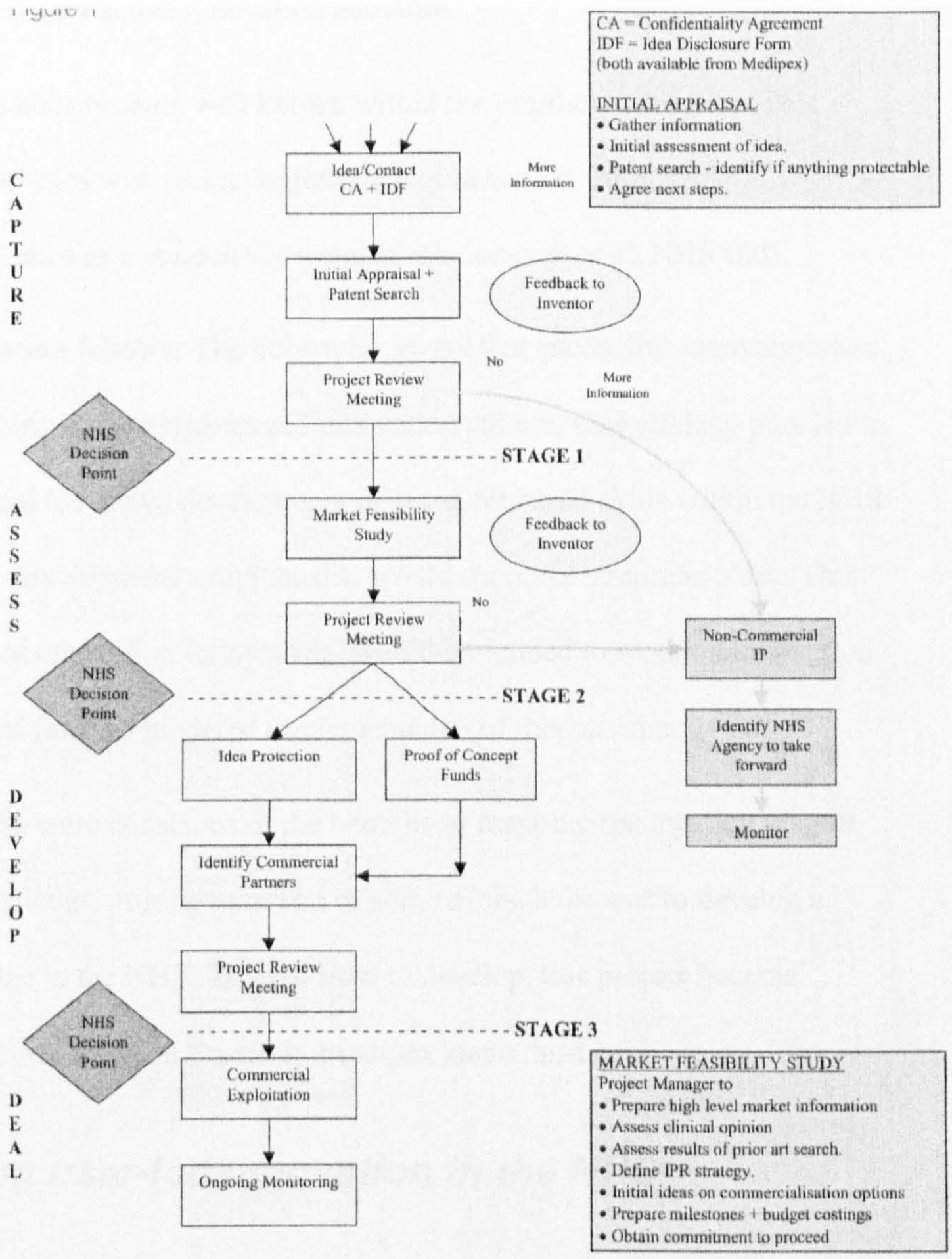


Figure 4.3 Medipex commercial exploitation process (Medipex 2004:10)

The ultimate aim of the innovation process for Medipex was the establishment of licensing agreements with established device manufacturers or the creation of spin off companies. Creation of spin-off companies was a particular focus for Medipex, because it was already structured to do this.

4.3.4 Initiatives developed

The aims of both Trustech and Medipex were very similar, and both hubs were conscious of the need to extend their activities resulting in development of a number of additional initiatives.

Technology opportunities workshops: A proactive approach to identifying potential areas of innovation in the NHS was by developing technology opportunities studies. These involved hub

staff working with groups of NHS staff to identify specific problems that technological innovation might solve. The development of technology opportunities workshops marked a shift in emphasis from reactive "pearl-searching" to proactive innovation activities.

Relationship brokering: Both hubs became well known within the healthcare industry. This meant that medical device companies with technologies that would benefit from NHS development, started to use the hubs as a conduit for forming relationships with NHS staff.

Entrepreneurship and innovation fellows: The hubs were aware that successful innovation was contingent on the NHS developing a more widespread innovation culture. One strategy pursued in response to this by Medipex, was the active development of entrepreneurial skills within the NHS. The hub aimed to operate staff development activities that would support entrepreneurship. One idea was to establish a system of innovation fellows who would be funded to work on innovation activities. Unfortunately, lack of funding hindered implementation of this scheme.

Knowledge mapping: The hubs were conscious of the benefits of mapping the location of staff holding specific skills and knowledge. A long term aim of some of the hubs was to develop a database that mapped knowledge in the NHS. Though slow to develop, this project became operational through a collaboration between Trustech, Medipex and a third hub.

4.4 Factors inhibiting user-led innovation in the NHS

Developments at NHS policy level towards innovation and the creation of the NHS hubs, were recognised by NHS innovation managers to be improving the context for user-led innovation in the NHS. The exploratory study however, identified several factors that inhibited this innovation. These are shown in Figure 4.4. Four groups of inhibiting factors were highlighted in the exploratory study:

- structural barriers to innovation;
- limitation to the existing innovation support services;
- presence of an anti-innovation culture;
- and the behavioural characteristics of NHS clinicians.

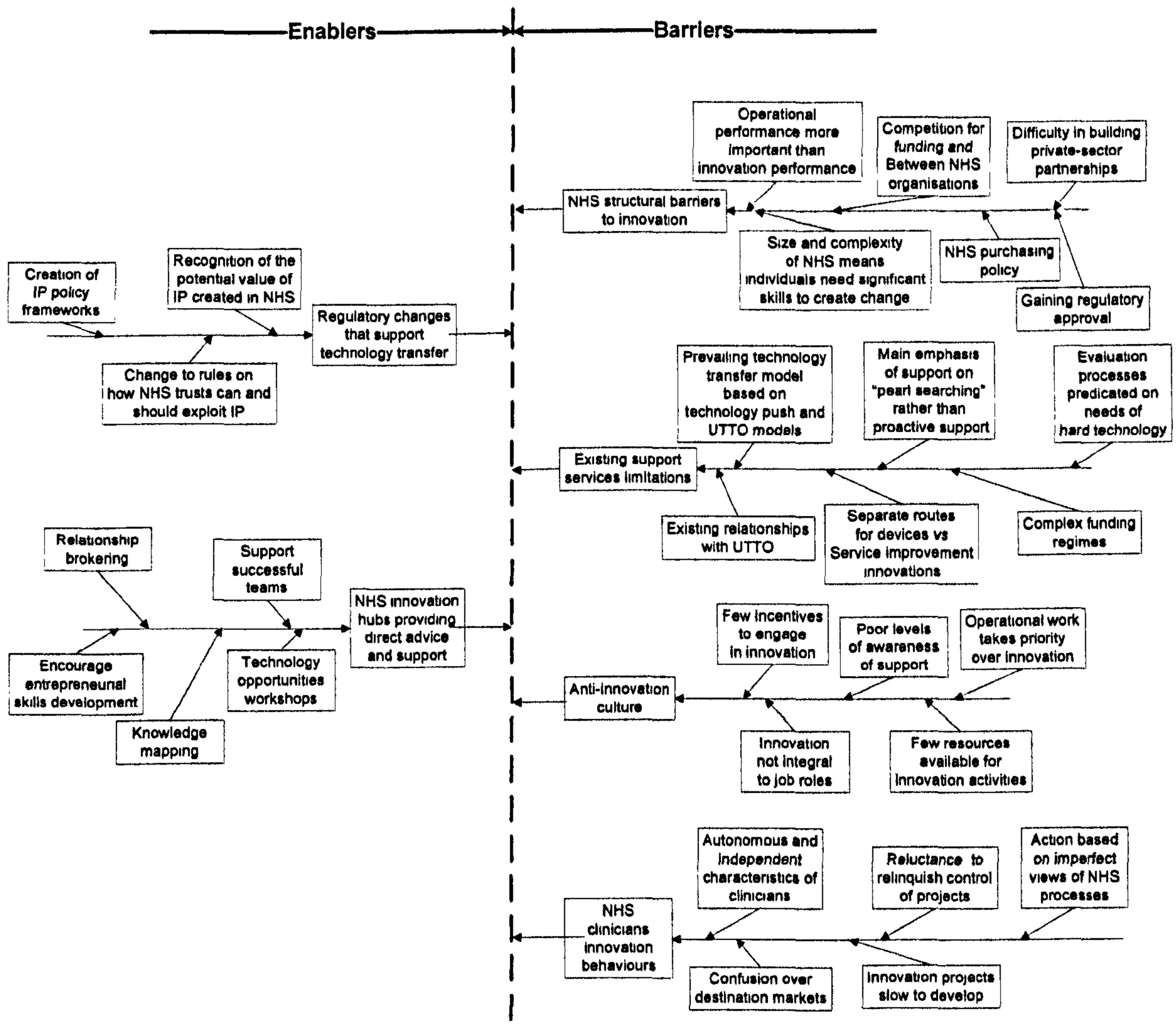


Figure 4.4: Enabling and inhibiting factors affecting user-led innovation in the NHS

4.4.1 Structural barriers to innovation

Despite the policy initiatives, several structural barriers to user-led innovation remained in the NHS. Some of these related to the way that user-led innovation activity was recognised, encouraged and enabled within the NHS, while others related to getting NHS-developed innovations widely adopted within the service.

The primary barrier was perceived to be the emphasis on operational performance of NHS organisations. The key performance indicators used to assess NHS trust performance were predominantly concerned with operational output measures, such as waiting times. This meant that even where a trust did demonstrate successful innovation it was unlikely to impact directly on their assessed performance or secure subsequent funding. This made the senior management teams of trusts more focused on short-term improvements that would have a direct impact on the performance indicators to which they had to work. This was exacerbated by the competition for

funding between NHS organisations, in turn creating barriers to knowledge flow between specialist centres. This emphasis on operational performance meant that there was no significant NHS funding available for development of innovations. The size and complexity of the NHS and the services that it provided created a significant barrier to user-led innovation. While top-down initiatives could force change across the NHS, in contrast, user-led innovation teams needed significant skill and political power to achieve change.

A major challenge for user-innovators in the NHS was getting their innovations adopted back into the NHS. At a regulatory level it was necessary to fund significant development and trialling of new technologies. This was costly and required development of private-sector partnerships; in turn requiring NHS innovators to gain significant business and management skills. Once an innovation had gained regulatory approval there was no guarantee it would automatically be adopted into the NHS. A number of gatekeeper organisations such as the Purchasing and Supply Agency (PASA) evaluated and effectively controlled use of new technologies. PASA in particular created a barrier to adoption of NHS-developed technologies. As the main purchasing arm of the NHS, it operated a list of products for which acceptable purchasing contracts had been negotiated. This essentially created a *de facto* standard set of technologies available to the NHS. Unfortunately, PASA was mainly concerned with purchase cost and little weighting was given to factors such as effectiveness. This created a situation where the assessment of NHS-developed technologies by PASA was based predominantly on purchase cost, even where the technologies had already enabled significant service improvement within the NHS.

Overall, the NHS was an operationally focused organisation that was passive in both encouraging user-led innovation activity and adopting the technologies created by NHS staff.

4.4.2 Limitations in existing innovation support services

The existing innovation support services in the NHS were limited. While there were some services available, often from UTTO and private technology transfer organisations, the majority of NHS staff had little access to innovation support services. The development of a network of NHS hubs was at an early stage and had limited capacity in comparison with the overall size and requirements of the NHS. The prevailing model of innovation support was based on technology transfer through

commercial exploitation of IP, drawing funding from a complex range of sources. Though this was appropriate in many cases its emphasis on technology push was limited and possibly counterproductive for the NHS as a whole. Effort was put into maximising the commercial exploitation of IP often identified through "pearl searching" processes rather than proactive innovation support. The emphasis on commercially exploitable IP was oriented more towards hard than soft technology innovation. This created technology evaluation processes predicated on the needs of hard technology and led to the development of separate routes for device *vs* service improvement innovations.

This overriding model of innovation management was adopted and developed from existing university technology transfer organisations, a model designed for exploiting IP developed in universities and PSREs. The findings of the exploratory study question whether the UTTO model of innovation management is optimal for the NHS (Savory 2006).

The problem identified by government was not that innovation fails to occur in the NHS, but that exploitation of inventions was not always as effective as it could be. The application of the UTTO model however failed to support user-led innovation. The hubs were conscious that explicit models of innovation management based on pipelines provided only a guiding framework for their work, with the detail of their work contingent on the characteristics of individual projects.

The underlying assumption when setting up the hubs has been that it was appropriate to assume that the NHS shared characteristics with universities and PSREs. However, the NHS has unique characteristics that make it distinct from universities and research institutes. Specifically it has an operationally focused, user-led innovation culture, rather than one driven by research activity, as in universities and PSREs. For this reason, the slavish application of the UTTO model represented a potentially sub-optimal approach.

4.4.3 Anti-innovation culture in the NHS

Within the NHS, there was an organisational culture that under-valued innovation activity. There were few financial or other incentives for staff to engage in innovation. Staff were generally unaware of the available innovation support and often so operationally focused that little priority was given to innovation projects. It was common for staff roles to have no explicit expectation to

engage in innovation activities. Few resources were available for supporting innovation projects developed by staff, unless part of major NHS–wide initiatives. These factors all led to innovation projects being both under resourced and very slow in development.

4.4.4 Behavioural characteristics of NHS clinicians

The characteristics of clinicians working in the NHS, and to a certain extent other staff in professions related to medicine, can act to inhibit successful innovation. NHS clinicians, especially those who have achieved consultant status, have significant professional autonomy. This created a risk that innovation was limited by the views of a single or small group of clinicians:

> Clinicians are an entirely autonomous and independent group and at the same time, they are fragmented and sceptical. (Goldberg 2006)

Clinicians can be a rich source of innovation; but can also be reluctant to relinquish control of their projects at the point where additional skills are required. It also implies that an innovation developed by one clinician may not be accepted by all clinicians in that specialism. The independence of clinicians can slow project progress:

> Of the most successful healthcare innovations that stemmed from clinicians, almost all of them took ten years or more to migrate from the innovators' imaginations before they even enter the commercialisation process, which adds another 7-10 years to the development life cycle before patients can benefit. (Goldberg 2006)

Finally, the progress of projects can be impeded by NHS staff basing decisions on flawed views of NHS processes. These false assumptions can be crucial especially when the size and ease of access to the NHS as a market is overestimated.

4.4.5 Internal and external markets for NHS innovations

The dilemma for innovation management in the NHS was that for the majority of innovations, some sort of private sector involvement was needed to supply funding and skills for development of the innovation. Unfortunately, private sector involvement does not guarantee adoption of the product by the NHS. Despite NHS origins products will still face the barriers presented by PASA or NICE. Figure 4.5 shows potential adoption routes for NHS-developed innovations. While

service innovations may be directly diffused within the NHS, product based innovations use market mechanisms.

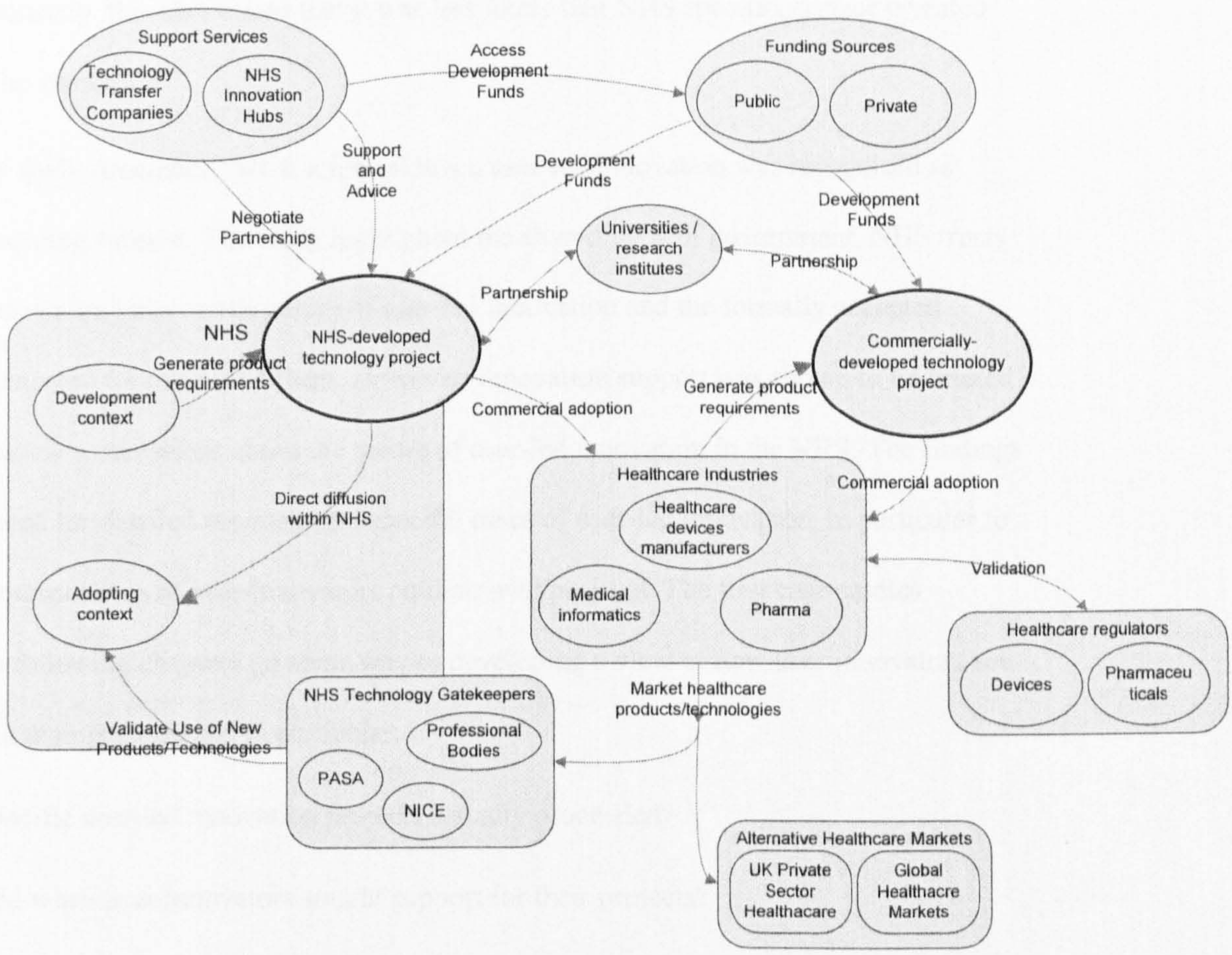


Figure 4.5: Routes to market for NHS innovations

4.5 Summary of the exploratory study

The findings of the exploratory study show that support for technology transfer out of the NHS was well defined, though based upon a narrow approach to innovation management. With respect to user-led innovation, the emphasis of the hubs was focused on commercially exploiting IP developed within NHS trusts. This was an important role, however, it meant that the hubs' main concern was hard technology, such as devices. Though aware of the large number of service improvement innovations generated within the NHS, the core processes operated by the hubs provided only limited support for their development. While the hubs were aware of this imbalance, their funding constrained the ways in which they could extend the support they provided.

The exploratory study raised issues about the role of innovation hubs in supporting NHS innovation. The hubs relied on short to medium term funding for their continued existence. The need to secure long term income streams led hubs to focus only on those innovations that had

potential to develop into commercial products, license agreements and possibly creation of spin-out companies. Through these initiatives, the hubs would gain longer term, more stable income streams. Unfortunately, this also meant that it was less likely that NHS specific, service oriented projects would be supported.

The exploratory study concluded that at a formal level, user-led innovation was recognised as important and needing support. The study highlighted the shared view of government, NHS trusts and the NHS innovation hubs on the nature of user-led innovation and the formally accepted processes implemented for managing them. However, innovation support was shown to be limited and based on narrow assumptions about the nature of user-led innovation in the NHS. The findings reinforced the need for detailed research into specific cases of user-led innovation, in particular to understand the perspectives of user-innovators on their own projects. The four case studies described in the following chapters go some way to developing a view of how user-innovators see the challenges in their projects and in particular:

- How specific user-led innovation projects actually proceeded?
- How and when user-innovators sought support for their projects?
- What enablers and barriers to project progress existed?
- How user-innovators understood the purpose of their projects, particularly in terms of what constituted successful innovation and for whom the innovations were targeted?

All four of the case studies in the following chapters are presented in a common structure. After an initial introduction, each case has the following sections:

Data collection for the case: This section briefly describes how the data for the case study was collected. It gives a brief overview the participants interviewed and general information on the conduct of the interviews. Secondary sources of data used in the case are also described.

Background: The background section provides a view of the technical area in which the innovation took place. It provides a brief introduction to the main issues affecting NHS provision of services in the specific technical area. Significant technical developments in the innovation area produced within or outside NHS are described.

Overview of the innovation: The overview section describes the innovation, its purpose, use of technology and degree of implementation and diffusion.

Innovation process: This section describes the process through which the innovation was developed and the key activities and events that marked its progress.

Organisational context: The organisational context of the case provides information about the organisational setting of the innovation and additional detail about key stakeholders in the innovation.

Emergent themes: This section discusses issues that emerged during the course of the research. It highlights the various themes that had a significant impact on the user-led innovation process, by either enabling or inhibiting the progress of the project.

Summary: The summary section summarises the main issues raised within the case that inform an understanding of user-led innovation within the NHS.

Chapter 5: Leg Ulcer Telemedicine System (LUTM) Case Study

5.1 Introduction

This case is concerned with the service re-design of the leg ulcer clinic of a general NHS hospital. Central to the service re-design was the development of a leg ulcer telemedicine system (LUTM) that supported both clinic and community-based staff in delivering effective leg ulcer care. The service re-design was driven by a consultant vascular surgeon, supported by a small team of staff. It is distinctive as it illustrates how both innovation of hard technology in the form of a telemedicine system and service re-design, can take place through user-led innovation processes. The innovation process adopted a pragmatic approach, based around prototyping and multiple approaches to technology evaluation. The result of the project has been a radically revised design of the leg ulcer service, that has demonstrated a significant improvement in efficiency. The revised service represented a proto-institution of leg ulcer care with the potential to create a step-change in leg ulcer care throughout the NHS.

5.2 Data collection for the case study

The data for this case study was collected through semi-structured interviews and a review of literature associated with the project. The first interview was with the consultant vascular surgeon who had driven much of the project. Two further interviews took place with the Specialist Vascular Nurse associated with the leg ulcer clinic and the Research Nurse who had been involved in the clinical trial of the telemedicine system. All the interviews took place on the same day and clarification of queries raised in the interview was done by email and during a second visit to the clinic.

The interviews followed a semi-structured format using the standard interview schedule (Appendix 1). The interviewer made contemporaneous notes during the interviews. The interviews were not

recorded. All participants appeared relaxed and comfortable about discussing the project during the interviews. The researcher felt confident that the participants' responses were based on thoughtful and genuine responses to the questions and did not appear evasive of any issues. All participants seemed to take part in the interviews enthusiastically and seemed to enjoy being given the opportunity to reflect on the project.

Additional data for the case was collected from a book written by the Vascular Surgeon that describes the project from his point of view. Though this source may give a revisionist view of some of the events in the project and provide a *post-hoc* rationalisation of events, the book is an important data source as it provides an understanding of how the Vascular Surgeon understands the process of user-led innovation.

An external evaluation report produced by Connecting for Health was an additional source of data for the case (NHS Connecting for Health: Integrated Service Improvement Programme 2006).

Published literature by staff at Good Hope on the innovations written (Hayes and Dodds 2003; Dodds 2005; Dodds 2002; Samad et al. 2002; Samad, Hayes, and Dodds 2002). Other secondary literature on leg ulcer care were also reviewed for the case (Angle and Bergan 1997; Ghauri et al. 2000; Grey, Harding, and Enoch 2006; Simon, Dix, and McCollum 2004; Moffatt et al. 2004; Franks and Bosanquet 2004; RCN 1998; Moffatt et al. 1992).

5.3 Background to leg ulcer treatment and service organisation

The treatment of patients with leg ulcers is provided through services where the majority of patients require treatment based on relatively well established procedures. Within the core treatments there continues to be advances in surgical techniques and specialist leg ulcer bandage technology that have an impact on speed of patient recovery.

Leg ulcers are a common disorder affecting over one percent of the population at some point during their lives (Angle and Bergan 1997). The risk of leg ulcers increases with age and they affect mainly older people. The majority of leg ulcers are related to poor circulation in the legs with approximately seventy percent being venous in character. Other forms of leg ulcer occur due to other factors such as diabetes. Leg ulcers are usually symptoms of underlying health problems and

treatment of the underlying cause can accelerate their healing. However, leg ulcers are painful, debilitating and often slow to heal, sometimes taking years if not carefully managed. These factors make their care important especially where elderly patients are living alone or have additional health problems. Recurrence of a leg ulcers is a significant problem with recurrence rates of up to fifty percent (Ghauri et al. 2000).

Before any treatment can be carried out a patient must be assessed to ascertain the type of leg ulcer and to develop a care plan. The assessment of leg ulcers requires a range of investigations. These can include:

- clinical history of the patient;
- family history of patient;
- history of the ulcer;
- physical examination;
- size of the ulcer
- measurement of blood pressure and weight;
- urine analysis;
- measurement of blood flow using doppler ultrasound
- bacterial swabbing of the ulcer to check for infection.

Several of these investigations may be repeated during the care of the ulcer. As with many medical conditions, the diagnosis is based on objective measurements and the application of experience gained from treating other patients. The implication is that successful care of leg ulcers is more likely where specialist staff are involved in the assessment, treatment and monitoring of patients (Simon, Dix, and McCollum 2004).

Treatment follows two main care paths. The first is based upon care in the community by nursing staff who regularly monitor the ulcer and use appropriate dressings to aid healing. The second route is through various forms of surgery. The surgical techniques aim to either improve circulation in the area of the ulcer, or treat the ulcer directly by techniques such as skin grafts (Angle and Bergan 1997). The paradox for many cases of leg ulcers is that while the best treatment methods are widely

available, the decisions for selecting and giving treatment must be made in a timely manner by either specialist staff or non-specialists given access to specialist knowledge. The key problem in this respect is managing knowledge across a multi-disciplinary team of health professionals working within hospital and community settings.

In common with other areas of the NHS, a major constraint is matching the high demand for services, with limited resources for delivery of services. In the case of leg ulcers demand for treatment services is high, with waiting time for access to specialists within a vascular department of a hospital being several weeks. Geographical location of vascular departments is limited to main hospitals because of the limited availability of specialist staff and capital cost of equipment.

5.3.1 Leg ulcer care services

It has been estimated that the cost of leg ulcers to the NHS exceeds £400m per year (Simon, Dix, and McCollum 2004). The main components of this cost are the time spent delivering community-based nursing care to the patient and the cost of specialist dressings. Reduction in treatment costs are most easily gained from improvements in healing rates. The human cost of leg ulcers is also very great. They are unpleasant, inconvenient and reduce quality of life for both patients and their carers. There is therefore a strong rational for improving leg ulcer services on both social and economic grounds.

Since the early 1990s there have been a number of changes that have affected the processes and structures that support leg ulcer services. Figure 5.1 shows the range of factors that have lead to performance improvement in leg ulcer services.

Advances in technology have affected care directly in three ways. First, advances in medical imaging have allowed better diagnostic techniques to be developed. Most importantly, the widespread use of doppler ultrasound equipment has enabled precise measurement of blood flow as part of the diagnostic process. This technology requires skilled operators and so tends to be only based within vascular care department of hospitals. The technology provides the data required to make a diagnosis of the cause of a patient's leg ulcer. Second, advances in surgical techniques have impacted on both the prevention and treatment of leg ulcers. For example, skin graft techniques that are relatively quick and low cost can improve recovery rates. Finally, for the majority of leg

ulcers, use of specialised bandages has improved recovery rates. These bandages require specialised nursing skills to be most effective.

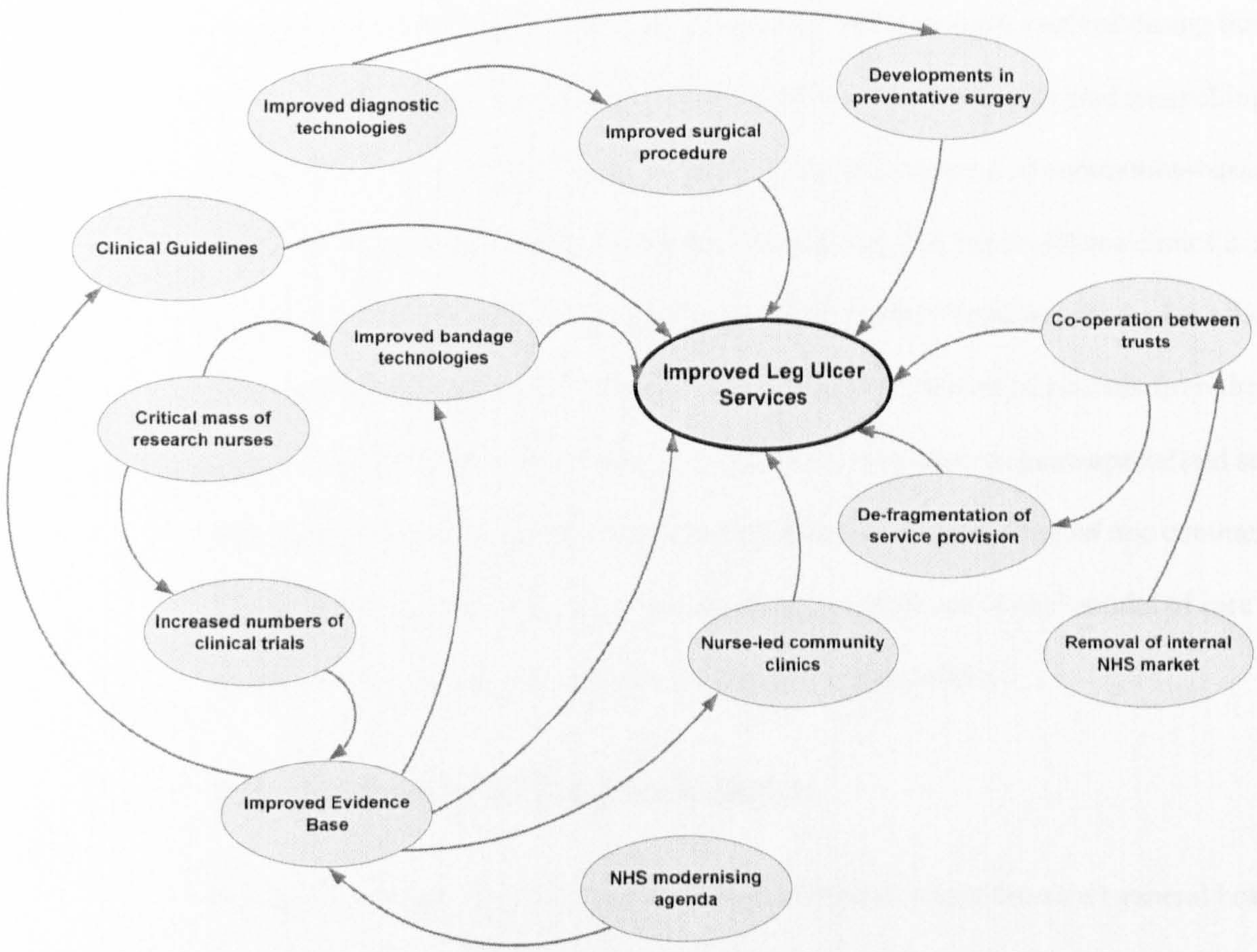


Figure 5.1: Multiple influences affecting the improvement of leg ulcer services

The availability of these technologies means that care of leg ulcer patients can be very effective. The challenge however is the co-ordination of the various services required to apply the most appropriate treatment plan for a specific patient. Leg-ulcer patients are normally cared for by community-nursing staff as out-patients. Community-based staff are rarely specialists in leg ulcer treatment and care plans need to be developed in collaboration with specialist staff based in hospital clinics. Effective treatment for leg ulcers requires the co-ordination of resources between acute and secondary care.

In addition to technological changes, the process of treatment has been carefully reviewed and improved. With the increased emphasis on evidence-based practice, especially in nursing, there has been a steady improvement in how nursing staff have adopted new treatment measures based on proven effectiveness. The clinical guidelines issued by the Royal College of Nursing in 1998

described the practices seen as most effective in assessing and treating leg ulcer patients (RCN 1998). These represented the "best practice" in leg ulcer treatment at the time.

The organisation structures that underpin leg ulcer services have evolved during the 1990s. Trials of new service designs (Ghauri et al. 2000; Moffatt et al. 1992) provided compelling evidence that healing rates can be improved significantly by the development of community-based clinics, staffed by nursing staff with a specialism in leg ulcers. The basis of these clinics is that expertise in care of leg ulcers is made more available at the community level improving both the assessment and treatment practices used. Streamlined processes for referral of patients from the community clinic to specialist hospital departments also improved access to more specialised services. Leg ulcers services over the period can be regarded as having gone from *ad hoc* community based care, with specialist services based only in hospitals, to a "hub and spoke" model of care where services are integrated across primary and secondary care organisations.

5.4 Overview of the innovation

The innovation was developed at Good Hope Hospital, a medium-sized general hospital in Birmingham. The innovation occurred at a time when NHS policy on IP exploitation in NHS trusts was not well developed and there was no significant support for technology transfer offered to NHS staff. The innovation was not centrally planned and was the result of work done by a vascular surgeon in the hospital, supported by nursing staff in his department.

Until the late 1990s vascular surgery at Good Hope was part of the general surgery department. In 1999, a new dedicated vascular department was formed with its own outpatients' clinic. Part of this clinic specialised in leg ulcer treatment and served patients referred by GP from an area with a mixed urban-rural population of 450,000 people. The leg ulcer clinic had originally been organised by a specialist vascular nurse who had set up many of the structures and processes from scratch. Unfortunately, as the clinic had grown it had developed a number of operational problems. The original process followed in the leg ulcer clinic is shown in Figure 5.2.

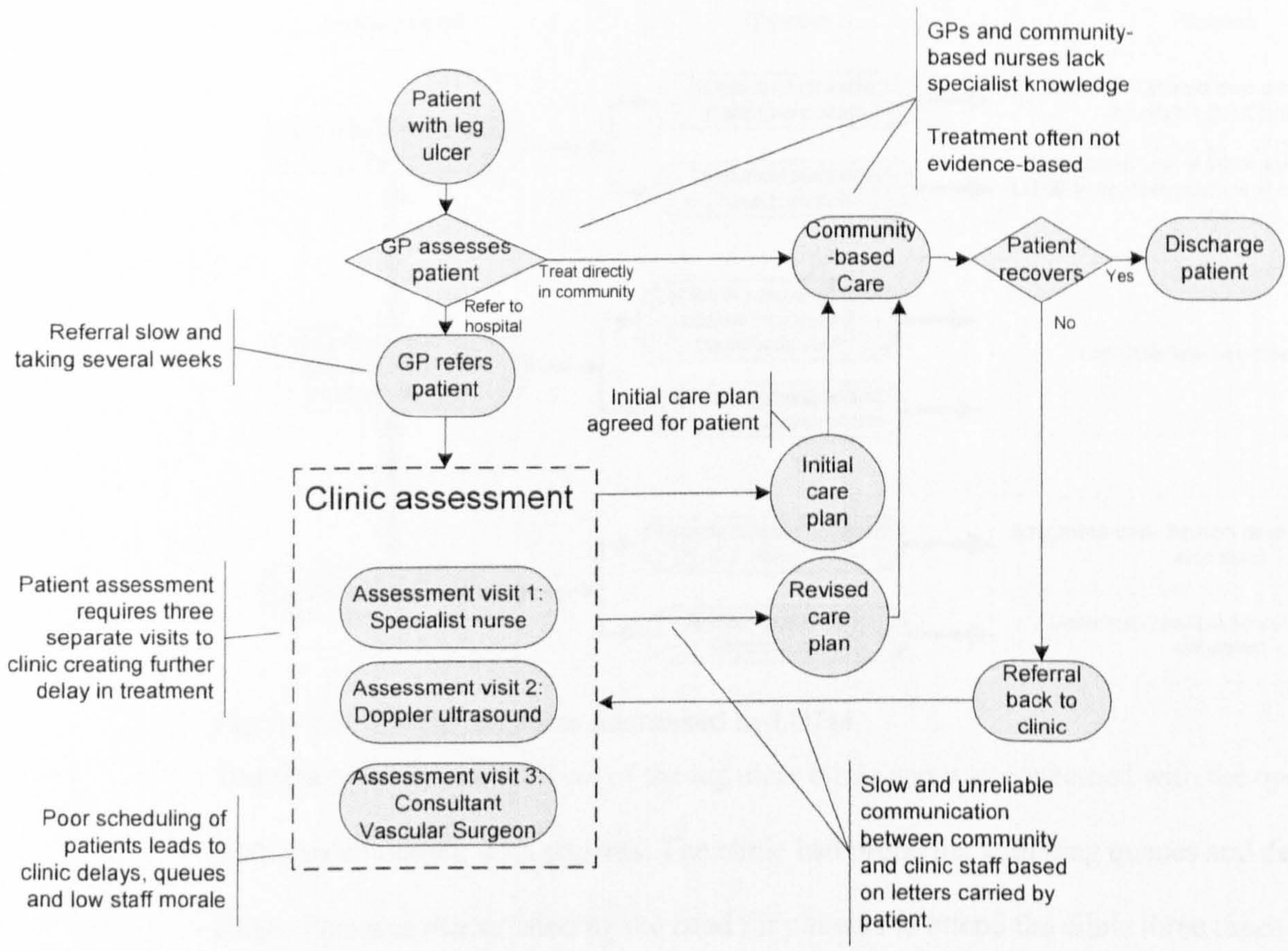


Figure 5.2: Original Leg Ulcer Clinic process

The innovation has resulted in a redesign of the leg ulcer clinic and its processes. This was in response to the problems in the clinic itself and other leg ulcer care delivered in the community. The redesign of the clinic was based around three distinct but related innovations: setting up of a one-stop shop clinic design; implementation of a telemedicine system; and improved scheduling of the clinic, through use of a computer simulation. These changes represent continuous innovation in both soft and hard technologies associated with the clinic and took place a period of several years.

5.4.1 Problem addressed by the innovation

The problem addressed by the innovation at Good Hope can be described at three levels (see Figure 5.3).

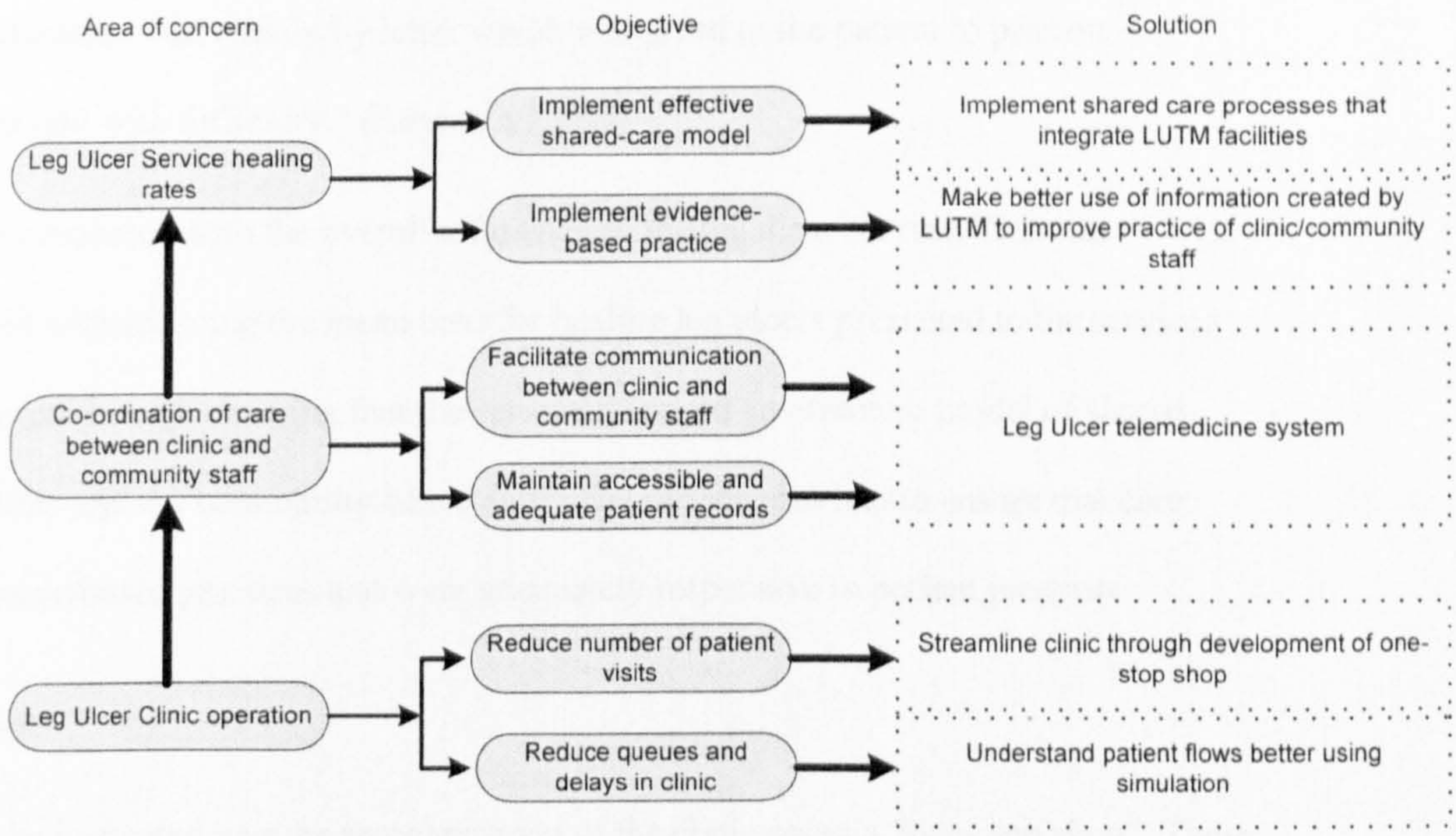


Figure 5.3: Clinical problems addressed by LUTM

The first level was at the level of the leg ulcer clinic and was concerned with the operational problems of dealing with patients. The clinic had problems with long queues and delays during the clinic. This was exacerbated by the need for patients to attend the clinic three times in order to gain a full assessment and consultation for their condition. The delays in the clinic placed additional pressure on staff and lowered their morale.

The second level was concerned with the coordination of care between the specialist clinic staff and community-based staff including GPs and nursing staff. Historically there was a poor level of communication between the hospital and community staff. This meant that referral to the clinic was slow and that the subsequent care plan could not be easily adjusted in response to a patient's progress. The community-based staff had poor access to the necessary specialist knowledge. A specific problem was that after patients attended the clinic, the care plan was often changed by community-based staff without any communication with the clinic. It was therefore unclear whether the care plans were actually followed and if they were changed it was not possible for the clinic to know what changes to the plan had occurred or why. These communication problems were, however, not just one-way.

> "The community nursing teams often had problems getting information from the hospital about their patient's visit, the results of tests and the reasons for the management plan etc. It is very difficult for nurses to contact each other during the

day. Communication was mainly by letter which was given to the patient to pass on – a situation fraught with difficulty." (Research Nurse)

The third level was concerned with the overall efficiency of the leg ulcer service. This was ultimately concerned with reducing the mean time for healing leg ulcers presented to the service. This could be achieved through ensuring that the service managed an effective model of shared-care between the clinic and the community-based staff. The service also had to ensure that care plans adopted evidence-based practices and were adequately responsive to patient progress.

One-stop-shop Clinic

The first change to be instigated was the reorganisation of the clinic using a "one-stop shop". These changes were made primarily to allow for care plans to be established quickly and during one visit to the hospital. Originally, patients would be referred to the clinic by GPs once initial community-based care had failed to lead to satisfactory healing. The clinic would then make an assessment of patients, usually over three visits, based on assessment by specialist nurses, radiography staff using doppler ultrasound and by consultants. In addition, location of radiography staff in their own department, in a separate part of the hospital from the clinic, created logistical problems as leg ulcer patients would need to be accompanied by clinic staff who would redress the patient's leg ulcer after ultrasound assessments. The one-stop shop design brought radiography staff physically into the clinic area, closer to the patients and specialist nursing staff. The reorganisation of the clinic allowed a patient's assessment to be completed and the care plan established during one hospital visit. Patients could then be returned to community-based care with mechanisms for monitoring their progress. The outcome of this reorganisation was that the clinic process was more patient centred, resulting in significantly reduced queues and delays in the clinic. This also resulted in a more even workload which in turn placed less stress on the nursing staff. Many of the changes made in implementing the one-stop-shop clinic were relatively simple changes and could be regarded as "quick wins". However, communication between hospital and community-based staff continued to be a problem and it was clear further improvement were possible.

Leg Ulcer Telemedicine System

The Leg Ulcer Telemedicine System (LUTM) was developed to enable a model of shared care across secondary and primary care organisations to be implemented. This system's primary purpose was to improve information and data managemnet between the hospital and community-based staff. At the core of the system was a secure patient record system with an intuitive and easy to use interface. The system maintained records of patients' care plans and information relating to their progress and recovery. The system stored all the data required to support the treatment of the patient including test results, notes and high quality, digital, colour images. Facilities were included for analysing data and monitoring progress such as: wound measurement, healing graphs and other analysis of progress and treatment outcomes. The system supported messaging between users of the system, for example between community and hospital based staff. The system operated using the NHS network allowing access to authorised staff, irrespective of their location within the NHS. The system acted as both a database and a communication medium.

The LUTM software was written by the Vascular Surgeon in his spare time. The initial functionality testing of the system was achieved with the collaboration of a local GP. The system's actual impact on the clinic was assessed using a randomised clinical trial of the system. The vascular surgeon worked hard and enthusiastically to ensure that staff in the clinic and in the community worked with the LUTM. While only a small proportion of the community-nursing staff used the system initially, support from both the vascular surgeon and specialist nurses in the clinic helped to ensure that problems were solved quickly. The trial had two important benefits. First, it provided hard evidence that the LUTM actually improved healing rates. The second benefit however was in embedding the LUTM into the day to day work of nursing staff. On completion of the trial, the use of the LUTM had to be stopped. This resulted in protests from nursing staff who had recognised the effectiveness of the system and had changed their own working practices to make use of it. This was evidence of not just the effectiveness of the system, but that it was successfully implemented.

The system resulted in a number of benefits in the clinic. The development of an integrated, electronic, wound care record overcame the problems previously experienced with patient records

dispersed between the hospital, GP/community staff and the patient. The system's facility to allow electronic referral allowed much faster access to the clinic by patients. This was partly due to community nursing staff being able to refer directly to the clinic without the intervention of a GP, which in the past had incurred a delay. During the course of caring for a patient, the community-based staff benefited from remote access to expert advice via the system. Evaluation of the system in the context of the one-stop shop clinic, has suggested that use of the system has lead to faster wound healing (Dodds 2002). This has in turn led to reduction in both number of hospital visits and treatment cost. The average number of clinic appointments has dropped from five to two per patient.

The contribution of the LUTM to improved treatment practices has had specific benefits. The use of digital images has allowed the monitoring of care to be shifted from the clinic. Images can be taken in the patient's own home and the images allow an automatic analysis of the wound healing i.e. by measurement of wound area. The clarity of the images also allows clinic staff to assess wounds remotely through being able to make a judgement on wound colour and texture from the images (Samad et al. 2002). The improved availability of data has also allowed better evaluation of care processes.

The LUTM has been successful because it has automated existing clinical processes and it has enabled a new shared-care process to be implemented. In 2004, the LUTM system received the NHS Innovation Award for Service Delivery 2004.

Care Pathway Simulator

The third innovation was to address the problem of patient flow through the clinic by introducing an optimised model for scheduling the clinic. To optimise the scheduling of the clinic the Vascular Surgeon wrote a computer simulation of the clinic, the Care Pathways Simulator (CPS). This simulator then enabled the team to re-think the scheduling of the clinic by understanding the bottlenecks within the existing system.

The CPS was initially developed by the Vascular Surgeon to support the redesign of the clinic scheduling template. He wrote the CPS software because he was unable to find commercial software that addressed the needs of clinicians/NHS managers wishing to re-design service

operations. The Vascular Surgeon perceived the available software to be neither patient-centred nor capable of modelling complex healthcare processes providing a highly customised service. The software addressed this by matching the complexity of the problem with the need to be usable by NHS staff.

The way in which the CPS tool was used developed over time. Initially the Vascular Surgeon created it as a design tool. Over time however, the CPS was used as a design testing tool and then as a teaching and learning tool. He felt that its value was in its ability to educate people to the dynamics of healthcare processes and to become more aware of bottlenecks that restrict wider system performance. He felt the CPS tools were valuable, as generally, "...the NHS does not think in terms of bottlenecks" (Vascular Surgeon). The simulator later became available to other NHS trusts under a software licence.

5.4.2 Result of implementation

The redesigned process within the leg ulcer service is shown in Figure 5.4. The result of the three innovations has been the improvement of the overall leg ulcer treatment delivered jointly by the leg ulcer clinic and community-based staff. At the heart of this improvement is the implementation of the shared-care model of leg ulcer treatment.

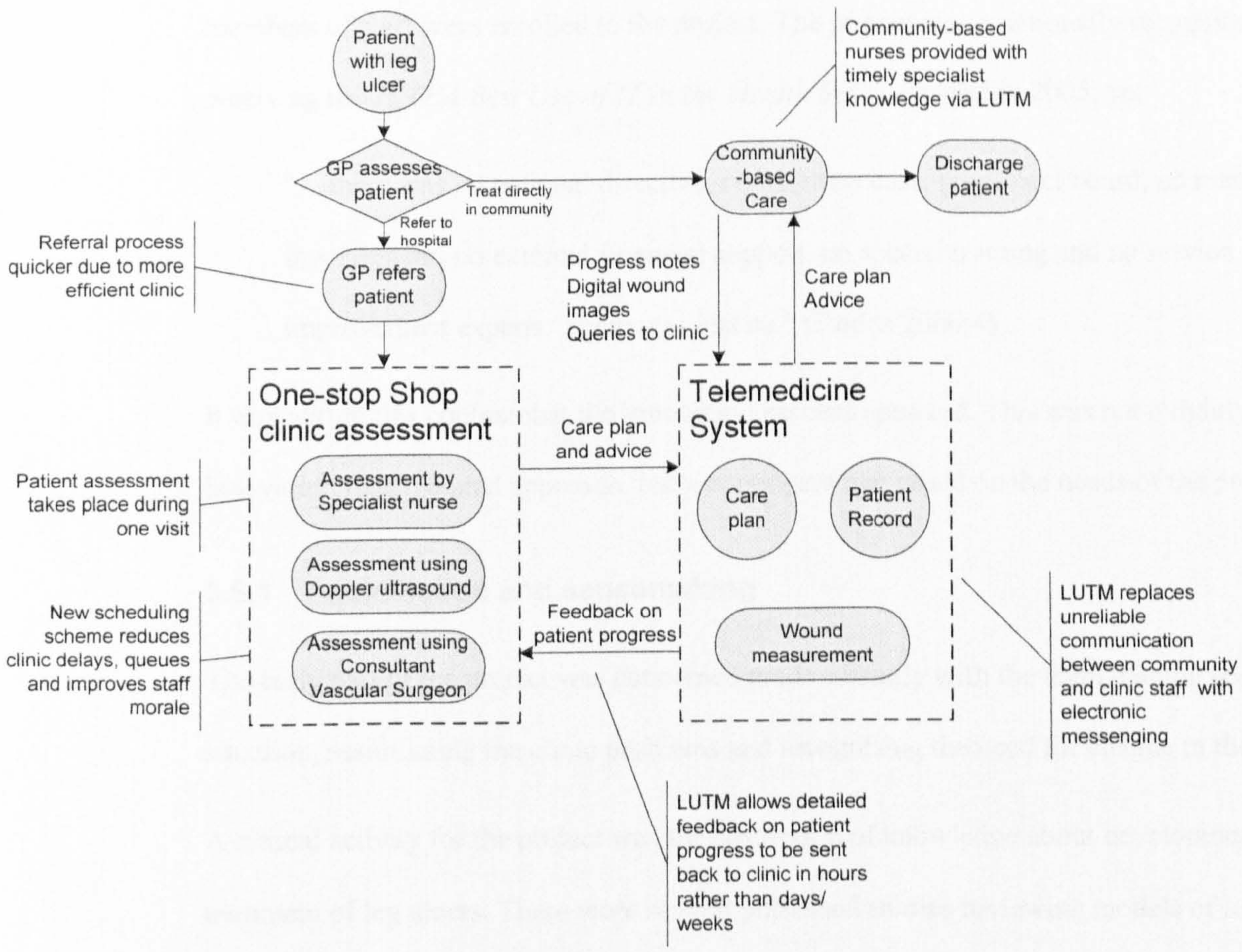


Figure 5.4: Revised Leg Ulcer Clinic process

5.5 The innovation process

This case does not describe a single innovation, but a series of linked innovations that occurred over a period of time. The individual innovations can be seen as part of a wider programme of change in the clinic. An account of the project has been given by the Vascular Surgeon in a book aimed at helping other clinicians lead innovation in healthcare systems (Dodds 2006).

The Vascular Surgeon suggested that the development followed three stages: innovation, investigation and implementation. This view however, fails to highlight some of the processes underpinning the user-led innovation process. This discussion of the project will therefore consider six distinct areas of activity from which the innovations were created. The overall process is shown in Figure 5.5.

The project was driven primarily by the Vascular Surgeon, supported by a small team of staff who maintained ownership of the project throughout its development. As the project progressed, further

members of staff were enrolled to the project. The project was a nationally recognised success, receiving the *HITEA Best Use of IT in the Health Service* award in 2005, yet

> "...there was no national directive, no business case, no project board, no management involvement, no external financial support, no special training and no service improvement experts. There was just us." (Dodds 2006:4)

It was within this context that the innovation process operated. This was not a tightly structured innovation management approach, but a contingent one based on the needs of the project.

5.5.1 Assimilation and sensemaking

The early part of the project was concerned predominantly with the team making sense of the situation, assimilating the clinic problems and recognising the need for change in the clinic.

A critical activity for the project was the absorption of knowledge about developments in the treatment of leg ulcers. There were several published studies reviewing models of leg ulcer treatment within the medical research literature during the 1990s. While the technology of leg ulcer treatment was relatively stable, these studies represented incremental improvements in the existing treatments and the services in which they were offered. The Vascular Surgeon had a long standing interest in the area and had tracked the developments over several years.

In addition to absorbing knowledge from outside the organisation, the project team developed an understanding of their workplace through experiencing day-to-day operation of the clinic. This gave the clinic staff a better view of the clinic's operational problems, than might be gained by an outsider observing the clinic. This tacit understanding of the clinic operation was a valuable resource for the team.

The first significant event in the project was at a monthly department meeting. The Vascular Surgeon encouraged staff to do a SWOT analysis on the clinic. This helped make problems and failings of the clinic explicit, opening up discussion about the potential for change. The Vascular Surgeon suggested that the analysis had several functions including:

> "...to get the whole team talking about where the anticipated problems lay; to agree on where the priorities were; and to decide who was going to do what."(Dodds 2006:11)

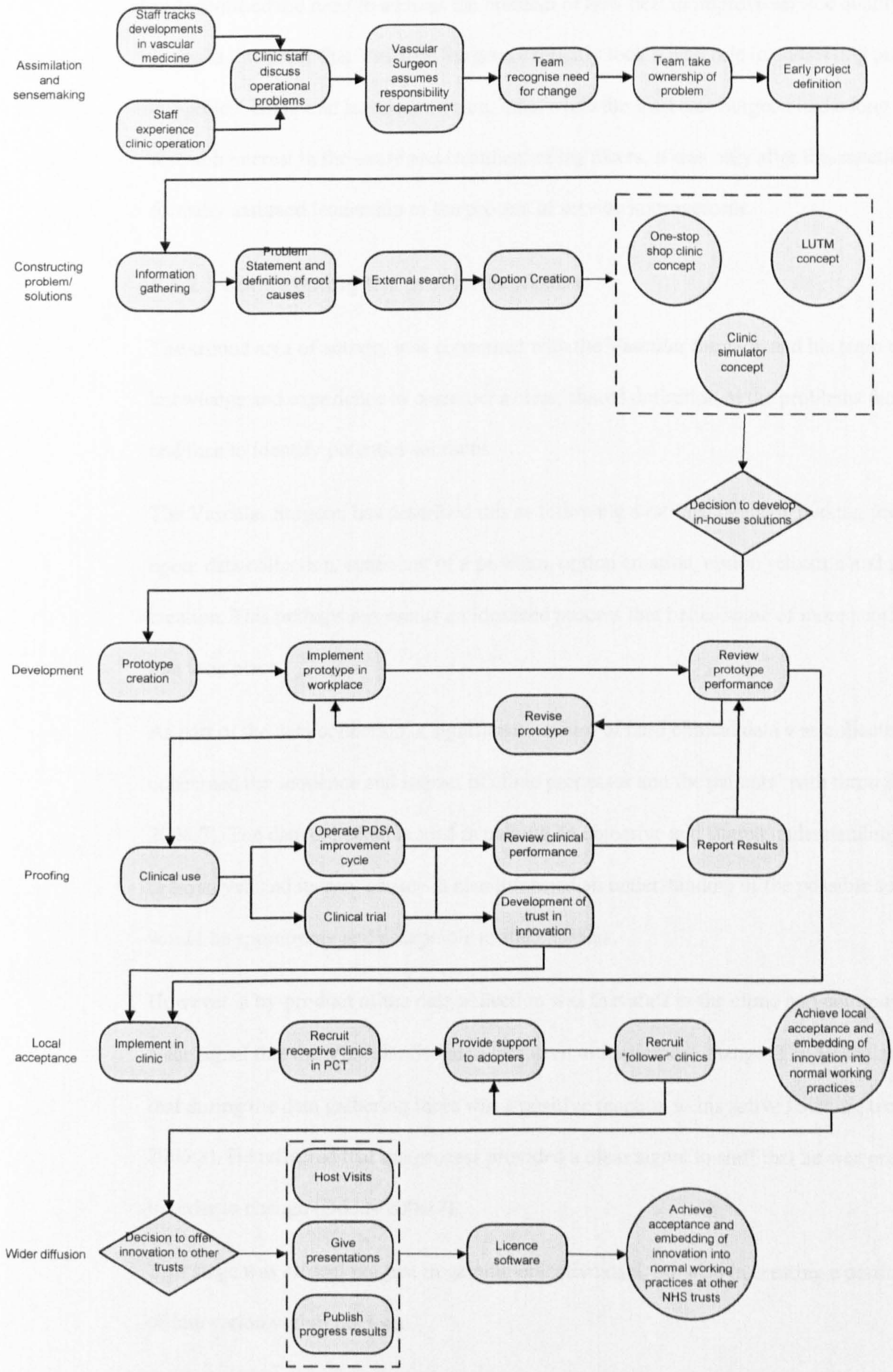


Figure 5.5: Innovation process of the LUTM system

This meeting signified the point where the team took ownership of the problems in the department and identified the need to address the problem of how best to improve service quality for patients. It was at this point that Vascular Surgeon explicitly took a lead role in addressing problems in the out-patient clinic and leg ulcer service. Thus while the Vascular Surgeon had a long standing research interest in the cause and treatment of leg ulcers, it was only after this meeting that he formally assumed leadership of the process of service improvement.

5.5.2 Constructing the problem/solution

The second area of activity was concerned with the Vascular Surgeon and his team using their knowledge and experience to construct a clear, shared definition of the problems facing the clinic and then to identify potential solutions.

The Vascular Surgeon has described this as following a rational decision making process based upon: data collection, statement of a problem, option creation, option selection and prototype creation. This perhaps represents an idealised process that belies some of more subtle interactions that took place.

As part of the data collection, a significant amount of hard clinical data was collected. This data concerned the sequence and impact of clinic processes and the patients' path through them (Dodds 2006:7). The data collected helped in gaining an objective and shared understanding of the problem to be solved and its root causes. It also informed an understanding of the possible solutions that would be appropriate and acceptable to stakeholders.

However, a by-product of the data collection was that staff in the clinic and community were sent a clear signal that the Vascular Surgeon was keen to implement change. The Vascular Surgeon noted that during the data gathering there was a positive reaction to his active listening technique (Dodds 2006:8). He reflected that the process provided a clear signal to staff that he was prepared to learn in order to change (Dodds 2006:7).

This stage was critical not just in gaining objective data, but also in creating a participative culture of innovation within the team.

The agreement of the problem allowed potential solutions to be identified, specifically: the redesign of the clinic into a one–stop shop; implementation of a telemedicine system; and measures to improve clinic scheduling. The decision on the telemedicine option was complicated by whether to develop an in-house solution. This was resolved once the Vascular Surgeon had carried out an external search for existing solutions. Though he was conscious of the danger of "reinventing the wheel", his conclusion was that the existing commercial telemedicine systems were not suitable as they were not aimed at specialist nurses, they had no objective data supporting their success; and they were prohibitively expensive (Dodds 2006:23).

5.5.3 Development

The development of all three solutions followed common pattern. Though the project included three different types of innovation, a similar approach was taken to all based upon a combination of iterative prototyping. Most notable however, was the explicit use of a PDSA (Plan-Do-Study-Act) cycle of improvement (Cleghorn and Headrick 1996). Figure 5.5 shows the development and proofing activities as separate, though interlinked parallel activities.

The development process was generally based around the creation of an initial prototype followed by review and revision. In the case of the one-stop shop clinic, the initial redesign was then modified during a period of continual improvement, while for the telemedicine system the software was treated as an evolutionary prototype (Crinnion 1991), with each iteration being used within the clinic. This approach to development was summed up in the Vascular Surgeon's pragmatic approach:

> "It is better to achieve something easily and quickly that has tangible benefit and which moves you along the path towards your goal than to give up because you can't see a whole solution." (Dodds 2006:24)

The prototyping approach was also seen as vital in allowing the team to learn as they proceeded through the project.

It is worth noting that the Vascular described himself as risk averse and valued knowledge that he perceived as "tried and tested". It is in this spirit the project approached the activities around

validating the innovations in service design and the telemedicine system itself. In conjunction with the development activities, three distinct evaluation approaches were used to validate the innovation.

5.5.4 Proofing

A pluralist approach to validating the innovation was adopted. The first was based around gaining scientific proof, principally through use of clinical trials. The second was based on data collection within a PDSA improvement cycle; a less rigorous approach than a clinical trial but with the advantage of flexibility and fast response to emergent issues. The final approach was based around encouraging the take up and use of the innovation. Based on the use of the innovation, staff would themselves make a judgement on the effectiveness of the innovation. The purpose of the proofing activities was to produce validation data acceptable to the various stakeholders. Figure 5.6 summarises the role of these approaches to evaluation of the leg ulcer clinic innovations.

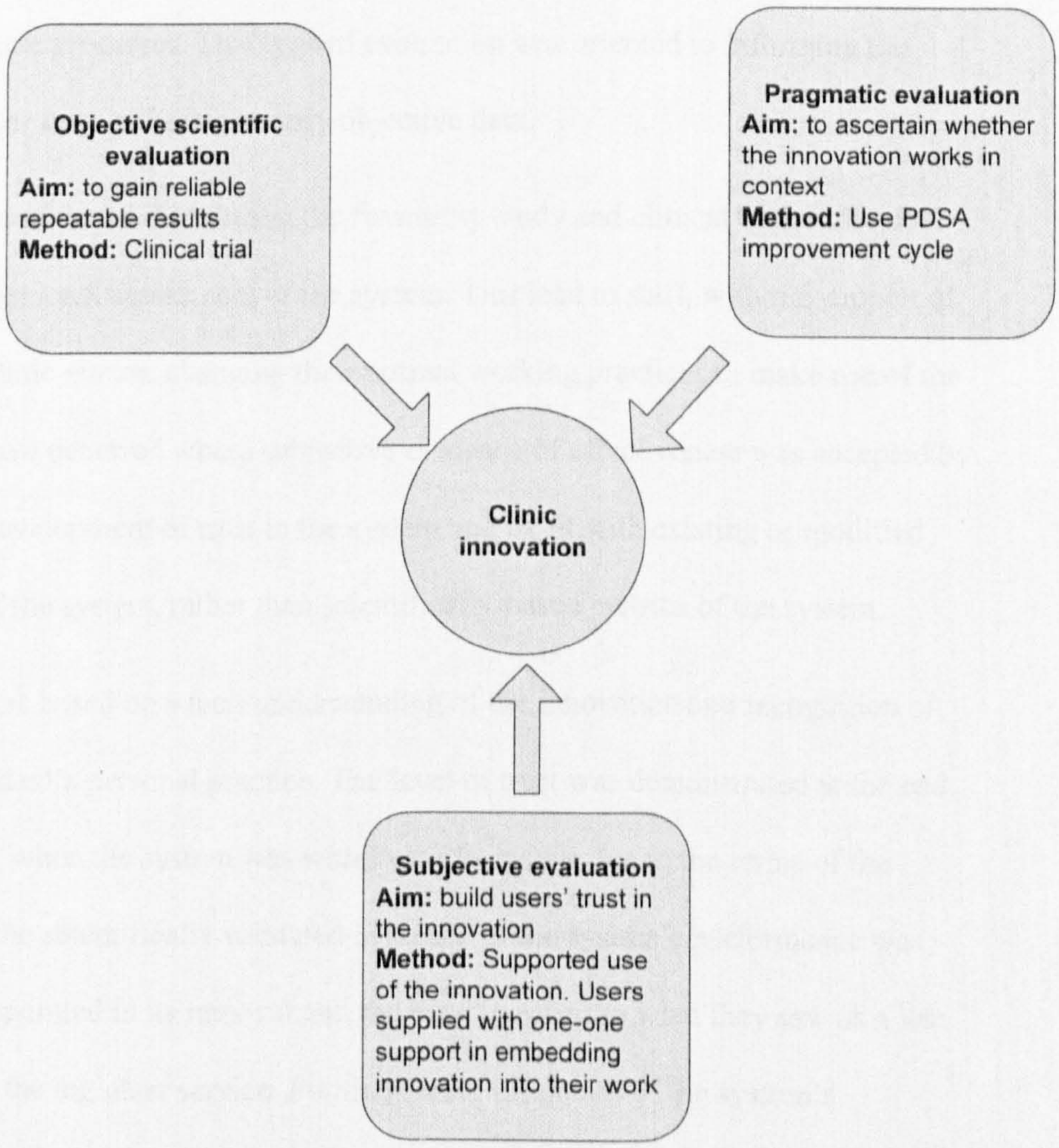


Figure 5.6: Three approaches to validating clinic innovations

Objective scientific evaluation was seen as the prime method of gaining validation for aspects of the innovation. The emphasis of this evaluation was on gaining objective, reliable and repeatable data on the clinic innovations. For example, a specific study was set up to validate the use of digital imaging to assess the size of an ulcer (Samad et al. 2002) and a substantial two year clinical trial of the LUTM system to compare the LUTM's performance against the existing paper based system (Dodds 2002). The results of these trials provided evaluation data for both internal use and for presenting results to the wider healthcare community. In addition to the clinical trails, the innovation has also been externally evaluated in 2006 as part of the Integrated Service Improvement Programme

Evaluation of the innovation also took place on an on-going manner within the PDSA improvement cycle that was operated. For these purposes, a mix of data was accepted for use in evaluation. This data ranged from hard data collected through aggregation of data from the LUTM database to professional judgement of the Vascular Surgeon and other staff based on their experience of working within revised clinic processes. This type of evaluation was oriented to informing the improvement process, rather than gathering strictly objective data.

Through the process of use of the LUTM during the feasibility study and clinical trial, individual members of staff made a personal assessment of the system. This lead to staff, with the support of the Vascular Surgeon or clinic nurses, changing their normal working practices to make use of the system. This could only have occurred where subjective evidence of effectiveness was accepted by the staff. In practice, the development of trust in the system and its fit with existing or modified practices grew from use of the system, rather than scientifically-based metrics of the system.

The trust that developed was based on a tacit understanding of the innovation and recognition of how it fitted into an individual's personal practice. The level of trust was demonstrated at the end of the LUTM clinical trial, when the system was withdrawn from use; due to the terms of the clinical trial. Even before the scientifically validated evidence of the system's performance was published, staff were disappointed in its removal and the need to revert to what they saw as a less effective way of operating the leg ulcer service. For these staff validation of the system's effectiveness was gained through their own personal use of the system.

The case suggests that during the evaluation of user-led innovation, a pluralist approach to evaluating the resulting technologies is adopted. The epistemological basis for evaluation ranges from scientific objective knowledge to participatively-based knowledge (Reason 1999).

5.5.5 Local acceptance

The innovation of the LUTM was such that there was no single point in time when local implementation occurred, or when it was accepted in the service. Instead, the local adoption of the LUTM was gradual. This was in contrast to the creation of the one-stop shop clinic or changes to its scheduling, which were step changes in organisation. These changes only affected hospital-based staff. However, the LUTM required acceptance by both the hospital-based and community-based staff working in the leg ulcer service. The process followed to gain acceptance of the LUTM by both secondary and primary care staff is a distinctive characteristic of this case.

The success of the LUTM relied on staff in both the clinic and the community making effective use of the system. The Vascular Surgeon was able to lead and support clinic staff in using the LUTM from an early stage. It was however more challenging to get community-based staff using the system because of their remoteness from the clinic and the required change in their ways of working. The most important group of community staff that needed to accept the system were community-nurses. Acceptance by GPs was seen as less important. Use of the LUTM by community nurses was necessary to ensure an integrated channel of communication between clinic staff who assessed the patient and agreed a care plan, and the staff administering the care plan directly with the patient. This communication would be wholly mediated by the LUTM.

Through out the changes in the clinic, a regular newsletter was sent to staff to keep them up to date. This went some way to engaging community staff in the process. The primary approach used for gaining acceptance of the LUTM however was recruitment of a small number of community nurses to the project.

The community nurses recruited early on in the project were generally staff who dealt with relatively large numbers of leg ulcer patients. The demographic profile of a community nurse's area often determined the number of patients they had to attend to, areas with high populations of over-70s having the highest rates. For nurses attached to GP clinics with relatively young patients,

occurrence of leg ulcers was generally much lower and hence less of a concern. The Vascular Surgeon reflected that many of the community nurses recruited early on in the project exhibited "early adopter" traits. Those recruited later were often those with fewer leg ulcer patients or who needed encouragement to gain the IT skills necessary to operate the LUTM. The later recruits to the project had often heard about the advantages of the system by word of mouth from the "early adopter" staff. The main mechanism for gaining acceptance of the LUTM was the support given by the clinic nurses. The Research Nurse was responsible introducing community nurses to the LUTM in the community setting. While the Specialist Vascular Nurse often invited community nurses to spend one or two days within the clinic.

Not all community nurses opted to use the LUTM. This was probably because they did not have a critical mass of leg ulcer patients to make adoption worthwhile. The Research Nurse however believed that a significant number nurses rejected use of the LUTM due to insufficient IT skills and/or they did not see use of computer as a part of their professional role.

Adoption of the system by a specific GP clinic was not always automatic. It was common for some groups to receive training on the LUTM system but then never to use the system. For example, in the case of the GP practice used to do an initial technical feasibility study, despite one of the GPs being an advocate of the system, the practice nurses did not adopt the system. The Research Nurse suggested that this was not just because they felt the system had been imposed upon them, it was also due to them being a small, very part-time staff with their own interdepartmental communication problems. Their part-time work meant they also had insufficient time to practice use of the system.

Adoption of the system by GPs was seen as less important. This perhaps reinforces the view that the LUTM system was seen by both consultants and GPs as a system to support nursing care rather than the work of doctors. It also highlights a process-view of ulcer care that defines the role of GP's as concerned with commissioning the process, but not integral to the care process itself.

Local adoption of the innovation was therefore based principally on staff gaining positive experiences of the LUTM and recognised how it fitted into their own work. The LUTM benefited community nurse because it enabled:

- access to specialist advice and knowledge;
- access to specialist nurses;
- access to a vascular consultant via the messaging system within the LUTM;
- ability to bypass GP's when referring patients;
- an increase in the speed of communication between all relevant staff.

Adoption of the LUTM within the hospital was predominantly by nursing staff; use by other consultants in the Vascular Department was very limited. This was mainly due to the system being seen as a "nursing system", rather than a consultant's system. This can be attributed to many consultants seeing the treatment of leg ulcers as a routine problem with routine solutions that do not require their further input. This is despite the fact that the LUTM's success was based on active engagement of the Vascular Surgeon in providing direct advice to community based staff via the system.

5.5.6 Wider diffusion

Limited adoption of the LUTM system in the wider NHS has been through gradual diffusion. The publicity gained by the project has prompted interest from predominantly specialist nursing staff in other NHS trusts. These staff visited the clinic and then championed the adoption of the LUTM in their own hospitals. Adoption of the LUTM software has been predominantly in the neighbouring trusts.

The LUTM was not adopted by any private sector organisations or healthcare providers outside the UK. While the software was made available through a licensing scheme, no major partnerships with large software providers to the healthcare industry have been sought. This has meant that maintenance and further development of the LUTM software has remained under the control of the Vascular Surgeon.

The level of wider adoption in other trusts is disappointing, especially when the number of potential NHS sites exist. The benefits that were demonstrated at the Good Hope clinic could be repeated in all the other leg ulcer clinics in the NHS. This would create a large cost saving for the NHS and a significant improvement in the care of leg ulcer patients in general.

5.6 Time dynamics of the innovation process

The LUTM project took place over several years, starting with the re-organisation of the Vascular Department in 1999. The results of the two year clinical trial on the LUTM system were published in January 2004. Subsequent diffusion of the LUTM to other trusts took place over the following year. This five-year period represented a steady, consistent effort by the Vascular Surgeon and the clinic nurses to develop and implement the system. The project developed at a steady pace and there were no significant periods where the project progress slowed or stalled. It was clear that throughout the project the Vascular Surgeon spent significant amounts of his own time on developing the project. Other clinic and community-based staff were generally able to work on implementation within the constraints of their normal working hours and were supported in doing this by their line managers.

5.7 Key team members

The development of the innovation was lead by a range of staff with the consultant vascular surgeon and two clinic nurses taking the most significant roles.

5.7.1 Vascular Surgeon

The Vascular Surgeon was the principal driver of the innovation. His role was pivotal in the whole of the project and his experience, knowledge and attitudes shaped its development. The Vascular Surgeon was articulate, self-confident, dedicated, hard-working and visionary.

A distinctive feature of the project was the Vascular Surgeon brought a multidisciplinary approach to the project, fusing knowledge of medicine and computer science. In addition to his medical training, he had a degree in computer science and had worked as a professional software developer. In addition, the Vascular Surgeon had an interest and commitment to the use of continuous improvement approaches within the NHS, such as lean thinking. Using these two specialisms, he could design and implement the clinic changes and write the necessary software. These skills made him capable of leading the process re-design in the clinic.

In common with other NHS consultants, the Vascular Surgeon had a large degree of autonomy in his work along with a degree of organisational power. These factors meant that he was relatively unrestricted, compared to many NHS staff, when acting to restructure the clinic processes. This base of power enabled him to implement changes that were not directly under his control. For example, when implementing his computer software on the hospital's IT systems, his expert knowledge as a qualified software developer and his status meant that the IT department allowed him to proceed, with very little resistance or controls imposed. The Vascular Surgeon suggested that this agreement was simply because he demonstrated that he spoke the "same language" as the IT staff.

The Vascular Surgeon suggests that his approach to innovation was based on the need to achieve three high level goals: improve the quality of healthcare service; improve the performance of healthcare services; and improve the quality of working life of healthcare staff. In the account of the project he gives in his book (Dodds 2006), he suggests that these goals drove the progress of the project. His belief was that any innovation process in the NHS would only be successful when addressing all three of these goals. It is unclear whether this represents a revisionist view of the project but is plausible that the Vascular Surgeon guided his actions using a set of heuristics based on these core beliefs about innovation in the NHS.

5.7.2 Clinic nurses

There were two nurses based in the leg ulcer clinic who played a central role in the project: the Specialist Vascular Nurse and a Research Nurse. These two nurses played a significant role in implementing the LUTM system and gaining participation in the project by community-based staff.

The Specialist Vascular Nurse had experience of general and vascular surgery; post-graduate nursing qualifications; and nursing research projects. Her clinic role was to co-ordinate the work of clinic staff and act as a point of contact for community-based staff. She was encouraged in her role to engage in innovation activities and enjoyed involvement in research projects.

The Research Nurse had been recruited to the clinic on a part-time basis, to carry out commercial clinical trials on leg ulcer dressings and to oversee the implementation of the LUTM. She also worked as a nurse trainer within the hospital and at the local university. She was interested in

promoting evidence-based practice and supported community nurses when carrying out research projects, as part of post-graduate nursing qualifications.

The involvement of the Specialist Vascular Nurse and Research Nurse were important for several reasons. First, they brought a nursing perspective to the project that the Vascular Surgeon would have been unable to provide. Second, they provided an important link with community-based nursing staff. In this role they were both able to provide information, training and general support to community –baaed staff. This was crucial to its implantation. Finally, their interest in evidence-based practice meant that they were capable and committed to operating the necessary clinical trials on the LUTM.

5.8 Emergent themes

Several enabling and constraining themes are raised by the case. Figure 5.7 shows how these issues act to enable or retard progress of the innovation.

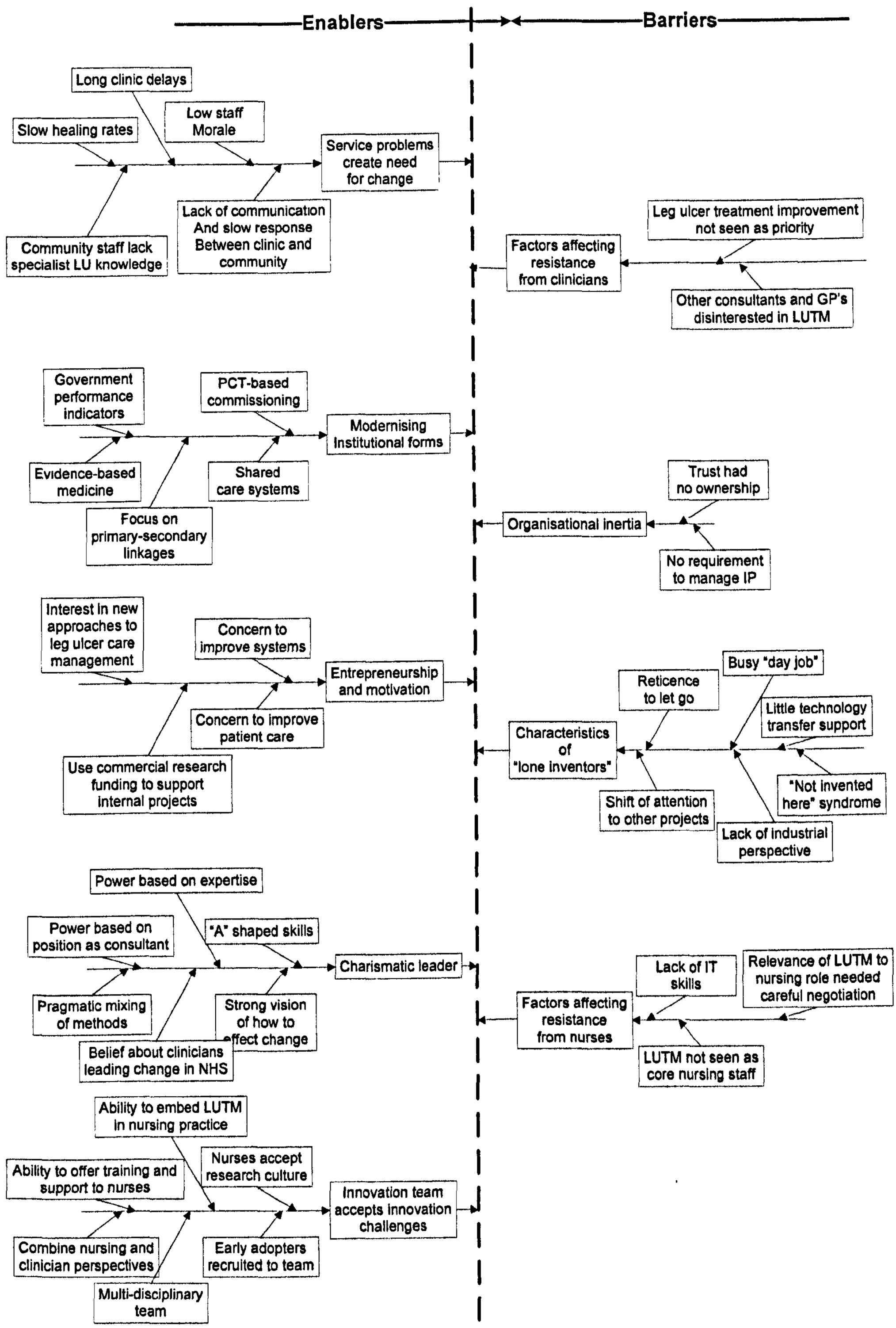


Figure 5.7: Enablers and barriers to innovation activity in the LUTM

5.8.1 Enablers

Two contextual themes contributed to the purpose and motivation behind the project. At a micro-level the operational issues around the leg ulcer service gave staff the motivation to engage with change. At a wider level, the modernising forces acting generally in the NHS helped create an environment for innovation activity.

The intrinsic motivation of staff to drive change was based in a professional concern to improve patient care but as noted by the Vascular Surgeon the motivation for nursing staff was also their own concern for "personal growth and greater responsibility" (Dodds 2006:17). Their entrepreneurial skills were also important, for example, the ability to negotiate resources or link research projects.

Central to the project was the leadership style of the Vascular Surgeon. His strong personality, skill set, pragmatic approach and vision strengthened the project and instilled the confidence of other team members in the project. He was motivated explicitly by the challenge to effect change and improve the running of the clinic. Similarly, the innovation team was strengthened by the combination of perspectives brought together from nursing and community-based staff.

> "... a nurse tends to see a whole person in a patient and the wider aspects of personal, social and psychological health in their therapeutic relationships. He/she looks in depth at how symptoms of illness affect the person and how they may be able to help. A doctor on the other hand is more concerned with the particular set of symptoms that the patient presents with and a solution to the immediate problem. It was very important to get the wording and the emphasis right in the electronic documentation in order to satisfy the needs of nurses. They need to know that quality of life issues have not been sacrificed in the technical wizardry." (Research Nurse)

The role of clinic nurse was important in linking and embedding the use of the LUTM into the everyday practice of community-based staff.

> "When recruiting patients into the trial I met the district nurse at the patient's house in order to explain the project to them and gain their consent. In meeting the district nurses and getting to know them and their 'patch' I gained valuable insight into the

> intricacies and difficulties of their work. They in turn were invited to visit us in the out-patient vascular clinic to gain a similar insight. This was useful in building up relationships and bridging the 'Primary/Secondary Care divide'." (Research Nurse)

The work of clinic staff was vital in the process of building knowledge of the work of the community-based staff and conversely building the knowledge base of community-based staff of how the clinic worked. This was a central factor in ensuring the acceptance of the LUTM system.

5.8.2 Barriers

In contrast, the barriers to the project from other clinicians and nurses ranged from ambivalence, to professional resistance to the LUTM. For example for some community-based staff, the use of computers was seen as peripheral to their work as a nurse. A common attitude was that they:

> "...came into nursing to carry out 'hands-on' nursing not to sit at a computer." (Research Nurse)

This was seen as symptomatic of a more general apathy towards the use of computers in nursing and the lack of IT skills held by many community-based nurses. The Research Nurse suggested that the reasons why some district nurses were reluctant to adopt the system was they tended to work in "fire fighting mode" and they had no time to take on work over "basic chores". The LUTM system was seen by these staff as a non essential chore that simply added to their workload with no guarantee of added value. However, for some adopting groups the benefits of the system was a major force in getting them to overcome computer literacy problems

It is also evident that the NHS trust provided little explicit support for the project showing little commitment to supporting innovation activity. The innovation did however occur before a significant infrastructure for innovation support to NHS staff had been put in place in the NHS.

Though the Vascular Surgeon was vital to the project, the case raises the issue of whether his dominance contributed to the limited diffusion of the innovation. The Vascular Surgeon maintained control over the project when licensing the LUTM software to other trusts. The question remains whether the involvement of an industrial partner, with a different perspective on exploiting the initial LUTM concept, might have improved levels of diffusion to other parts of the NHS

5.8.3 Creation of a proto-institution

One of the most notable aspects of this case is the extent to which the Vascular Surgeon and his team made radical changes to the leg ulcer service. This change represents not just a modification of the process of care but also the institutional framework in which the processes occur. This new model represents a revised institutional framework for the treatment of leg ulcers; its limited diffusion to other similar clinics suggesting it to be a proto-institution. The case therefore illustrates how user-led innovation can lead beyond innovation of hard technology but also innovation of the institutions that impact on technology use.

Table 5.1 illustrates five examples of how institutional carriers have been modified in developing the resulting proto-institution.

Table 5.1: Key differences between the existing institutional framework and the emergent proto-institution

Institutional carrier	Category of carrier	Existing Institutional framework	Proto-institution
Relationship between secondary and primary care trusts	Relational system	Clearly defined organisational boundaries and roles.	Integrated process that cuts across organisational boundary.
Role of GPs	Relational system	GPs maintain control of patient referral and oversee care plan	GPs delegate control to community nurses
Nursing role (community)	Routines	Generalist skill set with little direct contact with secondary care staff. ICT skills given low priority. Low expectation of ICT use.	Nursing role emphasises communication with secondary care staff. Increased use of ICT and encouragement to engage in research active.
Nursing role (Leg ulcer clinic)	Routines	Little scope for leading service change. Few mechanisms for influencing practice of community nurses	Encouraged to improve treatment through EBP supported by LUTM. Direct access to community nurses to influence patient care.
LUTM	Artefact	Role of ICT in leg ulcer service poorly defined.	ICT given a central role as both a communication medium, knowledge base and system for creating clinical evidence. LUTM controlled by and for nursing staff

The most important shift was in the relationship between the primary and secondary care trusts. Before the changes, the two trusts had very clearly defined boundaries and formal lines of communication. The treatment of leg ulcer patients was based on referral by GPs to the hospital and then on completion of an assessment, care would be passed back into control of the community staff. The relational system between the two trusts was characterised as having clear boundaries with responsibility for care passing from one side of the boundary to another. In the proto-

institution created in the boundary was blurred. There was much greater interaction of staff between the trusts at both a formal and informal level.

Related to the change in the relationship between the trusts was a shift in the role of GPs in the system. Previously the GPs had maintained control of the process holding the responsibility for referral and tracking of patient's progress. In the new proto-institution, much of this responsibility was delegated to community-nurses.

The proto-institution reflected a modification of the role of community nursing staff. Previously this role had emphasised a generalist set of caring skills. In the proto-institution the role of community nurses was enriched to include an expectation of ICT skills and usage, with the aim of improving their communication with clinic staff. This in turn enabled staff to gain the specialist skills need for their patients. Part of their new role was to engage in the development of evidence-based practice, for example through running research projects or responding to emerging clinical evidence.

The role in the leg ulcer clinic of specialist nurses was also modified in the proto-institution. The new role was enlarged to include support of the community-based staff. This implied use of ICT in the form of the LUTM, for which they were given responsibility and ownership. This role also extended to contributing to the building of a knowledge base to support evidence-based practice.

The LUTM was the central technological artefact that underpinned the proto-institution. It was important, as previously ICT had no significant role in supporting patient care. The LUTM enabled communication across the care process and acted as a knowledge repository. Its ownership by the nursing staff in both the clinic and community was vital to its acceptance, while allowing both GPs and some hospital consultants to reduce their involvement in the leg ulcer service.

The role of both formal and informal institutions is central to understanding the user-led innovation process in the clinic. The agency of staff, in particular the Vascular Surgeon, took place within frameworks set by various existing institutions. Some of these frameworks imposed limits on the agency of staff, while others actively empowered or supported the agency of staff.

The two formal organisations that had a fundamental influence on the innovation were the primary and acute care organisations that the leg ulcer service worked across. These influenced the project

through the regulative function they served. The root of the problem in leg ulcer care was caused by the discontinuity created by a single process being delivered across two organisations. The two organisations were both operationally focused and had very little resource to invest in research or innovation activities to bring about long term improvements in efficiency or effectiveness. It was in this context that the user-led innovation developed, with little centralised support or governance for the innovative activity. The project was separate from the formal strategies and plans of both organisations, but this separation enabled the team to operate autonomously. The agency of staff to make changes to the clinic processes were not limited by the "unofficial" nature of the project; for example relocation of specialist staff into the clinic area was negotiated by the Vascular Surgeon. The primary and acute organisations can be characterised as setting institutional constraints on the innovation through creation of regulative structures; these were however overcome through agency of the staff.

Professional organisations and the professions that they served were important institutional influences on the project. The Vascular Surgeon had a dual set of skills in medicine and computer science, both legitimised by professional qualifications. This allowed him to work legitimately in the areas of both vascular surgery and software development.

Change in the role of nurses in the service was supported by existing institutional structures. The nurses' professional bodies set out the expectation that they combine the role of carers with that of reflective practitioners involved in systematic improvement of clinical practice. Many of the clinic and community nurses were enthusiastic and skilled in operating clinical trials of new approaches. This enthusiasm was often based in their pursuit of further professional university-based qualifications.

However, two institutions exerted significant normative and social-cognitive influence on the innovation process. First, the institution of evidence-based medicine (EBM) has influenced the innovation process. EBM is an institution that has a strong influence on all aspects of modern medicine. It comprises a coherent and widely accepted set of methodologies for developing scientifically validated knowledge to inform patient care. The role of EBM has been crucial in validating the telemedicine system through the conduct of clinical trials, this approach to evaluating

clinical technologies is widely recognised as legitimate, providing "gold standard" evidence of its effectiveness. The design of the LUTM has also been influenced by EBM. Much of the data stored in the LUTM is used to provide information that itself supports an evidence-based approach to development of leg ulcer care. The institution of EBM has therefore been an enabler of change and a source of legitimation.

A second important institution is the community providing leg ulcer care services. This is a community of practice made up of staff from many organisations providing leg ulcer treatment. Loosely connected and geographically dispersed, the community is unified by their engagement with the professional and academic discourses on leg ulcer treatment. The Good Hope case highlights how the user-led innovation relied on reconfiguration of technologies and processes, many of which had been developed over a long period of time. The LUTM system made use of or built upon many ideas already in the discourse of leg ulcer treatment. From an institutional perspective, this community of practice provided legitimate knowledge on which to base the innovation.

The proto-institution of leg ulcer treatment is central feature of the Good Hope clinic and the smaller number of other clinics it has been licensed to. The LUTM encapsulates many of the features of the proto-institution and so it's diffusion to other sites has potential to institutionalise the knowledge created within the project. Unfortunately, the project is at a crucial stage where the proto-institution has been proved to be effective, yet until widely institutionalised it will have little impact on the effectiveness leg ulcer treatment in the wider NHS. This suggests that a critical point in user-led innovation is when a proto-institution has been developed. At this point, the path of the project may need to shift to enable the wider diffusion of a proto-institution, for example, through creation of industrial partnerships or even a change in leadership with the project.

5.8.4 Innovation as bricolage

The approach taken to innovation this case suggests that user-innovators are often in a position to either apply existing technologies or where necessary, create new technologies that fill perceived gaps. The Vascular Surgeon "borrowed" much from the general discourse on leg ulcer care. This meant that in reorganising the clinic he relied on developments that had been tested elsewhere. In

other cases however, he developed original solutions, most notably in the case of the LUTM and the care pathway simulator. The process of user-led innovation in this case illustrates the process of innovation as bricolage (Garud and Karnøe 2001).

The decision on whether to adopt an existing technology or whether to create a new technology was very much down to the Vascular Surgeon, with the resulting innovation a hybrid of existing and new technologies. For example, he consciously adopted soft technology, such as the shared-care model, and hard technology, such as digital cameras and other computer hardware. In contrast, he consciously rejected existing telemedicine systems and process improvement software, as they did no adequately fit the solution he was building, writing his own software to fill the gap.

5.9 Summary

This is a complex example of user-led innovation which demonstrates many important attributes of user-led innovation and the processes through which it occurs. The innovation had several foci: computer software, clinical procedures and knowledge management processes. At its heart was the LUTM system itself, a software system. The success of this hard technology however is coupled with the transformation of the processes of leg ulcer care across both the hospital and community-based organisations; it is an example of an innovation that has dramatically improved the effectiveness of processes crossing between secondary and primary care organisations. User-led innovation in the case has been holistically focused on the whole technology system, rather than simply focused on a single device or procedure. This is illustrated in the development of the CPS in which the software was used by staff to support their learning about the system in which they worked.

The case demonstrates that to understand the complexity of user-led innovation it is necessary to recognise that both hard and soft technologies are the focus of innovation. Their innovation is conditioned by structural factors such as organisational structures, professional roles etc. however; user-led innovation can lead to alteration and renewal of these institutional structures. The case has demonstrated that the innovation resulted in the localised formation of a new institutional structure, the proto-institution of leg ulcer care. This new structure (see Table 5.1) defined new: relationships between organisations; staff; skill sets; and norms for communication and knowledge sharing. It is

apparent that the proto-institution was of equal importance to other aspects of the innovation such as the LUTM and raises the issue that diffusion of the proto-institution is equally as critical as diffusion of hardware and software.

The case illustrated a range of approaches to both development and evaluation. Evaluation in particular was shown to be done in a range of ways, to serve multiple purposes. But most starkly is the organic nature of the process. Furthermore, the processes of development and evaluation have also been shown to be critical to the local adoption of the innovations. The process though idiosyncratic and dominated by a single individual has achieved a level of acceptance and use that centrally planned innovations may well have failed to achieve.

Chapter 6: ePAQ Case Study

6.1 Introduction

This case study outlines the development of an electronic questionnaire system to support the assessment of patients' symptoms prior to clinical interviews between consultants and patients in uro-gynaeocology clinics. The project was innovative because for the first time a simple to use computer-based questionnaire was developed that could be with uro-gynaecology patients. The resulting system was innovative in that it also incorporated a questionnaire builder, allowing questionnaires for other disorders to be easily created, maintained and incorporated into the system. An unintended outcome of the project was that the questionnaire prepared patients for the conversation they had during the clinical interview. The use of the questionnaire by staff in the primary care setting has also improved the process of triaging and referring patients to the uro-gynaecological department. The system has resulted in the development of a new commercial service designed to allow the questionnaire to be used by other NHS hospitals.

6.2 Data collection for the case study

The data for this case study was collected through eight semi-structured interviews and a review of literature associated with the project. The sequence of the interviews was defined by the availability of staff. The interviews took place over a number of weeks with clarification of queries raised in the interview done by email. Table 6.1 lists the participants interviewed for this case study.

The interviews followed a semi-structured format using the standard interview schedule (Appendix 1). All interviews were recorded with the interviewer making additional contemporaneous notes during and immediately after the interviews. All participants appeared relaxed and comfortable about discussing the project, however the researcher sensed that some participants, predominantly relatively junior members of staff, seemed uneasy about being critical of the project. This may have

made their accounts of the project slightly skewed. On the whole, the researcher felt confident that the participants' responses were based on thoughtful and genuine responses to the questions. All participants seemed to take part in the interviews enthusiastically and seemed to enjoy being given the opportunity to reflect on the project.

Published literature by staff associated with the project was also reviewed for the case (Bradshaw et al. 2006; Hiller, Bradshaw et al. 2002; Hiller, Radley et al. 2002; Radley and Brown 2005; Radley and Jones 2004; Radley et al. 2006).

Table 6.1: List of participants in the ePAQ case study

Participant	Abbreviation	
Consultant Uro-gynaecologist	Consultant A	Consultant A started working at the Royal Hallamshire Hospital in Sheffield in 2000. Consultant A was the user-innovator who created and developed the innovation.
Senior Consultant Uro-gynaecologist	Consultant B	Consultant B was the senior uro-gynaecologist in the department. Consultant B had used ePAQ for several years and had acted as a champion for the project.
Systems Development Manager	SDM	The SDM was the System Development Manager for the Department of Obstetrics, Gynaecology and Neonatalology". His main roles were to oversee the maintenance and operation of existing information systems in the department; develop new systems both in-house, or using outside suppliers; and to look at the management of data within the directorate.
Senior Sister		The Senior Sister became involved in the ePAQ project when the system was first brought to the Uro-gynaecology Department and used with patients prior to them meeting the consultant. She had responsibility for the introduction of the use of ePAQ in the clinic. This involved training both staff and patients in how to use the system and managing the patient consent process.
Research Nurse		The research nurse was brought into the project in 2003, at the point where clinical trials of the ePAQ were being carried out in GP practices and health centres, though some of the trial was based in the hospital clinic. She had worked on the project for 1 day a week, mainly during phase 2.
Scientific Computing Group	SCG	The Scientific Computing Group (SCG) was a section within the Medical Physics Department of the Royal Hallamshire Hospital. The Medical Physics Department had a general interest in development of imaging and instrumentation technologies. The Scientific Computing Group, as well as being involved in computing applications for instrumentation, had a history of being involved in the development of applications for use within the hospital, primarily based around Access databases for administrative systems.
Software House Director (SHD)	SHD	The SHD was the founder and director of Illuminaries Ltd, the company chosen as the industrial partner on the development of ePAQ system.
Technology Transfer Manager	TTM	The TTM worked for Medipex Ltd., the NHS innovation hub that provided technology transfer support to the project.

6.3 Urogynaecology and patient administered questionnaires

Urogynaecology is the "...branch of medicine concerned with the urological problems [such as urinary incontinence] of women." (Merriam-Webster Medical Dictionary) An important area of urogynaecology is pelvic floor medicine, which is concerned with symptoms of bowel and/or urinary dysfunction.

A characteristic of pelvic floor disorders is that specific symptoms have a number of interrelated causes. For example, urogenital prolapse may cause a variety of symptoms including: constipation; anal and urinary incontinence; and sexual dysfunction. In order to understand fully a patient's problem the clinician needs to ask the patient a comprehensive range of questions. Unfortunately, it is common for patients, many of whom are elderly, to find it embarrassing to discuss the symptoms associated with pelvic floor disorders. Consequently, clinical interviews are complicated by patients' reticence to discuss intimate details, especially with a male doctor. It is therefore common for patients, due to embarrassment, to provide incomplete accounts of symptoms during a clinical interview. This raised concerns about the reliability of data gained from patients during clinical interviews.

An important theme in urogynaecological interviews is the need for the clinician to make both objective and subjective assessments. The subjective assessments are often based on the need to asses the extent to which a symptom affects a patient's quality of life (QoL), as it is common for patients to react to certain symptoms differently. For example, sexual dysfunction may be unimportant to a woman who is no longer sexually active.

The diagnosis of uro-gynaecological problems relies on clinicians gaining detailed information from the patient, so that the nature of the problem and the extent to which it is troublesome to the patient are established. The clinician is able to develop an appropriate treatment plan only on the basis of a reliable assessment of these two factors. Figure 6.1 shows the relation of clinical interviews within the overall process of uro-gynaecological treatment process.

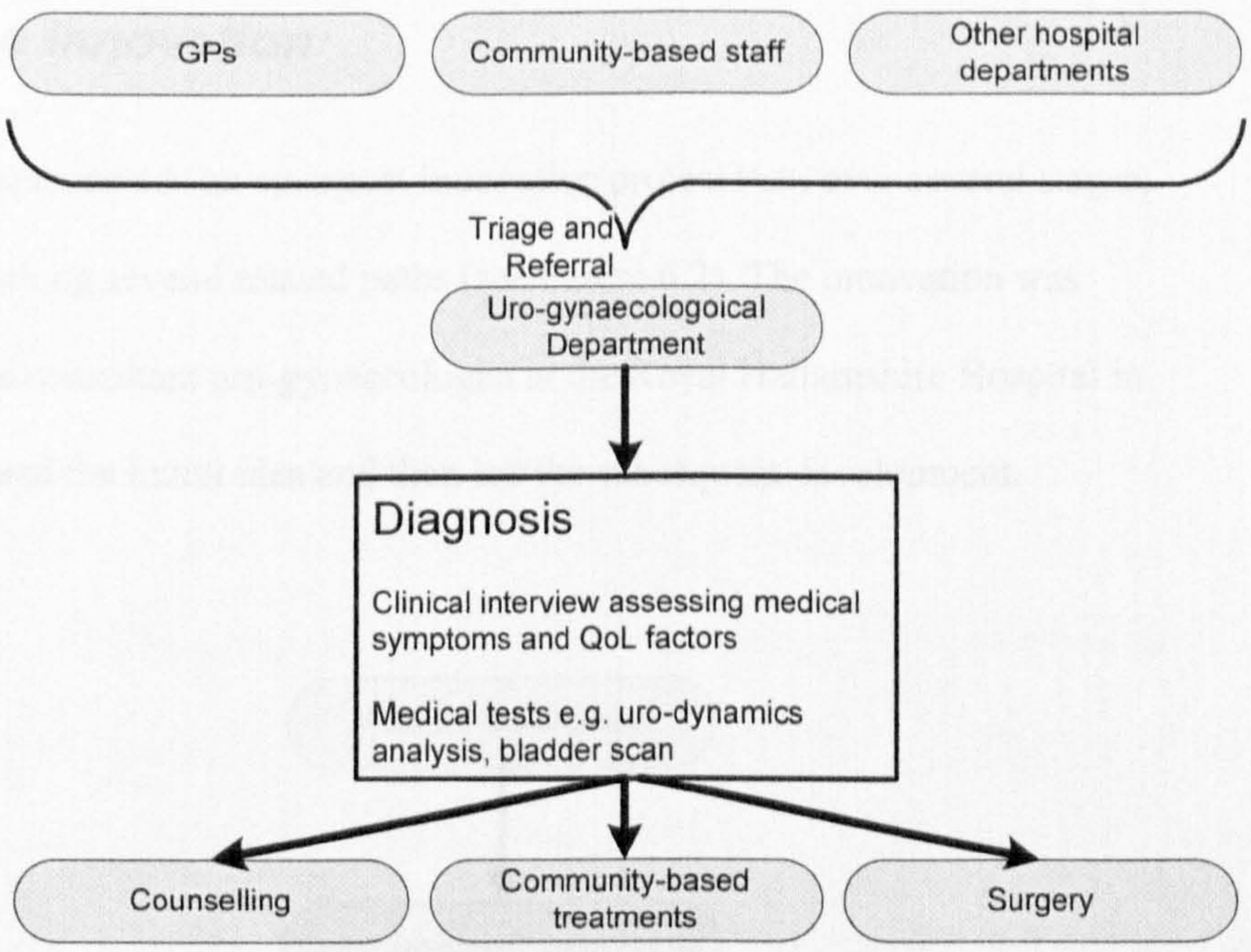


Figure 6.1: Clinical interviews within the overall process of uro-gynaecological treatment

Referral of patients to hospital urogynaecology clinics is normally by the patient's GP. It is however common for other primary care staff to refer patients, for example incontinence nurses. Unfortunately, due to the range of symptoms that patients present with, it is not always possible for primary care staff to identify precisely the best specialism to which to refer the patient. This means that patients are not always referred directly to the urogynaecology clinic. This has caused the referral process to be inefficient.

Once referred to an uro-gynaecology clinic diagnosis requires both a medical and quality of life assessment. An initial consultation will usually involve tests, such as an uro-dynamics analysis and bladder scan. It will then involve the patient having a clinical interview with a consultant. Several options exist for treatment of patients including surgery counselling and community-based interventions such as physiotherapy and.

The effective handling of the clinical interview is central to a successful diagnosis process of all gynaecological conditions. The sensitive nature of the symptoms is however problematic with some patients hiding and not discussing symptoms due to embarrassment. The impact of symptoms on quality of life also varies between patients. For example, in the case of incontinence, some patients may perceive the quality of life as greatly affected by the symptoms; while others will cope well and feel quality of life is unaffected. Quality-of-life assessment is an important part of a patient's assessment as it informs choice of treatment strategy.

6.4 Overview of the innovation

The development of ePAQ representeds an emergent innovation project that, over several stages, developed an initial concept along several related paths (see Figure 6.2). The innovation was developed by Consultant A, a consultant uro-gynaecologist at the Royal Hallamshire Hospital in Sheffield. Consultant A devised the initial idea and then led the subsequent development.

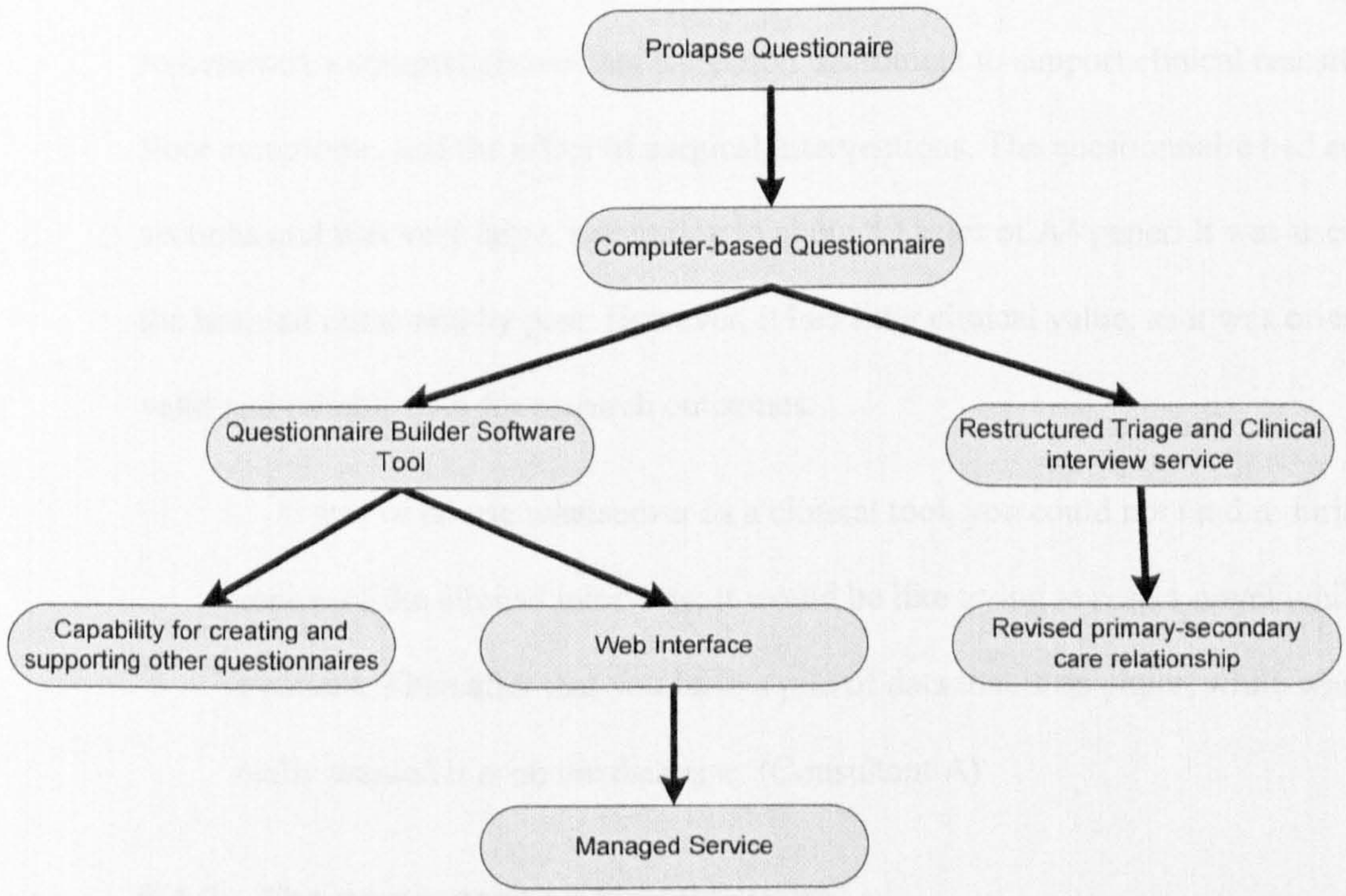


Figure 6.2: Innovation created by the project

6.4.1 Pelvic Floor assessment questionnaire

The first development was a questionnaire for gathering symptoms of prolapse. The questionnaire was to be administered to patients prior to a clinical interview with a consultant uro-gynaecologist. The questionnaire was notable as it represented a way of gathering accurate, valid and reliable data that was often difficult to elicit during an interview. The use of questionnaires to elicit information about symptoms was not novel, however the development of a questionnaire for prolapse was a new development. The questionnaire combined questions relating to medical and QoL factors relating to prolapse.

At the start of the innovation process Consultant A perceived the purpose of the paper-based questionnaire in very simple terms. The original intention of the questionnaire was to try to assess

and monitor patients during their treatment. Its value was to identify what was bothering the patient most and diagnosing underlying problems. By developing the questionnaire, Consultant A was attempting to augment the data collected within clinical interviews. He felt that the data collected using the questionnaire was different to the inherently unreliable data collected in a clinical interview.

The questionnaire was then combined with several other questionnaires produced by staff at other hospitals. The resulting questionnaire covered the core areas of pelvic floor medicine and represented a comprehensive data collection instrument to support clinical research into pelvic floor symptoms, and the effect of surgical interventions. The questionnaire had colour-coded sections and was very large, amounting to about 40 sides of A4 paper. It was used with patients in the hospital clinic and by post. However, it had little clinical value, as it was oriented to collecting valid and reliable data for research outcomes.

> ... it was of no use whatsoever as a clinical tool, you could not read it during the course of the clinical interview, it would be like trying to read a novel while talking to a patient. Then after that you have a pile of data that is on paper, while where you really wanted it is on the database. (Consultant A)

6.4.2 The computerised questionnaire

The second stage of development was of an electronic version of the questionnaire, used on a touch screen computer. The electronic pelvic-floor assessment questionnaire (ePAQ) used a complex set of rules for routing the patient through the questionnaire. The advantage of ePAQ was that it was quick to complete, as irrelevant sections of automatically bypassed. In addition, the software could rapidly analyse and present the results to the consultant, in a clear summarised form. An example of the report relating to how symptoms relate to a patients quality of life is shown in Figure 6.3.

Sexual			
Willing to answer?	Yes	Reconsider?	
Sexually active	Yes	Importance	
SEX & BLADDER Overall impact	0 1 2 3	Duration	6 - 12 months
Incontinence	0 1 2 3	Impact	0 1 2 3
Orgasm inco	0 1 2 3	Impact	
Penetration inco	0 1 2 3	Impact	
Post coital UTI	0 1 2 3	Impact	
Avoids	0 1 2 3	Impact	0 1 2 3
Partner avoids	0 1 2 3	Impact	0 1 2 3
Anxiety	0 1 2 3		
SEX & BOWEL Overall impact	0 1 2 3	Duration	3 - 5 years
Flatus inco	0 1 2 3	Impact	0 1 2 3
Faecal inco	0 1 2 3	Impact	0 1 2 3
Avoids	0 1 2 3	Impact	0 1 2 3
Partner avoids	0 1 2 3	Impact	0 1 2 3
Anxiety	0 1 2 3		
SEX & VAGINA Overall impact	0 1 2 3	Duration	
Dryness	0 1 2 3	Impact	0 1 2 3
Lack of sensation	0 1 2 3	Impact	
Discomfort & pain	0 1 2 3	Impact	
Tightness	0 1 2 3	Impact	
Obstruction	x	Impact	
Avoids	x	Impact	
Partner avoids	0 1 2 3	Impact	0 1 2 3
Anxiety	0 1 2 3		
SEX & HEALTH Overall problems	0 1 2 3	Duration	1 - 2 years
Loss of libido	0 1 2 3	Impact	0 1 2 3
Satisfied overall	0 1 2 3		
Own health & sex	0 1 2 3	Impact	
Partner's health	0 1 2 3	Impact	

Figure 6.3: Summary report from ePAQ® indicating impact of symptoms on quality of life

A comprehensive help system had been incorporated into ePAQ. This provided the patient with information on pelvic-floor symptoms and disorders, while they were completing the questionnaire.

Consultant A found that an unanticipated outcome of using the questionnaire was that it improved the experience of the clinical interview for the patient, making them better prepared to discuss intimate issues. Consultant A was surprised by the extent to which patients found the questionnaire helpful, empowering and enjoyable.

> … I did not expect it to be as good and helpful to patients as it worked out, I suppose I was doing it from my clinical practice and okay, if it is good for my clinical practice, it is good for my patients, but I was not quite [expecting how the questionnaire was]… empowering patients and making them better prepared for the clinical interview, that was slightly unexpected and the enjoyment of the questionnaire unexpected as well… and now getting onto health economics… potentially using this online, before the patient even gets to my clinic, that had not occurred to me before. (Consultant A)

Nursing staff involved with using ePAQ highlighted its impact on the patient's experience of the clinical interview. Patients were generally very anxious women and the ePAQ provided a means of acclimatising the patient to the type of questions likely to be asked in the clinical interview. The ePAQ modified the consultation process so that nurses had an opportunity to explain to patients

what and why certain issues would be discussed during the clinical interview, allowing patients to think about these issues in advance of the interview. The ePAQ enabled patients to communicate to the consultant that they did not want to discuss certain issues.

Nursing staff believed ePAQ significantly reduced the anxiety of patients during clinical interviews. Use of ePAQ was important in helping patients understand the inter-relationship between various symptoms and medical issues. This lead to patients experiencing the clinic as addressing the "whole problem" rather than individual issues. Patients were better placed to provide information about their symptoms, first via the ePAQ and then during the interview. The ePAQ was therefore not simply a system for gathering information on symptoms but aided the patient in expressing their symptoms precisely and comprehensively to clinicians.

The use of ePAQ was also accepted in the primary care setting where staff, including GPs and practice nurses, were better placed to refer patients directly to the ePAQ, shortening the patient journey. The success of ePAQ in the primary care sector was reported to be because patients were generally happier and more candid when talking about uro-gynaecology problems to practice nurses, with whom they had already built up a good relationship.

6.4.3 Development of the questionnaire builder

The development of the electronic questionnaire was predominantly in-house and had taken the form of a prototyping process. It became clear that the questionnaire had two weaknesses. First, it was difficult to maintain, making it difficult to extend or modify. Second, the questionnaire could not easily be modified for use in other areas of health in which sensitive information needed to be elicited from patients, such as the area of mens' health. In response to these two issues, the questionnaire was reverse engineered so that it could be split into two distinct parts, the questionnaire itself and a software–based questionnaire builder. The questionnaire builder allowed a rule-based questionnaire structure to be applied easily when building other clinical questionnaires. This stage of development was taken over by a software house in partnership with Consultant A.

The redevelopment of the software in this way then allowed further refinement of the questionnaire system. This resulted first in the development of a web-based interface for the system. This was an

important development as it allowed the questionnaire to be administered to patients away from hospital clinics for the first time. The web-interface enabled patients to complete the questionnaire at home and for the results to be accessed by clinicians at an early stage in the referral process.

The development of the web interface for the questionnaire also opened up an opportunity for providing the electronic questionnaire application as a managed service. This entailed running the software on a server operated by the software house. NHS trusts could then buy into the service, without the need to invest in either extra equipment or operational costs.

6.4.4 Service changes

The use of the electronic questionnaire has had two effects on the service provided. First, the consultation process between the patient and the consultant has been modified. The use of ePAQ has changed both the nature and role of the clinical interview, by preparing patients emotionally and providing them better information prior to the interview. This has made the clinical interview more focused and open. The likelihood of patients hiding symptoms out of embarrassment has to some extent been ameliorated.

Second, the relationship between primary and secondary care has been modified by enabling more effective triage of patients into the uro-gynaecology clinic. The availability of the ePAQ within community clinics and on the internet has bridged the divide been primary and acute services. Referral of patients by primary care staff can take place earlier and more reliably when supported with the ePAQ.

6.4.5 Clinical problem.

Despite the organic development of the ePAQ project, it is possible to define the clinical problems addressed by ePAQ. At the start of the project, the clinical problem was narrowly focused but by the end, the clinical problems addressed by the innovation could be viewed on three levels addressing: medical informatics for urogynaecology; clinical practice of urogynaecology staff; and supporting the clinical interview with urogynaecology patients. Figure 6.4 shows the main dimensions to the clinical problem addressed by ePAQ.

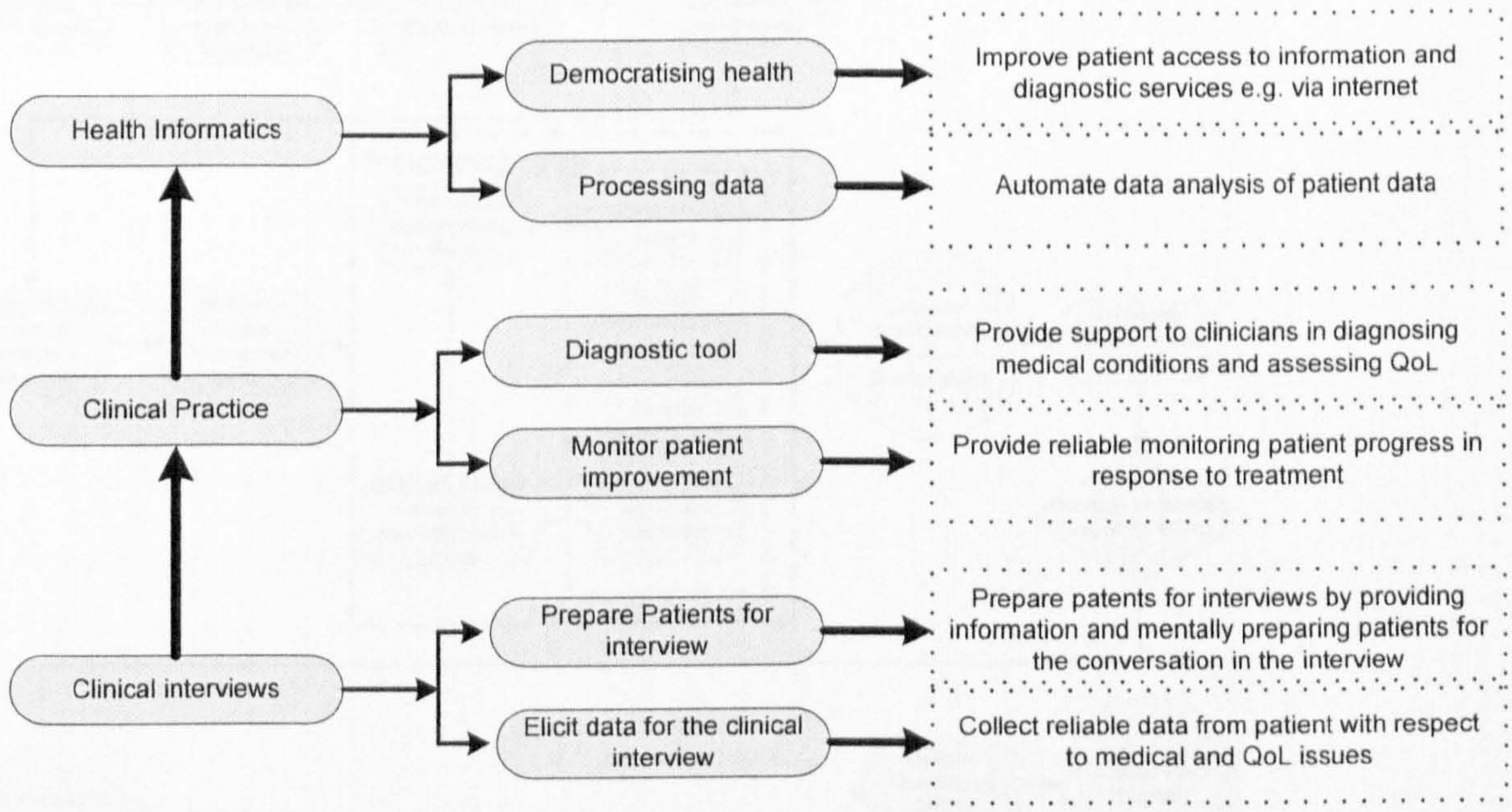


Figure 6.4: Clinical problem addressed by EPAQ

6.4.6 Extent of the innovation's Implementation

The ePAQ was successfully implemented into the uro-gynaecology clinic at the hospital and at several community clinics. A web-based ePAQ service has also been introduced. The ePAQ system has been recognized as important and in 2006 was winner of the Healthcare IT award.

6.5 Stages in the innovation process

The innovation process followed by ePAQ's development can be split into three phases. The first phase was concerned with developing the initial paper-based questionnaire. The second phase involved the development of the electronic questionnaire (ePAQ). The third phase can be seen as where the ePAQ development was shifted from within the hospital context to an industrial partner, Illuminaries Ltd. It was during this phase that the ePAQ system was re-engineered as a robust piece of software that could be operated on a standalone computer or as a web-based application. In addition, the industrial partner was in a position to provide a more formalised support mechanism for the system.

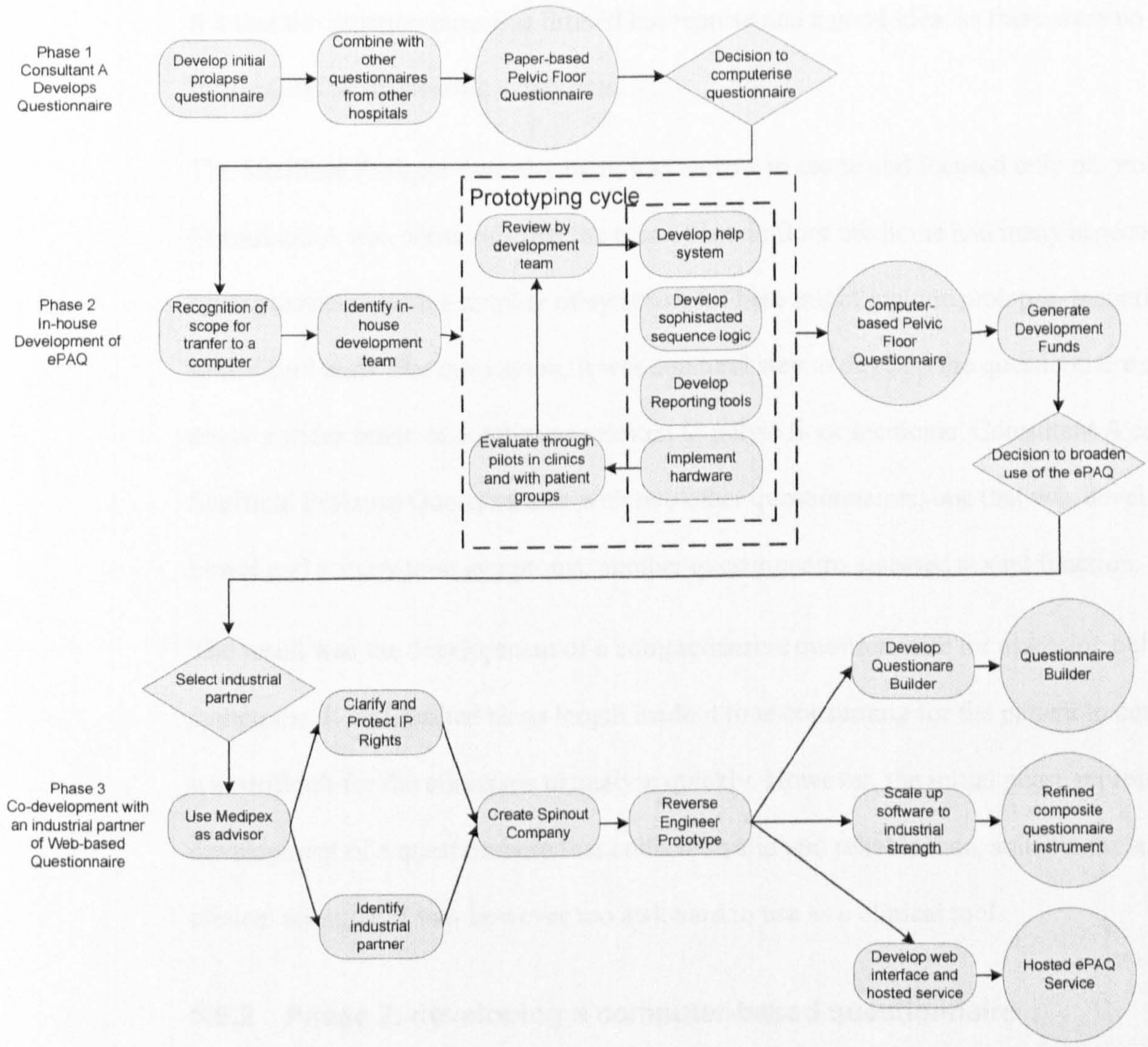


Figure 6.5: Three phases of the ePAQ innovation process

6.5.1 Phase 1: developing the questionnaire

The idea for the innovation started off when as a registrar, Consultant A began research into quality of life measurement in routine clinical practice. He felt that while QoL indicators were used in clinical research, including clinical trails, they were not used effectively in guiding the decisions made by clinicians in their day to day treatment of patients.

On becoming a consultant, he identified that in his area of urogynaecology, the main challenge was to embed objective measures of patient's symptoms and quality of life assessments, within clinical practice. He recognised that many outcome measures for treatment had been developed for research and were accepted as accurate, valid and reliable. They provided an opportunity to gain good quality data about patients. Consultant A then used these ideas to develop a questionnaire for women with prolapse. This was later termed the Sheffield Prolapse Questionnaire. Consultant A

felt that the questionnaire was limited but represented a good idea, as there were no other existing instruments for measuring symptoms.

The Sheffield Prolapse Questionnaire was narrow in scope and focused only on prolapse. Consultant A was conscious that the area of pelvic floor medicine had many aspects, with women often presenting with a number of symptoms. These might include prolapse, incontinence and sexual problems. For this reason, it was a natural step to develop the questionnaire so it would cover a wider range of conditions relevant to pelvic floor medicine. Consultant A combined the Sheffield Prolapse Questionnaire with two other questionnaires; one that was developed to assess bowel and urinary tract symptoms; another questionnaire assessed sexual function.

The result was the development of a comprehensive questionnaire for assessing pelvic floor symptoms. It was limited as its length made it time consuming for the patient to complete, and it was difficult for the clinicians to analyse quickly. However, the initial phase represented the development of a questionnaire that collected valid and reliable data, suitable for supporting clinical research. It was however too awkward to use as a clinical tool.

6.5.2 Phase 2: developing a computer-based questionnaire

The second phase of development involved the refinement of the questionnaire from a paper format to a computer-based format.

Initial idea

Consultant A believed that the second phase of the project was based on a "eureka moment" that he had while entering data from the paper-based questionnaires onto a computer database. The insight he realised at that moment combined a number of principles that focused the next phase of development. The principles were based on:

- Create an opportunity to apply technology by allowing the patient to enter the data themselves.
- Develop a higher level of interaction between the patient and the questionnaire. First by the use of screening questions that would allow parts of the questionnaire to be bypassed,

based on the response of the patient. Second, allowing patients to identify areas that they would prefer not to talk about during the clinical interview.

- Implementation of a help system that would allow the patient to gain information about terms used in the questionnaire. This would allow the questionnaire to have a role in informing the patient about pelvic floor disorders and treatments.
- Automation of the questionnaire analysis. This would allow faster analysis and would allow the results to be produced as scores or in graphical format. Rapid analysis would then allow the clinician to consider the questionnaire result as part of the clinical interview. Improved presentation of the results would make the information more accusable to both clinician and patient.

It was these principles that drove the next phase of development and underpinned a wider vision for the questionnaire.

> ...it could be a very good model for healthcare assessment in other areas: men's health... and other tricky areas...such as drug and alcohol addiction. (Consultant A)

Evaluation of the principles and vision for the progress of the project were not formerly evaluated; but adopted due to Consultant A's conviction that they represented the way forward for the project.

> I absolutely knew this was a good idea... I just sat there thinking this has got to be a good idea and I did visualise the simple, user-friendly instrument [suitable for]... even a little old lady who has never used a computer before. (Consultant A)

Based on the vision that Consultant A had developed for the questionnaire the development process proceeded based on a prototyping approach. During phase two distinct prototypes were developed. The development team for the first prototype was small, but was then extended to produce the second prototype.

Developing the idea through prototyping: Prototype 1

The first prototype was the product of medical student's project, suggested by Consultant A. The student was a self-confessed "computer geek" and was enthusiastic to carry out the project with the

aim of developing an electronic version of the pelvic floor questionnaire. Consultant A defined a minimal specification for the system:

- one question per screen;
- help page links;
- a specific look and feel;
- a simple unified structure;
- and report generating facility at the end.

During the project, the medical student carried out a literature review of some existing online questionnaires. Consultant A felt that based on this review, it was:

> ... clear that in healthcare it [online interviewing] has not taken off, it has not worked, it has not become universal for one reason or another. (Consultant A)

In contrast, several critical factors aided the project's success.

> ... what we did with the ePAQ, with the simplicity of approach... one question per page... designed to work with a little old lady... uniformity of approach... focusing on turning a research outcome measure into a clinical tool and making it user-friendly, feasible and useful was what we were doing felt right and I did not feel anything else out there really did that... certainly not in my field. (Consultant A)

Consultant A requested approximately 6 weeks support for the medical student from the Scientific Computing Group (SCG), a software development group based within the Medical Physics Department of the hospital. The purpose of this support was to develop a suitable computer database to underpin the electronic questionnaire. A post-doctoral software developer was assigned, though no charge was made for his time. The motive for providing the support was that the SCG were interested in building development capability within their department specifically for medical questionnaires. They thought the opportunity to build a generic questionnaire database would be useful to them in the future.

The result of the student project was the first working prototype of the electronic questionnaire (ePAQ) and was produced with minimal cost and resource. Despite this Consultant A felt that the initial prototype:

> ... translated these ideas into reality, fairly quickly actually, and very effectively, I would say as at the end of the day we had a working model. (Consultant A)

The initial prototype embodied many of the key features of the later versions. Two trials were then carried out using the prototype.

The first trial was on a maternity patient group, who represented a coherent group of potential users. The group compared use of the paper and electronic versions of the questionnaire. The ePAQ was received very positively.

A second trial of the ePAQ was carried out in the hospital's clinic. This trial focused on issues to do with whether the system was: difficult; too long; upsetting; enjoyable; and whether it helped support communication with the doctor. The results of this study were of some surprise:

> ... I was not expecting it to be quite so positive from the patients themselves. They were actually enjoying using it, and they felt it helped them communicate, and felt it improved the clinical episode... never mind my views on it, I obviously thought it was great as I was getting all this wonderful data... but they actually thought it was a positive experience. (Consultant A)

This showed ePAQ's potential for improving the communication in clinical interviews between patient and consultant. Typical comments specifically focused on how ePAQ was helpful in getting patients to think about their condition and to communicate better during the clinical interview.

The development of the first prototype was very informal. It is unlikely that the wider hospital management were aware of the development, and the project was not part of any centrally planned initiative. However, it was crucial in establishing proof of concept for ePAQ. The validity of the first prototype was assessed through gut feeling, professional judgement and rigorous trial based on formal research protocols (Radley et al. 2006).

Prototype 2

Based on the success of the first prototype, Consultant A gained several small grants from external organisations, such as pharma companies. This was used to fund a second phase of prototype development. This phase followed a more formal process in which a development effort by the SCG was charged for and the development team enlarged to include other specialists.

The role of SCG staff continued but with the software developer's time being formerly commissioned and paid for by the external funding. The developer was an enthusiastic member of staff who spent a significant amount of time, outside of normal working hours, developing the software; this unpaid effort significantly subsidised development costs.

The development team was extended to include a medical statistician and a professor of medicine (who was also a GP). The extended group was important in highlighting the wider potential of ePAQ and identifying how it could be developed to encompass other existing quality of life questionnaires. The development of the second prototype required implementation into the normal operation of the hospital department and so nursing staff joined the development team.

The second prototype used a touch screen and provided a better user interface. It was then used in an extended clinical trial based in both the hospital clinic and the community, supported by a research nurse. The research nurse was responsible for recruiting patients to the trial and supporting practice nurses in the use of the ePAQ. During this trial, it was found that the interface was intuitive to use and it was rare for additional training to be needed for staff or patients.

The results of the extended trial established the repeatability and reliability of the ePAQ and validated its use in both primary and secondary care settings. It confirmed that it was suitable for day-to-day clinic use. The trial also clarified the role of the ePAQ:

- as a diagnostic system that could be used effectively as a supplement to normal clinical interviews, eliciting more reliable information from the patient and subjecting them to lower levels of embarrassment;
- as an audit tool to allow the monitoring of the patient's condition pre and post procedure condition and response to treatment.

Summary of Phase 2

The prototyping approach to the development of ePAQ resulted in a robust, validated and well conceived electronic questionnaire system. By the end of this period of development, ePAQ had been implemented in the hospital clinic and was integrated into the day to day operation of the clinic.

Consultant A was however aware that in order to diffuse the system into other hospital departments the ePAQ system needed to be developed further. In particular, the software needed to have a robust system for its maintenance and support. It also had to have a legitimate status with hospital IT departments.

> ... if I wanted to give the software to another unit, they would not be interested in taking something that my Sheffield IT department had developed. A trust IT department would not let anything like that on the system, it would not happen. Similarly, I don't know what the liabilities are, but you do not have to have much imagination to think what if?... who was going to guarantee the software?... who was going to maintain the software?... when something goes wrong, who is going to answer the phone? (Consultant A)

Consultant A felt that by developing ePAQ with an established software house, the system would be legitimised in the eyes of potential users. It was this imperative that drove the third phase of the development.

6.5.3 Phase 3: developing a web-based questionnaire

Phase 3 of the ePAQ project was where a shift occurred to the involvement of organisations external to the NHS. This was a much more externally focused phase of the project. Key events were the involvement of an NHS innovation hub, creation of a spin-out company and partnership with a private sector software house. The ePAQ system itself was reverse engineered and rewritten. A new business model for the system has emerged that had potential to support the growth in user adoption.

Decision to outsource development

The third phase of development was initially planned to be carried out in-house within the SCG, by appointing a research assistant over a two to three year period. The objective was to consolidate on the development already completed, re-engineer the prototype to allow its routine use within clinical settings and to develop the underlying database structure so it could be easily adapted to other clinical areas. Despite the involvement of senior hospital trust managers and high level support in the trust for the project, no development funding could be agreed, resulting in the halting of any in-house development. The only option was for the project to involve external partners in the development of ePAQ.

It was at this point that Consultant A approached the local NHS innovation hub, Medipex Ltd. Medipex then played a crucial role in the project. First, by establishing the formal ownership of IP related to the project. This was a complicated task due to various parties having had a stake in the development effort. Ownership of IP in the project was unclear and rested between Consultant A, the trust, the software developer and other third parties. The second role was to search for a suitable business partner to engineer the software. The partnership with Medipex was important as it contributed a significant level of business planning expertise to the project.

After some negotiation, a local software house, Illuminaries Ltd was identified as a partner for the project. Consultant A believed several criteria were important to the decision. The first was that the company was located close to the hospital. Consultant A wanted to work closely with someone in Sheffield, rather than in another part of the country. Second, the company had existing links to the NHS and the hospital projects. Finally, Medipex were recommended the collaboration.

As a result of searching for a partner a spin-out company was formed, ePAQ Systems Ltd, that would control the future development ePAQ. The company represented a partnership between the hospital trust (40%); Medipex (5%); Consultant A (40%), and Illuminaries Ltd (15%). The new company owned the IP rights associated with ePAQ comprising: the questionnaire; the software; any new future questionnaires.

Role of Illuminaries in developing ePAQ

The involvement of Illuminaries signalled a change in the way the development of ePAQ progressed. Their involvement marked a greater emphasis on software engineering of the system, to ensure its scalability and reliability. The focus of the development, while maintaining the clinical perspective, emphasised the need to produce industrial strength software. Most importantly, the Illuminaries' involvement led to the innovation taking on a different trajectory. Illuminaries used the second prototype developed by the SCG as a throwaway prototype and proceeded to reverse engineer the system. Figure 6.6 shows how the development proceeded.

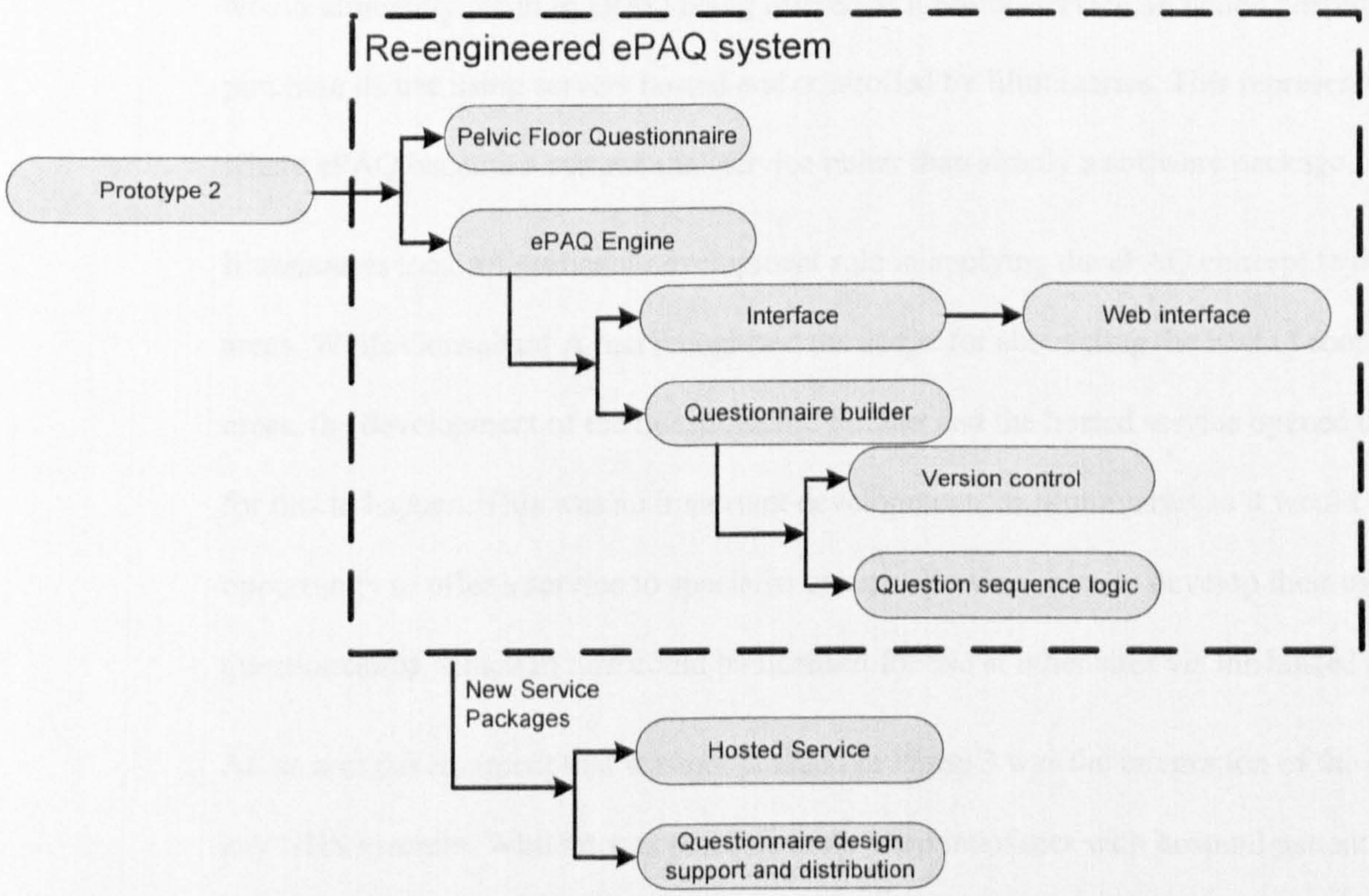


Figure 6.6: Developing on from the throwaway prototype

Once development of ePAQ had been taken over by Illuminaries the type of development and its direction changed. The first stage of Illuminaries' development focused on the reverse engineering of the prototype. This was done for two reasons. The first to separate out the questionnaire from the sequence logic that had been hardcoded into the ePAQ system. Second, through reverse engineering the system could migrate to a more robust and scalable software environment.

The result of the reverse engineering was that the ePAQ system was redeveloped into discrete components. A questionnaire builder was developed that would allow several distinct

questionnaires to be developed with their own sets of questions and sequence logic. The interface design was reviewed and redeveloped, ultimately leading to a web-based version of ePAQ.

The involvement of Illuminaries also resulted in the innovation taking a new trajectory. When the development was done within the hospital, the primary driver for development was the ePAQ's operation from a clinical perspective. In contrast, Illuminaries introduced a second focus based on the concern to implement and support the system across several sites. This was a concern for Illuminaries as they were only a small software house, with relatively little resource available for software support. Consequently, development of ePAQ focused on scalability. This development would ultimately result in ePAQ being offered as a hosted-service, in which hospitals would purchase its use using servers hosted and controlled by Illuminaries. This represented the point where ePAQ became a commercial service rather than simply a software package.

Illuminaries took a significant development role in applying the ePAQ concept to other specialist areas. While Consultant A had recognised the scope for abstracting the EPAQ concept to other areas, the development of the questionnaire builder and the hosted service opened up the potential for this to happen. This was an important development for Illuminaries as it would then offer the opportunity to offer a service to specialist groups allowing them to develop their own questionnaires, which in turn could be licensed for use at other sites via the hosted service.

An area of development that was not pursued in Phase 3 was the integration of the ePAQ system to any NHS systems. While it was possible to develop interfaces with hospital patient administration systems, it was decided that this would have reduced its portability. Patient administration systems were not standard to all hospitals, making the development of a single, universal interface to all systems very difficult to develop. By maintaining ePAQ as a stand-alone system, the complexity of implementing the system into other sites was much reduced.

6.6 Time dynamics of the innovation process

The three phases of the ePAQ project extended over several years. The first phase, involving the development of the paper-based questionnaire, started when Consultant A was a Registrar and was completed after he had become a consultant uro-gynaecologist. This extended period of time did

not reflect a continual level of effort and it likely that project progress was halted for extended periods of time. The second phase of development involved a small group and took place over a period of months, mirroring the pattern of a student project. Initial software development support lasted six weeks and indicates that the phases were characterised by periods of intense development, punctuated with periods of trialling and review. Clinical trials of the software typically took place over several months (Radley et al. 2006) and so pace of development was constrained over these periods. The final phase of development involved reverse-engineering of the prototype created in Phase 2, and took several months. However, the development has continued for several years and is on-going.

6.7 Organisational context

The development of the ePAQ took place primarily in the Gynaecology Department of the Royal Hallamshire Hospital in Sheffield. The hospital is a well established teaching hospital and part of the Sheffield Teaching Hospitals Trust. Development was supported by other departments in the hospital, in particular the Scientific Computing Group (SCG) based in the Medical Physics Department. It is useful to review the context of these departments both in general terms and in relation to the ePAQ project.

6.7.1 The Gynaecology Department

The department was based in a new building in the hospital. Its day-to-day operation was well co-ordinated and the department's clinic generally ran smoothly, rarely running behind schedule. Several factors were suggested that contributed to this. Consultants maintained a high level of time management ensuring that patient consultations started and ended on time; relationships between nurses and other staff working in the clinic were good; leadership of the department was well respected by both consultants and nursing staff; and generally the department operated successfully as a multi-disciplinary team with well educated, motivated staff willing to address change.

The department was generally very receptive to change with most staff having positive attitudes to change. This was underpinned with a culture that valued evidence–based practice. The existence of clinical nurse educators, governance sisters, an evidence-based practice group, and a supportive

matron, had allowed all nursing staff to be supported in using EBP principles. Most nursing staff were undergoing continuous professional development, for example, Level 3 professional nursing qualifications. All these factors acted to create a culture open to learning, change and implementation of new technology

The department's culture was important in ensuring successful implementation of ePAQ. The general reaction of nursing staff to ePAQ was positive, with staff recognising that it could improve patient care. The general sense was that they needed to move ahead with such improvements, despite implications for staff workload. The implementation of ePAQ increased staff workloads because it added an extra diagnostic test with extra time required to introduce patients to the system, train them in its operation and then to support them in answering queries. The process added around 15 minutes of staff work to a consultation.

Despite the workload implications, the implementation of ePAQ took take place in an enthusiastic and altruistic culture. The arrangement of meetings for management of the project was usually outside of normal working hours and participation of staff in the project was often based on them giving their time freely.

6.7.2 Attitudes towards consultant's leading innovation

The department's culture was supportive of the innovative activity of consultants. Consultant A was encouraged to engage in innovative activity in a formal sense through research; an activity that was an explicit part of his contract. His position as a consultant in a teaching hospital also gave him a level of credibility and status outside organisations. This made it easier for him to obtain unrestricted research grants and other sources of funding. Over the early years of the project this has exceeded £100,000.

At a less formal level, Consultant A was supported by the department and the wider hospital's openness to innovation. Since he moved to the hospital seven years earlier, he has found the department very supportive of his "...funny ideas and innovation activities" (Consultant A).

Consultant A felt his position as a consultant in a teaching hospital gave him a privileged position, a lot of autonomy and status in the eyes of outside organisations such as pharmaceutical companies

and charities. He believed that it would have been more difficult to pursue the project at a non-teaching hospital, where he felt he would have had less support or freedom to act. However, even as a consultant in a teaching hospital he still had a significant pressure on his time from both clinical and administrative duties.

Consultant A's activities were also supported by the senior consultant in the department (Consultant B). Consultant B acted as a champion for the ePAQ project and was important in ensuring time was made available for Consultant A to work on the ePAQ project. Consultant B recognized the enormous amount of time required to develop an innovative technology and had to deal with the problem of how much NHS resource should be made available:

> ... for me, in my lead gynaecologist hat... with the NHS taking some of the funding... who gets the cash benefit? Is it the developer? Is it the hospital? How much NHS time do you give someone in their job plan, for these [activities] ... the NHS will benefit financially. So is it reasonable to say that two hours a week is devoted to ePAQ or other projects or not, that is an issue, I don't have a definitive view on that... these things are developed by enthusiasts and inevitably, they spill over. (Consultant B)

Consultant B believed that some of the time spent on the ePAQ project was accounted for as administration time or as professional activities.

6.7.3 Support from the trust

There was very little explicit, formal support for the ePAQ project. This was predominantly due to the emergent nature of the project. Consultant A saw the project as carried out by:

> ... a bunch of enthusiastic amateurs... it was not on my job plan to create an electronic questionnaire... it was done in my spare time... it was a medical student project... nobody said your medical student must do this project... it was not commissioned by anyone except me, saying. I have got this idea... and I think that is quite a good way of doing things... but you can only go so far with that approach. (Consultant A)

Despite aspects of the projects being discussed at various trust committees, it was not until a relatively late stage that the project was formerly recognised by the hospital or seen as any sort of

strategic project. It appears that the trust management were not conscious of the project despite interacting with the project at various points, for example: approval by the ethics committee; awarding the medical student a best paper prize for his work on the project; and the managing the internal charging of the postdoctoral software developer's time. The lack of recognition, while limiting the support available, did however ensure the team's autonomy.

6.7.4 Trust support for IT projects

The normal path for development projects like ePAQ would have been through the trust's IT Department. At the time however, the CfH programme meant that the IT department had no spare capacity, and so in common with other small-scale projects were not able to provide any development support.

The implication of CfH was that only systems which needed emergency action were given priority by the IT Department. For example, an accident and emergency system had to be revamped in order to comply with national targets on minimal waiting times. Consequently, because ePAQ did not fit in with national targets, it was given very little priority by the trust or the IT Department. The trust had no explicit mechanism for managing portfolios of innovation projects that were being developed "bottom-up" in the trust. The evaluation of non-CfH IT project proposals emphasised risk reduction more than any other factor. Projects were given a higher priority if they addressed a clinical risk, rather than other benefits such as cost reduction or improvement in patient care.

The emphasis on risk reduction meant that the potential efficiency and effectiveness benefits of ePAQ were not really taken into account. In addition, the ePAQ project had very little relevance to CfH programme.

> ... ePAQ is so specialised, too small-scale for the National Programme for IT [CfH] to pick up on that need, they are looking at national requirements... they are looking at connecting up primary and secondary care and looking to connect records, I think ePAQ would be well below the type of thing they would be looking at... the strategic Health Authority might be the level it might get picked up at some stage. (Systems Development Manager)

6.7.5 Role of the trust's IT Department

During the period around 2002, the IT Department's capacity for taking on projects was stretched due to the CfH programme. The result of this was that the resources in the IT department were devoted to work on key priorities. This created a period of "planning blight" in which projects that did not fit with the CfH programme were given low priority.

The trust's IT department was well regarded and there is little doubt that it would the necessary capabilities to develop the ePAQ project. In particular, they had a good balance between technical skills and the capability to provide a IT service. The ePAQ project was however only one of many small scale projects that the IT Department had to allocate resources to. The hospital has a proliferation of small, independent IT systems, many of which are not part of a conscious portfolio. It was probably very difficult for the IT Department to take a strategic view of many of these projects.

> ... the problem is that there will be a lot of systems being used that the IT Department have no idea about, again it comes down to Access databases, a lot of the time. There will be systems that have grown from very simple systems that somebody knocked together in a couple of hours and over time have progressed into a system that people rely on... people just grow these things because there is no one developing in a focused way, if somebody needs it they will do it. (Software Development Manager)

6.7.6 Scientific Computing Group (SCG)

The lack of available support from the IT Department meant that a less formal route for the project was adopted. From the perspective of Illuminaries, the trust was a relatively passive partner in the ePAQ project, despite having a substantial stake in the spin-out company that was ultimately created. Their primary involvement was to allow staff to spend time on the project. The SHD believed that a possible reason for this was the lack of fit between the ePAQ project and other IT projects that were pursued:

> ... it was a research project that has somehow spun out into this commercial thing. (SHD)

It was for this reason that the SCG took a significant development role in the project.

The SCG took on projects on an *ad hoc* basis, and had sufficient autonomy to allow work on new embryonic projects. The work of staff in the SCG was not rigidly accounted for, for example, there has never been any attempt to log their work under specific job numbers. It is perhaps for this reason that they had the organisational slack necessary to take up the ePAQ project in the first place. In some cases, projects had been brought to the SCG as there has been no development capacity in the IT department available. In these cases, the SCG has carried out the work, charging the work back to the "customer" department. The type of work taken up by the group was often experimental in nature and it had become common practice for them to develop small application systems used in the hospital.

> It was not unusual for them to become involved in developing systems in the hospital, possibly without senior managers being aware of the project. (SHD)

The approach taken to software development within SCG differed from the IT Department. The IT Department operated a more managed environment, compared to the Medical Physics Department's more organic and *ad hoc* approach. The diversity of projects taken on by the SCG meant that it was not possible to organise common sets of development tools and methods. The approach taken had the advantage of allowing end users to be closely linked with the development of software.

> ... the advantage of the ePAQ project is it is custom-designed for a particular job by the people who were using it, so there is very little problem with ePAQ about people saying, why does it do that, if I'd done it I would have done it differently, because the people who use it certainly here, are the people who either consciously or subconsciously evolved it. (Software Development Manager)

The SCG can be characterised as lacking a strict methodological approach but also likened to a "skunk works" department, working on innovation projects that were yet to be formally recognised. The structure and culture of the department was aligned to this type of development project. This was in stark contrast to the formal environment of the IT Department, which had a greater responsibility for day to day provision of large scale IT services and strategic IT project

development. The SCG's separation from the IT Department was an important factor in allowing the ePAQ system to develop.

6.8 Emergent Themes

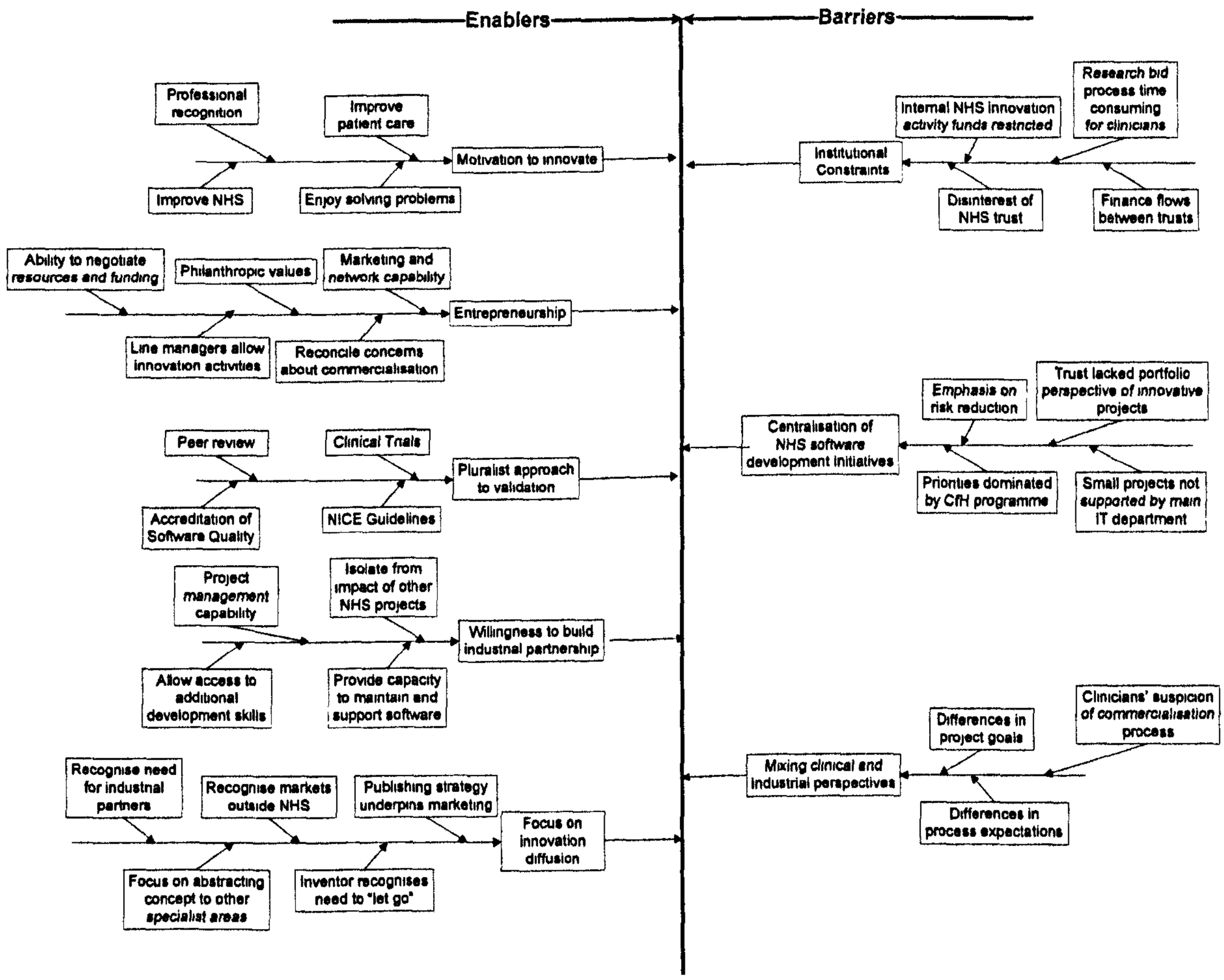


Figure 6.7: Enabling and inhibiting factors in the ePAQ innovation

6.8.1 Motivation to innovate and entrepreneurship

The motivation for Consultant A to pursue the innovation was based on several factors that related to his professional identity and personal values. Many of these values were shared by the NHS staff who worked with him on the project. The wish to improve the care of individual patients, the care processes and the NHS in general were strong motivating forces and represented the ethical factors driving the innovation. In addition, all the NHS staff in the team evidently saw solving innovation problems as an attractive challenge.

Though commercial success could have been a motivating factor for Consultant A, it appears unlikely to have been the primary driving force for the project, reflecting the view that it was rare

for clinicians to make significant fortunes from their innovation. Consultant B noted that the motivation of Consultant A was principally:

> ...a wish to be at the fore of something... to be a leader of ideas on the stage of play... most doctors who make fortunes make it from things other than medicine. (Consultant B)

In fact, Consultant A demonstrated a reticence to focus purely on commercial success and relished professional recognition.

> ... basically, I enjoy it, I love it, it is good fun, I get national recognition, I get to go to conferences and talk about it, I get e-mails from Australia. It is getting a bit more serious now with it being commercial, up until recently, it was just a bit of a hobby. Although you think that this is the ultimate aim. Actually the journey there can be more fun than arriving... my god, that great idea I had a few years ago is now a commercial reality, now what do I do? I suppose the next thing to do now is to turn that commercial entity into something that is profitable and viable. That is likely to be more stressful and slightly less fun... I am hoping that ultimately it will become viable, and I will be able to relax a bit and let others get on with it. We have a few people around the UK who are really enthusiastic about it, and maybe they will take it forward and it won't be me just banging on about it, it will be somebody else banging on about it... that will be really nice and I'll be able to say I have done all the hard work and I can start focusing on something else. (Consultant A)

Consultant A exhibited many entrepreneurial traits that contributed to the project's success. In particular, his skills in negotiating resources from within and outside NHS trust were important. Within the trust he as able to justify both his own time and that of other staff on the project to line managers. He was also able to negotiate funding from external organisations such as charities and pharmaceutical companies. Of equal importance were the professional networks that he maintained that enabled access to knowledge but strong marketing opportunities.

Consultant A's philanthropic perspective on the project did however differ to that of a conventional business entrepreneur, in particular, his attitude to commercialisation of the innovation.

> ... people don't see it as a commercial thing, that word commercial always grates with doctors, because we work in this wonderful institution called the NHS, which is kind of free, money is actually a dirty word in medicine, and we are all slightly embarrassed about talking about money or private practice... now we are becoming more commercially aware... there is a slight feel good factor because I did this not for commercial reasons, but because I thought it was a good idea for me and my patients... (Consultant A)

Though this attitude did change during the project, it continued to cause some concern to the industrial partners. For example, the director of Illuminaries noted that at certain points in the project:

> ...he [Consultant A] would give it away to his mates almost to get a ground swell and then say we can then start charging them. (Software House Director)

However, by the end of the project Consultant A recognised that the commercialisation process was important and vital to the long term prospects of the project:

> ... I was always slightly allergic to the word 'commercial' as I felt it meant for profit, where as what I meant was 'commercially viable', that you could give or sell to somebody, something that you would be able to use... for me setting up the company was to make sure the project was viable, not for me to make a profit. (Consultant A)

6.8.2 Pluralist approaches validation

The validation of the ePAQ system took place in a number of ways. Formal clinical trials validated both the questionnaire and the user interface. However, other factors such as peer acceptance and gaining the routine use of ePAQ by staff were both powerful validation mechanisms. Other mechanisms were employed to validate and legitimise the innovation such as alignment with NICE guidelines and use of established software quality assurance accreditations.

Peer acceptance of ePAQ was significant factor validating ePAQ and legitimising its use. Publishing of peer reviewed articles was successful strategy for gaining acceptance of ePAQ. Consultant B believed that the publications related to ePAQ (Radley et al. 2006; Bradshaw et al.

2006; Hiller, Radley et al. 2002; Hiller, Bradshaw et al. 2002; Radley and Jones 2004; Radley and Brown 2005) were important in creating kudos for the project, rather than generating a formal research profile for Consultant A and others in the team.

> ... publications and getting it accepted by others... people from outside the hospital were big steps... peer review validated the technology, getting it taken on by other people is peer review acceptance. (Consultant B)

In addition to positive peer review, the reaction of staff and patients using the system was critical in validating ePAQ. Based on their experiences with sitting with patients, nurses in particular, were aware that the use of ePAQ improved the engagement of patients and their overall experience of the clinical interview. The first hand experience of nursing staff made them strong advocates of ePAQ and contributed to the validation of the system.

The acceptance of ePAQ has been helped by linking its advantages to guidelines set out by NICE. The NICE guidelines on incontinence care (NICE 2006) could be used to justify the use of ePAQ.

> ... a very useful political thing which has helped rather to our surprise, has been the NICE guidelines on incontinence... we have used the ePAQ to sort of justify the NICE guidelines. (Consultant B)

The final strategy for validating the technology was to have the system re-written by an accredited software house. Illuminaries had a number of accreditations that recognised its quality assurance processes and its processes in for developing software using Microsoft products, including ISO9001 The accreditation was useful to Illuminaries when putting together a public tenders, as it often represented "a box to tick". Though it was felt that many healthcare clients did not see accreditation as a high priority. Accreditation may however have been a necessity for gaining acceptance for ePAQ.

6.8.3 Industrial partnerships

An important part of the ePAQ project was the decision to collaborate with an industrial partner. The decision to develop software using a partner in the private sector can be seen as a strategy to

assure the longer term stability of the project and to avoid it being sidelined by higher priority national projects, such as the CfH programme.

Several other operational advantages have also been suggested in the case of the ePAQ project. First, small development projects within the hospital were not subject to any significant project management processes. By outsourcing development, the project gained not just software development skill but also project management expertise. In turn, software houses were better placed, through establishment of maintenance contracts, for providing long term maintenance and software support services, than the hospital's IT department.

6.8.4 Focus on innovation diffusion activities

A critical enabling theme within the project was the extent to which the ultimate diffusion of ePAQ was maintained as a focus of activity. The recognition of the need for industrial partners, such as Medipex and Illuminaries, is indicative of the long term perspective adopted during the project. This has in turn led to recognition of external markets outside the NHS, as well as highlighting the need to abstract the ePAQ concept to other specialist areas.

One of the most difficult aspects of the diffusion process is the extent to which the inventor, Consultant A, should continue to maintain control over the project. The director of Illuminaries was clear about the need to broaden the pool of ideas during the development stage and highlighted that:

> ... if the system is going to grow, the inventor has to let go because they can't do it all and therefore you have to let other people do that, as soon as you let other people do it, they are going to have their own ideas, and some of these can be bloody good ideas and you really have to encourage that... in a sense [Consultant A] has let go to a certain extent. (Software House Director)

It was clear that in time Consultant A would take less of a role in the commercial development, despite having a strong emotional attachment, a high level of knowledge and a wide range of contacts.

> ...you know, rightly or wrongly, I developed this, this is my idea and have driven it to the point where it is potentially a very successful project, I have brought all the money in, and an international list of potential clients... clearly the best person to take it further forward... that could be a significant impediment to its further development... I would like to get to the point where I can say it has gone but still be involved, but not quite so intensely, perhaps have somebody else market it, somebody else sell it. Because at the moment, I seem to do everything: R&D, marketing, talking about it, planning all the meetings, and so forth... I would not mind if somebody else would help me take it on. (Consultant A)

6.8.5 Institutional constraints and the centralisation of NHS software development

The ePAQ project has had to contend with significant organisational inertia and institutional constraints. Lack of easily accessible development funding meant that Consultant A had to invest significant time in bidding for research funding or negotiating funding from charities. This was made more difficult by the lack of interest shown by the trust in the project and lack of senior management support.

Within the context of software development, there were significant institutional constraints on the project. The emphasis on risk reduction meant that projects focusing on other aspects of healthcare services were given less priority. In addition, the nationally set priorities for software set by the Connections for Health programme dominated planning of software development within the trust. This lead to the IT strategies of the trust being aligned only to these projects; in contrast, small projects were often allowed to develop with little guidance, support or controls.

6.8.6 Mixing clinical and commercial perspectives

The SHD was very conscious of the difference in perspective taken by clinicians to software development compared to that of software engineers. The difference in perspective was a cause of conflict in the project.

> ...it is difficult working with doctors because they think they know everything... you can't go and cut people open without having absolute confidence in yourself... I have

done a lot of work with doctors over the last fourteen years and they are pretty much all the same to a greater or lesser extent that they are all supremely confident that they know everything and it that includes how to write computer software at times... so they can be challenges from our point of view because we are saying really lets do it like this, and we have had heated discussions on certain matters throughout the last couple of years. (SHD)

Typical sources of conflict included areas such as software engineering best practice, user interface design or data protection principles. The SHD felt that Consultant A was not always fully aware of the implications of some decisions, reflecting that:

> ... it can be difficult, because they have an idea about how they want something. Actually, it should not be like that because technologically we can't do it like that...or because of best practice in software engineering, or user interface design or data protection... we have argued endlessly with him [Consultant A] over issues of data protection for the web facing version, what we can and can't hold on the server. (SHD)

6.9 Summary

The ePAQ case provides a detailed account of how a user-led innovation project develops from the work of a single NHS employee, to a software product supported by a commercial company. The case has tracked the development through three distinct stages and illustrates the extent to which both the team and the development methods adopted have grown organically. The organic development enabled the project to benefit from access to a range of staff from both within and external to the host organisation.

The case also highlights the informal nature of user-led innovation and exemplifies how am innovation may be invisible to the wider organisation and its senior management. This case study exemplifies how the pressure placed on the trust by top-down government initiatives, such as the CfH programme, impedes the trust's ability to mange locally developed, innovative, IT projects. In this case it contributed to the trust taking a disinterested view of the ePAQ project, despite it having part ownership of the IP developed during the project.

The case illustrates the role that institutional structures play in setting normative limits on user-led innovation process. The case illustrates how the values and norms of NHS staff were challenged by the innovation process. This conflict was particularly apparent with respect to the user-innovator's philanthropic motives juxtaposed against commercial imperatives. The philanthropic values were strongly aligned with the professional expectations of the user-innovator's profession.

Finally, the case shows the way in which the purpose of a technology develops over the course of a user-led innovation project. Implicit in his development is the way the attributed meanings and significance of the innovative technology changes over time. The focus of the project was the electronic questionnaire, a hard technology. However, the major benefit of the innovation was improvement in the way clinical interviews were conducted. In this respect, innovation of the soft technology of clinical interviewing was the central part of the case, prompting the parallel development of a proto-institution that supported an improved institutional structure for supporting clinical interviews.

Chapter 7: Cleft Lip and Palate Study Model Case Study

7.1 Introduction

This case study is concerned with a process innovation developed by a technologist working within a teaching hospital in the NHS. The innovation concerned the development of a new technique for producing a plaster study model of a patient with a cleft lip or palate. The study model provides a physical representation of a patient's mouth and face, prior to surgery. Study models enable surgeons to maintain records to assess the results of surgery on a patient over a number of years. The development of the study model technique had potential to underpin a wider system of cross-centre evaluation of cleft lip and palate surgery.

At one level the innovation is an example of incremental development of a technique, however, the innovation is distinctive because it is also relevant to the wider innovation of cleft and lip palate surgery in general. The case study is therefore useful in illustrating the role of micro-level innovation of processes in relation to macro level initiatives in the NHS.

The case study illustrates that though the user-led innovation of a micro-level process can be viewed as occurring successfully, at a macro level the improvement can be seen as providing only limited support to the wider goals of the organisation. The use of the technology of plaster study models is shown as having limited utility to a wider goal of allowing the auditing of surgery across several hospitals. This is partially due to the difficulties in diffusing the innovation, but is probably more likely to be due to it being a sub-optimum technology for the purpose.

The case study identifies a number of emergent issues that relate to user-led innovation in the NHS including: motivation of NHS staff to innovate; the impact of formal innovation support on staff behaviour; the extent to which the roles of staff need to be flexible and open to change, in order for innovation to occur; the means by which process innovations are evaluated by innovators; and the

extent to which rigidity in the use of a technology can lead to user-led innovations becoming self-limiting.

7.2 Data Collection for the Case Study

The data for this case study was collected through two semi-structured interviews and a review of literature associated with the project. The first interview was with the Senior Chief Technologist (SCT) in Maxillofacial Laboratory. The SCT had been responsible for developing the innovative technique for producing study models. A second interview was done with the Plastic Surgeon with whom the SCT worked. The interviews took place several weeks apart due to delays in setting up interviews. Clarification of queries raised in the interviews was done by email.

The interviews followed a semi-structured format using the standard interview schedule (Appendix 1). The researcher made contemporaneous notes during the interview with the SCT. The interview with the Plastic Surgeon was recorded using a digital voice recorder. Both participants were enthusiastic in talking about the project and the interviews substantially exceeded the planned time for the interviews. The body language of the Plastic Surgeon during the interview, suggested to the researcher that the interviews was prompting the Plastic Surgeon to reflect and consider the project in more depth than he had previously done before. The Plastic Surgeon seemed to find the interview useful in enabling him to reflect upon the project. The reaction of the two participants during the interviews gave the researcher confidence that the views given were valid and reliable.

There was no specific published literature on the innovation itself, though a PowerPoint™ presentation on the new technique, produced by the SCT, was made available to the researcher. Secondary literature on the use of study models and the evaluation of cleft lip and palate surgery was reviewed for the case (Ali, Mossey, and Gillgrass 2006; Atack et al. 1997; Mars et al. 1992; Roberts, Semb, and Shaw 1991; Sandy et al. 1998; Shaw et al. 1996; Williams et al. 2001).

7.3 Background to Cleft Palate Surgery evaluation

A cleft palate is a congenital condition in which the soft palate at the rear of the roof of the mouth, or the hard palate at the front, fails to develop fully during the early stages of an embryo's

development. This can result in a cavity in the roof of the mouth. A cleft lip is the condition in which the upper lip or gum fails to develop fully, resulting in an opening or notch.

In the UK, 600-700 children per year are born with a cleft lip or palate (CLP). The condition may run in families but cases also occur without anyone else in the family having one. Babies with cleft palate may in extreme cases have difficulty breathing. Babies with cleft lip may have difficulty feeding and need additional help. For children who undergo cleft palate surgery, it is likely that their speech and hearing will develop normally, however, normal teeth development may be affected. In addition to physical development, attention is also needed for caring for the child's psychological needs.

CLP surgery is now based on well established procedures and can be carried out from within weeks of birth, to when the child has reached their late teens. Early stage surgery occurs within the first few months or years of a baby's life and involves the repair of the lip or palate. Bone grafts may be carried out on children between nine and ten. Later corrective surgery on children in their late teens may be needed to correct other features, such as jaw alignment. The treatment of children with cleft lip or palate is long term, extending over many years. Treatment is now generally safe and reliable.

Due to the range of associated issues, it is now the norm for treatment to be given by a multi-disciplinary team. This will typically include the following staff:

- Surgeon (plastic, oral and maxillofacial)
- Cleft Nurse
- Orthodontist
- Paediatrician
- Speech and Language Therapist
- Psychologist
- Geneticist

During the 1990s, there was a surge of interest in the development of strategies to improve the outcome of treatment for CLP patients (Roberts, Semb, and Shaw 1991). It had been recognised that the primary surgery undertaken on patients was crucial, as if it was poorly performed, facial

growth and dental development would be compromised (Mars et al. 1992). An important aspect of the perceived problem at this time was that there was inadequate data to provide clear guidance on what and when a specific technique should be used:

> It is also evident that a wide range of surgical techniques exist to correct this anomaly but with no clear-cut guidelines for optimal timing or method. As a result, when the outcome with one technique appears disappointing, surgeons are likely to make modifications to, or radical departures from, their current regimes. These changes are often made with little data or rationale. (Atack et al. 1997)

Due to the range of surgeons carrying out the procedures, on a large, diverse population of patients, it was difficult to obtain scientifically valid data on the best protocol to use for a specific patient. This highlighted the need to apply a more rigorous audit system to underpin an evidence-based approach to cleft surgery.

In 1996 a study was started that would review and make recommendations on the standards of clinical care for children with congenital cleft lip and or palate. The study was to be supervised by the Clinical Standards Advisory Group (CSAG) and the resulting report made a number of recommendations (Sandy et al. 1998). The underlying assumption behind these recommendations was that cleft care would be improved by concentrating the national provision of services, so that care would only be carried out by a small number of specialist teams equipped with all the necessary clinical skills. The report made several important recommendations:

- The number of CLP treatment centres in the UK should be reduced from 57 centres to between 8-15 centres. This would allow expertise and resources to be concentrated.
- NHS commissioners should clearly specify the expertise required in treatment teams to achieve process quality standards and clinical outcomes. Only centres providing the required specification should be commissioned.
- NHS trusts should concentrate their CLP services in collaboration with purchasers and practitioners.
- Clinicians should agree on a common database for all CLP patients. Information on all CLP patients should be made available for comparative studies.

- Training of specialist CLP clinicians should follow agreed training pathways and take place within specialist centres.

The emphasis of the recommendations centred on the need for an improved information system to allow auditing and improvement of services provided. By concentrating activity, it was hoped that the knowledge created through the experience of carrying out CLP procedures, would be used more effectively. Nationally it had been found that CLP services were provided by 75 surgeons, working in 59 centres. This lead to an average caseload of less than one unilateral cleft palate per surgeon, per year. On this basis, it was very difficult for individual surgeons to understand the effect of any specific surgical protocol. It had also been suggested that a minimum case load was required to maintain competence and proficiency (Shaw et al. 1996). It was proposed that instead of the total number of procedures being spread across a wide range of centres, in which practitioners would do a small number of procedures per year, a smaller number of practitioners would carry out a higher volume of procedures each year. This was done to concentrate the work of CLP surgery, enabling specialist skills to be developed and facilitate the systematic building of an evidence base to inform future surgery.

In 2002, the recommendations of the CSAG guided the reorganisation of CLP services in the UK. This was done in the context of other critical reviews of the existing system for organisation of cleft palate services in the UK (Williams et al. 2001). The restructuring resulted in the reduction of CLP service provision to just nine centres.

During facial development, sections of the palate drift apart and the width between various structures in the mouth are used as indicators of growth. A physical record of the palate has traditionally been kept using a plaster impression. Measurements include features of both soft and bony tissue. It is not crucial for the image of the face and the palate to be integrated. The traditional approach to measurement has used point to point dimensions rather than volume-based measurements. The method of measurements has been institutionalised by ortho-dentists who use tables of measurements based on specific dimensions.

The assessment of the effectiveness of a specific CLP procedure relies on the availability of data collected over several years. This includes data before the procedure was carried out and then at

various points in time afterwards. Data would often need to be collected over durations in excess of a decade. Central to the data collection was a study model, a 3-dimesional model of the topology of a child's palate and lip. Study model are typically plaster casts made directly from impressions taken of a patients mouth. Use of plaster study models was widespread, though has been augmented with 2D photography (Ali, Mossey, and Gillgrass 2006; Atack et al. 1997). However, it is normal for study models to be produced in order to audit the progress of treatment. This has traditionally been done by dental or plastic surgeons taking moulds from babys' mouths; the mould then being passed on to the maxillofacial technologist to complete.

Other technologies have started to be used for modelling the topology of a cleft palate, notably photography and other imaging techniques. These techniques however are still lacking in detail, often with shadowing of the images making them less useful than a traditional plaster model. The main imaging problem is that the tissues of the face are soft and so will not always be easy to image. Imaging of the palate could be done using a CT scan or an MRI scan. This is however not practical as it would be necessary to anesthetise babies to carry out the imaging. CT scans are also suitable, due to the burden of x-ray dosage. Some new technologies such as 3d surface photography imaging techniques such as 3dMDFACE are however now becoming available.

The cost of plaster models is also very low and so alternative technologies need to provide significant benefits to merit any extra costs. Overall, a computer-based 3D model would be preferred, as this would allow easy and accurate measurement of key dimensions.

This case study is concerned with the technology that supports the auditing of treatment of patients with CLP. Figure 7.1 shows the relationship of audit technologies within the wider system of CLP services in the UK. This case is concerned with the relationship between three main sub-systems: the organisations that govern and deliver CLP services; the system of treatment technologies comprising surgical techniques and surgical protocols; and the audit technologies available that allow the long term evaluation and improvement of the treatment technologies.

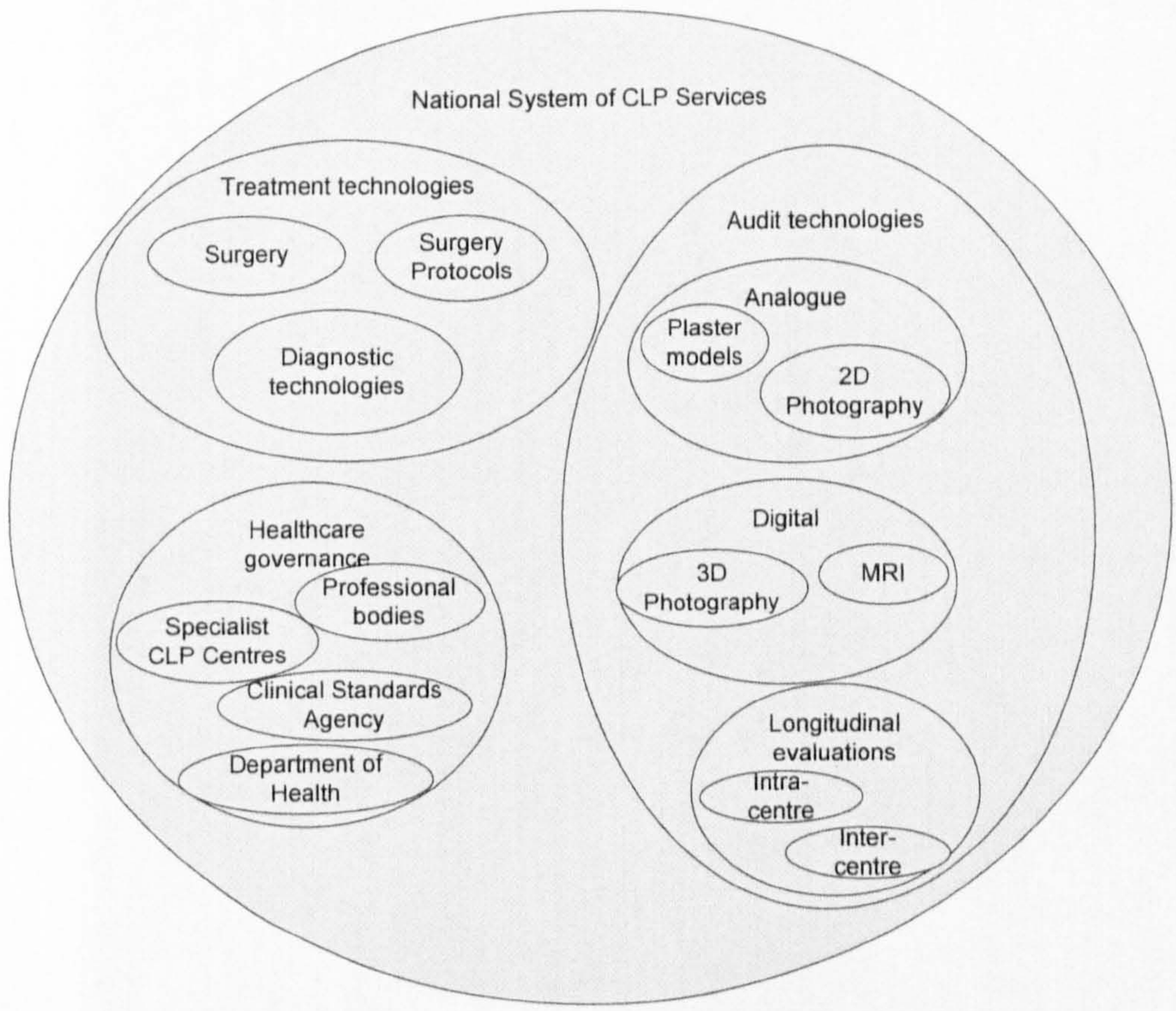


Figure 7.1: Audit technologies within the CLP service

7.4 Overview of the innovation

The innovation was centred on the development of a new process for producing a study model from a CLP patient. The new process was developed at Addenbrooke's Hospital in Cambridge. The process was new, however, it represented a development of an existing process, combined with a technique demonstrated at a conference attended by SCT.

The innovation used a technique by which the mould taken from patients was made up of three layers of material, rather than a single material that was used in the existing process. The new process used silicon putty for moulding the internal details of the mouth. Alginate was then used to take the moulding of the external face detail. Fast setting impression plaster was used as further layer to provide the supportive base for the two other materials. By using this combination of materials, it became possible to increase the extent of the moulding to cover the lips, nose and eyes. Once the mould had been used to cast the final plaster study model it was possible to produce a study model that showed the complete topology of the palate, lips and face in one model (see Figure 7.2).

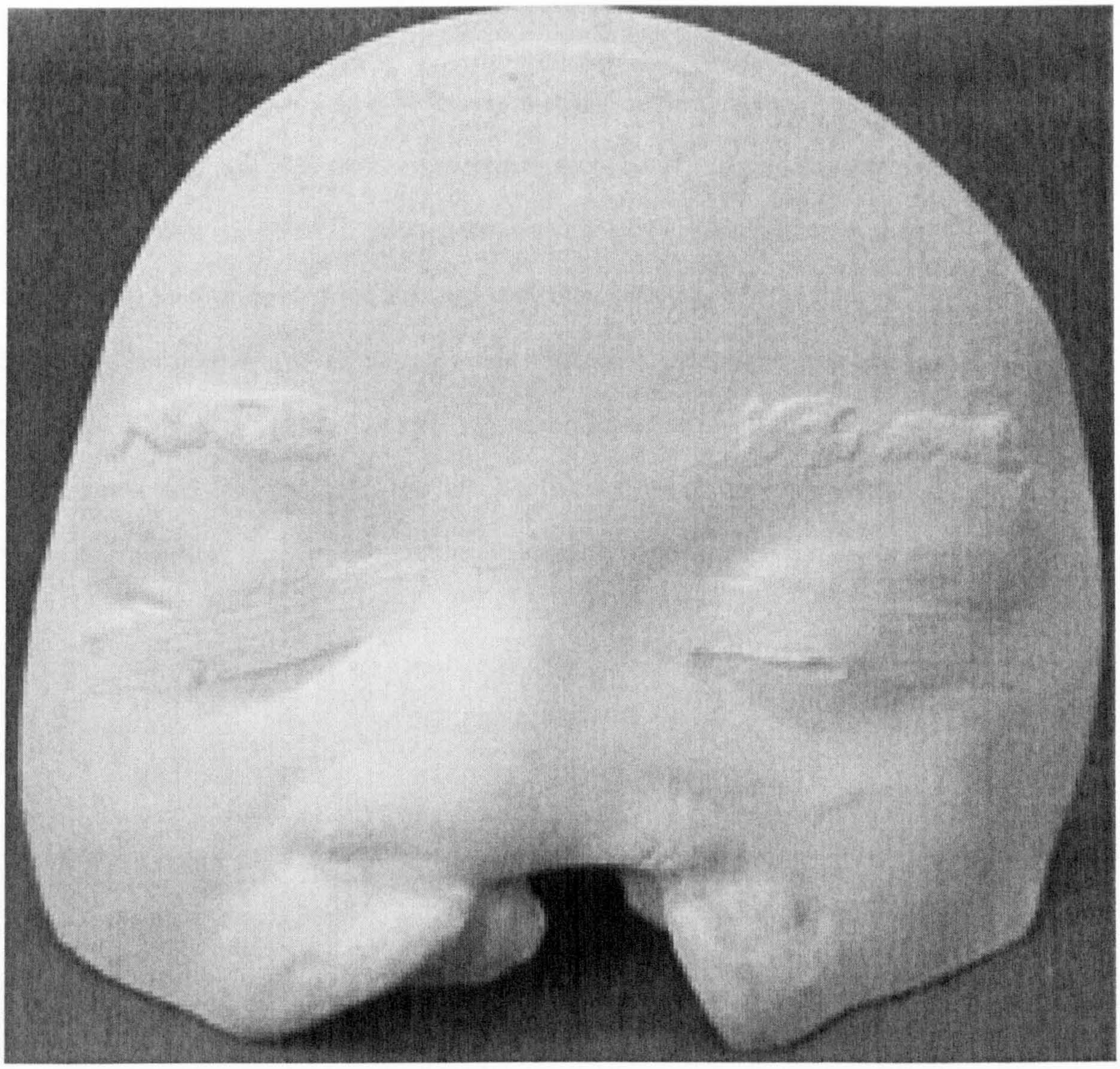


Figure 7.2: Study model of palate, lips and face

The new study model process allowed better study models to be produced for monitoring the progress of an individual patient over the period of their treatment. The improved model improved the opportunity for comparing the outcomes of surgery between patients treated by the Addenbrookes CLP clinic, but also potentially for carrying out cross-centre comparisons as part of a CLP audit.

For over seven years, the innovation provided a cheap method of modelling the face of the patient. The cost for the procedure was small, requiring 20 minutes of the technologist's time in theatre, followed by about two hours laboratory time. It was a low risk procedure, using standard materials that had been in general use for many years, with no significant side-effects.

7.4.1 Clinical problem

The innovation in this case study can be viewed as addressing a clinical problem at three levels of analysis (see Figure 7.3). The first is to view the innovation in terms of how the day-to-day process of producing plaster study models was changed, through the innovation of a procedure carried out in the operating theatre. This innovation involved a change in method, materials and the roles of staff involved. The second perspective is to see the innovation in terms of a addressing how best to collect topographical data of a patient's palate, lips and face. At this level, the innovation has enabled more data to be collected that previously. The final level of analysis is concerned with a much broader process of innovation; the innovation of the evaluation system for CLP surgery in the UK.

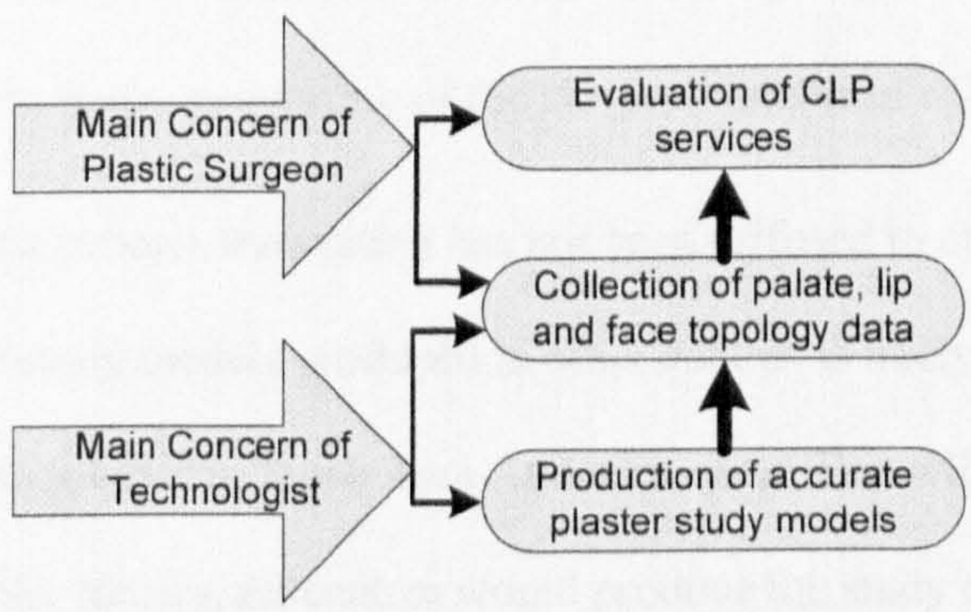


Figure 7.3: Three levels of clinical problem

7.4.2 Perceived purpose and market

The development of the innovation was based upon the need to solve a problem that confronted the two members of staff at a local level. The innovation developed primarily as an improvement to the way they worked; neither member of staff consciously developed the process with a view to its application outside of Addenbrooke's. They were not intending to develop a process that would be commercialised in any way. They had not actively considered whether they would transfer the new process to other CLP services.

While the innovation sought to address clinical problems at three levels, The two members of staff involved in the innovation focused on different problems. The plastic surgeon was more concerned with the problem of evaluating CLP service, while the technologist was primarily concerned with the production of plaster study models. The supportive role of the Plastic Surgeon in the innovation was rooted in his strategic view of the need to evaluate CLP services. In contrast, the bottom-up

innovation of the process of making the study model emerged from the technologist's motivation to improve the current way of working.

7.4.3 Extent and result of implementation

The process innovation has been completely integrated into the work of the CLP service at Addenbrookes. It is now a "normal" procedure and where appropriate is used for producing study models. In this respect, the process innovation can be regarded as fully implemented locally. There are however, three aspects of the innovation that would suggest the benefits of the innovation have not been fully realised.

First of all, though the centre continues to develop a comprehensive set of study models of its patients, it is yet to implement a system for analysing the data held in the study models. This is a longer term issue, as auditing of the surgical outcomes will have to be done over a long period.

Second, the process innovation has not been diffused to other cleft services. This means that the quality of study models produced in other centres is likely to be, at best incompatible, or in the worst case, inferior to those from Addenbrookes. This will make auditing outcomes across centres less reliable. Ideally, all centres would produce the study models in a uniform manner.

Third, a key mechanism for the diffusion of the technique would be that it is reintroduced into the practice of surgeons or other technologists. This might naturally happen once the technologist has refined the process and "packaged" the process into form that facilitates its use by other staff, either at Addenbrookes or other CLP centres. This might include the development of a specific set of tools or codification of the process, to help surgeons or technologist master the technique. The packaging of the process in this way would also make it easier to include within CLP clinician training.

The outcome of innovation has addressed the clinical problem, of making better plaster study models. Unfortunately, the innovation has only partly addressed the other two clinical problems. In hindsight, the problem of collecting accurate study model data for comparison across centres, has not been wholly addressed and the continued use of plaster study models has not made the precise measurement of the topology of the mouth any easier. At some point there will have to be a process

for digitising the plaster study models; a process that will incur significant costs in terms of staff time and equipment costs. Other candidate technologies such as 3D scanning may have provided better solutions than the use of plaster models.

This case provides an example of where continuous improvement of processes may prevent innovation, due to the tendency to create a rigidity in thinking, in this case not to question the role of the plaster study model. This resulted in the team not following a rational search for the solution of the problem of gaining topographical data.

The project has taken a fairly introspective view of the problems. It has operated mainly within the scope of the existing technologies used by the staff. There was no process for formally evaluating other candidate technologies, especially those from other sectors where topographical modelling is carried out, such as the automotive design industry.

7.5 Stages in the process

Figure 7.4 shows an overview of the process followed in developing the innovation. The development was gradual and organic rather than following a specific project plan. It is therefore difficult to identify clear stages in the development process. The process can be viewed as following three distinct phases: a negotiation of the setting, iterative development of the problems and solution; and post development activities.

7.5.1 Negotiation of the setting

The innovation stemmed from the recognition by the SCT and the Plastic Surgeon that the quality of impressions used to make study models during reconstruction surgery was poor. It was felt that that they did not meet the "gold standard". Together they accepted that the reason for the poor quality of moulds was that the surgeons had a lack of experience in using the mould materials and lacked the expectation that the final moulding could be more detailed and precise. The surgeons therefore underestimated the precision that could be achieved and the subsequent benefits that could be gained from improved study models.

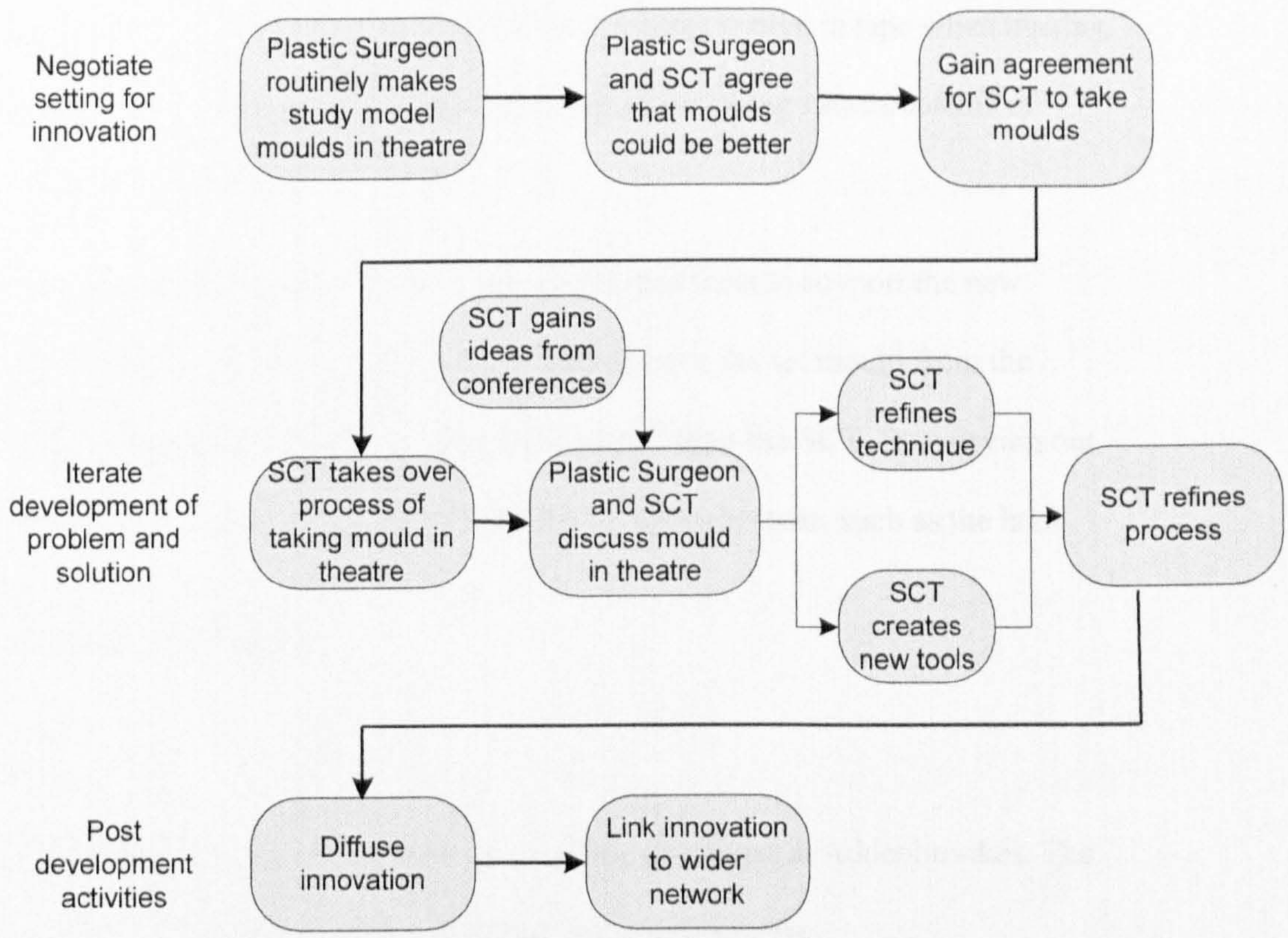


Figure 7.4: Innovation process for the CLP study model technique

7.5.2 Iterative development of the problems and solution

It was during these activities that the SCT and the surgeon discussed the scope for modifying the procedure:

> …while standing around waiting for the putty to set we talked about other ways of doing the procedure. (Plastic Surgeon)

The SCT was probably the key driver of the innovation at this point, however the Plastic Surgeon took a supportive role:

> …encouraging him [the SCT] on from the sidelines. (Plastic Surgeon)

Over a period of time, the SCT developed a new procedure for taking moulds of babys' mouths. Originally, the mould only produced an impression of the palate. A significant feature of the revised method was to make an integrated impression that incorporated the palate, lips, nose and eyes into one moulding. The resulting study model provided a more precise representation of the topology of the face.

One example of the iterative development of the process has been the change in position of tape applied to the patient's eyes during the process. The procedure was changed so that the inner

canthus of the eye is left visible, previously the whole of the eye was covered in tape when making the mould. This allowed a precise datum on the face to be created for taking measurements of subsequent changes in the patients face.

In addition to the innovation of the process, the SCT also developed tools to support the new process. One such item was a hook, that could be used to help remove the set mould from the mouth of the baby. The hook had been named a "Nowakian Hook" after the SCT. By carrying out the procedure himself, the SCT was better placed for designing auxiliary tools, such as the hook.

7.5.3 Post development activities

Diffusion activities

The technique used for making the study model is now a routine procedure at Addenbrookes. The surgeon reflected that they had probably forgotten that it was a novel process;

> ...the sad thing is that it has become such a routine for us, we do not even think about it. (Plastic Surgeon)

It is now as routine as other processes, such as use of 3D photography. It is perhaps for this reason that the innovation has not been actively promoted and then taken up by any other cleft palate centres.

The technique of producing the study models has been presented as some events attended by either surgeons or maxillofacial technologists. The surgeon does regret however, the lack of adoption of the technique. The SCT had produced a computer presentation of the technique, but probably due to his self-effacing nature had not written any articles that may have been published in relevant journals.

The surgeon reflected that at a meeting of the Cranial and Facial Society, a group attended by many cleft palate surgeons, a presentation referred to the Addenbrookes Study Model system. Several positive comments came from the floor that confirmed interest in the technique. There was no subsequent adoption of the technique by any of the other cleft palate centres. The surgeon suggests

> ...may be just the inertia of things, you go to a meeting and then go back to office...and it has gone and you carry on as before. (Plastic Surgeon)

The first time the techniques was given wider publicity was when the Healthcare Science Group within Addenbrookes included the technique in an exhibition for Health Science Week. This was staged in the concourse within the hospital. It was at this event that the SCT met a representative from Cambridge Enterprise (the Cambridge University TTO). As a result of this meeting the SCT was encouraged to enter the innovation competition run by Health Enterprise East (the local NHS innovation hub). The encouragement to enter the competition came from Cambridge Enterprise.

The driver for diffusion of the technique does remain however as there is a strong argument for all the cleft palate centres using a standard method of data collection, including the process of making study models.

The SCT felt that the adoption of the procedure in other CLP Centres was less certain. This was based on the uncertainty around the role of technologists carrying out internal procedures, even under close supervision. This grey area of practice while being supported in the teaching hospital environment of Addenbrookes, may not occur in other hospitals. Legal and regulatory issues may create a barrier to further diffusion.

In the future to aid diffusion of the technique the senior cleft consultant will take the idea to conferences. The SCT also intends to demonstrate to local group of the Institute of Maxillofacial Prosthetists and Technologists. He may present to national level event of the institute, though nothing is planned. The SCT felt less comfortable about writing up the innovation, for example as a journal article.

Linking to the wider innovation network

The cleft palate centres created in 2002 were all committed to doing an inter-centre audit of outcomes. This was yet to be organised (as at June 2007) for cases of new born babies compared to their development at five years old. The study models created at Addenbrookes represent a valuable resource for this audit, however, the data was yet to be analysed. The use of a plaster mould is sub-optimal as a CT or MRI scan gives more accurate data in a digitised form. The Plastic Surgeon acknowledges that the plaster impression is " ...a poor man's CT scan" (Plastic Surgeon). Overall, for the process of comparison of study model data across CLP centres would be made easier if the data was held in digital rather than analogue format.

There was a huge amount of data in the plaster study models produced over several years, but no clear strategy was developed for them to be measured. The aim was to maintain a record of all cleft-palate cases, approximately eighty per year. These records would include the study models, along with video of procedures, recordings of speech, x-rays and 2D and 3D photographs. This in itself was causing some problems, as the infrastructure for archiving this information was not in place. Ad hoc arrangements were in place for collecting, recording and archiving the records together. There was a risk that data would be lost or poorly archived, meaning that some data was prone to be lost over the long term. The archiving problem was rooted in lack of suitable space and creation of a dedicated archivist role. The surgeon worried that the task rested with him and that he did not have the time to take on the role effectively.

The analysis of the data in the long term was potentially problematic. In addition to the technical problems of digitising the study models, the overhead of time, motivation and expertise to carry out the analysis was not currently available. The surgeon hoped that after fifteen years it would be possible to review progress of the service at Addenbrookes using the archived data. This was however dependent on the availability of staff able to do the analysis. It was probable that this would need to be a registrar, who would do the analysis as part of a project done to support their career progression. No other resources were immediately available for this analysis work.

The data collected by the surgeon was potentially complete and precise. This would make it as valid as similar data held "fastidiously" in some Scandinavian hospitals. In Scandinavia surgical procedures were carefully evaluated and systematically modified over long periods of time. Despite the culture of evidence-based medicine in the NHS there was no obvious way of funding the archival of data. This problem was exacerbated by the emphasis of data collection in the NHS being on management information to support monitoring of targets and performance indicators.

Attempts had been made to produce computer models from the plaster models. This has been done successfully using a CT scanner that was then able to produce images in the portable DICOM (Digital Imaging and Communications in Medicine) image standard. Attempts to digitise the plaster impressions using 3D photography had been less successful due to the unsuitable texture of

the plaster surface. The surgeon had not had the time to investigate fully the possible methods for digitising plaster impressions.

7.6 Time dynamics of the innovation process

The development of the CLP innovation occurred over a period of months of gradual continuous improvement activity. The process of continuous improvement was an integral part of the SCT's role and the project was pursued during his normal working hours.

7.7 Organisational context

The innovation was developed in the organisational context of a major teaching hospital. The close relationship between Addenbrookes Hospital and the University of Cambridge meant that there was a long history of collaboration between medical research and provision of patient services. Technology transfer from both the university and the hospital is well developed and had been supported by Cambridge Enterprise, the university's technology transfer office. At the time of the innovation, the development of the NHS innovation hubs was still in its early stages.

The two members of staff involved in the innovation, a plastic surgeon and a maxillofacial; technologist, were both members of staff at Addenbrookes. Their roles were very different and so it is important to understand their respective perspectives on the innovation.

7.7.1 Plastic Surgeon

The Plastic Surgeon had been at Addenbrookes since 1996. He took over what was then a small cleft palate service. At that time, it was one of the fifty nine centres in the UK NHS carrying out cleft palate surgery. After the restructuring of cleft services in 2002, the centre at Addenbrooke's treated eighty babies a year with two surgeons. Despite the patient population still being very diverse, the number of operations carried out was sufficient to allow a systematic study of outcomes to be done. The centre was in a position to start building a database of evidence that would allow the effects of procedures on outcomes to be monitored. Ideally, this review would follow patients' development from baby through to aged fifteen.

The Plastic Surgeon believed that the challenge for cleft palate surgery, at the time the service was restructured, was gaining an understanding of the effectiveness of specific surgical interventions. Key variables were how an operation was performed, its sequence relative to other related operations and the age of the patient. It was unclear how these variables affected two outcomes: cosmetic appearance and facial growth. The Plastic Surgeon was aware of a study in Sri Lanka that had concluded that surgery does affect facial growth, while cleft palate without surgery did not impair normal growth. There was a national and international interest on the effect surgery has on facial growth. The Plastic Surgeon recognised that the sequence of operations was seen as important, though different centres took different approaches. In Scandinavian countries, there is a long history of evaluating cleft palate surgery. For example, in Gothenburg the sequence of operations started at the back operating on the soft palate first, leaving the hard palate open; in Oslo repair to the front, hard palate was carried out first.

7.7.2 Senior Chief Technologist and the Maxillofacial Laboratory

In common with the other CLP centres, Addenbrookes operated a multi-disciplinary team of clinicians. In support of this team was a small and well established maxillofacial laboratory. This was small department that provided a technical service to departments including the CLP service. The department at Addenbrookes employed two technologists. The Senior Chief Technologist (SCT) in the department played a central role in the innovation of the process for making study models. They provided a wide range of services to patients from several hospital departments:

- Oral and Maxillofacial Surgery including the Orthodontics, Cleft Lip and Palate, and Facial Deformity (orthognathic) Clinics;
- Plastic Surgery;
- Ear, Nose and Throat (ENT);
- Ophthalmic Department;
- Oncology;
- Neurosurgery;
- Their role was to fabricate a range of prostheses and appliances including:

- Facial prostheses;
- Maxillary and jaw prostheses;
- Prostheses to improve the contours of the limbs or torso;
- Silicone implants;
- Breast and nipple prostheses;
- Skullplates (in titanium or acrylic;
- Intraoral splints, for emergency trauma or for elective surgery;
- Orthodontic braces.

The department operated very much as a "jobbing shop" and the staff had significant autonomy in their work. Through strong relationship with other departments such as the engineering workshop, they were able to produce one off components, and were free to innovate the design of components. The staff in the department was keen to solve problems encountered in designing and producing various prostheses and appliances. The culture of the department encompassed that of the problem solving engineer.

The work of maxillofacial technologists was specialised and supported by their professional body, the Institute of Maxillofacial Prosthetists and Technologists. The relationship between the professional institutions of the technologists and the clinicians (British Oral & Maxillofacial Surgeons) was a positive and mutually supportive one. Technologists needed to be both technical and clinical specialists, fabricating devices and then fitting them in either the maxillofacial prosthetic clinics or alongside surgical staff during operations. The technologist's role involves extensive professional autonomy due to the high degree of patient contact and clinical responsibility. The technical specialism grew out of the need for technical support, required by dental and medically qualified surgical staff working in oral surgery units after the Second World War. It is a specialism that requires technologists to work with a range of materials, within relevant regulatory frameworks.

Maxillofacial technologists have played a role in the treatment of babies with cleft palate for a long time. In the past, a key task has been the creation of feeding plates that could be fitted to babies to

improve their feeding. This has required the construction of a plate based on a moulding taken of the roof of the baby's mouth. With the introduction of other techniques for feeding this process is now less common.

The SCT saw the department as a "back room" area of the hospital but felt that they had significant levels of contact with patients, especially when fitting prostheses. This was an activity requiring sensitivity and excellent technical and craft skills. For example, making and fitting a facial prosthesis required good technical skills in order for the prosthesis to be effective and good interpersonal skills when dealing with the patient.

In the course of the work of the department, they often had to address technical problems and develop effective solutions. The solutions were often variations on current methods and as such were not sufficiently novel to warrant IP protection. However, many of the improvements provide improved patient care, for example the development of improvement fixing methods for prostheses. The SCT believed that many of their ideas were not often acted on by the wider hospital. A key relationship for the department was with the hospital's engineering workshop. This relationship was important in enabling ideas developed by the technologists to be transformed into final products. One example of this was the development of stud fixings for prostheses developed by the department. These have been developed from conventional clips to a "flattened doughnut" shaped stud. The new design of stud had been manufactured by the engineering workshop.

The method of working in the Maxillofacial Laboratory was very much an in-house process. The SCT suggested that this process had, to some extent, reduced the regulatory obstacles to innovation, especially as the work is in the context of a teaching hospital. There is a level of trust between the technologists, engineering workshop and the clinicians that all necessary measures were taken to ensure all devices were made from appropriate materials and designed with a careful consideration. This was the essence of the professionalism of the department. The SCT felt that this type of working would not be accepted in a private sector organisation, where the costs of meeting regulatory controls would be more prohibitive.

7.8 Emergent themes

The innovation of the process for producing plaster study models was affected by a number of issues. Figure 7.5 illustrates the main enabling and retarding issues within the case.

7.8.1 Motivation of staff to innovate

The innovation was driven by the motivation of two members of staff, the SCT and the Plastic Surgeon. For both members of staff their motivation stemmed from their professional identities.

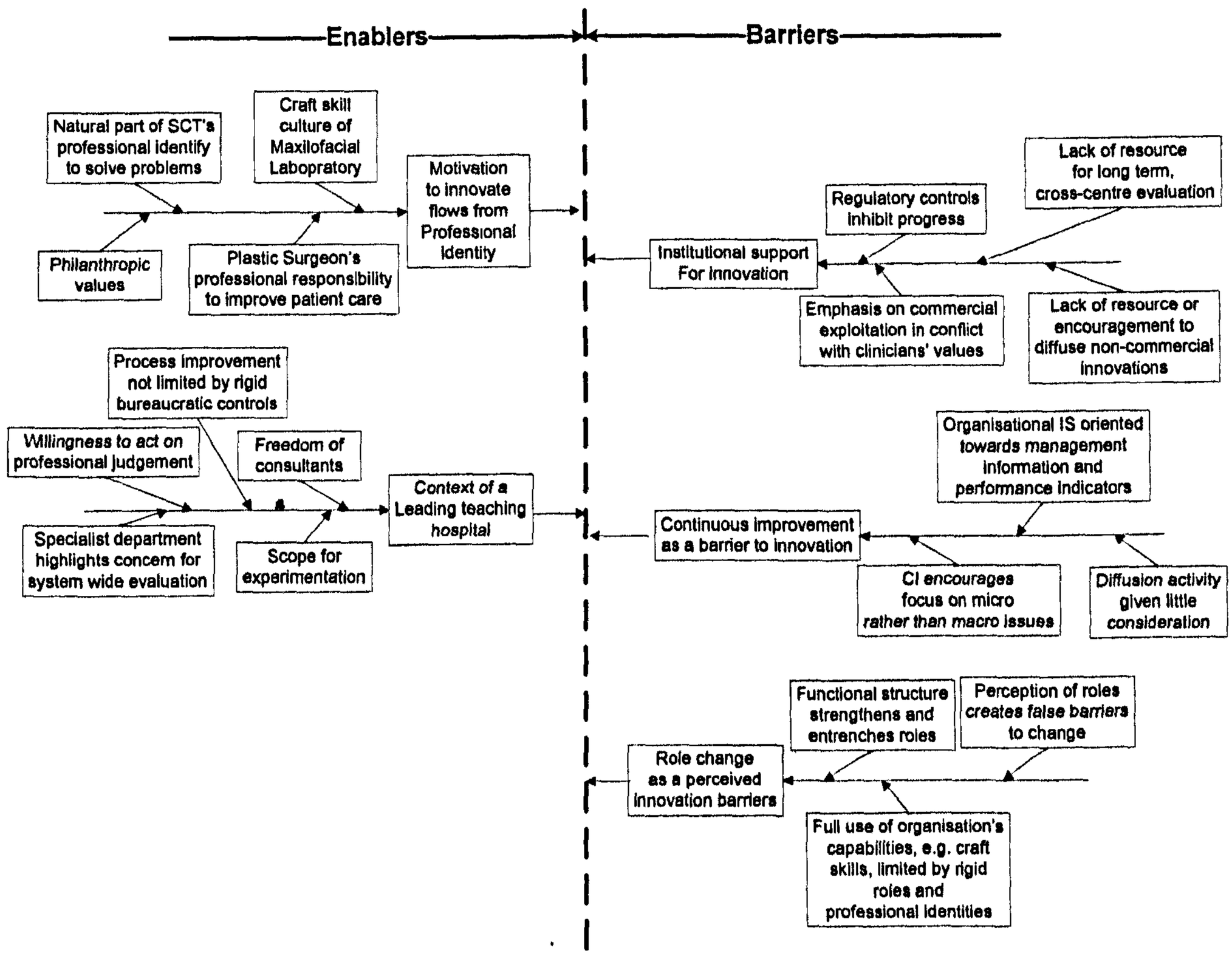


Figure 7.5: Enabling and retarding factors in the CLP innovation process

The SCT was motivated to pursue the innovation as he saw it as a natural part of his role. He felt that a distinctive aspect of his work was to identify and solve technical problems. He was proud of many small innovations he had made during the course of his work, many of which he felt were not sufficiently novel to require patenting or other IP protection. They were however instances where a

problem had been solved through careful engineering. It was clear that the problem solving part of his role was important to the SCT.

The motivation of the surgeon to be involved in innovation work was also based around his professional identity. He was primarily motivated by the need to improve patient care. He felt that the reward for this should be professional respect and recognition. He has little interest in the potential financial gains from innovation, as shown by his involvement in a separate innovation project in which he had played a central role. The other project has resulted in a commercial product, supported by £10m of venture capital. In this other project, he has adopted the role of ensuring the product had scientific validity and he had no financial interest in the product. His innovation work was driven by a philanthropic spirit rather than an economic one. He saw the reward for innovation being based around professional recognition, he had joked with the company producing the device that "...he would like to be famous one day" (Plastic Surgeon). He felt however that the company would never really acknowledge his input into the product.

7.8.2 Teaching hospital as a context for innovation

The extent to which the context of a teaching hospital has supported the innovation was raised by the SCT. He felt that the culture of the teaching hospital made "experimentation" with the process legitimate. This was particularly the case in relation to the impact of regulatory controls on medical devices. He felt that this may not have been the case at other hospitals or in private companies. The extent to which this is a real factor is unclear. The SCT's experience was predominantly at Addenbrookes and not in a general hospital and so this may simply be a misconception. It does however raise the issue of whether user-led innovation activity is affected by whether the hospital is a general hospital or a teaching hospital.

7.8.3 Institutional support.

The philanthropic motivation that underpinned the work of the Plastic Surgeon conflicted with the ethos of innovation management in the NHS. The Plastic Surgeon experienced the support for R&D and innovation as focused primarily on exploitation of IP. His contact with R&D staff within and external to the hospital had made him feel the focus has been wrongly placed on maximising

revenue from IP. He felt that external agencies, such as large medical research charities, had placed the potential commercial success of an innovation above other factors, such as impact on NHS patients. He believed there needed to be a commercial interest to create a pressure to deliver. Overall, he believed that the innovation support infrastructure of the NHS was "...thwarting innovation" (Plastic Surgeon). In addition, the regulatory framework around innovation, such as ethical and R&D approval processes inhibited progress. The Plastic Surgeon reflected "... unless you have an enthusiastic registrar whose life depends upon getting a paper..." innovation projects would not even get started. He understood that there was a need to protect patients, but the balance had gone too far.

The result of the emphasis on commercial exploitation was that there was no encouragement or resources available for the diffusing innovations that had a low commercial value, such as the study model technique. This was also reflected in the lack of funding available for activities that would underpin cross-centre evaluation of CLP surgery.

7.8.4 Continuous improvement as an innovation barrier

The project has highlighted the potentially limited nature of continuous improvement. The pursuit of incremental improvement of the process of producing study models may have encouraged a focus on micro rather than macro issues. This potentially lead to the wrong problem being addressed, where the macro level problem was how to store topographical study model data over the long term, rather than the best way of producing a plaster study model.

Continuous improvement relies on the availability of adequate information systems to supply feedback on change. Unfortunately, the information systems in the hospital were oriented to management information and measurement of services against performance targets. This emphasis meant that there was little scope for investment in systems that would have allowed long term evaluation of CLP surgery. This meant that despite improvement in the quality of the study models wider systems for archiving and analysing the data held in the models was not considered. If a clearer innovation proposal had been developed then these wider systems could have been planned and resourced more effectively.

Finally, the emphasis on continuous improvement underemphasised the need to diffuse the techniques to other specialist CLP centres. While the innovation was adopted and accepted within the normal working practice of the department, there was no motivation to drive the wider diffusion of the process improvement.

7.8.5 Role Changes: Innovation in roles taken by staff

An important emergent theme in this case study was the extent to which the roles of the surgeon and the technologist shifted. The role change enabled two aspects of the innovation to occur. First, of all the shift in roles fundamentally underpinned the innovation of the process, i.e. the technologist carrying out the procedure rather than the surgeon. Second, the shift in role meant that the technologist was better placed to apply his experience in refining the process; he was no longer a passive observer but was experiencing the procedure himself. This meant that the innovation was based on a progressive refinement of the new procedure, rather than it simply being a single shift in procedure. It is useful to consider in more detail why the shift in roles was necessary and how the shift came about.

Prior to the SCT developing the new process for producing the study models, the Plastic Surgeon would take the palate impressions himself. He was not well equipped to do this, using an NHS desert spoon instead of a dedicated tray, for holding the silicon putty when taking the impression. The Plastic Surgeon felt he lacked the necessary craft skill to produce a good quality impression. The result was that despite the best efforts of the technologists when producing the plaster impression from the silicon impression, the results were sub-optimal. The plastic surgeon's goal was to be able to keep suitable records to aid decision-making and to demonstrate that the centre was serious about keeping audit data. This provided a significant source of motivation for the change of role to occur.

The accepted relationship between maxiliofacial technologists and clinical staff was clearly defined. The technologists worked primarily for and to support the work of orthodentists. Their work was therefore directed by orthodentists. Traditionally, technologists would not take internal impressions, even on patients in their teens. The orthodentist would be responsible for taking the impression, which would then be passed to the technologist to cast up. It was not accepted practice

for a technologist to carry out internal procedures, particularly on babies under anaesthetic. It was however common for technologists to take external moulds from patients. Within this system, the technologist would be unlikely to interact directly with the patient. This contrasted with the role taken by the technologists in other aspects of their work, where their role required them to interact with patients, such as when fitting prostheses.

The respective roles taken by the Plastic Surgeon and the SCT were an expected and accepted feature of their professional identities, common in all hospitals and not just Addenbrookes. It was however, a relationship that was based on accepted custom and practice rather than any objective breakdown of the work content of the procedure. Two issues were raised by the existing division of work implied by the accepted roles. First, the craft skills needed to work with the mould materials were held predominantly by the technologist. In addition, the technologist had a full understanding of the complete process for making a plaster study model. This deeper knowledge of the process enabled him to develop improvements to the process, e.g. developing new tools such as the carrier for the silicon putty. Second, the technologist had a higher expectation, of the potential detail that could be achieved by plaster study models.

The renegotiation of roles took place through consultation with other clinicians and service mangers. It did not attract any significant resistance when the proposal to allow the SCT to take the palate impressions in the operating theatre, under the supervision of the surgeon and other theatre staff. Potential resistance to this change could have developed because it was encroaching on the work of the maxillofacial/dental surgeons; however, the change of roles was probably more a perceived barrier to change, rather than one set in formal regulations.

The change of procedure was a rather grey area in terms of the regulatory situation. It was not wrong for technologist to take moulds, but the context was seen as potentially very sensitive by the technologist. In contrast, the surgeon felt that the decision to allow the SCT to take the impressions was neither unusual nor controversial. The surgeon reflected that:

> I probably just bludgeoned my way through, not thinking that I was crossing a big boundary, I did not think it was an issue...I was surprised when someone said that technicians [SCT] were not supposed to take models...it did not appear to me that I

> was being cavalier or what you would make a fuss about...I just needed the information and as you so often do in hospitals, you suddenly come across someone who is a bloody amazing resource, who is just around the corner, and we just said let's do it, and it just evolved, without reference to anyone else, and not particularly discussing it with each other. (Plastic Surgeon)

For the Plastic Surgeon, the extended role of the SCT was seen as the logical way of evolving the process. By involving the SCT in the actual procedure in the operating theatre, the SCT was able to refine the tools and techniques used. He developed new trays for holding the putty in place and mastered distributing putty in the mouth, so that an optimum impression of the complete horseshoe of the mouth could be taken.

The SCT however, saw the change as more radical. He perceived the change as quite fundamental and initially found the prospect of carrying out the procedure on an anesthetised baby slightly daunting. He believed that two factors had eased the change of roles. First, the SCT was a well established member of staff with twenty years of experience in the hospital. This position gave him a position of authority based on his technical knowledge. The clinicians trusted his judgement that the new procedure would have a significant benefit. He felt it unlikely that a technologist who was either less senior or was new to the hospital would have been able to suggest such as change. Secondly, the procedure would be carried out in an operating theatre in the presence of specialist surgical staff. This setting meant that any hazards associated with the procedure were adequately addressed.

The change of role in this case study is a central one, allowing the technologist to apply his knowledge more effectively. Whether the resistance to role change constituted a barrier to innovation is, however, less clear cut. From the perspective of the technologist, it was perceived as a major barrier. In contrast, the plastic surgeon was much less conscious of it being a significant issue and was far more concerned that the process was done in the most effective way. It seems likely that the role change was more manifestation of the perceived power differential between the technologist and the plastic surgeon. In this case, the technologist's perception was that surgeons would be reticent or even hostile about allowing technologists to carry out procedures on

anaesthetised patients. In this case, this turned out to be an incorrect assumption. The power of the plastic surgeon to effect change made the barrier insignificant; from his point of view. It does however suggest that such perceptions can form significant barriers to innovation.

7.8.6 Validation evaluation of innovation

From an evaluation perspective process, this case presents a distinctive example. The process of producing study models was part of a wider system of evaluation: audit of the results of CLP surgery. As such, the evaluation of the process did not lend itself to evaluation through clinical trial, as it did not have any direct impact on the effectiveness of any specific patient's treatment. Instead, the evaluation of the process has been based much more within a process of continual improvement of the process overtime, based on the judgements made by the SCT. The development of the process was based closely on a cycle of PDSA approach.

No explicit evaluation of the techniques was carried out, but the technologist was satisfied and confident that they were producing better quality study models. His judgement was based on his own experience of producing plaster study model. His belief in the technique is also backed up by the judgements made by the Plastic Surgeon, and other clinicians, that the study models will underpin an improved basis for planning CLP surgery. This illustrated that the principal form of validation for the innovation was professional judgement, rather than systematic evaluations such as clinical trials.

Some external validation of the process was gained when it was awarded a commendation in the 2005 Enterprise East NHS innovations competition. It is however unclear to what extent the process was evaluated, in comparison to other potential solutions to the clinical problems it addressed.

The case highlights an important issue for evaluation of process improvements. The use a PDSA approach to improvement, worked well for the innovation of the study model process. Decisions on improvements could be made quickly and with minimum level of bureaucratic controls. The overriding basis for evaluation was the critical judgement of the staff involved, based on their professional knowledge, in contrast to more formal evidence-based approaches. This suggests that

while evidence-based approaches are important in healthcare, they may not provide the only basis for evaluating process innovations.

7.9 Summary

The case highlights how relatively small process innovations develop through user-led innovation. The challenge in managing these types is in ensuring clarity of project goals, removing barriers to the wider diffusion of innovations that have been successfully implemented locally and providing appropriate and timely innovation support.

7.9.1 Clarity of project goals

This case illustrates the high level of coupling between high level and more locally oriented goals of user-led innovation projects. The multiple levels of clinical problem that the project has sought to address can mean that the purpose of the innovation can lose focus. The use of plaster study models was in fact a tool constructed to support higher level processes. Maintaining a consistency of goal across all levels would be challenging in a highly managed environment; in the context of a user-led innovation project there are few controls ensuring that the project consistently addresses all relevant goals.

The case illustrates some important features of where innovation at the micro level can result in poor innovation at the macro level. Within the case, the focus of the development effort has been to improve the process of making a plaster cast. Unfortunately, due to the problems of using the plaster study model in large scale audits, it was probably the wrong thing to put effort into. Instead, it may have been more effective to consider the higher level clinical problem of how best to collect topographical data of CLP patients. This might have involved a very different investigation and development. It suggests that for many user-led innovations care needs to taken that the right clinical question is being asked.

7.9.2 Barriers to innovation diffusion

The case is an example of a process innovation that exhibited no significant diffusion. The characteristics of the innovation can be seen in terms of the knowledge required by the technologist to carry out the process, in combination with the tools and materials used in the process. In order

for the innovation to diffuse, two processes need to occur. First, the knowledge of the process held by the technologist must be codified into a form that allows the process to be taught to other surgeons or technologist. Second, any tools developed e.g. the "Nowakian Hook", need to be made available for others to use. This would undoubtedly require additional development e.g. to allow manufacture or fulfil regulatory controls. By completing these two processes, the innovation can be seen as having been "packaged" for wider use. It moves the process to one that is specialised, to one that has become more routine and less specialised in focus.

7.9.3 Support to user-led innovation projects

The problems of diffusing the user-led innovation, discussed above, suggest that innovators may benefit from additional support. The case suggests that specific types of support, at specific stages, may reduce the risk that innovation effort is misplaced. In particular, the case highlights two possible forms of support. First, the review of whether the right clinical problem is being addressed. Second, provision of timely advice to help innovators act to diffuse their innovations and to understand better the specific barriers to diffusion. Finally, this case illustrates the problem of how the full value of an innovation is not realised because of a lack of staff time to engage with the diffusion process.

Chapter 8: Pain Management Service (PMS) Case Study

8.1 Introduction

This case study reviews the innovation of the Pain Management Service (PMS), a service based at Southampton University Hospitals Trust (SUHT). The innovation involved the redesign of services to ensure that chronic pain patients were able to access expert help based in the primary and secondary care sectors, quickly and precisely. The service innovation resulted in the implementation of a bio-psychosocial model of pain to develop a collaborative, managed-care system, managed using a multi-disciplinary triage system.

The new service design represented a complex new set of roles, relationships, processes and structures in the PMS. In addition, the case provides an insight into how the actions of staff involved in the original innovation acted to diffuse the new model of the PMS service design.

The case study is important to understanding user-led innovation because it highlights how the entrepreneurial action of clinicians and mangers can affect shifts in attitude and changes in professional roles to support innovation of NHS services. The case highlights the role of multiple approaches to technology evaluation and suggests that service re-design must take a pluralistic view of evaluation methods. The case provides an example of how clinicians can act to influence professional groups and shift norms of practice in order to diffuse innovation beyond its original context.

8.2 Data collection for the case study

The data for this case study was collected through three semi-structured interviews and a review of literature associated with the project. The first interview was with the Consultant in Pain Management (PM Consultant) who had driven much of the project. Interviews were then carried out with two of the NHS managers involved in the project. The first, Manager A, was based in the pain management service of the hospital, with the PM Consultant. The PM Consultant and

Manager A were the two key members of staff at the core of the innovation project team. The second manager, Manager B, was based in a primary care trust and was involved, though from a primary care perspective. Due to their workload commitments, Manager A and Manager B were interviewed several months after the PM Consultant.

Interviews with the three members of staff followed a semi-structured format using the standard interview schedule (Appendix 1). All the interviews were recorded and took place during 2007. The interviews were planned to last less than an hour each, however, in all cases the interviews extended to up to two hours each. All participants appeared relaxed and comfortable about discussing the project during the interviews. The researcher felt confident that the participants' responses were based on thoughtful, candid responses to the questions and did not appear evasive of any issues. All participants seemed to take part in the interviews enthusiastically and seemed to enjoy being given the opportunity to reflect on the project. Notably, the PM Consultant described the interview as "interesting". It was clear that during the interviews all participants had difficulty in clearly recollecting the chronological order and precise timing of events during the project, as several years had passed since the project's inception in 2002.

Additional data for the case has been gained from the literature on pain and pain management (BPS 2004; Engel 1977; Loeser 2000; Von Korff, Glasgow, and Sharpe 2002; Waddell 1987). Articles produced by members of the team were also considered (Price 2006; Price and Swales 2004), as were notes from a presentation at a British Pain Association meeting (Price 2007).

8.3 Background to pain management services

The clinical organisation of pain management services is complex as the potential treatment for chronic pain includes one or a combination of therapies such as: counselling, drug therapies, surgery, physiotherapy and acupuncture. The challenge for a pain service is to ensure that patients are referred to the most appropriate treatments in a timely manner, whether provided by specialists based in hospitals or other staff based within the primary care sector.

The British Pain Society (BPS) defines chronic pain as a continuous, long-term pain extending over a period of at least 12 weeks. In contrast, acute pain is shorter term and usually associated with a

specific cause; chronic pain may be less easily attributed to a specific illness. Chronic pain is experienced by a diverse range of patients with conditions such as: arthritis, back pain, damage to the nervous system, pain resulting from surgery and cancer. Patients range from children through to the elderly.

Chronic pain is a significant problem in society causing many social and economic problems. The BPS proposed several consequences of chronic pain in the UK:

- untreated pain can affect quality of life for sufferers and carers resulting in helplessness, isolation, depression and family breakdown;
- musculoskeletal conditions have a more negative effect on quality of life than cardiovascular, chronic respiratory and gastrointestinal disease and visual impairment;
- two thirds of people with chronic pain surveyed across Europe reported inadequate pain control with only 16% saying they had seen a pain specialist;
- poorly managed chronic pain accounts for 208 million days off work equating to £18 billion a year;
- Currently nearly 4.2% of the working population is on incapacity benefit, 24% of which are due to diseases of the musculoskeletal system and connective tissue, almost two thirds of whom are male. This equates to a cost of £6.7 billion. (BPS 2004)

Traditional pain management services have reflected a predominantly bio-medical perspective on the treatment of pain. The bio-medical view of pain assumed pain to be related to physical disease, rather than illness or disability. The implication of this has been that the structuring of pain services was predicated on an assumption that pain should be treated using medical approaches. Hence, pain services in NHS trusts were commonly centred on hospitals, with medical specialists in areas such as orthopaedics and anaesthetics occupying powerful positions. The consequence of this was that the prime means of treatment were based on either surgical or pharmaceutical interventions.

However, since the 1970s, following on from work by Engel on the bio-psychosocial model of disease (Engel 1977), a broader approach to the treatment of pain was developed. Figure 8.1 illustrates a bio-psychosocial model of pain and suffering developed to inform pain management (Loeser 2000).

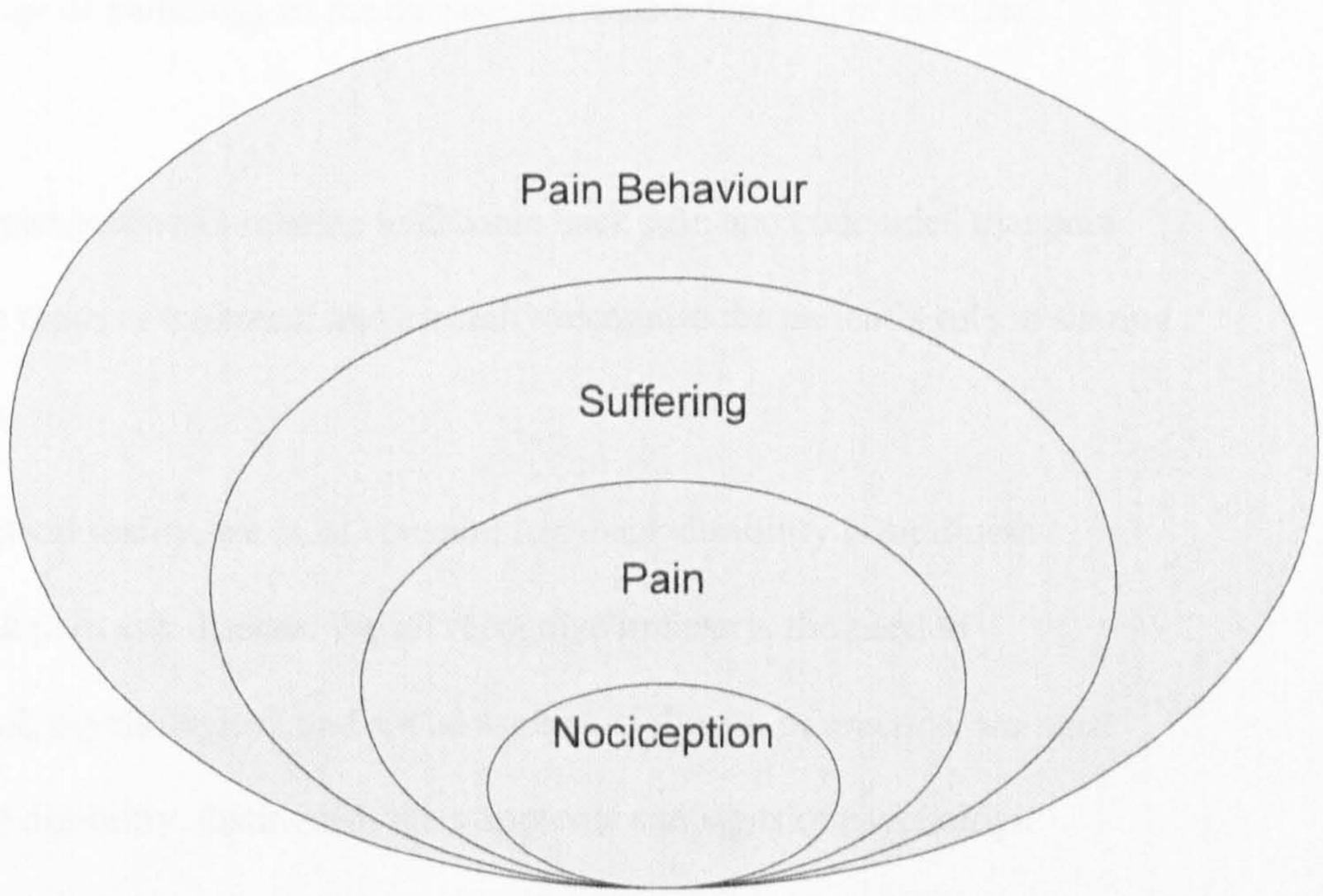


Figure 8.1: Bio-psychosocial model of pain (adapted from Loeser (2000))

Based on Loeser's model it became clear that pain services needed to take a more holistic view of pain and suffering. Part of the reason for the emphasis on the bi-medical view of pain was in part because of the dominance of certain professional groups and commercial interests of pharmaceutical companies.

> The search for the biologic mechanisms underlying pain has been fuelled in large part by the pharmaceutical industry. It has funded much of the research and the majority of the meetings addressing this topic. The pursuit of mechanisms of pain (usually called the neurobiology of pain) currently seems to focus almost exclusively upon somatic tissues, the peripheral nerves, or the dorsal horns. (Loeser 2000)

Loeser suggested that other strategies were needed to help patients cope with pain, with particular attention to the suffering experienced by a patient.

> Suffering, however, cannot be found if we examine patients' bodies alone, for it exists only in the mind. The events that lead to suffering will differ from one patient to another. There are no physical examination clues or laboratory tests or imaging studies

> that reveal its presence. We must ask the patient and listen to his or her narrative to find suffering. Often, just listening to the patient will ameliorate his or her suffering, but the data are not objective. One cannot assess suffering in a patient whom one does not know. One can, however, help the patient deal with his or her suffering without knowing the aetiology or pathology of the disease that causes the patient to suffer. (Loeser 2000)

Waddel applied a similar perspective in relation to chronic back pain and concluded that pain services should extend the types of treatment and crucially recognise the patient's role in sharing responsibility for progress

> To make this a practical reality, we must consider low-back disability is an illness rather than low-back pain as a disease. We all recognize in theory, the need to consider the physical, psychological, and social aspects of illness. In practice, we must distinguish pain and disability, distinguish the symptoms and signs of psychologic stress and illness behaviour from those of physical disease, and direct treatment to restoration of function as well as relief of pain. It is unlikely there will ever be a magic cure for all low-back pain, so the physician's role as healer must be accompanied by his or her more ancient role as counsellor, helping patients to cope with their problems. The patient's role must correspondingly change from passive recipient of treatment to a more active sharing of responsibility for his or her own progress. (Waddell 1987)

The bio-psychosocial model has been elaborated through combination with collaborative and stepped care systems, such as those operated in North America, for example, Kaiser Permante's managed care system. Von Korff *et al* made two important contributions to the structuring of pain management services. First, by emphasising the need for pain management services to include collaborative models of care where patients, their families and clinicians are all involved in decision making. Second, an efficient model of stepped care (see Figure 8.2) is needed where the sophistication of interventions is increased only when simpler ones have failed:

Interventions are best organised in a stepped fashion - that is, the most complex and expensive interventions are given only when simpler and cheaper ones have been shown to be inadequate inappropriate. (Von Korff, Glasgow, and Sharpe 2002)

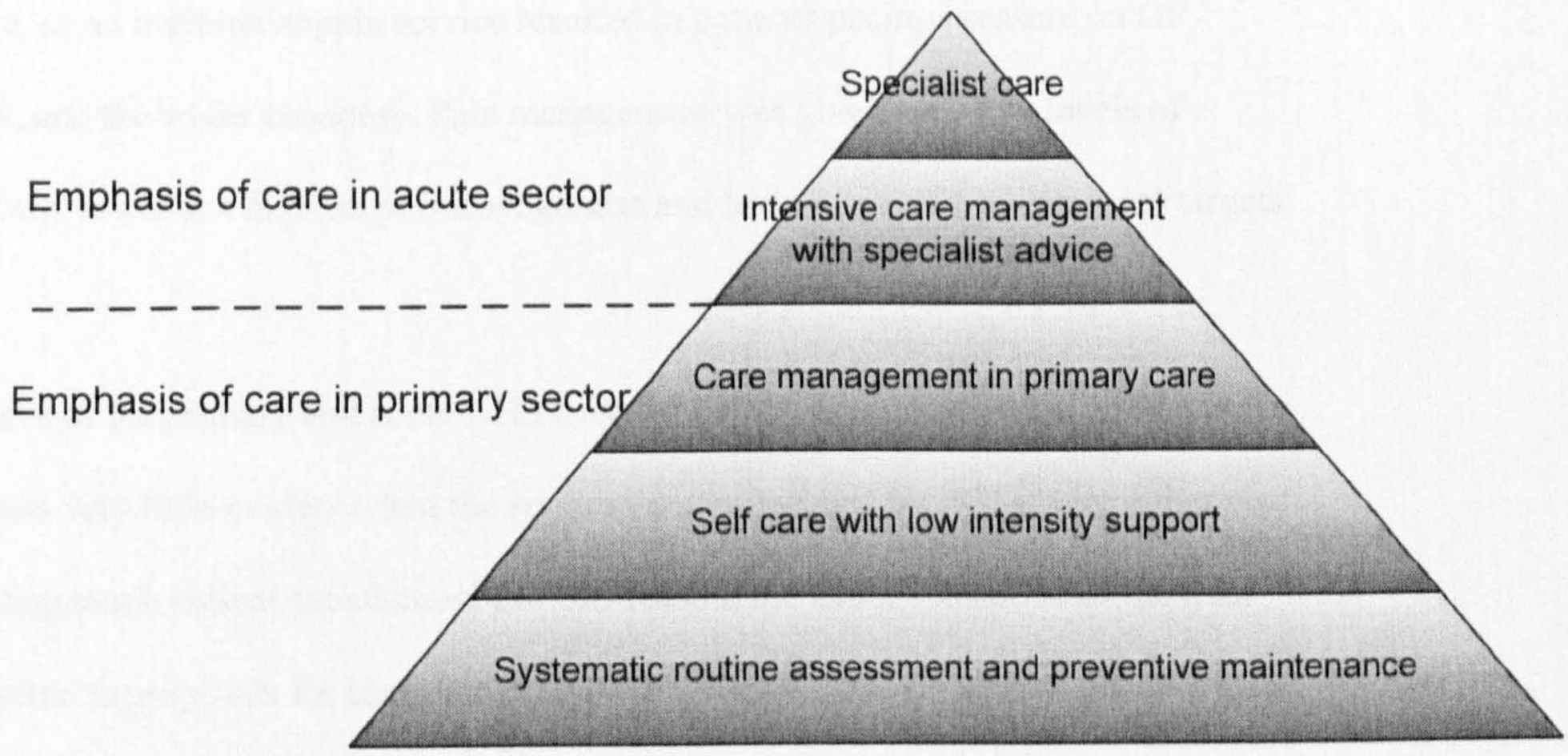


Figure 8.2: Stepped model of collaborative care

It is in the context of these advances in the organisation of pain management services that the changes at the PMS took place. The result being to implement a collaborative, staged-care, pain management system based on the assumptions in the bio-psychosocial model of pain.

8.4 Overview of the Innovation

The PMS was based in Southampton Universities Healthcare Trust (SUHT), a secondary care trust serving five PCTs. Services used by the PMS were based across both the primary and secondary sectors. Medical and surgical care tending to be based in the secondary sector while other services such as physiotherapy were based in the PCTs. Care tended to be fragmented between trusts, with few mechanisms for managing care across trust boundaries. Within the PCTs some small scale initiatives were started to provide improved services, for example a pain management programme that was staffed by primary and secondary care specialists. These initiatives however tended to be fragmented and did little to improve the overall performance of pain services. These efforts were

also impeded by differences in strategic priorities, structures and funding between trusts. This had meant that PMS staff had only made minor changes that failed to solve the underlying problems.

The staff in the PMS believed it to be a cinderella service, but recognised its function as critical. There was a proven link between chronic pain and problems such as: family breakdown, loss of work or depression, so an ineffective pain service resulted in patients pacing pressure on GP practices, the NHS, and the wider economy. Pain management was given very low levels of management scrutiny. It was not high on political agendas and had no specific government targets set for it.

From the perspective of the primary and acute NHS trusts, the PMS was perceived as ineffective operation. There was very little evidence that the services commissioned by PCTs were either cost effective e generating much patient satisfaction. For this reason, the Chief Executive of the trust (SUHT) was receptive to proposals for improving the PMS.

In 2002, the problems in the service all acted to cause a hiatus in the PMS. The service was in a long term cycle of periodically hitting a problem and having to close for a period of time. During that time, some patients would leave the service and eventually the service would reopen, though without changing the PMS itself. It was not unusual for patients referred to the service to have to wait two years before being seen. The pressure of work in the service was such that morale of staff was very low and there was feeling that problems were dealt with on a fire-fighting basis. The problems in the PMS were not unique and it was found that they were common in pain services in many other NHS trusts.

8.4.1 Problem addressed by the innovation

The innovation in the PMS was in response to an organisational problem rather than a single, narrow clinical problem. While there were a number of clinical issues central to the problems impacting on the PMS but many other issues were based on organisational issues. The problem was complex with various interrelated issues combining to cause serious deficiencies in the PMS. Figure 8.3 shows the key relationships between problems experienced by the PMS and their root causes.

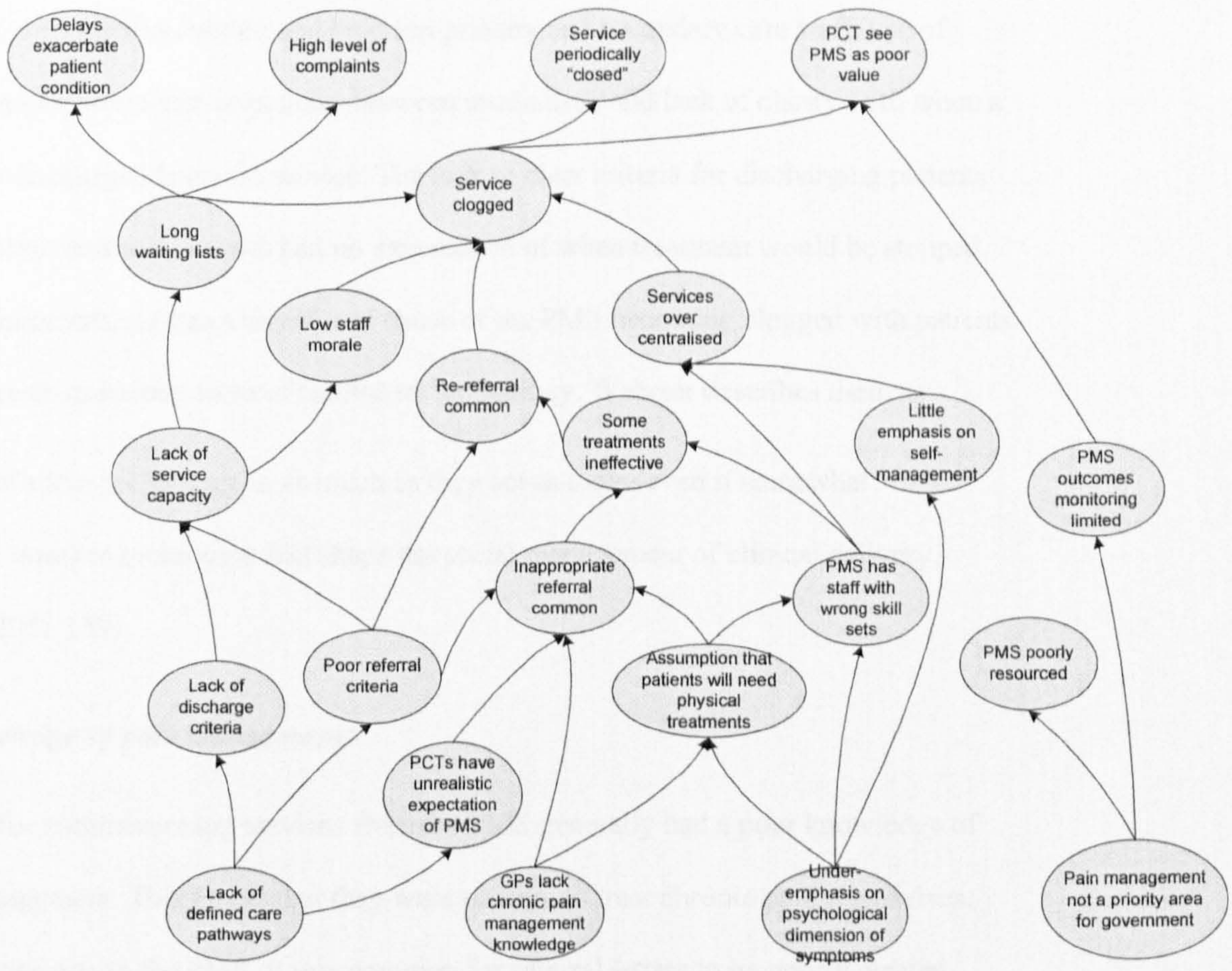


Figure 8.3: Problem relationships in the PMS

The most visible problems in the pain management service were well defined in the service. The PMS suffered from a very high level of complaints that were disproportionate to its size and made the failings of the service prominent in the mind of senior trust managers.

The cause of the complaints was predominantly delays in accessing the service of up to two years. This resulted in the physical and mental deterioration of patients by the time they were accepted into the service. In addition, the discharge rates from the services were very low, periodically prompting the closure of the service to new patients. This in turn exacerbated the problem of waiting times. Overall, these problems lead to the service being perceived as poor value for money by the PCT commissioning services form the PMS. Several factors were identified that undermined the effective operation of the PMS.

Poorly defined care pathways

Foremost of these was the absence of clear care pathways for patients with chronic pain and it was common for patients to be referred to more than one speciality at once, though their care was not

co-ordinated between the specialities. The absence of clear care pathways lead to imprecise referral practices; lack of co-ordination within and between primary and secondary care staff; use of ineffective treatments; re-referral of patients between specialists; and lack of clarity as to when a patient should be discharged from the service. The lack of clear criteria for discharging patients meant that both clinicians and patients had no expectation of when treatment would be stopped. The lack of discharge criteria was a significant cause of the PMS becoming clogged with patients. Care pathways are an important form of healthcare technology. Webster describes them as:

> ...a form of socio-technology in as much as they act as tools (even if somewhat insensitive ones) to orchestrate and shape the social management of clinical delivery. (Webster 2007:139)

GPs lacked knowledge of pain management

GPs responsible for commissioning services from the PMS generally had a poor knowledge of chronic pain management. This meant that they were reticent to treat chronic pain themselves; instead referring patients to the PMS. It was common for referral letters to be poorly written, omitting critical information required for assessing patients. While many treatments were available within the acute sector, there were many other treatments also available in the primary care sector. Many GPs did not have the knowledge to select an appropriate care pathway.

> ... there was an assumption that patients needed a high level of expert input and to have a needle stuck in them, and fancy drugs, but they didn't. There were some people, no matter how many needles and drugs you are going to pump into them, mentally they could not cope with their pain, and that is when the clinical psychologist was really important. (Manager A)

Dominance of the bio-medical view of pain

The predominant view of pain management taken in the service was bio-medical and under-emphasised the psychological dimension of pain. The general operation of the service involved the referral of patients to consultants who maintain control of the decision-making about patients' care plans. Nurses, GPs and other community-based staff rarely lead the development of care plans. The

specialist area of the consultants involved in the pain service tended to emphasise medical or surgical interventions. This resulted in patients' treatment often being skewed towards drug treatment or surgery. The centralisation of the service on specialist departments in the hospital tended to exclude community-based services such as physiotherapist, psychologists and pharmacists.

Little emphasis on collaborative case management

The service lacked an emphasis on collaborative case management and underemphasised the role of the carers and patient in management of pain. In particular, little emphasis was based on how to support patient's self-management of their pain.

Pain management services given low priority

Pain management was not a government priority and so little resource was put into it. There was an absence of effective management systems put in place to monitor and manage outcomes from the PMS.

8.4.2 Innovation in the PMS

In response to the issues raised above a fundamental change was made to the PMS. These changes were related to the soft technology of organising pain management for patients rather than a specific hard technology. The change was analogous to a shift from consultant centred "jobbing shop", to a process that facilitated the mass customisation of a range of services for each patient using clearly defined care pathways. The process change prompted fundamental changes in social aspects of the service delivery. Changes to levels of autonomy and job roles were central to the innovation, for example, the role of nursing staff was modified to emphasise higher level skills.

The starting point

The initial situation in the PMS that existed before the innovation was chaotic, ineffective and unsustainable. The general process of referring and treating patients is shown in Figure 8.4.

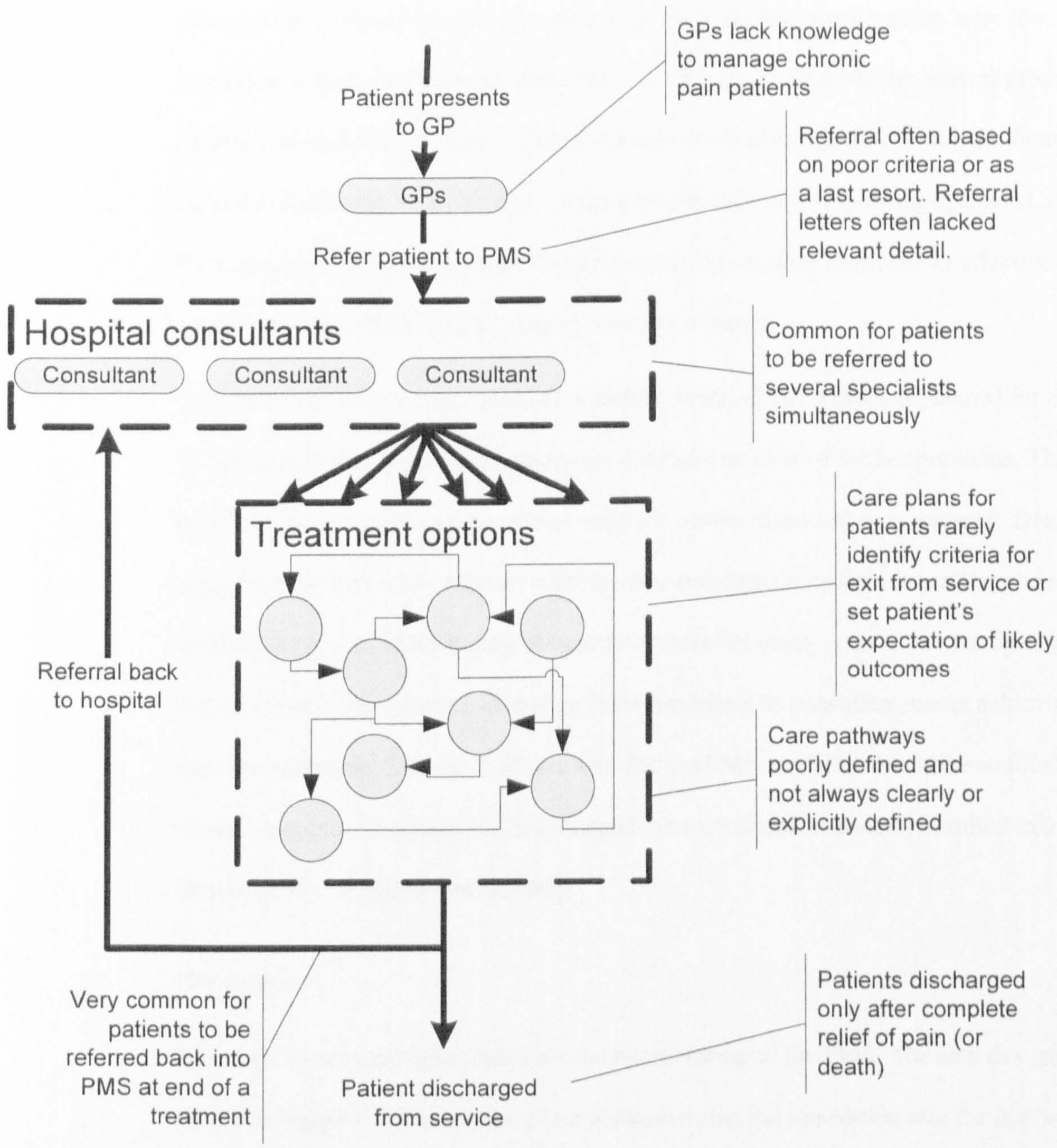


Figure 8.4: Initial process layout for Pain Management Service

Patients would initially present to GPs with pain problems relating to a range of conditions such as back pain, post operative pain. Patients with chronic pain in particular would often recurrently return to GPs for treatment. In many cases, GPs had very little knowledge of how to manage patients with chronic pain and so referral of patients to the PMS was frequent and often based on poor referral criteria. It was common for patients with chronic pain to be referred simply as a last resort for the patient as the GP had run out of ideas on how to treat the patient. Referral letters to the PMS would often be lacking in detail. Once referred patients would have to wait for appointments to see consultants working in the PMS. Waiting time was considerable and it would be common for patients to be referred in parallel to more than one consultant. In some situations,

patients were referred to some consultants on the basis that waiting times were low, despite the consultant's speciality being inappropriate for the patient. Overall, the referral process was inconsistent and did not assure patients the correct route to effective treatment. In addition, the quantity of referrals, poor referral information and referral to the wrong specialist, overloaded the PMS system. This in turn created longer waiting list, waiting times and in effective use of specialists' clinic time, further exacerbating the situation.

Once referred to consultants patients would be assessed and treatment planned for them. Unfortunately, the lack of care guidelines created a number of further problems. The expectation of the likely outcome of a course of treatment was rarely discussed with patients. Treatment such as physiotherapy was often planned without clear end dates or criteria for exiting the service. This resulted in patients often staying within the service for many years either continuing with treatment that had previously failed or migrating from consultant to consultant, never achieving a satisfactory treatment outcome. The result of this was that the PMS would tend to become filled with patients whom were never discharged. This clogged the service and eventually resulted in the periodic closure of the service to new patients.

The solution

The result of the innovation has been the restructuring of the PMS. The new design of the service is shown in Figure 8.5. The central principle underlying the innovation was the implementation of the bi-psychosocial perspective on the PMS. This was achieved by the explicit definition of care pathways, with clear referral and discharge criteria. To implement these pathways effectively a multi-disciplinary triage system was implemented. The development of the care pathways and triage system facilitated secondary changes that resulted in the implementation of a collaborative care model. Through these changes, the PMS was able to manage patients effectively based on stepped-care principles. The innovation in the PMS was the result of applying and merging a combination of new and existing approaches to healthcare service design. This has involved translating ideas from within the area of pain management and the wider healthcare sector. The innovation represents the implementation of a whole systems approach to pain management.

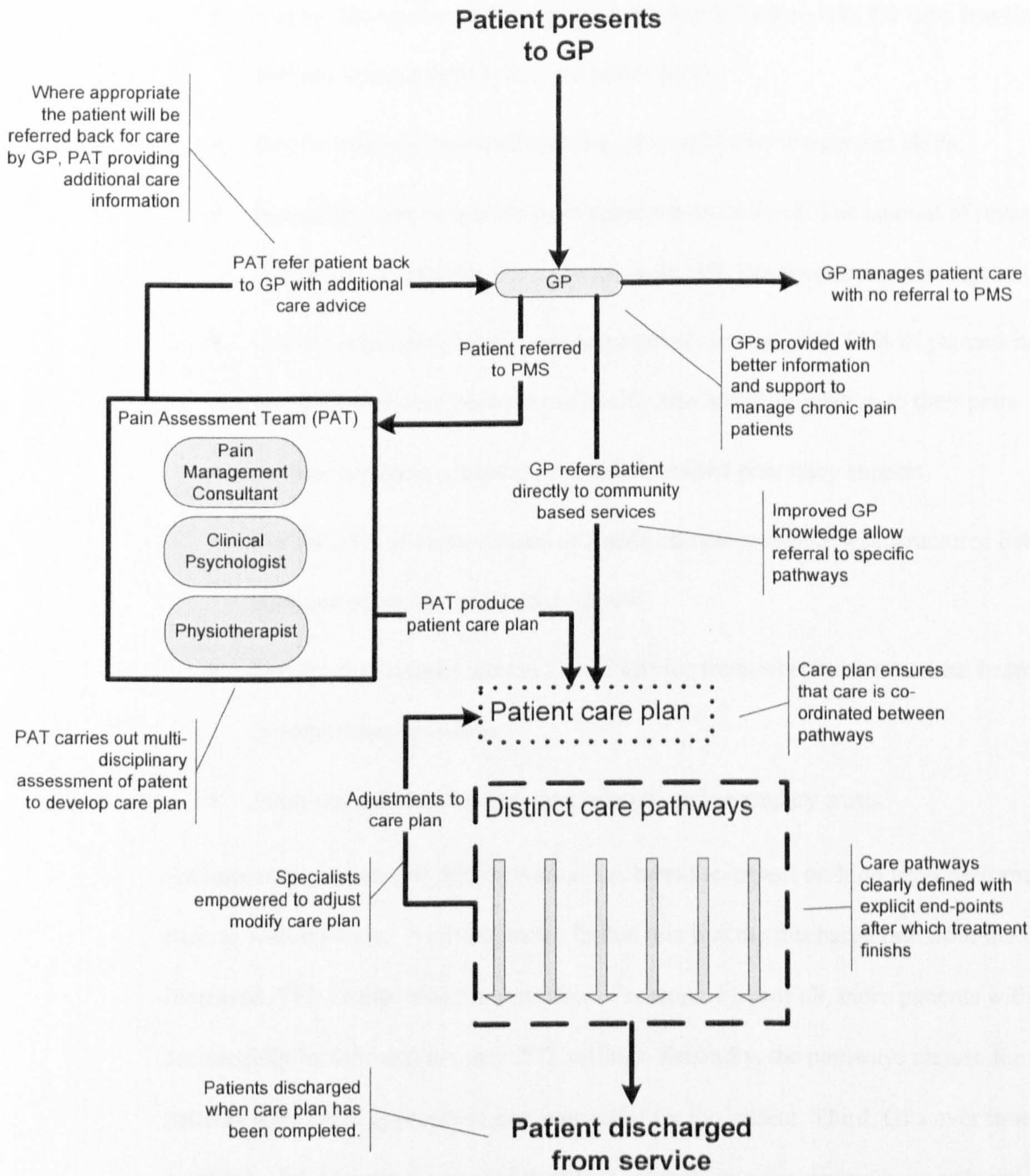


Figure 8.5: Re-designed process layout for Pain Management Service

The main outcomes of the innovation have been a significant improvement in both efficiency and effectiveness of the PMS. Some of the main outcomes included:

- Waiting time for accessing the service was reduced from up to two year to less than six weeks.
- The numbers of inappropriate referrals to the service was reduced by 30%.
- The number of medical follow-ups reduced.

- Significant numbers of patients being referred back to GPs for care; less than 50% of patients being treated in the secondary sector
- Greater and emphasis and use of coping and self-management skills.
- Secondary care budget for pain management reduced. The amount of invasive management carried out on patients was reduced, with 50% fewer operations being carried out.
- Greater emphasis placed on psychological services, with 25% of patients now being recognised as needing a mental health assessment in relation to their pain.
- Greater emphasis placed on community-based pharmacy support.
- For the 25% of cases classed as highly complex, service was structured better to give complex individual case management.
- Service restructured around a local service framework with treatment based outside hospital where possible.
- Improved relationship between primary and secondary trusts.

An important outcome of the innovation has been the impact on high level performance indicators, such as waiting times. A critical factor in this was that the discharge rate from the PMS was greatly increased. This change was for a number of reasons. First of all, more patients with treated successfully by GPs and in other PCT settings. Secondly, the pathways chosen for individual patients were more appropriate and successful for the patient. Third, GPs over time became more confident about treating pain, and therefore referrals into the system were reduced. Finally, discharge rates increased due to the effective implementation of discrete exit points from the service.

8.5 Innovation process

The nature of the innovation in this project required a major step change in the operation of the PMS. For this reason, the process followed was relatively linear. Figure 8.6 shows the overall process followed.

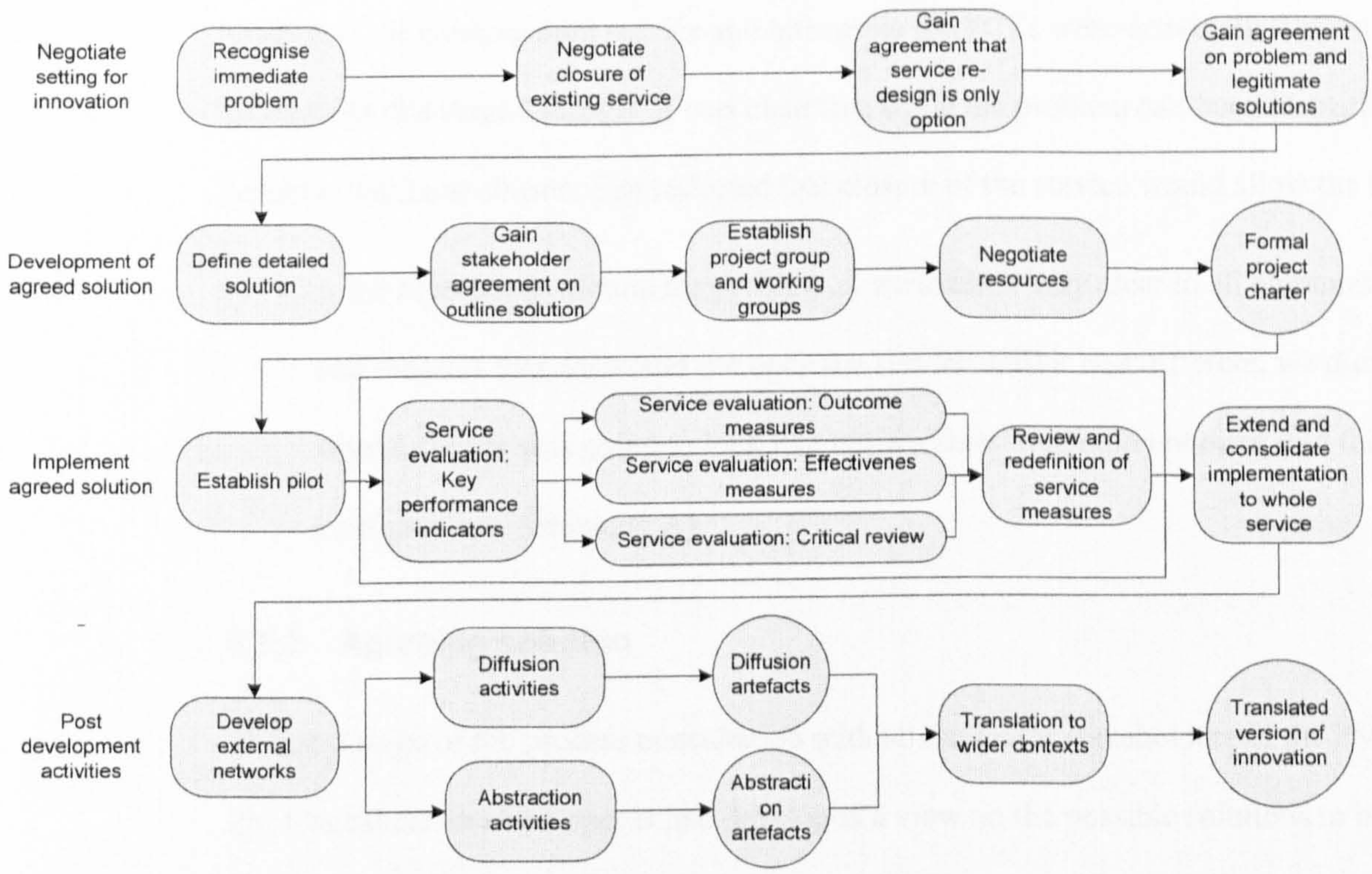


Figure 8.6: The PMS innovation process

8.5.1 Initial actions

The innovation process was triggered by the chaotic state of the PMS in 2002. The long waiting times for patients accessing the service and the subsequent complaints created a period where the organisation was not able to cope. It was at this point that the PM Consultant and Manager A proposed a solution to the problems and pursued a process of innovation.

The first step in this process was the negotiation of the closure of the PMS to new patients. The rational for this was that the PMS delivered a poor level of service; that had several structural limitations in its current configuration; and that to solve the root problems of the service, time was needed for decision-making and the subsequent reconfiguration of the service. The closure of the service was seen by many as an emotive issue and needed to be handled carefully. Manager A felt there was no alternative as in the face of continuing pressure to reduce waiting times, it was only through a radical restructuring that the PMS could become successful.

After an initial meeting with the Chief Executive of the acute trust. It was agreed that the service should close, with the exception of provision for paediatric and cancer pain services. The decision was then communicated to the DoH and the PCTs involved with the service. The decision was initially met with dismay by the PCTSs, however, the stakeholders had few illusions about the

quality of the existing pain service and ultimately the PCTs were extremely supportive of the project. At this stage Manager A was clear that while the problem had been identified, no specific solution had been chosen. She reflected that closure of the service would allow the team to:

> ...get their heads around the problem... we made it very clear to all commissioners and the trust that we would not open the service until it was different, we didn't know what different was going to look like but we knew we could not open it in the same configuration. (Manager A)

8.5.2 Agreeing solution

The next stage of the process consultation with all the major stakeholders of the PMS. Though the PM Consultant and Manager B had developed a view on the possible solutions to be adopted, they recognised that there needed to be a consensus amongst senior management and the PMS stakeholders.

Two preliminary meetings with PCT senior staff and the medical director of the acute trust were held prior to the workshop. These were crucial in gaining high level support for the project. Once the initial problem had been defined, the potential solution based on a triage system feeding patients to well defined care pathways, was agreed with senior trust management.

Following these meeting the PM Consultant and the Manager A set up a workshop for all the service stakeholders, believing that without early engagement of all of the PMS stakeholders it was unlikely that any significant change could be achieved. This was important, as there was a wide range of staff involved, with very broad ranging attitudes to how much change was acceptable. Some staff were very keen to support change, while others were resistant to change.

Staff were invited to the workshop on the basis that it was a meeting to improve the way the PMS operated, for "...anyone who wanted to sort this thing out" (PM Consultant). Manager A was very concerned that the event needed to maximise the attendance of as many of the key stakeholders responsible for decisions in the local PCTs.

The workshop was sponsored by a pharmaceuticals company and held at a hotel venue. Waiting lists were suspended for the day to allow staff the opportunity to attend. As an incentive to GPs, the event was officially approved as professional development.

The workshop was well attended by a wide range of staff including: consultants; GPs; rehabilitation professionals; staff from the Expert Patient Programme; mental health staff; Trust managers, commissioners from the PCTs; and GP leads from the PCT. The PM Consultant considered this a representative mix of staff, with all key groups represented. She was pleased that "jobbing" GPs attended and not just those linked with committees. Several senior members of staff from the acute and primary trusts also attended.

The aim of the workshop was to clarify the problems underlying the PMS and identify a way forward for the service. The workshop was facilitated by the Manager A and had several aims based around introduction of care pathways and a triage system:

- identify current care pathways;
- identify patient groups served by the service;
- assess the practicality of a triage system;
- make an initial attempt to define a set of clear care pathways;
- clarify what the end-points for care pathways should be.

Two keynote speakers were chosen for the workshop. The first was a clinician responsible for the PMS. They talked about the way the services were structured at the time. The second speaker was the director of modernisation at the acute trust, whose commercial background provided a different time perspective on the service and how it could develop.

Two initial group activities involved the attendees first, mapping the current problems in the PMS and then developing view of how the service should look like in the future. Manager A saw these activities as successful because all groups mapped the same problems; and also mapped the same possible solutions. She felt that the result of the activities was a united view of the way the PMS should develop:

> ...that was great because everyone in the room felt the same about the service, frustrated with the problems and sees the solution. (Manager A)

Despite gaining agreement on the problems within the service, gaining consensus from the workshop attendees on a solution was more problematic. Manager A and the PM Consultant proposed key principles for restructuring the service. These were:

- discrete pathways needed to be defined for treating patients;
- patients treatment should be prompt, to avoid their problems becoming worse over time, especially from a psychological perspective;
- care should be customised to the patient, with the patient's care plan agreed at an early stage, incorporating one or more treatment pathway;
- the care plan would clearly define the exit strategy from the service and on completion of the care plan, patients would be discharged from the service;
- patients' expectations of the service should be managed carefully, especially in terms of what treatment they were to be given and at what stage they would be discharged from the service;
- patients that failed to respond to treatment should be discharged at the end of their course of treatment.

The most contentious of these principles was that all patients should have an exit strategy from the service. Several staff including hospital consultants felt strongly that they had a duty to provide unlimited courses of care to patients.

Manager B felt after the workshop the mood amongst staff in both the acute and primary trusts, was that there was no option but to do something. Some staff were enthusiastic about the suggested path of the project, however, even those with reservations, took the position that it was better to do something that nothing.

> ... they were in crisis, and they had to do something, they were coming up with this idea that looked as though it was going to work, it was not costing massive amounts of money, and were not asking for massive investment, I think the people who were

> working within the service, some of them thought it was a great idea, others probably had their reservations, but they all wanted things to change because it was so dire. So in a way it helped because it was so dire. (Manager B)

The workshop successfully generated support and agreement for the subsequent change. The formal consensus of the stakeholders was that multiple care pathways existed, with multiple points of access to the service, leading to inconsistent and inefficient use of the services. It was highlighted that both referrers and patients were unclear about the potential outcomes of various pathways. Three important issues were agreed at the workshop. First, it was accepted that the end point to treatment should be when the patient was adapted to their pain. Without this acceptance, it would have been problematic to develop care pathways. Secondly, it was accepted that GPs could be much more proactive in referring patients directly to specific services, when given appropriate support from the PMS. Finally, there was a need to manage the patient expectation of what to expect from the service and when they would leave it.

The impact of the workshop on the attendees' attitudes to triage teams was important because it:

> ...sowed the seeds in people's minds about the assessment [triage] teams. (Manager B)

The financial case for the proposal were also well received. The chair of the Professional Executive Committee (an important budget allocating committee in the PCT) was very interested. His interest directly resulted in the team being able to get some financial backing for the project.

Manager A reflected that an important function of the workshop was that it allowed a short deadline to be placed on agreeing the next steps. By the end of the workshop, agreement had been achieved on the next set of stages in the restructuring.

8.5.3 Pilot

The outcome of the workshop was to run a pilot of a revised PMS system, based on a triage system and clearly defined care pathways. To oversee the operation of the pilot a Pain Steering Group was set up with two sub-groups: a clinical group and an operational group. The clinical group was responsible for clinical governance and referral criteria. The operational group was responsible for implementing the new service. The operational group was headed by a project manager. Support

and funding from the acute trust and one of the PCTs was gained for the pilot, along with agreement on the use of a site owned by the PCT. The PCT had previously run a small pain management programme on the site.

The most significant change to the service made when setting up the pilot scheme was the creation of a triage team. The pain assessment and triage team (PAT team) was a multidisciplinary team. It was made up of a group of experts. It comprised of a consultant in pain management, a clinical psychologist and a physiotherapist. Patients were referred to the team by GPs. A patient would then be assessed by the team and the programme of care developed for the individual, Using one or a combination of defined pathways. The pilot also involved the development of psychology as an explicit pathway within the service;

Besides, the setting up of the PAT team, a large amount of work was done educating GPs in the management of chronic pain. The PM Consultant took a key role in educating GPs and producing documentation to support them. An important part of this work during the pilot was to improve the communication between GPs and the PAT team. At the start of the pilot, many of the referral letters received from GPs were inadequate in terms of providing background information on the patient. In these cases, the PAT team had to refer back to the GP to gain more information. Much of the work done by the PM Consultant was in improving the standard of communication from GP to PAT team. As a result of the efforts of the PM Consultant the relationships with the GPs improved greatly. This allowed patients to be referred back to the GPs for further care; the PAT team providing the GP with specific advice on how treatment should proceed.

The pilot was set up initially for three months but was extended to six months. This was a consequence of the recognition that the measurement of the service outcomes had to take place over a longer timeframe. The evaluation of the service changes became an important part of the pilot and the PM Consultant was active in evaluating the changes that were made.

The evaluation of the pilot was driven by three concerns. The first was the scrutiny by the project's operational group. The second was the recognition that in the future the PM Consultant may be expected to defend the changes made and prove why the success of the triage system. Third, it was important to gain information that would inform the ongoing development of the service.

Provision of evaluation data to the operations group was initially difficulty. Data was not always available from existing information systems; where data was held it was often spread across several systems. Over the first few months of the project, data was presented to the group but it took several iterations for the operations group to agree on the amount and specific sets of data required. The main concerns of the group were:

- waiting times;
- patient access;
- discharge rate;
- effect of the triage team.

The audit data was eventually produced by the consultant by integrating data from several sources onto a spreadsheet. This was done mainly in her own time for the first year, though later the spreadsheets have been maintained by administrative staff.

Some of the data such as waiting times and discharge rates were maintained by existing hospital tracking systems, developed for government reports. However, these did not provide the level of detail needed to evaluate the triage system. Additional systems were developed to monitor the case-mix handled by the service. This was a detailed system that allowed them to monitor the distribution of users in the service, especially in terms how severe cases were then referred to secondary care.

Modification to existing information systems were initially made a priority by the Trust's IS department and were carried out relatively quickly and without delay. The PM Consultant believed that this was due to the PMS being treated as a problem area and so requests for changes were backed by the Chief Executive and the Medical Director. Later in the project, she felt that as the PMS improved its performance, it became more difficult to request system modifications.

8.5.4 Consolidation of the local implementation

The successful outcome of the pilot meant that other PCTs served by the acute trust were gradually recruited to the newly configured PMS. During this phase of the project, the service underwent a

period of continuous improvement. Changes were made to address emergent issues that had developed because of the reconfiguration of the service.

It was recognized that in addition to the development of the triage systems and care pathways other process and structure changes were required. Many of these issues required fundamental change and included:

- recognizing that the nursing model was no longer appropriate and service needed to employ advanced practitioners;
- due to increased care by the primary sector. It was recognized that 50% of the capacity in the acute sector was no longer needed;
- the traditional staffing model was seen as in inadequate, and it was recognized that more multidisciplinary staff were required for example physiotherapists with acupuncture skills;
- a higher level of pharmacy input was required to review medication provided to patients.

The new service design has essentially highlighted the need for the whole workforce to change.

8.5.5 Wider diffusion of the innovation

The final phase of the project was the transfer of the innovation to pain management services in other trusts. This was achieved through a range of activities; however, the lack of any exploitable IP in the innovation, such as software meant that diffusion could not occur through conventional technology transfer mechanisms.

This activity involved members of the innovation team communicating the service principles to staff from other trusts. This was done through two main mechanisms. The first was through diffusion activities that allowed the knowledge gained about organising the PMS to be transferred to staff from other services. The primary method for doing this was through codifying aspects of the system, producing diffusion artefacts such as:

- articles in professional journals;
- information packs that included useful documentation such as clinical guidelines that have been developed, patient assessment questionnaires and standard letters.

Diffusion of the knowledge was also carried out through personal contact between the PMS staff and visitors. The team worked hard to host visits and present information about their project at conferences and workshops. This method of diffusion can be seen as closer to "apprenticeship" than simple codification, so addressing the transfer of more tacit aspects of the service.

The second mechanism was through abstracting knowledge of pain management created in the PMS to a more general level. The primary example of this was in informing national policy and care guidelines developed by professional bodies.

The wider diffusion of the PMS model received significant support from drug companies. Manager B suggested that drug companies played an important role in diffusion activities. First of all the networks of relationships associated with drug companies were very useful when setting up workshops and identifying appropriate groups of NHS staff to invite. This saved the NHS staff time in setting up meetings with relevant people in other trusts. Second, drug companies also provided project management experience and expertise for trusts, who tried to set up services using specific pathways. Manager B believed that the relationship between the NHS and these drug companies was mutually beneficial. A pharmaceutical company had funded the PM Consultant to give talks and produce the resource packs. It has also funded a cost-benefit analysis of the service. The motive for the pharmaceutical company may have been that the triage system created opportunities for marketing products to GPs, however, overall it was a symbiotic relationship.

8.6 Time dynamics of the innovation process

The PMS project was instigated in 2002 when service problems reached a hiatus; circumstances essentially forced the start of the project. As a result of this urgency, the initial stages involving problem recognition and development of a planned solution took a period of a few months. The subsequent stages involving implementing the project through a pilot and then expansion of the service took place over an extended period of time. The planned three-month pilot scheme was extended to six months. This extra time was required for the project team to identify and collect relevant evaluation data. It is likely that the pilot would have taken significantly longer without the PM Consultant and Service Manager A contributing a significant amount of their own time at evening and weekends. The expansion of the service to cover five PCTs and then diffusion of the

innovation to other pain management services in the NHS took place over a period of several years and is on-going.

8.7 Organisational Context

8.7.1 Team experience

The experience of project members prior to the project was relevant to the development of the innovation. The knowledge gained through these experiences informed both the solution achieved but also the process followed.

The PM Consultant brought significant experience to the project. Her work experience in North-American healthcare systems had given her insights into alternative models of structuring healthcare services. Her work as a specialist in pain management had highlighted to her the need for a holistic view of pain, encompassing bi-psychosocial perspectives. Based on this she was a strong advocate for recognising the involvement of clinical psychologists in treating chronic pain. During her experience of working as a consultant at SUHT she had recognised several operational problems with the service:

- patients referred to her could often have been referred directly to services in the primary care sector;
- there was a lack of ownership of the PMS;
- no overall strategy for the development fo the PMS;
- low levels of funding risked the service stagnating;
- locally developed improvement initiatives were fragmented and lacked co-ordination.

Manager A's experience of working within the NHS had made her confident in dealing with other staff, especially clinicians:

> ... because I have been in the NHS a long time, I know the best ways to get clinical engagement. (Manager A)

She had worked on process change in other areas of the NHS and had visited America to look at different models of healthcare processes, for example, 23 hour clinics. This had been important in

her previous job, when she had been setting up a day surgery unit. When she attended a seminar on acute pain, she had been made aware of principles that could be applied in chronic pain services:

- the service could not keep patients forever;
- patients were not in the service to be cured of their pain;
- the service was to help people live with their pain.

Similarly, Manager B had experience that made her question existing NHS practice. Prior to the project, she had spent a year working for a BUPA hospital. This experience had made her more conscious of how the NHS could improve service levels, budgetary management and emphasise discrete care pathways. She was particularly interested in how pathways could be managed between primary and secondary sectors and the assumption that:

> ... you keep all patients in the PCT or in the acute trust and that you never managed them in and out. (Manager B)

Overall, the experiences gained by staff involved in the project influenced the framing of the problem and potential solutions that could be adopted. From an early stage of the project both the PM Consultant and Manager A had a conviction that the solution to problems in the PMS lay in implementation of a triage system that allocated patients systematically to well defined care pathways that integrated services across the primary and secondary sectors.

8.7.2 Learning culture

The culture in the acute trust was generally conducive to learning. While part of this culture was attributable to the teaching activities in the hospital providing a mechanism for reflection on practice in the hospital:

> ...we have to deliver a lot of lectures and so have to be able to justify it [the service changes] to many students. (PM Consultant)

The PM Consultant believed the culture encouraged staff to question what they did and lead to some flexibility and openness to innovation. However, the emphasis was still on the individual to be reflective, identify problems and then seek solutions:

> ...if you are not inquisitive and want to change things there is no point in being flexible and what happens then is you cannot see why you want to do it because you are not identifying the problems, thinking what you might do about them. (PM Consultant).

The flexibility given to individuals to take action was central to the project, even the service closure decision was made bottom-up, that in a less de-centralised organisation might have been opposed:

> ... I strongly feel that if we had not closed the service, if the chief executive had said, you close that service, you are losing your job, if I was put under pressure, we would not have moved forward. (Manager A)

Similarly, in the PCT there was a culture of trust that supported innovation. Manager B felt that both managers and health care staff in the primary trust, where they could see its rationale, were adaptable and supportive of change. This was in contrast to her experience of BUPA that was far less flexible or innovative.

The relationship between the acute and the primary trust was not typical of the NHS at that time. Manager B characterised the relationship between many NHS organisations as more competitive than co-operative. She felt that the close working relationship and the focus on the patient journey was very new:

> ... I tell you what was new at the time, you don't think of it now, but then it was really new to be working, a PCT with an acute trust, on a project like that because it was so much ' us and them' then, I don't think it is like that now, but then it was really competitive, almost... people in charge of this project put the patient first... whatever we did, whichever trust it is we have to look at this patient and look at their journey. I think we had started to look at patient journeys and I think it was quite a new thing at the time, but people do it now. (Manager B)

8.8 Enablers and barriers to the innovation

Figure 8.7 depicts the enablers and barriers to innovation that acted on the PMS and the reconfiguration of its services. Several issues affected the progress of the project from a user-led innovation perspective including: the initial crisis situation; institutional factors that had a modernising influence on the PMS; professional resistance to the changes; organisational inertia and structural barriers to change; motivation of the innovation team; and evaluation processes.

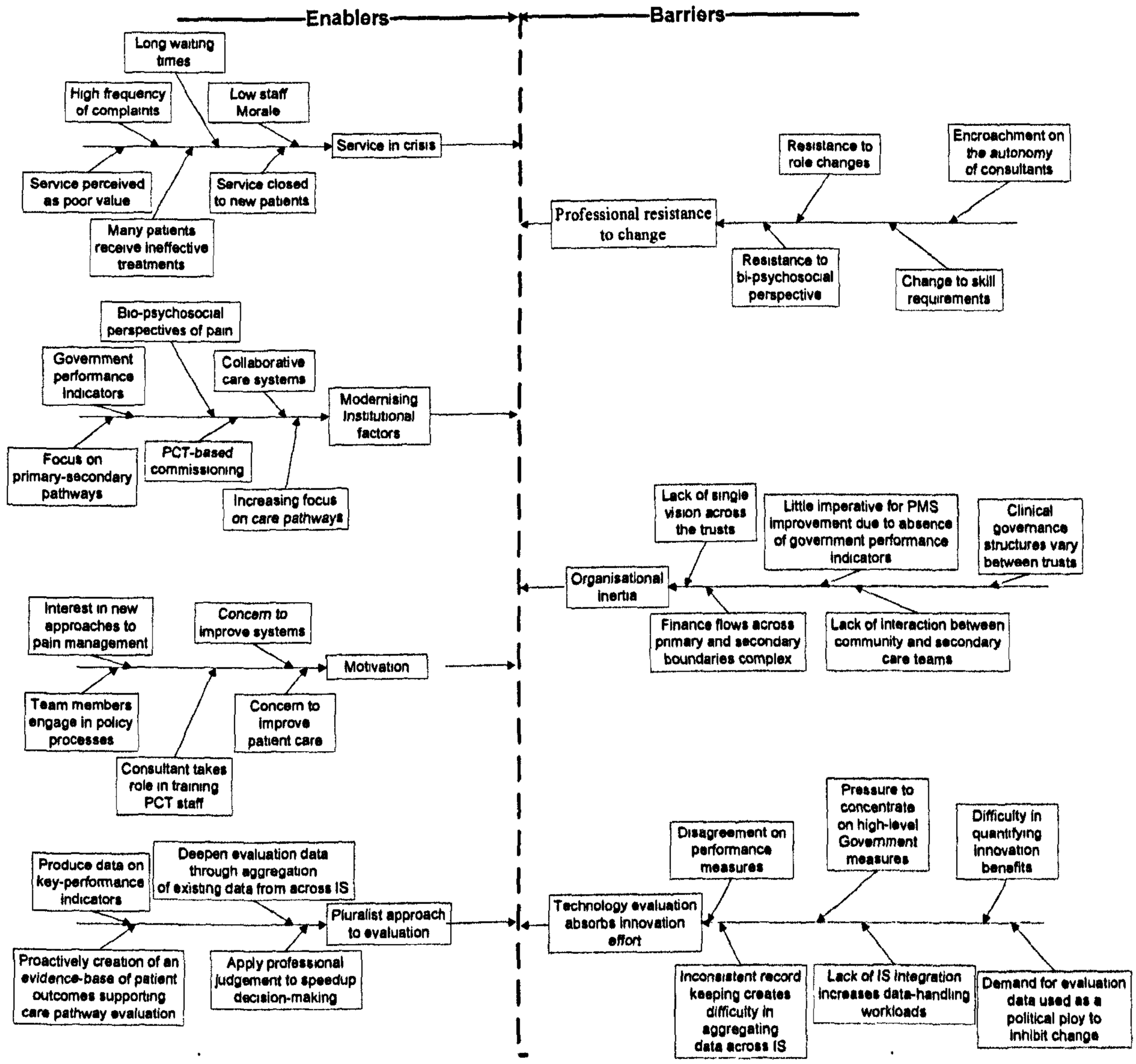


Figure 8.7: Enablers and barriers PMS innovation

8.8.1 Service in crisis

The "cinderella" status of the PMS was a root cause of the crisis that overtook the service. Unlike other service areas, pain management was not the focus of any specific government performance indicators. For this reason, it had little strategic visibility in the trust and in turn attracted little

interest from senior management. The crisis was manifested in an increase in waiting times, increased complaints, lowering of staff morale and a general perception by the PCTs that the service represented poor value. Staff in the service were aware that many patients were having either ineffective or inappropriate treatments.

The crisis that ensued in the service was however critical in setting a context for innovation. Manager A noted that it took a crisis in the service before the change could be achieved:

> ... it is a shame that something so radical had to happen in the NHS to make change happen and why we can't be a bit more predictive, more forward thinking.
> (Manager A)

The conditions created by the crisis legitimised the closure of the service to new patients, raised awareness of the problems with senior managers and provided an opportunity for an innovation project to be instigated.

8.8.2 Modernising institutional factors

Once problems revealed by the crisis had triggered an innovation project, several institutional factors conditioned the project's subsequent development. Besides the increased influence of government performance indicators within the NHS, increased emphasis on PCT-based commissioning shifted the balance of power from secondary to primary trusts. This meant that a viable solution had to recognise the shift in responsibility for commissioning services from the PMS. Other institutional changes were occurring with respect to importance of care pathways, especially when crossing primary and secondary boundaries. Finally, the development of new perspectives on medicine and care were impacting on the underlying values and expectations underpinning healthcare; in particular, the acceptance of the bio-psychosocial model of pain and collaborative models of care.

8.8.3 Professional resistance to change

The fundamental shift in perspective embedded in the innovation was not welcomed by all of the consultants and staff within the PMS. Two issues in particular represented the difference in perspective: the PMS no longer emphasised drug or surgery based treatments, putting greater

emphasis on community-based treatments; and the new service design emphasised care pathways with explicit exit points from the service. The team experienced a significant level of resistance to the innovation. The PM Consultant reflected that many people resisted the need to shift their values and ideas about their role in the service, not least other consultants in the PMS. She reflected:

> ...I had not really appreciated what brickbats we were going to get...were they being threatened?...did they think that they would be asked to make changes, I think that was what was going on...we had gone out on a limb really...were we dumbing down the service by taking it into the primary sector?...by creating the threshold, were we denying patients the treatment they should have?...I had not realised how controversial we were going to be until I presented at a local pain management meeting about four months into what we were doing, and I got a real 'what do you think you are doing!' (PM Consultant)

The reaction of some staff to the service redesign was varied. Manager A believed that it was a shock to staff when the service was redesigned. She felt that many people thought they were doing a good job and were comfortable that they were carrying out their roles. The implementation of the innovation created a range of negative reactions. Some staff, including some consultants, withdrew from working in the PMS or continued resisting the change by remaining in post but ignoring the wider systemic problems that they were causing to the service.

The re-structuring of the service has resulted in changes in the roles of staff in the PMS at two levels. First, at the level of an individual, different mixes of skills are required to carry out existing roles. For example, the role of nurses in the PMS and the set of skills they are expected to use, has undergone a significant shift. Second, the mix of skills across the whole PMS has shifted as a change in emphasis of the type and location of treatment has changed.

Nurses working in the PMS were required to change their roles significantly in response to the wider changes in the service. The role of nurses became a key strategic issue.

> ... we were talking very openly at the monthly team meetings and we had very open and frank discussions about the sort of expertise that we needed and it was very

> obvious that the traditional nursing model was no longer effective for a patients and good for the efficiency of the service. (Manager A)

For some of the existing staff in the service the change in skill set was too great and resulted in them leaving.

> ...there were a couple of very good nurses, but some did very basic nursing, and it became clear that there was no place for that sort of nursing. Some nurses would have come to chronic pain because they thought it an easy way to finish off their career. The service had changed and you could not carry people. If you're going to have a service that is efficient, value for money, good quality for the patients, the sort of people that you needed were people that knew exactly what they were doing, that could offer a variety of service... (Manager A)

The nature of the nursing role within the PMS had shifted dramatically with nurses being expected to have more specialist knowledge and to take on more decision-making:

> ...changing the front end of the service so that the patients that were coming into the hospital pathway with a patient that really needed expertise, because the basic nursing they could get in primary care with their GP. So, these patients needed very close monitoring, good nursing input, nurses that knew chronic pain, that could see patients, take a history, make decisions... and nurses would probably have their own caseload. (Manager A)

The change in role was not an easy transition and a central concern of many staff, including nurses was that in changing role they were overstepping professional boundaries.

One proposal was that nurses would run their own clinics and no longer simply accompany patients in clinics run by consultants. The PM Consultant reflected that nurses were reluctant to take on these new roles as in the past they has not been empowered to make decisions. This anxiety was rooted in the professional expectations of what decisions nurses should make. By running their own clinic, they were crossing a perceived professional boundary over the types of decisions for which they were responsible. A typical concern expressed by nurses to the PM Consultant was:

> ...if I say it, I could get prosecuted because my professional society will not support me...am I safe? (PM Consultant)

In response to this concern a skills analysis by the HR department of the trust was carried out. This concluded that nurses could, and had always been able to carry out the work legitimately, if provided with appropriate supervision. The result of the change was that nurses were empowered to run their own clinics. The consultant feels the crucial action was to

> ...create the environment where they [nurses] think it is the right thing to do; and that they should be doing it. (PM Consultant)

Role change was not restricted to nursing staff. There was an increased expectation that staff in all roles, especially those based in PCTs, would act more independently. They were encouraged to make decisions about patients rather than simply referring them back to the GP or consultant:

> ... in the past, if you're worried about what was wrong with the patient you sent them straight back to the GP. Where as now you're expected to be more proactive about their treatment plan. (Manager B)

As a result of the service redesign, the clinics remained consultant-led, with the consultant having ultimate responsibility, but an expectation to act proactively was explicitly placed on other staff.

8.8.4 Entrepreneurship and motivation

The motivation to develop an innovative solution to the problems with the PMS were based predominantly in a concern to improve patient care, NHS systems and the working environment of staff. The PM Consultant reflected that the state of the service was so poor that change was crucial:

> ...it has got to be something you really badly want to fix because I could not have carried on working in the environment much longer...I would have left.
> (PM Consultant)

Similarly, Manager A was motivated to solve a problem that she knew would recur in the future. She felt that it was easier to solve a problem than simply have to fire fight problems into the future. The PMS was only a small part of her responsibility, but she felt that it took up a disproportionate

amount of her time and was a major source of stress. The service was small compared to her other services that she was responsible for. She reflected that it

> ... drives me nuts, giving me more of a headache and taking more of my time than three intensive care units. (Manager A)

Manager A felt that her motivation to change the service also increased as she came to understand the importance of the PMS. During the project, she became increasingly aware of how big a problem. chronic pain is within the population and the importance of treating it. She felt strongly that the few patients who had been accepted into the system were blocking services for other equally well deserving patients; she saw the situation as: "... not benefiting the greater good" (Manager A) prompting her to adopt a utilitarian view towards PMS and felt that she had a

> ... passion for all patients with pain to benefit from it [the PMS] and not just the select few that got in to it when they are desperate and keep swirling around forever and a day... hundreds of other people are desperate. (Manager A)

8.8.5 Organisational inertia

In contrast to the energetic and proactive actions of the PM Consultant and Manager A, the NHS trusts with which the PMS had to operate presented a two significant structural constraints on the project. First of these was the lack of a single strategic vision for pain management services that was consistent across the secondary and primary care trusts. The absence of government performance indicators for pain management contributed to this lack of vision. Second, clinical governance structures varied between each trust varied. This made coordination of pain management services problematic in terms of interaction between community-based and secondary care teams. The differences in governance arrangements also led to difficulties in managing finance flows between trusts.

Overall, the organisational inertia preventing the development of the project was based around the difficulties in managing care services across primary and secondary care organisations. These structural problems prevented integration of processes, information flows, inter-trust communication and overall management control of the service.

8.8.6 Evaluation as enabler and barrier

Evaluation processes played an important role in the PMS case both in enabling and inhibiting the innovation project. Central themes in these evaluation activities were the purposes that they served, for whom they were carried out and the basis for judging evaluation data as valid and legitimate. Evaluation within the project served several purposes including the need to:

- meet government requirements for data on key performance indicators;
- provide high-level evaluation data to the project steering group;
- allow the team to evaluate on-going changes they made to the service;
- provide data supporting the planning of future service-changes;
- establish costs and benefits of the service changes;
- and provide evidence that service changes were legitimate and defensible.

The emphasis of evaluation activity early in the project was to provide data to the project's operational group and to address government performance indicators. The evaluation processes however evolved to serve the project team enabling them to assess the changes that they made. Unfortunately, the data requirements of government, the steering group and the team itself were very different.

Government defined key performance indicators

Much of the evaluation workload in the early part of the project was oriented towards the requirement to measure performance of the PMS, based on key performance indicators.

> ... well, it is government led, we have to give them the statistics they ask for, so we have to look at our waiting lists, we have to keep our waiting lists down, we have to look at our budgets, and they have been the main drivers over the past few years.
> (Manager B)

These tended to be emphasise highly aggregated data such as waiting times, access rates and discharge rates from the service, with little emphasis on measuring patient outcomes from treatment in the PMS. These therefore provided only a relatively crude measure of the effectiveness of the innovation in the PMS.

Evaluation processes for the steering group and project team

The lack of granularity in government defined key performance indicators meant that they were unsuitable for evaluating change in the PMS. This problem was exacerbated by the difference in the unit of analysis used by government compared to the PMS. For evaluating the PMS, the unit of analysis for evaluation needed to be the complete care pathway and its performance in terms of outcome achieved for individual patients. Government indicators lacked the sophistication to cope with multiple-factors and the outcomes achieved by the whole system:

> ...the other thing about gaining the evidence over something like this, is that it is difficult because it is a pathway you are looking at, you are not looking at something like the effects of this drug on this patient, you were looking at a whole pathway and so there are so many different factors that affect it, not least of which are the types of patient that come to the service, but as time goes on, and you change the system is the type of patient coming through is different, because it is not just part of the service which is changing, it is the whole service which that we looked at and the types of patient coming through are different, therefore, the results you are getting are skewed because of that.... you can't really do a research project on it because there are so many variables. (Manager B)

The team believed the main emphasis of evaluation of the re-organisation of the PMS should be clinically driven, with a focus on patient outcomes. Typical indicators to support evaluation of the service-changes included: average waiting times; patient satisfaction ratings; follow-up ratios; and patient referral rates to specific acute and primary-based services. Much of this data was already held on systems in the primary and secondary care trusts, however, it was often hidden due to lack of system integration.

The dominance of government sponsored information systems, oriented towards collecting performance management data, meant that the systems were not optimised for tracking patients through the PMS. This meant that measuring treatment outcomes for specific patients required the development of new or parallel information systems.

The PM Consultant and the managers had great difficulty in aggregating data across disparate systems. This was made more difficult due to the inconsistencies in record keeping between trusts:

> ... as far as referrals to things like orthopaedics, it is very tricky for us to keep tabs on. I think because we are working across more than one trust, that is one of the problems, in that perhaps one trust keeps detailed records about one thing and the other trust keeps details of another type of data. It is difficult to marry them up. (Manager B)

In addition, the PMS lacked a culture in which detailed data necessary to support evaluation was maintained.

The benefit of focusing on treatment outcomes over specific high-level performance measures was that the project team had a greater opportunity to understand the story beneath the data in order to identify problems and inform their solution. One example of this was when a PCT served by the service, experienced a rise in waiting times. The underlying cause was that GPs, attracted to the one-stop shop concept, were switching patients to the service from other hospitals. It was only the availability of detailed evaluation data that enabled PMS team to understand the cause of the rise in waiting times. Detailed evaluation was crucial to understanding the underlying mechanisms affecting the PMS.

A further role of the detailed evaluation data was to provide evidence that the changes made by the PM Consultant and Manager A were appropriate and defensible. In this respect, evaluation data took on a political role.

> ...if you don't have the audit data you are continually challenged about why things are the way they are. Five years down the line, I may be asked by a new Chief Executive to explain why... (Consultant)

Validity of evaluation data

Overall, the PMS project used a range of types of data to evaluate the innovation. These were based on varied assumptions about data validity, each creating a different perspective on the innovation's performance. The government defined performance indicators relied on highly aggregated measures relating to specific process points such as referral waiting times. In contrast, the

operations group and the innovation team recognised the need to develop evaluation data based on patients outcomes, This data was more problematic to produce requiring more detailed data collection, across several NHS trusts. However, outcome based data provided a clearer insight into the effectiveness of the overall care pathways. It also was more useful for understanding dynamics of the PMS system.

The project team were aware however, that the benefits realised by the innovation were difficult and complex to describe in purely quantitative terms. The team recognised that chronic pain had potential to be an "NHS resource eater" but many benefits were difficult to quantify in financial terms.

> You know that you are taking a group of patients that would have been bouncing around the NHS for years and you are managing them, and almost putting them back into society a different person, because they can cope with their pain, they have adapted their lifestyle to live and that pain. You stop them from being a burden on the NHS, but it is very difficult to quantify. (Manager A)

> ... what you can do quite easily is look at patient flows, but what you can't look at is the amount of money you have saved on drugs, it is more difficult to do that because you have to take quite a large sample of patients to be to do that. It is tricky, like all long-term conditions, such as diabetes, it is very difficult to quantify ... we almost need a full time research person to help us with this really, to do a research project on, this is the sort of thing we are looking for. (Manager B)

Evidence-based approaches to re-designing the service had been used, for example in assessing the success of acupuncture treatments in the service. However, the nature of the PMS was such that it could take several months to monitor the results of a change and to develop an evidence-base of its effectiveness. The need for rapid change meant that professional judgements, rather than evidence-based methods, often guided service-redesign.

> We are always doing new things, trying out new things and we don't always measure it as we are going along, it is a kind of hunch that if we do this... sometimes we think this is not working and we are the looking at the evidence we have got from past

> experience, that is not always data, we have not got six months to collect data if we know something is not working, we have to do something about it here and now, especially with waiting times. (Manager B)

In several cases, bottlenecks in the system were clearly visible to all the main stakeholders and clinicians in the service so the need for comprehensive data to support a change was often avoided. However, in some cases, demands for evidence to support change were based on political ploys to block change. The team had experienced projects where clinicians who were antipathetic to a change would demand high levels of supporting evidence:

> ...some of the things I managed to get changed without the need to present data, because in their heart of hearts, they know it is true. Sometimes they asked for data as a staller. (Manager A)

8.9 Summary

This case has reinforced the understanding of user-led innovation as a bottom-up activity.

However, in contrast to other examples of user-led innovation, this project was sanctioned and supported by senior management. It is important to note that this support was based on the crisis situation faced by the NHS trust at the time and the absence of any other plan. The high-level support for the project was however critical to implementing major changes to the PMS successfully.

The PMS case study is distinctive in that it is predominantly about the innovation of soft technology. Though at the level of patient treatment hard technologies are important, the PMS was predominantly concerned with soft technology. As such, the innovation process created a number of important soft technologies: care pathways, triage systems and many processes that were concerned with managing expert knowledge within the service. Therefore, unlike other case studies in this thesis, the innovation process reported was concerned with the knowledge-based dimension of NHS organisations.

The process changes described in the case reflect fundamental shifts in the management of pain services. The changes represented shifts from bio-medical to bio-psychosocial models of pain

resulting in significant role change for service staff, for example the need for a new model of nursing care. The implementation of collaborative care models triggered the creation of triage teams. Consequently, the overall product of the innovation process has been a proto-institution of pain management, established across several primary and secondary care organisations. It is the institutionalisation of this proto-institution that represents the biggest challenge in gaining the widespread diffusion of the innovation.

Finally, the case exemplifies the limitation of the evidence-based model of evaluation in the context of NHS services. The innovation process has illustrated the use of PDSA as a critical basis for evaluating service change, but also the need for critical reflection and application of professional judgement. The case has shown that though the EBM model has a role in guiding service change and its evaluation, it can also represent a considerable draw on resources. The problems of aggregating data from disparate information systems and ensuring effective data collection across the whole of the PMS was in itself shown to be a significant task.

Chapter 9: Research Questions Revisited

9.1 Introduction

The previous chapters have presented four detailed examples of user-led innovation in the NHS. The exploratory study and the four cases have presented varying accounts of the purpose and means by which user-led innovation occur. This chapter will review the case findings in relation to the research questions set out in Chapter 1. The cross-case review of each question includes three streams of analysis. First, it identifies emergent themes raised by the cases. Second, it assesses the relevance of the theoretical frameworks discussed in Chapter 2. Finally, where appropriate, it presents and develops refined theoretical explanations, synthesised from both the case studies and the theoretical frameworks discussed in Chapter 2.

The review of the research findings in the four cases studies is based around each of the research questions identified in Chapter 1.

- What are the characteristics of user-led innovation projects in the NHS in terms of: their purpose, the people involved and the criteria used for judging success? This question is addressed in section 9.2.
- How do user-innovators in the NHS manage and structure the innovation process? This question is addressed in section 9.3
- What is the nature of the technology created through user-led innovation in the NHS? This question is addressed in section 9.4.
- How and for what purpose do user-innovators evaluate their innovations as they are developed? This question is addressed in section 9.5.

9.1.1 Emergent themes

The exploratory study and then the four case studies have highlighted a range of themes that impact on the progress of user-led innovation in the NHS. Figure 9.1 aggregates issues from specific cases and categorises them into four groupings: purpose, team characteristics, process factors and institutional factors. The subsequent sections of this chapter build on the themes developed in Figure 9.1. Section 9.2 considers the characteristics of user-led innovation and draws on the themes affecting project purpose and team characteristics. Section 9.3 considers the process of user-led innovation and develops the themes affecting the user-led innovation process. The themes relating to the institutional themes within the cases is considered and extended in Section 9.4. The inter-relationships between factors does mean that certain themes inform answers to several of the research questions.

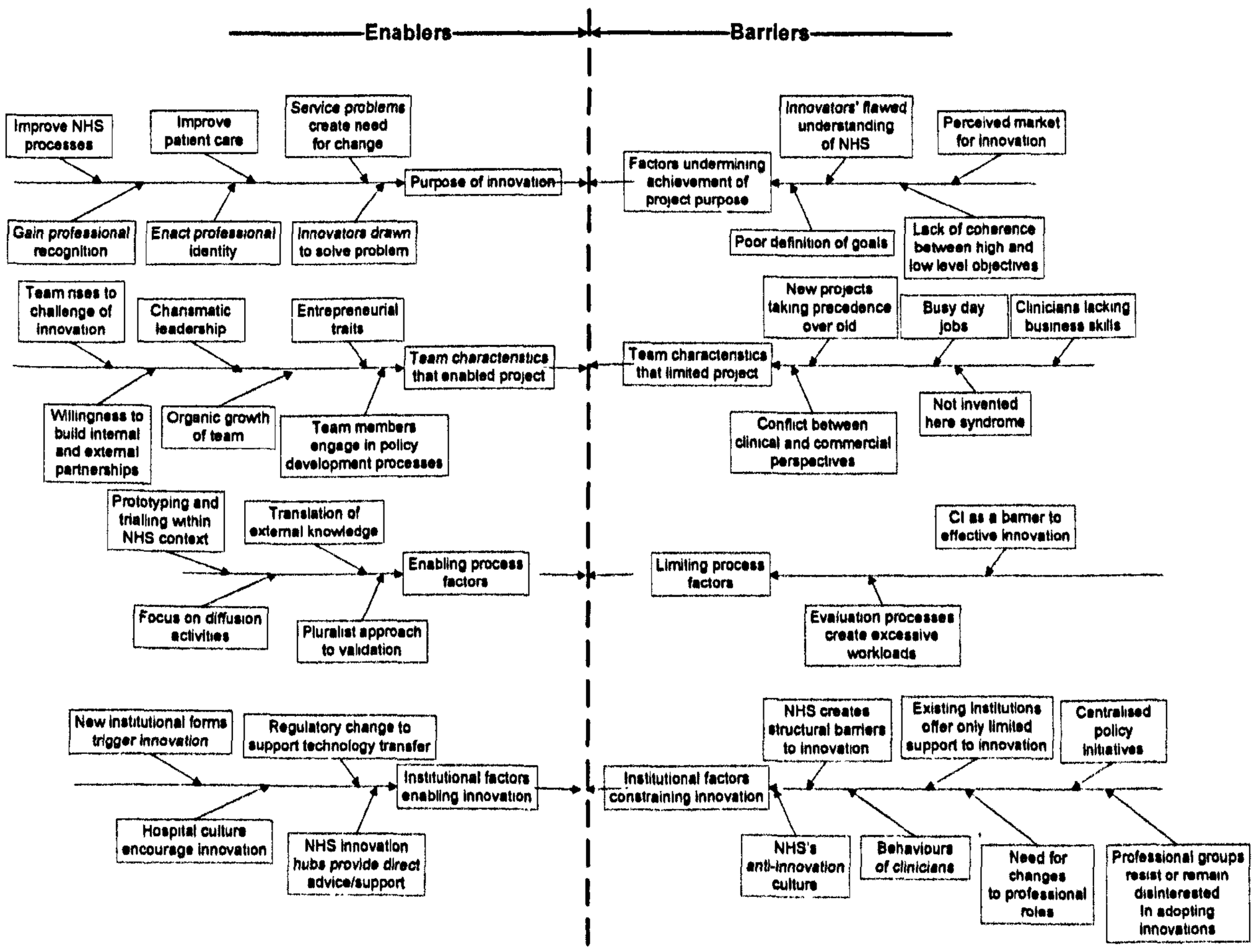


Figure 9.1: Aggregate of enabling and inhibiting factors affecting user-led innovation

9.2 Characteristics of user-led innovation projects in the NHS

This section addresses the research question:

What are the characteristics of user-led innovation projects in the NHS in terms of: their purpose, the people involved and key success criteria?

User-led innovation in the NHS represents a gap in the research literature, with no clear definition or description having been made of what constitutes a user-led innovation project. Other researchers have taken a macro view of innovation networks over an extended period of time, often based around innovative users of technology, for example, the role of "hero surgeons" in the innovation of cataract surgery (Metcalfe, James, and Mina 2005; Metcalfe and Pickstone 2006). Unfortunately, there are no accounts of how the micro-processes of user-led innovation in the NHS have occurred.

The four case studies, of course, do not represent a comprehensive survey nor do they provide a statistically significant set of findings. They do however suggest that user-led innovations in the NHS might be characterised in certain ways, based on common and distinguishing characteristics of the cases. It is useful to consider not just how the cases are similar but also how they differ. This can be considered in terms of the purpose of the projects, the characteristics of the people involved in the projects, the mechanisms through which they become involved and the criteria that might be used for assessing their success.

9.2.1 Multiple-purposes of user-led innovation projects

The stated purposes attributed to the user-led innovations in the cases studied were complex and often changed over the course of the project. The cases illustrate that user-led innovation projects in the NHS are distinct from innovation projects in other sectors. The purpose of the specific projects ranged from well defined, focused, project charters, as in the PMS case study; to projects in which the purposes of the innovation developed and evolved over time. This implied that user-led innovation projects may not always fit into conventional innovation management processes, such as stage-gate processes. This makes recognising the potential of a specific user-led innovation project very hard to evaluate, due to the evolving purposes that it will serve.

A critical factor that may have contributed to modification to the purpose and aims of individual projects, was the lack of independent critical review at an early stage. The informal nature of three of the projects in the case studies meant that the plans underwent less critical review than might be

expected in a formal innovation project. As noted in the exploratory study, a potential trap for user-innovators in the NHS is that their understanding of the wider NHS and its processes can be flawed, leading to incorrect assumptions about how an innovation would be adopted and implemented. Though none of the case studies illustrated this explicitly, it is clear that the teams had to work hard to ensure that the goals of their projects were not just consistent to their local context but also to the wider NHS or external healthcare organisations. The LUTM project illustrates how the perceived goal of the project was specifically based in the context of NHS vascular care units. While this focus ensured a close fit between the innovation and the NHS context, it is clear the perceived market for the LUTM was the UK NHS, a perception that would undoubtedly set limits on the project scope and goals. A further factor is related to the emergent nature of the project goals. This is illustrated in the CLP case where the organic growth of the project created a divergence between high and low level objectives.

Overall, the cases suggest that user-led innovation projects commonly serve multiple purposes including:

- to translate or apply existing knowledge to solve a specific problem encountered by NHS staff;
- to address a root problem related to a clinical or service delivery issue;
- to create solutions that fit into existing NHS structures and processes;
- to address professional and philanthropic motives, rather than purely commercial purposes;
- subject to limited independent critical review during the early stages of the project.

Focus on applying and translating existing knowledge

All four of the cases, in common with many of the innovations managed by NHS innovation hubs, were projects triggered by problems perceived by user-innovators in the course of their work. The purpose of all four cases was to address practical issues. None of the cases however would be described as concerned with carrying out, or even applying, "blue sky" thinking or forms of fundamental research. Instead, the projects were concerned with translating knowledge gained from other contexts to a specific problem encountered by the user-innovators. This placed them into a

category of innovation project concerned with combining technologies or "bricolage" (Garud and Karnøe 2001:23).

Addressing clinical and service delivery issues

In the PMS case, the root problem was a critical service failure that created a situation in which there was no alternative but to produce an innovative solution to a service design problem. In contrast, the LUTM and ePAQ cases were in response to the user-innovators recognising clinical and service delivery problems. The underlying problems were complex, combining purely clinical problems with issues relating to service delivery and the design of NHS processes. In these cases, the full purpose of the innovation was not always clearly understood from the start.

The ePAQ project was rooted in a relatively narrow field, medical research questionnaires, with little relationship to the broader area of NHS service design. However, the development of ePAQ created opportunities for service re-design that cut across acute and primary care. Similarly, the LUTM was developed initially as a communication tool but its purpose diversified to enable treatment audit and radical service re-design. Finally, the CLP case illustrates how innovation of a relatively minor process, producing individual plaster study models, became relevant to the higher-level purpose of improving cross-centre evaluation of CLP surgery. This suggests that user-led innovations predominantly address complex problems, combining both clinical and service design issues.

Fit existing NHS structures and processes

The case studies demonstrated a concern to improve and complement existing NHS technology. Though the resulting innovations may have had applicability outside the NHS, for example ePAQ's potential use in other healthcare systems, it was evident that the user-innovator's primary intent was to develop technology to benefit specifically NHS patients. All the user-innovators were motivated to improve care of their NHS patients and so the ultimate design of the innovations was predicated on a requirement to be fit for NHS use. The development of the LUTM, ePAQ or PMS innovations were created with close reference to specific NHS processes and structures. User-led innovation in the NHS can therefore be seen as a form of innovation concerned with improving and

evolving legacy systems within the NHS, rather than creation of radical innovations that disregard or abandon existing structures and processes. This focus on legacy is advantageous in that it may improve the potential rates of innovation adoption across the NHS. Conversely, the emphasis on legacy may also constrain the degree of change enabled by an innovation, constraining the creation of optimal solutions.

Evolution of project goals

The cases suggest that user-led innovation projects in the NHS are distinct from innovation projects in other sectors. The purpose and goals of specific user-led innovation projects ranged from well defined, focused, project charters, as in the PMS case study; to projects in which the purposes of the innovation developed and evolved over time. This implied that user-led innovation projects may not always fit into conventional innovation management processes, such as stage-gate processes. This makes recognising the potential of a specific user-led innovation project very hard to evaluate, due to the evolving purposes that it will serve.

Addressing professional and philanthropic motives

The user-led innovations studied primarily sought to address clinical or service problems, but it was evident that secondary reasons existed for the projects. The user-innovators were often drawn to the problem out of curiosity or desire to improve a situation. For all of the cases studies there was a sense that the projects served the purpose of allowing professionals to enact their professional role. The purpose of the projects can therefore be seen in terms of user-innovators pursuing projects because they fitted their own professional identities. For example, the expectation to engage in research activity is embodied in the contracts of hospital consultants. None of the user-innovators who participated in the research described themselves as motivated by the opportunity to make money out of their innovations. In fact, the investment in time and personal risk associated with pursuing an innovation was based around philanthropic values. It was common for the user-innovators' preferred reward to be professional recognition. This is in stark contrast to business entrepreneurs where the investment in innovation is predominantly focused on financial reward.

The purposes of the projects are also closely aligned with the professional identities of the user-innovators. This has implications for the incentives given to NHS staff for engaging in innovation activity. There are now clear guidelines in the NHS on attributing ownership of IP and subsequent payment of royalties. It must however be recognised that, though important, financial reward may not be the critical motivating factor for staff to engage in innovation activity. NHS innovation policy needs to recognise that in addition to financial remuneration, philanthropic actions must be rewarded through recognition and practical support.

9.2.2 Team Characteristics

The user-led innovation studies in this research were created by user-innovators working with teams that they formed to support their projects. The cases studied suggest a number of team characteristics were important to the progress of the innovations:

- leadership characteristics;
- organic growth of project team;
- team roles;
- willingness to build internal and external partnerships;
- team members engage in policy development processes.

Leadership characteristics

Leadership has long been recognised as an important variable in studies of innovation, entrepreneurial activity, and change management. Various schools of thought have developed, such as trait (Stogdill 1974), contingency theories (Fiedler and University of Illinois at Urbana-Champaign. Group Effectiveness Research Laboratory. 1963) and transactional approaches (Bass and Avolio 1993). Key leadership 'characteristic's, such as charisma, the ability to communicate, and risk taking, have been identified (Bryman 1996). There is not the space to delve more fully into this subject here, however. Consequently, the discussion that follows focuses on those aspects of leadership that were of particular significance in the context of the four case studies.

The user-innovators who participated in the research exhibited a number of characteristics that underpinned the development of the projects. Three of the projects were led by hospital

consultants. This discussion will look specifically at the characteristics of consultants in relation to the user-led innovation.

User-innovators as charismatic leaders: One of the most important factors affecting the teams in the cases was the personality of the consultants. The nature of the medical profession in the UK means that consultants are generally regarded as highly intelligent, and that they address problems in a creative, imaginative and self-confident manner. This meant that for the staff working within teams the consultants were perceived as strong and charismatic leaders. They were able to communicate and gain support for their own view of a solution and where necessary, successfully persuade other stakeholders. This was illustrated in the LUTM case where the Vascular Surgeon was able to negotiate for significant change to support the LUTM. It was clear that for the LUTM, ePAQ and PMS projects the consultants were able to gain considerable loyalty and commitment from other staff.

User-innovators as entrepreneurs: In addition to distinctive leadership characteristics, the user-innovators were often very entrepreneurial in their approach to the projects. In both the ePAQ and PMS cases, the consultants negotiated considerable resources both from within their hospitals and from external organisations such as pharmaceutical companies. Much of this entrepreneurial activity stemmed from the consultants' professional networks.

User-innovators and power: It would be too simplistic to assume that the success of the user-innovators was based on good leadership and resourceful entrepreneurship. It was clear that a significant root of their success was the power that they were able to use. The consultants were in a considerable position of power with respect to developing and implementing innovation. By applying Lukes' analysis of three-dimensional power (Lukes 1974), it is possible to see that hospital consultants utilise significant power resources when progressing their innovations. At a basic level, the power of a consultant stems both from their organisational position and their specialist knowledge. This enables them to exercise significant power in decision making processes, by influencing agendas and the decisions chosen for discussion, as well as affecting the formal outcome of decisions. Within the LUTM case, the Vascular Surgeon exerted significant power in decisions such as whether the LUTM software should be run on the hospital IT systems.

At a second level, the consultants also had significant authority in the setting of agendas. This was shown starkly in the PMS case study where the consultant, in collaboration with Manager A, set the agenda for the hospital trust's management in terms of how the service should be re-structured before re-opening the service. Finally, the most subtle dimension of power exerted by the user-innovators was in terms of their ability to shape the values, norms and underlying mental models that underpinned their specific specialist area. Within the PMS case, the innovation was based on the acceptance and adoption of the bio-psychosocial model of pain. Though resisted by some staff, gaining widespread adoption of this new model changed many assumptions and values within the service further allowing the innovation to be accepted. The PM Consultant employed this power further when engaging in the policy development and the setting of clinical guidelines. The role of power within user-led innovation is discussed further in section 9.5.

User-innovators as lone inventors: The ability of consultants to drive innovation was substantial, though several characteristics may have had less beneficial effects. NHS consultants have significant workloads and calls on their time; for many of the consultants in this research, innovation activities were often slowed by the lack of available time. They often had to restrict work on innovations to evenings and weekends. Similarly, as new projects developed the attention that the consultant could give to existing projects was also compromised.

The approach to development taken by consultants was also subject to the risk of "not invented here" syndrome, in which technological solutions were seen as better developed in-house than bought in. Examples of this would be in the case of questionnaire software in the ePAQ project and process simulation software in the LUTM case. Though decisions to embark on in-house development may well have been taken for good reasons, it is unclear how rigorously these decisions were tested.

A common comment from consultants was that they became very aware of their lack of business skills as their projects developed. This was often cited as a major challenge, when clinicians tried to balance effectively both clinical and commercial views of their projects.

Organic growth of project teams

The four case studies illustrate a range of ways that projects develop and especially how staff are drawn to become members of the project team. Though the CLP project team remained small, the three other cases all exhibited a progressive growth and evolution of the project teams.

The most stark example of this was the ePAQ project, in which after working mainly on his own, Consultant A drew in members of staff to provide complementary skills. This was initially to gain access to specific technical skills but over time progressed to include management skills from Medipex and commercial perspectives from Illuminaries.

The cases suggest that the enrolment of staff to a project team is initially based on opportunity and availability, but is critical to the development of the project. For example in the LUTM case it was to some extent serendipity that resulted in the project enrolling nursing staff with research interests that could support development. Conversely, it is important to note that the user-innovators have a strong influence on the how the team changed. For example, in the ePAQ project the recruitment of industrial partners was mediated by the wish of Consultant A to maintain a local group of team members. In the PMS case it was evident that one role of the user-innovators was to progressively facilitate the shift of project ownership from secondary-care staff to staff in primary-care organisations.

More fundamentally, the change in project team makeup allowed the augmentation of the user-innovator's primarily clinically oriented perspective, with technical and commercial perspectives. Thus for the ePAQ project the partnership between clinician, technology transfer company and software house allowed an effective balance of perspectives.

The dynamic makeup of the teams involved in user-led innovation projects benefits the project in several ways. First, enrolment of appropriate staff to the project improves the absorptive capacity (Cohen and Levinthal 1990; Zahra and George 2002) of the project, allowing it to access and apply knowledge from outside the user-innovator's normal context. Second, the evolution of the project team can improve coordination between clinical, technical and commercial perspectives. Finally, the increased number of perspectives applied to the project improves the capability of the team to translate and apply knowledge.

The dynamic makeup of project teams highlights the bottom-up nature of user-led innovation and the need to facilitate organic growth of the team. In the cases studied, three factors were crucial to this organic growth. First, it was important for the user-innovator to have knowledge of where they could access staff with suitable skills and have the opportunity to recruit them to projects. A second factor was the point at which the user-innovator recognised, or was advised, to change the make up of the development team. This was shown clearly in the ePAQ project where the development of the software was shifted to an external software house. Finally, though not illustrated in any of the case studies, it seems likely that user-innovators may need support in deciding at what point they relinquish control of their projects. For example, the question remains whether the vascular surgeon should have passed the LUTM project onto a commercial software developer, allowing it to be developed further.

Team Roles

The bottom-up nature of the projects meant that at no point was a project team explicitly selected and structured. Instead, the team tended to grow organically with members joining and leaving of the course of the project. It is useful to note however that the project teams would typically comprise several categories of staff, shown in Table 9.1.

Central to the team was the original user-innovator. For all of the cases the user-innovator role was taken by one or two individuals. The user-innovators were crucial in driving the project and negotiating change. The second category of team member was members of staff who normally worked with the user-innovator. These were often key team members who played an important role in implementing the innovation, often also contributing to its development. A critical category of staff in the project teams were the early adopters of the innovation. These team members were crucial, as they were willing to take up the innovation and provide important feedback to the user-innovator. As projects progressed it was common for specialists to be recruited to the project, these were members of staff who could provide specialist skills to the development of the innovation. The final category of project member were the project champions, usually senior members of staff in the organization. These project members were important in adding legitimacy to the project, aiding the negotiation of resources and protecting resources allocated to the project.

Table 9.1: Team roles within user led innovation projects

Member category	Description	LUTM	EPAQ	CLP	PMS
User-innovator	Devises initial idea for innovation and drives protect	Vascular surgeon	Consultant A	Maxillofacial technologists	PM consultant Service Manager
Team member	Supports user-innovator in developing and implementing project	Specialist nurse research nurse	Medical student Clinic nurse	Plastic surgeon	Service managers
Early adopters	Staff willing to adopt the implementation and provide feedback to user-innovator	GPs District nurses	Clinic staff research nurse PCT staff		GPs PCT service managers specially staff e.g. psychologists physiotherapists etc.
Specialist	Provide critical specialties knowledge to the project team		Software development staff social scientist NHS innovation hub		Project manager Researcher
Project Champions	Provide senior management level support to the project		Consultant B	Plastic Surgeon	Senior trust managers

LUTM: This project was conceived predominantly by the vascular surgeon and the progress of the project remained predominantly under his control throughout the course of the project. Staff from within the hospital and associated PCTs, were enrolled to the team but the project remained under the vascular surgeons control throughout.

EPAQ: The ePAQ was a project with very clear and distinctive phases, with each phase was characterised by a different project team. Phase 1 was predominately based around Consultant A. Phase 2 used a multidisciplinary project team enrolled from within the hospital. During the final stage, the project team was based on members from across several organizations.

CLP: This project was conceived by maxillofacial technologist and subsequently only a small number of people enrolled to the project.

PMS: This project exhibited a gradual enrolment of staff from across several organisations. It is notable that as the project progressed the balance of ownership of the PMS shifted from the hospital to the PCTs.

Willingness to build internal and external partnerships

A critical success factor for the teams was their willingness to engage in building internal and external partnerships. Some relationship building illustrated in the cases was routine, for example the relationship between the SCT in the CLP case with the engineering workshop. Other relationships were however critical to the project and were not necessarily routine. For example within the ePAQ project, the internal relationship with the Scientific Computing Department was fundamental to the success of the project. It was evident that external relationships had potential to effect the most leverage on projects. In the PMS case, the PM Consultant and the Manager A were very active in engaging with staff based in the PCTs. Similarly, in the LUTM project the relationships forged by the Research Nurse underpinned the LUTM's successful adoption by community-based staff. It is useful to note that in the CLP case, a possible cause for the lack of diffusion of the innovation were the limited external partnerships that were developed.

Team members engage in policy development processes

Part of the process in building external partnerships has been active engagement in policy formation. Many of the staff involved in the cases, particularly consultants, were active in policy formation processes. For example, the PM Consultant was active within her professional body in setting new care guidelines. In addition, many staff involved in the projects produced publications for professional and academic journals that would have the potential to affect policy debate in specific fields.

9.2.3 Dimensions of user-led innovation success

By definition, all of the cases reported in this research represent projects that have achieved some measure of success. This is because the projects were selected as a result of their success in innovation competitions; therefore, the research was oriented to looking at successful projects. To assume however, that the cases studied in this research were complete successes would be wrong. The success of an innovation in any particular competition is only an approximate proxy for more general project success. The purpose of innovation competitions in the NHS is generally to provide a showcase for innovation projects, with the prime intention of many entrants being to use the

competition for publicity purposes. The competitions are commonly seen as and structured to be mechanisms for building relationships with investors or industrial partners. In this context, success in winning a prize in such competitions is probably more a reflection of an innovation project's commercial potential than any absolute assessment of overall importance to the NHS or wider healthcare industry. It is also unlikely to reflect the extent to which the innovation project is well managed. The implication of this is that it is quite likely that some very successful projects, or conversely failed projects, are not entered into competitions. The motive for entering a competition may also be inwardly focused, rather than based on an intention of promoting a project to a wider audience. The PMS case is an example of an innovation that was entered into a competition primarily to prove the innovation's success to staff within the participating organisations. The PM Consultant's motive for entering the PMS project into the Medical Futures innovation competition was not as a way of promoting the project externally to other pain management services. Instead, it was to send a positive message about the project to the staff in the service and senior trust managers. She saw the award as potentially countering some of the resistance and internal criticism of the project.

> ...we had had a hard time from colleagues and we were doing a good job and I actually thought, if we win it, there we go. We will have done alright...you do not really know what drives them [other consultants] to be so critical sometimes...the award would say that we were doing alright. (PM Consultant)

The cases selected should therefore be treated not as examples of excellent or exemplary projects, but simply as cases that achieved some level of competent achievement.

The range of measures that could be used for measuring success are diverse. This research suggests that five dimensions of success provide a useful framework for comparing cases: degree of local adoption; efficiency benefits; effectiveness benefits; diffusion within the NHS; and the commercial vale of the intellectual property generated by the innovation. The relative performance of the projects along these dimensions is difficult to compare precisely, but there is scope in further research to consider how quantitative measures could be developed for project evaluation. The performance of the projects in the cases are compared and discussed below.

Local adoption

The extent to which an innovation is actually adopted in its original context is an important outcome of a user-led innovation project, as if it is rejected locally then it stands little chance of further diffusion within the NHS or other healthcare settings. For ePAQ and the PMS case, it was evident that the innovation was very successfully embedded into the operation of the associated service. The CLP case showed a similar level of adoption, in fact it had become a normal routine. It did not however create the same level of service change as in the case of the ePAQ and PMS cases. The LUTM case was an innovation that was successfully implemented and generated significant service change. It however worth noting that the LUTM was widely accepted by nursing staff within the clinic and those working in the community; the system was however not used by any other consultants within the vascular department.

Efficiency benefits

In assessing the efficiency benefits of the innovations, it was not possible in the research to develop precise, comparable data on efficiency changes. The LUTM cases is the only one for which the efficiency of the associated service was precisely quantified, with the dramatic reduction in mean time for healing representing a significant improvement in efficiency of the leg ulcer treatment service. The PMS case however, also demonstrates that the innovation lad to some significant improvements in efficiency as indicated by reduction in waiting times, throughput of patients and the reduction in capacity required for back operations. In contrast, the ePAQ and CLP projects were not primarily focused on gaining service efficiencies. Both innovations provided marginal improvements in efficiency. For the ePAQ it would be difficult to assess whether the increased time and resources needed to guide a patient through the ePAQ has a consequential improvement in the efficiency of the clinical interview. Similarly, the CLP project has not directly increased the efficiency of producing a study model or carrying out a cross-centre evaluation of surgical procedures. These two cases however, illustrate that the use of efficiency benefits, when assessing either the potential or ultimate success of user-led innovations, provides only a partial view of overall project success.

Effectiveness benefits

The assessment of the benefits in terms of improved effectiveness of the associated service is not a trivial problem. For the LUTM, ePAQ and PMS projects it was evident that they all led to significant improvements in service effectiveness. They all led to the improved patient care, but also to more appropriate use of staff; empowerment of staff, patients and carers; more effective knowledge management; and often delivery of more appropriate treatment. The assessment of the effectiveness benefits are however, very difficult to quantify, especially when faced with the pressure to demonstrate the innovations performance against government defined indicators, that were more oriented towards efficiency targets. In assessing innovation projects the robust assessment of potential improvements in service effectiveness remains a central challenge in evaluating user-led innovation. This issue is discussed further in section 9.5.

Diffusion into the NHS and beyond

Successful local adoption of an innovation indicates only a partial view of the success of an innovation. The wider adoption of the innovation, especially into the NHS, indicates the success of the innovation's utility or extent to which it is useful. Diffusion of the innovation also indicates that the efficiency and effectiveness benefits can potentially be reproduced in other settings. Assessing the project in this dimension is however not simple. For the LUTM and ePAQ projects, the innovations had been adopted by a relatively small number of all potential NHS sites. Over time however, the process of licensing or provision of a hosted service may increase the number of sites using the innovations. In contrast, the PMS case study represents an innovation in which it s unlikely that the service design developed by the team will be reproduced exactly. This does not mean that innovation is unlikely to impact on other NHS sites. Instead, the process of diffusion is likely to be based on abstraction of the service principles and then their translation into other services. The work of the team in the PMS case indicates that simple reproduction of the use of the innovation in other settings does not give a full picture of diffusion. The team's informal and formal diffusion actions, such as influencing national care guidelines, will have far reaching consequences for the effectiveness and efficiency of the NHS. This would suggest that while the

rate of adoption of hard technologies gives some indication of successful user-led innovation, the diffusion or translation of technological capability needs more subtle measures.

Value of the IP

The emphasis of NHS policy on technology transfer out of the NHS would suggest that a useful characteristic of success is the value of the IP that results from the project. The four case studies illustrate examples of innovation that produce varying levels of IP value. Two of the cases, PMS and CLP, had no IP produced that could benefit from either IP protection or commercial exploitation. In commercial terms their only potential value would have been based on the extent to which team members could commercially exploit their knowledge through consultancy, training, books etc. The LUTM and the ePAQ cases represent examples where user-led innovation has resulted in the creation of valuable IP. This was done respectively by creation of a licensed software package and creation of a business start-up.

9.2.4 Section summary

This section has discussed the characteristics of user-led innovation projects, based on the findings in the case studies. It has outlined the general characteristics of user-led innovation projects and the purposes that they serve. The teams that are involved in user-led innovation have been characterised in terms of their leadership, their patterns of development during the project, the role of internal and external partnerships and roles that team members assume external to the projects, particularly with respect to policy formation. Finally, the section has developed a potential framework for assessing the success of user-led innovation projects that augments financial valuation of IP.

The nature of user-led innovation has been shown as distinct from other models of innovation that seek to involve technology users in development. While open (Chesbrough 2003) or lead-user models (Hippel 2005) of innovation recognise the value of user involvement, the balance of power in the development process still rests with the technology producer. In contrast, user-led innovation is distinct as users assume control of the innovation process, setting their own objectives and management controls for projects. This has the potential to enable creative solutions to be

developed that are not necessarily within the stated strategic plans of the host organisation. There is however, a risk that user-led innovation projects could be either: dominated by a user-innovator imposing a sub-optimal solution; or an isolated team might not have the resources or knowledge to develop solutions that have applicability outside their own context.

The distinctive nature of user-led innovation suggests that the process through which they develop will also be distinctive. The next section considers the process through which the user-led innovation projects proceed.

9.3 NHS Managing and structuring the user-led innovation process

This section addresses the research question:

How do user-innovators in the NHS manage and structure the innovation process?

The research set out to identify the process followed in user-led innovation projects. Despite the attraction of being able to define a single generic process, the research findings suggest that across the four cases it would be wrong to assume such a model could reflect the diverse range of activities underpinning user-led innovation. The underlying reasons for this diversity are that the variation in the problem addressed by user-innovators, motivation of staff, makeup of the innovation team and other contextual factors that supports or inhibit user-led innovation.

The four cases represent contrasting approaches to the development process, with the overall innovation process adjusting accordingly. The LUTM case was centred around an evolutionary prototyping approach to software development, in which a working prototype was modified and refined. The EPAQ project was based around three distinct phases, at the end of which a robust prototype had been developed. The CLP case study provides an example of user-innovator's experimenting with a process, gradually improving it on the basis of their experiences. Finally, the PMS case study illustrates how major service redesign was based around specifying a solution, implementing the solution through a radical re-organisation which was completed by a period of continuous improvement.

While the cases do not represent all user-led innovation projects, they suggest that the user-led innovation process is contingent on the development context and the preferred methods of the user-innovators.

Despite the process differences, the four cases do suggest that there are some common patterns of activity followed in user-led innovation. Table 9.2 presents a cross-case analysis of some of the distinctive activities followed by user-innovators and their teams. This analysis informs the development of a general activity model of user-led innovation. The lack of a normative model that fits all four cases suggests that it is more appropriate to represent the innovation process in terms of six interlinked areas of activity (see Figure 9.2). These activities occur sometimes in sequence but more often as parallel activities. The figure does indicate a sequence but that sequence is based on the order in which they started, not necessarily the order in which they end.

This section discusses the activities that underpin this model and then discusses how the model relates to more general innovation models.

9.3.1 Activity model of user-led innovation

When reviewing the cases in the research it is evident that it is not possible to characterise the innovation process as a set of sequential activities. This is because the four user-led innovation projects all had an emergent quality and often involved periods of iteration or parallel activity.

The project methodologies adopted within each project illustrate a process difference between other areas of technological innovation e.g. new product development and lead-user innovation. At the core of this difference, is that the projects are often pursued in the spare time of user-innovators, under the pretext of a heading such as "administration", or where available organisational slack time exists. The projects were often pursued on an unofficial, "skunk works" basis, particularly during their early stages. This means that projects are often given little support or resource from the organisation. This is illustrated in the ePAQ project in which the NHS trust was seen as taking a very passive role with respect to the project, despite have a commercial interest in the IP developed in the project. The LUTM project provides an example of where the NHS trust had no ownership rights of the project IP, due to the software being written in the surgeon's spare time. The unofficial nature of the projects means that the methodology adopted for the project development was often

emergent and based on opportunism. Only the PMS project had a formal project manager and reflected the need to make a large-scale change in service design, in order to implement the innovation. In contrast, the other three cases involved a process of piloting and gradual implementation. An important theme in the project methodologies of the user-led innovation projects was the diverse range of approaches to technology evaluation adopted. Despite this, the user-led processes often used distinct development methodologies, such as prototyping.

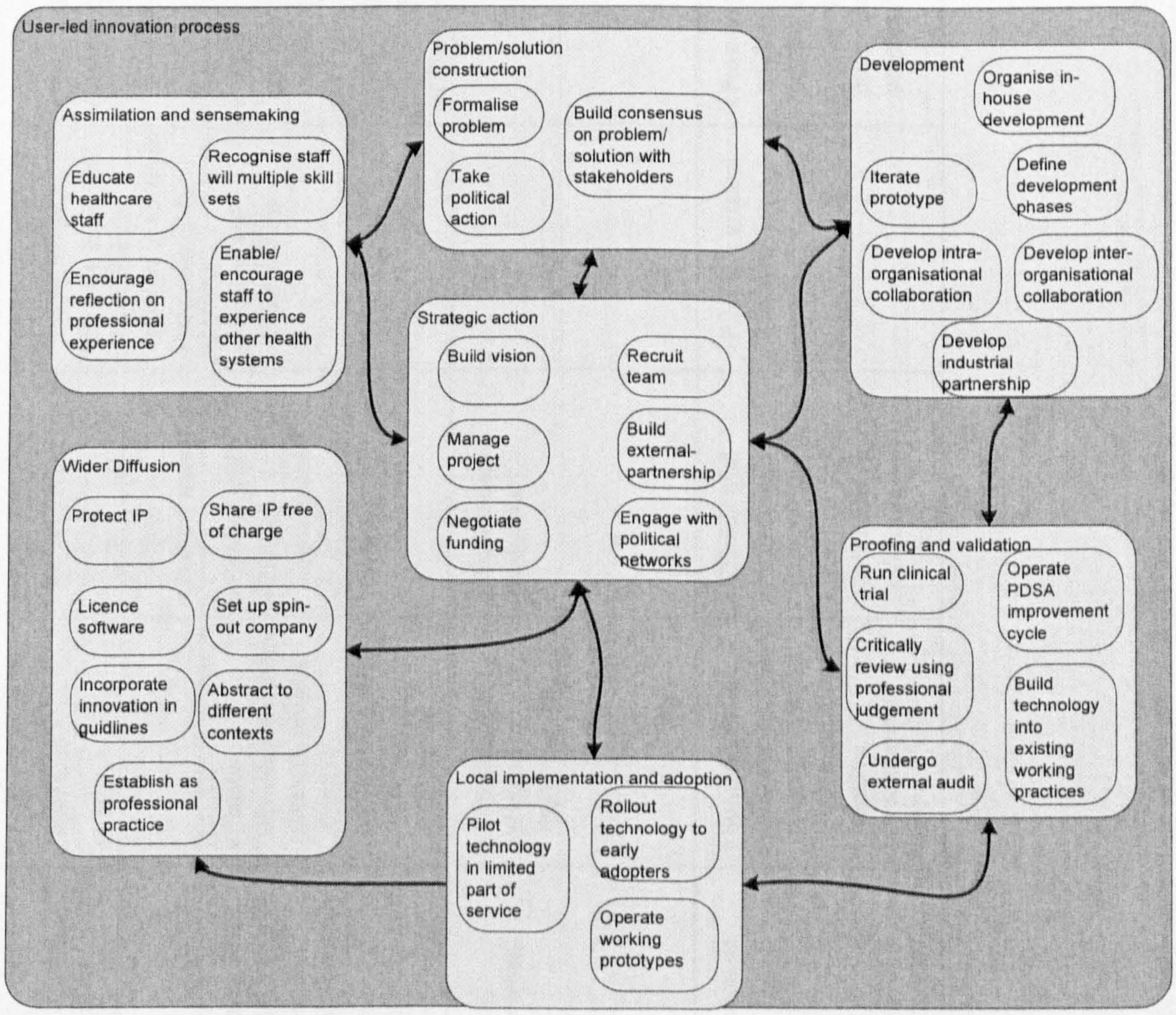


Figure 9.2: Activity model of user-led innovation processes

Table 9.2: Cross-case analysis of the activities supporting user-led innovation

	Assimilation and sensemaking	Problem /solution construction	Development	Validation	Local implementation	Wider diffusion	Strategic action
LUTM	• Experience local situation • Contrast with external developments • View situation from a medical and	• Define problem detail • Build consensus on problem and viable solution	• Create prototype • Use and iterate prototypes	• Clinical trials • Follow PDSA improvement cycle and apply professional judgement • Publish results of	• Use pilot to gain adoption by keen "early adopters" • Provide clear and rapid lines of support to adopters • Negotiate role	• Presentations and publishing • Host visits • License software	• Assume leadership of department • Negotiate resources
ePAQ	• Investigate research problem • Recognise weakness in clinical practice • Extend research problem to impact	• Recognise link between research problem and clinical practice • Organic development of the problem being	• Phased development from research project, iterative prototyping and software engineering	• Clinical trials • PDSA improvement • Publishing of results	• Piloting and clinical trials	• Access professional networks • Industrial partnerships • Software Licensing • Development of	• Engage participation from within organisation • Resource negotiation
CLP	• Visit conferences • Discussion between clinicians and technologists	• Process improvement	• Experimental process improvement	• Professional judgement			
PMS	• Crisis creates opportunity to change • Staff experience healthcare systems outside NHS	• Reflection on	• Solution design followed by phased project managed implementation • Iterative development	• Clinical trial • Professional judgement • Detailed data collection support evidence-based practice	• Pilot and gradual adoption	• Presentations, workshops and hosting visits • Engagement with policy development process	• Assuming control within a policy vacuum

A striking characteristic of all the cases was that the innovations had no clearly defined start point. In common with new product development projects, the front-end of projects were inherently fuzzy (Zhang and Doll 2001). This lack of a clear project purpose may have been partially due to a lack of formal project management processes. However, it was evident that the user-innovators spent a significant period of time assimilating and making sense of the problem situation; a process that continued throughout the projects.

This set of activities were critical to how the user-innovators' cognitive frameworks developed when understanding the innovation context and was critical in mediating the development of the beliefs and assumptions that individuals and groups made about their working context. The activities extended over many years and encompassed the stakeholders' educational and professional lives. Four activities are of particular importance: education; professional experience; interests pursued in parallel to professional activities; and experiencing other healthcare systems.

The education process for clinician has a fundamental impact on the way that they develop an understanding of their working context. In addition to developing clinical skills, their education will impact on the skills that they have for solving technological problems. The Vascular Surgeon in the LUTM case was clearly deeply influenced in the way that he approached and solved problems due to his dual skills in medicine and software development. Similarly, the development of ePAQ was rooted in the interest that Consultant A developed in applying QoL assessments into clinical practice, a research problem that he had worked on during his own medical training.

The professional experience of staff within their working context is at the core of where user-led innovations develop. Through the process of making sense of the problems encountered on a day to day basis, staff developed a clear understanding of the problems they believe need to be solved and start to develop potential solutions. Their proximity to the problem gave them a unique insight, unavailable to other developers of healthcare technology. Often their experience of working in a particular field is complemented by views they have had of other healthcare systems. For all the cases in this research, the user-innovators have acted because they have seen contrasting approaches applied elsewhere. For example in the PMS case the experience of the PM Consultant,

Manager A and Manager B brought together approaches to structuring healthcare systems from North America and the private sector.

Problem/Solution construction

The problem/solution construction activities are concerned with formally articulating the problem situation and gaining agreement on a viable solution. The actual process through which this occurs varied between the cases. For ePAQ the problem was initially articulated and considered by Consultant A in isolation and it was only through the course of the project that the problem was gradually formalised, revised and a consensus to its solution achieved. In contrast, the PMS case illustrates that for radical service re-design significant political action was needed, including shutting down the service and lobbying of senior managers. The PMS case illustrated that an explicit consensus building process was required at the start of the project. The projects illustrated however that the construction of the problem/solution continued throughout the life of the projects.

Development

A broad range of development approaches are demonstrated within the four cases. This would suggest that the user-led innovation process adopts development approaches appropriate for the change and based on the personal preferences of the user-innovator. In the case of the LUTM case, use of a predominantly evolutionary-prototyping approach was probably adopted, not just because that suited the development task, but as it was an approach preferred by the Vascular Surgeon. The phased prototypes developed by the ePAQ team reflected the more team oriented approach of the development, in which development and use of the systems was more separate. The CLP case illustrated the gradual refinement of a technique over time. The PMS project in contrast was characterised more as large scale implementation followed by a period of continuous improvement. In addition to the overall development approach, the extent to which development is based around an individual, a team or inter-organisational is also illustrated in the cases.

The implication of these cases for managing user-led innovation is that it is not realistic to assume a project will follow a specific development approach or methodology. This suggests that to

encourage user-led innovation care must be taken that any management controls on projects, such as innovator pipelines, do not mitigate against a particular mode of development.

Proofing and Validation

The evaluation of the technology developed by the user-led innovation projects was a crucial process. The evaluations, however, often served multiple purposes. Clinical trials were used to provide gold standard clinical evidence of the innovation's performance and served an evidence-based medicine agenda. In contrast, PDSA approaches to improvement were used to incrementally improve or refine innovations. The powerful organisational position held by the clinicians in the cases also allowed professional judgement to be used when evaluating solutions. Finally, routine use or operation of the innovation was often critical to demonstrating the effectiveness of the innovation to staff and hence facilitating implementation. Some of these themes are discussed further later in this chapter.

Local Implementation and adoption

One of the most impressive aspects of the four cases was the extent to which the innovations was the degree of adoption achieved within the user-innovators' organisations. The LUTM and PMS cases demonstrate significant levels of change at a technical and organisational level. Three activities were of particular importance in enabling successful acceptance and adoption: use of pilots, engagement of "early adopter" categories of staff and use of working prototypes.

A typical pattern of implementation involved small-scale trials. These trials were based around either a relatively informal pilot study, or through a formal study such as a clinical trial. The impact of trials was to establish the use of the innovation within the working the environment giving staff an opportunity to apply the innovation in practice. An important outcome of this was that during the trial staff would adapt their own working practices to make use of the innovation. This was most starkly illustrated in the LUTM where at the end of the clinical trail when community-based staff complained at the withdrawal of the telemedicine system.

Linked to the use of trials was the extent to which user-innovators were careful to recruit staff open to adopting innovative solutions, despite the risk of implementation problems. The Vascular

Surgeon reflected that he had unconsciously enrolled staff characterised as "early adopter" types (Rogers 2003:283) to pilot studies. This was a pattern reflected in both the PMS and LUTM cases. The enthusiasm for the innovations expressed by the "early adopter" staff translated into the recruitment of further staff to the pilots, increasing the overall implementation and adoption of the innovation.

The involvement of "early adopter" types of staff had a follow on impact on success of the prototype development, as these staff were comfortable with working with prototypes. This facilitated collaborative models of development, between staff and the user-innovators, improving the effectiveness of the iterative development of working prototypes.

Wider Diffusion

All the cases highlight how the wider diffusion of the innovations is a significant hurdle. It is made difficult for three reasons. First , the technical difficulty of protecting IPR, then subsequently gaining value from the IP through licensing or development of spin-out companies. This is particularly challenging, as it may be necessary for complementary capabilities to be accessed, for example software development capabilities. Second, the challenge of gaining the wider acceptance and adoption of the innovation by other groups in the NHS or wider healthcare industry. Finally, the process of gaining wider diffusion of the innovation requires intense effort and strong commercial skills. For clinicians who have developed user-led innovations, they may not wish to pursue a business career and so the decision to hand over control of the project becomes a critical decision point in a project. This is illustrated in the LUTM case, where control was never passed on from the Vascular Surgeon. In contrast, the ePAQ project reached a point where the decision was recognised by both Consultant A and other stakeholders in the project.

The four cases do however suggest that several strategies are taken by user-innovators to gain a wider diffusion of their innovations. A critical process for enabling wider diffusion of the innovation was ensuring the wider adoption of novel institutional structures resulting from the innovation activity. This is discussed later in this chapter with respect to the role of proto-institutions in user-led innovation.

Strategic Action

The coordination of user-led innovation project is an activity that required significant effort from the user-innovators. Typically, it was necessary for the user-innovators to lead the development of the project vision, recruit staff to the development team, carry out project management, negotiate funding and negotiate external partnerships. In addition, they were often involved in political negotiation that would allow the project from being impeded by organizational barriers.

The coordination activities absorbed significant amounts of time and yet the user-innovators felt they were least prepared for this aspect of the projects. It was common for clinicians involved in the projects to experience a steep learning curve. The role of the NHS innovation hub in supporting the ePAQ project highlights that there is a critical point where user-innovators benefit from addition management support.

9.3.2 Section summary

The activity model emphasises three aspects of the nature of user-led innovation. First, the process of innovation shares characteristics with other models of innovation. In particular, there are parallels with Rothwell's third-generation innovation models. Second, the nature of user-led innovation is heavily influenced by the need to operate within "organised anarchies" such as public-sector healthcare organisations. Finally, user-led innovation is an example of sensemaking on the part of user-innovators and their teams.

User-led innovation as third-generation innovation process

The four cases are all examples of where neither technology-push nor market pull are the primary drivers of innovation. It is therefore useful to compare user-led innovation against the process models suggested by Rothwell (Rothwell 1994). Most of the innovations were in response to a problem experienced within the user-innovator's own organisation, rather than to apply new knowledge created research projects. However, for all the cases it was not always clear to the innovators what "market" their innovation was aimed at. User-led innovation is not a linear, sequential process, following either first-generation or second-generation patterns. Instead, the process has been shown to much be more characteristic of Rothwell's third-generation model of

innovation, in which a range of activities are linked in a complex iterative set of relationships. The contrast however is that formal role of the organisation in instigating and managing innovation projects is substituted for a self-appointed, self-managed structure, controlled by the user-innovator. This has the advantage of enabling an innovation-accepting and entrepreneurial culture. Unfortunately, the key corporate level factors, identified by Rothwell as underpinning third-generation innovation, are not present. Thus, user-led innovation projects operate despite minimal: top management commitment or visible support; integration to high level corporate or technology strategies; or long term financial commitment. It is this lack of corporate level support that prevents the progress of user-led innovation mirroring either an integrated or parallel development model.

Role of "organised anarchies"

A distinctive feature of the organisational contexts for all of the cases was that the projects did not fit into any coherent set of shared organisational goals. Within the PMS case, though senior management provided support to the project, the innovation developed bottom-up, in response to a crisis for which senior management had few solutions. The decision making involved in the user-led projects was therefore done in a situation of goal ambiguity. This suggests that the case organisations shared decision-making characteristics with organisational anarchies. Cohen *et al* suggest the "Garbage Can" metaphor for decision-making in such organisations, where decisions emerge from the relationship between a flux of problems, solutions, decision-making participants and choice opportunities (Cohen, March, and Olsen 1972). The cases exhibit some of these characteristics and show how user-led innovation emerges from organisational context in which there is little strategic imperative for the projects.

All the cases illustrated how user-innovators chose to exert energy solving a perceived problem. The choice of solution however was often linked to the existence of existing solutions or in the terms of Cohen *et al* "...an answer actively looking for a question" (Cohen, March, and Olsen 1972:3). User-innovators in the cases made choices to select familiar solutions and combine them: models of shared care, custom-written software, medical questionnaires etc. There is therefore a

sense that the activities supporting user-led innovation are based on the requirement to create a "brocolage" solution in situations where there is a degree of goal ambiguity.

User-led innovation as sensemaking

The activity model explicitly identifies a set of activities that support "assimilation and sensemaking" by user-innovators and their team. It would be a mistake however, to assume that this set of activities as a discrete stage of projects. Instead, it should be recognised that throughout in the cases studied, the user-innovators were continually making and revising their understanding of their projects. The other groups of activities can therefore be seen as all having a role in the on-going process of sensemaking (Weick 1995; Weick 2001). This was very well illustrated in the ePAQ case, where through each of the three development phases the user-innovator continued to make and revise the sense of the problem that he was addressing. Recognising the role of sensemaking in user-led innovation is important as user-innovators can both create valuable new knowledge, but could equally develop flawed cultural mindsets (Weick and Sutcliffe 2003).

9.4 Scope of the healthcare technology system created through user-led innovation.

This section addresses the research question:

What is the nature of the technology created through user-led innovation in the NHS?

The cases discussed in this research are very distinct from innovation projects based on commercial new product development. A major distinction is that the cases demonstrate the complex mix of hard and soft technologies on which user-led innovation focuses; in contrast to the predominant hard technology focus in new product development. It was highlighted in Chapter 4 how the overarching model of innovation being applied to the NHS is one based on technology transfer. The underlying assumption of the technology transfer perspective is that it emphasises the innovation of hard technology, such as new medical devices. Consequently, the support structure for NHS staff was oriented towards protection of IP and the subsequent commercial exploitation of associated IP. However, the four cases studies in this research emphasise how user-led innovation projects within the NHS are oriented towards the development of both hard and soft technologies.

The innovations created new soft technologies that complemented new or existing hard technologies. Two of the cases focused predominantly on innovation of soft technology: a pain management service design, and techniques for developing plaster study models.

In order to understand the scope of technology developed by user-led innovation, the cases suggest that it is important to recognise the role of the complete technology system. Chapter 2 introduced Orlikowski's model of technology (Orlikowski 1992) and discussed four distinct elements of technology: hard and soft technology; institutional structures and human agency. This section builds on Orlikowski's work and introduces a synthesised model of healthcare technology systems (HTS). The model is important as it highlights that an HTS is not neutral in relation to innovation, but conditions the choices and actions taken by user-innovators. Modelling healthcare technology as a system provides an analytical lens on the relationships between institutions, human agency and embedded hard and soft technologies. This model provides a novel analysis of the relationship between healthcare technology and institutions, enabling a better understanding of the complex and dynamic nature of the cases.

This section first sets out the model of an HTS. It then discusses the interactions that accompany a user-led innovation intervention. Finally, the section highlights the critical role of proto-institutions, both as a product of user-led innovation but also as a critical factor in the wider diffusion of innovations.

9.4.1 Sub-systems within the HTS

The model represents an HTS as comprising four significant sub-systems. These are hard technology, soft technology, the institutional framework associated with a technology and human agency related to the creation and use of technology. The model is shown in Figure 9.3.

Hard technology

Within the model, hard technology is a sub-system that includes the hardware and software relating to healthcare technology. Hardware includes machines, devices, pharmaceuticals and other physical artefact that that supports diagnosis, treatment, care, or operation of healthcare systems. As such, drugs, medical devices and healthcare facilities are all treated as hardware within the

model. Software relates to computer programs and any other mechanism in which logical processes are described in a form in which they can be implemented, independently of direct human actions. Examples of hard technologies in the case studies include the plaster study models, telemedicine software and computer-based medical questionnaires. The PMS case study is perhaps distinctive as, at the level of analysis of the service, there were no significant hard technologies influenced by the innovation.

Figure 9.3: Synthesised model of an HTS

Soft technology

Soft technology, as defined in Chapter 2, relates to two distinct sub-systems: technological competence and technology capability. Soft technologies comprise both tacit and explicit forms of knowledge. Technological competence is the ability held by an individual or organisation to use hard technology in practical situations. Competence is built-up through the use of hard technologies

over a period of time and can be understood in terms of single-loop organisational learning. In contrast, technological capability is concerned with how use of a hard technology is modified over time through double-loop learning processes. Technological capability is therefore concerned with the ability of individuals or groups to improve the level of competence achieved in using hard technologies.

The case studies illustrate several examples of technological competences influenced by the user-led innovation process. Technological competence encompasses both tacit and explicit knowledge relating to skills, procedures or large-scale service designs. Examples of these from the cases are summarised in Table 9.3.

Table 9.3: Examples of technological competences illustrated in the case studies

	Examples in the cases	**Tacit/explicit knowledge content**
Embodied knowledge and skills	Technique developed in the CLP case for producing plaster study models.	High tacit knowledge content
Procedural knowledge	Procedure allowing the clinical interview between consultant and patient to be supported by an additional source of information gained from the ePAQ questionnaire.	Mix of tacit and explicitly held knowledge
Service design	Service design that implements a collaborative care model of pain management and the bio-psychosocial model of pain. Redesigned service for the leg ulcer clinic that enables effective embedding of the telemedicine system.	High explicit knowledge content

In contrast, technology capability relates to the technology of improvement and change with respect to both technological competence and the wider HTS. Within the cases, both dynamic capabilities and performance improvement capabilities were illustrated. Most importantly to this research, user-led innovation processes themselves can be regarded as part of a dynamic capability. Table 9.4 summarises examples from across the cases.

Table 9.4: Examples of technological capabilities illustrated in the case studies

Dynamic capabilities	User-led innovation process System for the cross centre auditing of surgical outcomes on CLP patients ·
Performance improvement capabilities	Use of the PDSA cycle as a process of continuous improvement was evident in all of the cases Use of clinical trials in the LUTM and ePAQ. Evolutionary prototyping Evidence-based medicine

Institutions

The cases illustrated that a wide range of institutional structures affected, and in turn were affected by, the process of user-led innovation. Institutional structures were significant within the cases in

three ways. First, by conditioning the innovation process by creating enabling or retarding factors. Second, the institutional structures placed an inertia to change through retaining historical HTS elements. Finally, the institutional structures were critical in embodying learning gained over time within HTS, through processes of institutionalisation. This is critical in enabling knowledge gained, perhaps in a narrow localised setting, to be generalised, diffused and applied across the wider NHS.

Scott's model of institution (Scott 2001:77) is useful for analysing and differentiating between the various institutional structures within the HTS. The institutional context of the cases can be viewed in terms of the regulative, normative and cultural-cognitive pillars identified by Scott. The impact of these various pillars cut across formal organisation structures and reflects the impact of institutions ranging from "...the conscious to the unconscious, from the legally enforced to the taken for granted" (Hoffman 1997:36). The various institutions within the cases combined a range of regulative, normative or cultural-cognitive influences on the user-led innovation process. Table 9.5 illustrates the various institutional structures within the cases.

Table 9.5: Institutions within the cases

Institution	Example within cases
Formal organisations	NHS acute and primary care trusts NHS as a federation Department of Health NHS innovation hubs Intra-organisational patients services Inter-organisational patients services
Professional organisations and networks	Formal professional bodies for clinicians and other professions allied to medicine Informal networks of staff specialists
Institutionalised technologies	Evidence-based medicine Collaborative care Bio-psychosocial medicine Software engineering

The cases in this research emphasise three categories of institution of particular importance: formal organisations; professional organisations and networks; and institutionalised technologies. Formal organisations provided the context in which user-led innovation took place. These organisations had clear objectives and purposes and built up sets of rules, expectation and shared understandings that supported a specific purpose, such as providing acute acre services. The professional organisations and informal networks were however, more oriented towards professional practice and though possessing some regulatory powers, were predominantly concerned with setting norms of practice and establishing shared values and perspectives on healthcare practices. Finally, several

technologies themselves had corresponding institutions. These can be viewed as institutionalised technologies. Though often cutting across both formal organisations and professional networks, the institutional technologies had significant roles within user-led innovation projects. For example, evidence-based medicine, a soft technology for improving the practice of healthcare processes. It has become institutionalised through the development of regulative, normative and cultural-cognitive pillars, as illustrated in Figure 9.6.

Table 9.6: EBM as an institutionalised technology

	Regulative	**Normative**	**Cultural-cognitive**
Symbolic systems	Requirement by government for use of evidence-based treatments	Expectations of the vale	
Relational systems		Role of National Institute for Health Research in gathering and disseminating research evidence on health and public health	Embedding of training in EBM within professional education Recognition of advanced practitioners
Routines	Clinical trials Systematic reviews and meta-analyses of healthcare interventions	Professional expectation on the following of EBM principles and transfer into evidence-based practice	
Artefacts	Medical databases e.g. Cochrane library	Systematic review documents	Care guidelines

The implication of including institutional structures within the HTS, is that it recognises the extent to which soft technology becomes deeply embedded within institutions.

Human agency

The final sub-system within the model is the agency of individuals to make choices and take action in relation to healthcare technologies. Human action is central to the HTS with both hard and soft technologies created through human action. As noted in Chapter 2 however, human action is conditioned by structural factors such as institutions and existing technologies. This suggests that individuals have limited freedom to act, constrained by regulatory, normative or social-cognitive institutional factors.

Applying the three elements of agency suggested by Emirbayer and Mische of iterational, practical evaluation and projective (Emirbayer and Mische 1998), three modes of agency can be differentiated with respect to technology within the HTS.

Within the iterational mode, the agency of individuals is manifest in their habitual use of a technology. This implies an unconscious application of existing competences to apply existing

technologies to routine tasks and solve routine problems. This suggests individuals make unconscious choices to use existing technology, in specific ways, within the constraints of prevailing values, assumptions and cognitive frames. An example of this in the cases was in the PMS case, where many staff were resistant to change due to their choice to continue with current ways of working, in particular based around assumptions rooted n the bio-medical perspective on pain management. A second example was in the CLP case where once implemented the innovation became part of routine practice, the innovation was then forgotten about. In both cases, the choice made to use technology remained essentially unconscious.

The second mode of agency relates to the practical-evaluative mode. Within this mode, individuals make conscious choices about the use of technology to address evolving and novel situations. This includes conscious choices to improve existing competences, for example through continuous improvement. This mode of agency extends to the development and adjustment of existing hard technologies, but also the creation of new technologies. Three of the cases illustrate the practical-evaluative mode as central to the user-led innovation process. The LUTM, ePAQ and CLP cases all relate to actions taken by user-innovators faced by evolving situations, resulting in the adjustment of existing competences and also the creation and re-configuration of hard technologies.

The third mode of agency related to the projective mode and is concerned with strategic action, implying actions informed by double-loop learning. In relation to technology, this mode of agency is concerned with radical change to the *status quo* and is supported dynamic capability. Within the cases, there were examples of where the actions of user-innovators transcended simply responses to current problems, within contemporary frames of reference. The PMS and LUTM cases both demonstrate the re-design of healthcare systems based on shifts in underlying paradigms. These resulted in creation of novel soft and hard technologies.

9.4.2 Interactions between the sub-systems

The strength of the HTS model is that it presents an integrated view of the relationship between hard and soft technologies, human agency and the institutional context. These build on the set of interactions suggested by Orlilowski's structurational model of technology (Orlikowski 1992), while incorporating the distinction between hard and soft technologies.

However, the HTS model is distinct from Orlikowski's model as it adopts an institutional view of technology, recognising the independent existence of institutional structures from human agency. In contrast to a structurational view, the model recognises that the institutional structures develop over time, through the ongoing interaction with both hard and soft technologies. Institutions therefore reflect not just current hard and soft technologies but also those in the past. This can lead to the institutional structures remaining out of step with both hard and soft technologies.

The model incorporates seven interactions between the four sub-systems.

- Structural influence on humans interacting with technology
- Hard technology as a product of human action
- Hard technology facilitating and constraining human action
- Hard technology influencing institutional properties
- Soft technology as a product of human action
- Soft technology as facilitating and constraining human action
- Soft technology influencing institutional properties

9.4.3 Proto-institutions as products of user-led innovation

The model of HTS is useful as it suggests the challenge in managing innovation diffusion is not simply a technology transfer problem, but one based on institutional change processes. The model suggests that innovation diffusion is not simply a case of reproducing hard technology, but requires the reproduction on a wide scale of the institutional framework supporting associated technological capabilities.

An important element of the user-led innovation process within the cases was localised change to the institutional structures. These supported implementation of both hard and soft technologies. The localised institutional change in the cases can be regarded as a resulting in development of proto-institutions. The findings of the research suggest that the resulting proto-institutions are significant elements in the innovation diffusion process. This raises the question of what constitutes a viable proto-institution and at what stage is it adequately mature to become more widely institutionalised?

The challenge for managing the institutionalisation process can be broken into three steps based on recognising the critical components of the proto-institution; recognising the point when the proto-institution has reached a level of stability and maturity; and identifying strategies to support the wider institutionalisation process.

Critical carriers that underpin the proto-institution: the first challenge is to recognise the critical carriers that underpin the proto-institution that has been created during the innovation. Within the cases, there is evidence that several carriers were vital to the proto-institutions formed in the innovation projects. These are summarised in Table 9.7. The explicit identification of these carriers may not always be straightforward, as they may have become so routine that they are not even perceived as innovative any more. This is exemplified by the CLP case in which there was a sense that the innovation had become part of the normal routine of the operating theatre.

Assessing maturity of the proto-institution: The second challenge is assess the extent to which the proto-institution has reached a sufficiently mature state. This is the point where carriers have stabilised and are effective in supporting the innovation. The carriers must also be capable of wider institutionalisation. This is concerned with their propensity to be codified and abstracted.

Strategies for facilitating the broader institutionalisation: The third challenge is concerned with identifying strategies for facilitating the broader institutionalisation process.

Maturity of proto-institutions and innovation diffusion

The point at which a proto-institution has formed is a critical stage in a user-led innovation project. It marks the point of the project when processes of codification and abstraction are needed to facilitate the diffusion process. The cases in this research suggest that there will be point where the emphasis of the project must change from development to diffusion activities. This is shown as point 'A' in Figure 9.4. This represents the point at which the project has developed a mature and stable proto-institution.

Table 9.7: Institutional carriers within proto-institutions underpinning innovations in the cases

	LUTM	ePAQ	CLP	PMS
Symbolic Systems	• Commitment to a shared care model for the whole service process across secondary and primary care providers	• Increased emphasis on QoL assessment and incorporation into clinical practice • Commitment to earlier triage of patients	• Better quality study models will underpin the wider system of long term surgery evaluation.	• Multidisciplinary triage • Exit strategy from survive integral to care plans • Service aim to:"adapt patients to their pain" • Bio-psychosocial view of pain integral o the service • Collaborative model of care central to service design
Relational systems	• Community-bas staff given direct access to clinic staff • Nursing staff encouraged to emphasis skills in research	• Greater level of health democratisation due to increased scope for patients gaining understanding of medical issues •	• Technologist empowered to work in operating theatre context • Recognition that non-clinicians may have skills important within operating theatre •	• Definition of care plan made the responsibility of the PAT • Nurses, physiotherapists empowered to make decisions about care plan with referral to consultants • Ownership of PMS shifted closer to the PCTs and away from secondary care trust. • Decision-making delegated from secondary care specialists to PCT-based specialist staff • Consultants from secondary care work in primary contexts and educate PCT staff, resulting in replication of knowledge from secondary to PCTS
Routines	• Direct communication between community-based staff • Community-based staff expected to engage with development of care plans	• Reliable system for gathering pre-clinical interview information from patient	• Process of taking the mould for the study model embedded into the normal operation of the operating theatre.	• Care pathways • GPs take on routine management of pain. • Patients and carers take a greater role in pain management • Nursing staff are required to be advanced practitioners, rather than only carers
Artefacts/ objects	• Processing capability of wound photographs • Messaging system	• Touch screen computers • Web interface	• Study model of mouth, lips and face	

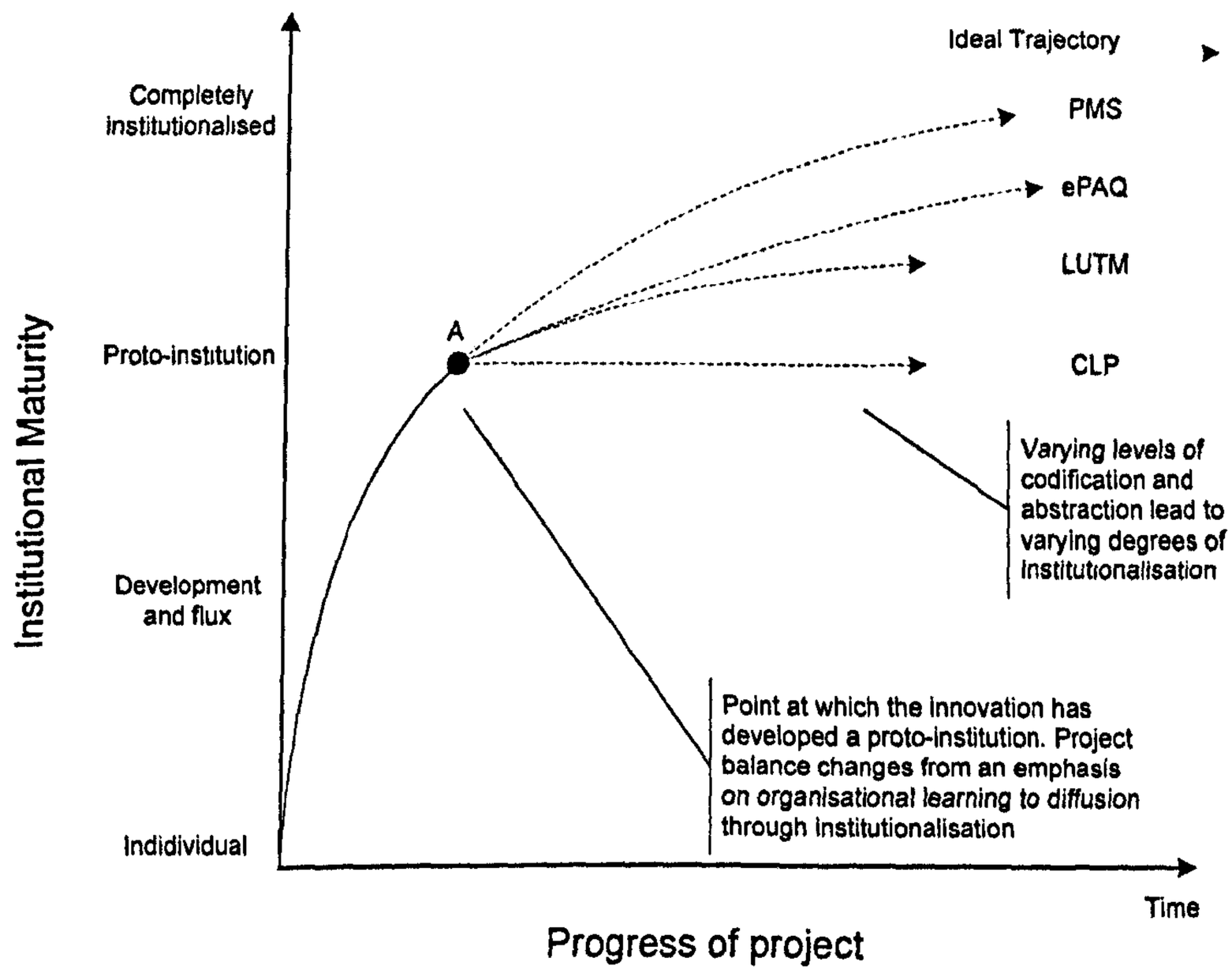


Figure 9.4: Proto-institutions and institutional maturity

The four cases all reached the point of having developed viable proto-institutions, but the extent to which further institutionalisation developed varied between the cases. In the CLP case, it was apparent that no significant institutionalisation outside of the original setting occurred. The LUTM case was again successfully implemented into the original setting but though mechanisms were put in place to diffuse the software, less effort was put into the institutionalisation process. In contrast, the PMS cases demonstrated steps that enabled both the codification and abstraction of the proto-institutions. Point A can therefore be seen as a critical point as it represents the stage of the project where additional support and expertise may be needed by a user-led innovation project team.

9.4.4 Development and diffusion of a proto-institution

One of the most significant themes raised in the PMS case was the process through which a proto-institution of pain management services was developed and then diffused. In contrast to the LUTM and CLP cases, the user-innovators were both proactive and successful in diffusing the proto-institution that they had developed around the PMS.

The creation of the proto-institution of pain management services was dependent on the establishment of several institutional carriers. These are shown in Table 9.8. Three categories of carriers were relevant to the case: symbolic, relational systems and routines. The proto-institution represented the essential institutional structures that had to be diffused in order to re-create the service in other contexts.

Table 9.8: Institutional carriers underpinning the PMS

Pillars / Carriers	Regulative	Normative	Cultural-cognitive
Symbolic Systems	Rules, laws All patients referred should have an initial multi-disciplinary assessment of their condition, resulting in a care plan. All patients should have an exit strategy from the service defined in their care plan	Values, expectations Bio-psychosocial view of pain management rather than a narrow bio-medical perspective Collaborative care by specialists, GPs, carers and patients	Categories, typifications, schema Purpose of the PMS is to "adapt patients to their pain" rather than seek to cure.
Relational systems	Governance, power systems Definition of care plan made the responsibility of the PAT Nurses, physiotherapists empowered to make decisions about care plan with referral to consultants	Regimes, authority systems Ownership of PMS shifted closer to the PCTs and away from secondary care trust. Decision-making delegated from secondary care specialists to PCT-based specialist staff	Structural isomorphism Consultants from secondary care work in primary contexts and educate PCT staff, resulting in replication of knowledge from secondary to PCTS
Routines	Protocols, operation procedures Care pathways	Jobs, roles, duty GPs take on routine management of pain. Patients and carers take a greater role in pain management Nursing staff are required to be advanced practitioners, rather than only carers	

The strategy adopted for diffusing the proto-institution to other sites is an important part of the PMS case. While at the time of the research the PMS model was yet to become a "standard" for NHS pain management services, it was evident that the process of institutionalisation had started. Two strategies were used by the user-innovators to support the institutionalisation process.

Formal measures taken to aid diffusion

The most significant element of this was the active role that the PM Consultant adopted in professional bodies to standardise the care pathways established in the PMS as national care

guidelines. The PM Consultant's specialist society, the British Pain Society (BPS) was very supportive of the project. It saw the triage system as an important strategy for reducing waiting times and so fitted in with its own initiatives in improving patient care. The PM Consultant was an active member of the society and chaired the society's "Clinical Information Special Interest Group". The BPS has had a role in legitimising the care pathways as a "best practice". Her position in the BPS has also allowed her to influence DoH initiatives. The engagement of SUHT staff with professional and other institution has been an important diffusion strategy.

The care pathways have been the key mechanism for diffusing the innovation. The PM Consultant reflected that they

> ...disseminated to quite a few places [and] ...have been a really good thing as I have been able to influence policy. (Consultant)

The development of generally applicable care pathways was difficult, requiring the abstraction of key service principles:

> ...this is hard, as you have to pull out things that are very general and not specific to our service. (PM Consultant)

In addition to the formal care pathways, the BPS commissioned information packs that support other trusts in contextualising the care pathways. The pack provides guidance on issues such as workforce planning and emphasising the inter-disciplinary working required between the pain service and other teams. It also contains useful specimen documentation such as standard letters.

Informal measures taken to aid diffusion

Project staff used informal mechanisms to support diffusion. The PM Consultant felt she had provided emotional support to other trusts looking to implement the pathways. The team had been active in providing support to other hospitals who have asked for advice. The support included hosting visits to the PMS by staff from other trusts and giving presentations about the service.

Several other trusts have visited the service with a view to learning how a similar service could be set up. When people come to look at the service the PM Consultant stressed that they needed to think about how to implement the systems in their own context, rather than simply copying the

service exactly. These visits provide the opportunity for other trusts to understand process of implementation of the new system. This includes the need to:

- educate staff in what networks of services and relationships are available;
- include primary care staff, especially GPs, in the implementation;
- recognise that the general principles encapsulated in the guidelines need to be careful contextualised.

The strategy for diffusing the proto-institution can be seen as based on one of codification in terms of publishing care pathways and other guidelines. It can also be seen as an abstraction process, where the elements of the PMS are developed into more generalised principles.

9.4.5 Section summary

The model of an HTS presented in this section is a clarification of Orlikowski's structurational model of technology. The model has been developed specifically in the context of healthcare technology and reflects the close coupling between hard and soft technologies within the sector. This integrative view of healthcare technology is critical as all hard healthcare technologies are used in relation to soft technologies encompassing skills, knowledge, procedures and processes. The healthcare context is also one that is strongly influenced by institutions that impose regulatory, normative and cultural-cognitive influences on the use of technology and the actions of individuals in relation to it.

This section has emphasised how the use of the model of HTS is useful in understanding the technological focus of user-led innovation in the NHS. First, it provides an integrated view of the technological innovation in terms of both hard and soft technology. Second, it emphasises the role of structure and agency in the innovation process and that the resulting innovative system is an emergent property of interactions between hard/soft technologies, institutional structures and human agency. Finally, the section highlights proto-institutions as significant products of user-led innovation. Proto-institutions are a product of the early stages of institutionalisation of soft technologies and so when attempting to diffuse technological innovations, the proto-institution is a critical element represent the set of institutional structures that support the implementation and use

of innovative hard/soft technologies. When considering how to diffuse user-led innovations the research suggests that attention should be paid to mechanisms that enable the proto-institution to become more widely established. For example, this may be done through codification and abstraction processes.

The following section discusses the various ways in which evaluation is used by user-innovators.

9.5 Strategies adopted by user-innovators to evaluate their innovations.

This section addresses the research question:

> How and for what purpose do user-innovators evaluate their innovations as they are developed?

One of the key characteristics of user-led innovation in the NHS is that it is a predominantly bottom-up process. This might suggest that selection of evaluation methods by user-innovators is based on a contingency. This section identifies that four generic approaches to evaluation were used in the cases. The discussion suggests that their selection and use is based on contingent factors. However, the approaches adopted can be viewed as relating to three distinct purposes: assessment of the efficiency and effectiveness of the innovation; build confidence, trust and reputation in the innovation with users and potential users of the innovation; and as means of promoting the power interests of user-innovators. However, the evaluation strategies are themselves institutionalised technologies that condition the choices made by user-innovators in following their projects.

9.5.1 Evaluation within the cases

The strategies adopted for evaluating health care technologies were distinct in each of the four case studies. One of the striking points about the cases is the variety of approaches that were used to evaluate technologies.

In the LUTM and ePAQ cases clinical trials were used to evaluate aspects of the innovations. Use of clinical trials, providing a "gold standard" of evidence, are perhaps the most legitimate ways of

evaluating healthcare technologies as they fit within the EBM paradigm. In contrast several cases used applied a continuous improvement based on the PDSA cycle. Though commonly used as a legitimate approach in other sectors, PDSA could be seen as less rigorous, within a healthcare context than approaches based within the EBM paradigm. The PDSA cycle evaluation however enabled development of the innovations through prototyping. The cases illustrate that when it was impractical to test a range of solutions, either through clinical trial or be PDSA, evaluation was done on the basis of a professional judgment. The final mode of evaluation identified involved reflection on the clinical use of the innovation by the users who had adopted it. In this mode of evaluation, the technology is based on the personal assessment of the innovation by the team and early adopters. Through the use of the technology, an assessment was made about the the technology in context, often based substantially on tacit understanding of the technology developed by users. The evaluation of the technology in this way is not admissible as "scientific proof" of a technology's effectiveness; but its use seems to be a powerful factor in facilitating adoption of innovations. Users who have a positive view of a technology would often encourage the adoption of the innovation by other colleagues or staff from elsewhere.

LUTM: This case is perhaps one of the best examples of where multiple approaches to evaluation were taken. The solution to the clinic's problems was formed by selection of options based on the professional judgment of the vascular surgeon, using his clinical and software development experience. The use of an evolutionary, working prototype also represented the application of a PDSA approach to improvement. The primary use of the clinical trials in this context can be seen as to provide an objective account of the effectiveness of the LUTM. Secondary motives were to: support the political activities of the vascular surgeon in gaining wider acceptance of the technology; increase project credibility in order to gain additional funding; and to provide evidence to defend the professional decisions made by the vascular surgeon in pursuing the innovation. The LUTM provides the most stark example of how powerful use of the technology can be in evaluation. It was clear that by the end of the clinical trial both the clinic and community-based nursing staff had accepted and recognised the effectiveness of the LUTM, despite the analysis of the clinical trial being incomplete.

ePAQ: In common with the LUTM case, the ePAQ project included several clinical trials that evaluated the questionnaire and software interface. The results validated the reliability and repeatability of both the questionnaire and the interface. However, the clinical trials did not provide an assessment of the ePAQ's impact on the service redesign. Ironically, the legitimacy endowed by the clinical trial may have resulted in the further development of ePAQ being restrained. This restraint was rooted in the belief of consultant A that once validated by clinical trial certain aspects of the ePAQ, in particular the user interface, should not be modified. This was in contrast to the professional judgment of the SHD who believed the system software should be modified to conform to industry norms for software interface design. Consultant A demonstrated use of professional judgment when assessing the various options for ePAQ's design, his belief that the system needed to be suitable for the archetypal "old lady" is a prominent example of this. This use of professional judgment in assessing options however risks innovations becoming trapped within, sometimes implicitly stated, sets of assumptions.

CLP: The CLP case is distinct from the other cases as it did not use clinical trials to evaluate the innovation. In contrast, the CLP innovation was concerned primarily with the innovation of the improvement system for CLP surgery, essentially denoting a change in how clinical trials are operated and analyzed. The evaluation of the CLP project is therefore more based around a PDSA cycle and professional judgment of the technology. The very low level diffusion of the innovation meant that there was no opportunity for other users of the technology to provide any use-based assessment of the innovation.

PMS: The PMS case was complex as it was unrealistic to operate a clinical trial, due to the massive organisational change required. Instead a complex information gathering and analysis system was set up on an *ad hoc* manner to evaluate changes as they occurred and where necessary to plan further change. This resulted in a formal system of evaluation close to a conventional PDSA cycle. The use of PDSA, over the reliance on clinical trials, has been that the evaluation system was able to develop with the service through a series of continuous improvement cycles. However, as noted in the cases several changes to the service design were made on the basis of professional judgement with no other evaluation done prior to implementation.

9.5.2 Generic approaches to evaluation

The range of approaches to evaluation illustrated in the cases, suggest that within user-led innovation projects, evaluation serves several purposes. This suggests evaluation is not just used in a purely instrumental manner to assess efficiency or effectiveness of an innovation in objective terms. Instead, evaluation can have other purposes. The four evaluation approaches identified in this research were used in very specific ways.

EBM

The adoption of the EBM paradigm and the use of controlled clinical trials is now the most widely accepted evaluation approach used in healthcare. Within a publicly funded service, such as the NHS, clinical trials form the core of the evidence-based approach to practicing medicine, that not only ensures treatment is effective but also that the services provide value for money. The use of clinical trials is therefore critical ensuring that any new technology has scientifically tested data to back up its use; clinical trials therefore lend scientific legitimacy to healthcare technology.

The dominance of the EBM paradigm means that clinical trials are always likely to be central part of any user-led innovation project. Without a clinical trial, it is unlikely that a technological innovation will be viewed by clinicians or other stakeholders, as either effective or safe. The strength of using a clinical trial is that it lends credibility to a project, opening up sources of funding and lowering barriers to innovation diffusion. The clinical trial can also confer political legitimacy on a project, potentially adding the lobbying of stakeholders or even defending the actions of user-innovators against criticism. The clinical trial is however problematic in user-led innovation. First, it can be difficult to set up for some innovations, especially where radical service re-design takes place. Second, unlike clinical trials of a distinct device or drug, it is often difficult to reverse the process of trialling the innovation. As shown in the LUTM and PMS cases, there was a significant change in the expectations, attitudes and skill sets of staff and patients when implementing the innovation. The implementation of the LUTM and PMS innovations was non-reversible and so assuming the trial to be a "constrained experiment" that can be forgotten or its effect reversed is misguided. The LUTM and PMS projects showed how the implementation of the innovations invoked significant levels of organisational learning and so repeating the same trial

would not be possible in that organisational context. Finally, it seems likely that for many user-led innovations the availability of time to carry out a clinical trial is simply not available. The PMS case illustrates how the user-led innovation was in reaction to a crisis situation in which action had to be taken based on professional judgement, rather than "hard evidence". Overall, clinical trails have a role in both proving technologies developed through user-led innovation and providing them with some sort of legitimacy. The clinical trial is however, a blunt instrument that may hold back innovation by creating delays or blocking creativity. Especially for innovations impacting on service design the clinical trial may not adequately take into account the extent to which contextual differences e.g. between different NHS trusts, impact on the performance of an innovation.

PDSA

In contrast to clinical trials, the use of a PDSA improvement cycle offers several advantages for user-led innovation in the NHS. The first of these is that it provides a flexible and long term evaluation method. The use of PDSA may provide a quickly established approach that can evolve to fit the needs of the on-going project. This makes it particularly applicable to the evaluation of innovations that incorporate significant service re-design or where development depends on the evolution of a prototype. As illustrated in all four cases, operating within the PDSA approach means that incremental changes could be made quickly in response to problems to which the user-innovators became aware. Finally, the PDSA approach can probably aid the local implementation of innovations. The use of PDSA does present some problems for the user-innovator. First, in comparison to a clinical trial, the results of the innovation do not have the same legitimacy. Secondly, success will be dependent on the involvement of staff with an interest and ability to review critically the performance of an innovation. Finally, the PMS case illustrates the problems of creating appropriate information systems to collect and present information about the on-going progress of a project. Especially in the NHS, significant IS effort has been put into developing systems that measure against national performance targets. This means that there is little resource available for development of systems with a finer level of information granularity, as would be needed for measuring and monitoring the impact of service re-design on specific treatment outcomes.

Professional judgement

Within the healthcare sector, there is a tension between the EBM paradigm and the power held by clinicians to exert their own professional judgement. A dilemma exists because though the EBM paradigm is widely advocated by NHS clinicians, managers and policy makers, the definition of what constitutes evidence is still contested. For clinicians in particular it is possible that the evidence presented to support a specific procedure or technology, will be subject to their own cognitive filters. Professional judgement is therefore an important mechanism when evaluating a technology. The advantage of professional judgement is that clinicians can see the potential of a technology, when due to its immaturity it still has a relatively low performance level compared to an existing technology. Clinicians may also be able to see beyond a specific context in which a clinical trial was done, or see a specific application within their own practice. Professional judgement can be powerful evaluation mode within a user-led innovation project, as the judgment can be made faster than relying on evidence-based methods or operation of a PDSA cycle. Reliance on the professional judgement of a clinician also recognises the intellectual qualities of clinicians as well educated and intelligent people; making them well placed to arbitrate on the efficacy of a technology. The reliability of professional judgement in evaluation is however subject to problems of the judgement being constrained by a clinician's own cognition.

Reflection on use

The fourth mode of evaluation is the reflection on the clinical use of a technology the individuals or groups who have adopted the innovation. The cases illustrate how staff modified their own working practices and assessed the effectiveness of a technology through using it. This mode of evaluation has great potential as it assesses the technology in a real setting and is an integral part of the implementation process. The reaction of staff to using the technology will also represent their tacit understanding of the technology's usefulness. The cases reflect the scope for building these assessments into user-led innovation project in a systematic manner, for example by implementing an action research framework on the project. This mode of evaluation emphasises the relationship between the technology and the context and so can be seen as complementary to evaluation done using a clinical trial.

9.5.3 Who was the evaluation for?

A reason for the range of evaluation approaches adopted within user-led innovation projects is partly due to the range of stakeholders requiring judgements on efficiency or effectiveness. The cases suggest that evaluation serves three groups of stakeholder: the user-innovator themselves; users and other stakeholders of the innovation within the organisation; and stakeholders based outside the user-innovators' organisations.

Evaluation was often based on the need for user-innovators to prove to themselves that the technologies that they had created were effective. In addition, due to the bottom-up characteristics of the projects, there were few formal management demands for evaluation data, or imposition of a specific evaluation methodology. User-innovators therefore had a broad choice in how they chose to evaluate their innovations.

A second group for whom the evaluation of innovations was aimed are stakeholders within user-innovators' own organisations. The function of evaluation from their perspective was to gain their acceptance of the innovation by validating the novel technology. This was to ensure that the stakeholders trusted the technology in order to either adopt it or to invest in its further development. Such investment taking the form of financial backing or availability of the necessary resources required for further development.

The role of evaluation in relation to external stakeholders was primarily to either gain legitimacy e.g. from the healthcare community, or to secure external investment in the innovation. Evaluation was critical in ensuring that the user-innovators' peers within professional networks accepted the innovations. Peer-reviewed publications and presentations at conferences were often the main conduit for evaluation results and so evaluation methods were often prescribed by the user-innovators' peers.

9.5.4 Three functions of evaluation

The range of approaches used in the cases was contingent on the nature of the innovation, the stakeholders for whom evaluation data was required and the purpose of evaluating the innovation itself. The cases demonstrate that the function of evaluation was not just to provide an objective

measure of the efficiency or effectiveness of the innovation. Instead, evaluation was also to aid the development and understanding of the innovative technology and to act a political tool to reduce resistance to adoption and other barriers to the progress of the innovation project. In short, evaluation as suggested by the classic clinical trial is not a neutral process within user-led innovation projects. The function of evaluation in user-led innovation in the NHS is therefore threefold. First, as an instrumental and objective attempt to assess whether a technology achieves a satisfactory level of efficiency or effectiveness. Second, to facilitate the ongoing development of the meanings and purposes attributed to a technology by users and other stakeholders of the innovation. Thus, evaluation is part of the process through which the innovation is socially constructed. Finally, evaluation processes provide user-innovators with a level of power in relation to innovation and is a means of enabling the user-innovator to achieve specific goals. Control over the evaluation process is a substantial power resource for the user-innovator.

Instrumentality

Evaluation is carried out to demonstrate to the user-innovator themselves and other stakeholders that an innovation has achieved improvement in efficiency or effectiveness. This is primarily to inform on the progress of the innovation process and to guide future development. To this end, user-innovators were selective in the performance indicators that they measured.

A recurring problem in the cases was the difficulty in gaining appropriate evaluation data. This was particularly acute with respect to the effectiveness of service re-design. At the core of this problem is that high-level performance indicators are an emergent property of the whole healthcare system and so creating an unequivocal link between system-level process improvement and development of a specific technological innovation is problematic.

Choice of indicators used in evaluation is also problematic for user-innovators. As noted by Christenson (Christensen 2000), the performance measures for radical technologies differ significantly from current technologies. The basis for evaluating service-level performance will therefore be difficult where measures of performance differ. This may be important in cases of radical innovation on which the measures of performance differ from those used for judging current technologies.

Social construction of technology

The evaluation process can be an important activity in supporting how the adopters' understanding of technological innovations develops over time. To this end, evaluation can be seen as central to the social construction of the technologies that result from user-led innovation (Bijker 1995). The evaluation process has a role in identifying and engaging with the specific relevant groups using a technology. Through reflection on the use of the innovation, evaluation influences the process of interpretive flexibility and ultimately the rhetorical closure on a technology. This is illustrated in the cases where the purpose of innovations developed during their development. For example, in the ePAQ case the final understanding of ePAQ as a web-based service was very different from its original concept of a narrowly based clinical questionnaire.

The role of evaluation in the social construction of user-led innovations highlights the scope for interpretive evaluation. This mirrors similar calls for interpretive evaluation more generally in information systems field and highlights that the purpose of evaluation is not simply to generate performance indicators but also to "...deepen understanding and to generate motivation and commitment (Walsham 1999:374). The evaluation process is therefore not a distant, objective process but one that should be seen as an active intervention within a healthcare technology system.

Power resource

The third function of evaluation is as a tool to enable user-innovators to pursue their own interests. Evaluation is a political process and a scientific rational view of evaluation provides an incomplete picture. As noted within evaluation processes within information systems development:

> The rational elements are tools used by participants to gain new ground or to protect ground already won. They also serve as "facades" to mask political motives and legitimise self-interest. (Franz and Robey 1984)

Within a healthcare context EBM provides an example of where evaluation is a rational objective process however, the power to choose how the clinical trial is conducted and its results published is significant. Control over the evaluation process represents a potential resource that enables user-

innovators to pursue their own interests. This is illustrated in Table 9.9 in which Lukes' three dimensions of power are considered in relation to evaluation strategies illustrated within the cases.

Table 9.9: Role of evaluation in enabling user-innovators to achieve their purposes

	Clinical Trial	PDSA	Professional judgement	Evaluation through reflection on use
Power over decision-making	User-innovator chooses what to evaluate, where, when and method used for CT	Reduces the range of stakeholders involved in the decision-making process, making decisions more localised and potentially subject to less scrutiny	Professional status of clinicians legitimatise professional judgement and subsequent actions.	For consultants leading innovation projects their organisational power was often such that it is unlikely that the decision to implement their own innovation was unlikely to be opposed, except by other consultants.
Power over agenda setting and informal influences on decision-making	Potential for user-innovators to publish evaluation results selectively. CT results used to influence opinion in wider community of specialists	User-innovators set performance criteria to be monitored and assessed	Enables innovation projects to be created outside the normal formal decision-making processes	By implementing an innovation and developing it through prototyping processes, the user-innovator has a means of
Power to shape preferences, values and norms	Long term clinical trials become part of the normal way of doing things	By embedding an innovation within an operational context the stakeholders of innovation will gradually see the innovation as a normal way of doing things	User-innovators leadership can deeply influence the preferences, values and norms of the staff involved in innovation	By implementing an innovation it is made "normal" and hence shapes the preferences, values and norms

All four of the approaches to evaluation illustrated in the cases show political dimensions and illustrate that the process of evaluation is not politically neutral and in all the cases there was use of evaluation techniques to enable user-innovators to development and implement their projects.

9.5.5 Section summary

This section has identified four generic approaches to evaluation in user-led innovation projects. The cases suggest that the choice and use of these approaches is based on a need to address the needs of specific stakeholders. However, the process of evaluation is not a neutral process or one based only on rational scientific approaches. Evaluation was also used by user-innovators to support the on-going social-construction of the purposes and meaning of new technologies, by staff adopting the innovation. Finally, evaluation was shown to serve a political purpose that enabled user-innovators to legitimise their innovations, exert control on decision-making around the innovation, and to remove potential conflict over the innovation.

9.6 Chapter summary

This chapter has made several important contributions to the development of a theory of user-led innovation. The contributions are the:

- distinct characteristics of user-led innovation within the NHS;
- development of an activity model underpinning the user-led innovation process;
- development of a model of healthcare technology systems that underpins an understanding of the process of user-led innovation;
- identification of the role of proto-institutions in the user-led innovation process.
- and, an analysis of the multiple roles of evaluation within user-led innovation.

These contributions are important as they suggest a shift in thinking from supplier-led innovation, in which the balance of power resides with technology suppliers, to one based on innovation conceived, lead, developed and controlled by technology users. The implication of this is that the facilitation of user-led innovation needs to be re-assessed, especially where support is oriented to technology transfer models of innovation. This research has highlighted that user-led innovation requires careful facilitation to ensure that benefits of user-led development based in technological competence, capability and institutional development are not lost in a rush to the relative narrow benefits of commercial exploitation of IP.

Chapter 10: Conclusion

This chapter concludes this thesis. It reviews how the research has achieved the aims and objectives set out in Chapter 1and summarises the main contribution to knowledge that has been made. Finally, further areas of research arising from the work are suggested.

10.1 Overview of the thesis

This thesis has set out an account of research carried out into user-led innovation of healthcare technology in the UK National Health Service (NHS) and presented the results of that research. The research has made a contribution to a better understanding of the phenomenon. In particular, it has made progress in relation to the research aim of correcting the imbalance within the existing literature towards industrial contexts.

The research problem generated from this aim was the production of a reliable and valid perspective on patterns of user-led innovation within the NHS, and the drivers and constraints that predispose them to be successful or to fail. The research was conducted using an interpretive, multiple case-study methodology. Each of the chapters within the thesis reflects specific research objectives. Figure 10.1 illustrates how each chapter of the thesis contributed to the achievement of the research objectives. A short summary of how the research objectives were achieved is provided below.

To review the literature that underpins an understanding of the phenomenon of user-led innovation the NHS

Chapter 2 provides an in-depth discussion of the literature that underpins an understanding of user-led innovation. It first reviewed the literature regarding the nature of technology and considered the role of institutions and institutional change in relation to hard and soft technologies. It then looked at literature relating to user-led innovation and its relationship with other modes of innovation. A third theme was the knowledge management processes that underpin user-led

innovation particularly with respect to the process of absorbing and translating knowledge. Finally, the review assessed the NHS as a context for innovation and considered how its culture, structure and policy frameworks might support user-led innovation. The review recognised that the NHS represents a complex context for innovation and though provision was made for implementing technology transfer processes, doubts existed, as to whether this was an appropriate model of innovation for the NHS.

Set out an appropriate methodology that will enable rigorous investigation of user-led innovation in the NHS.

Chapter 3 sets out the rationale for the choice of methodology used in this research. It discusses the methodological framework adopted for this research and sets out the research design used in the research. The multiple-case study approach that was adopted is discussed, along with reflections on the process followed.

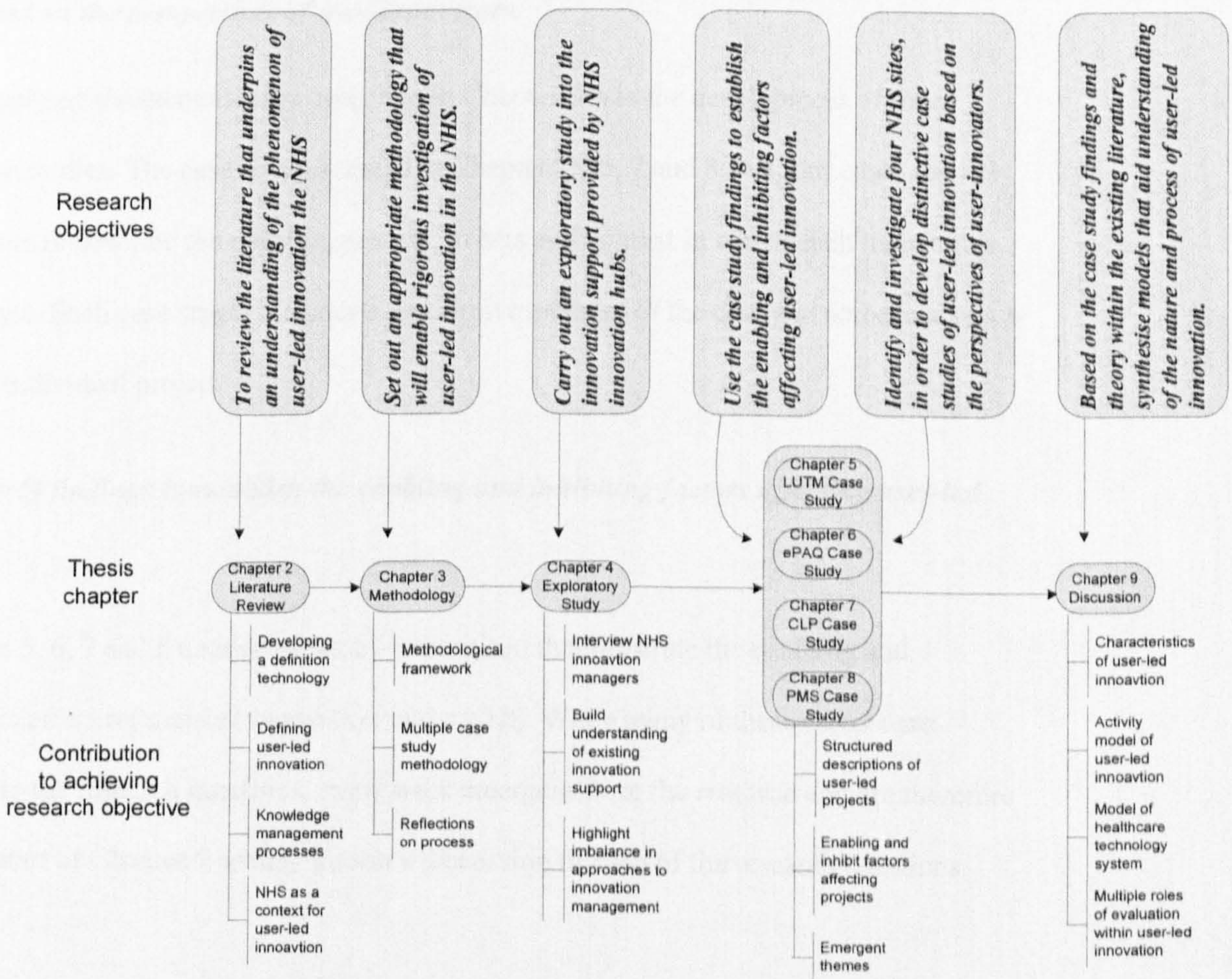


Figure 10.1: Relationship between research objectives, thesis chapters and achievement of research objectives

Carry out an exploratory study into the innovation support provided by NHS innovation hubs.

Prior to selecting the case study sites, an exploratory study was carried out. An overview of the findings of this study is given in Chapter 4. The study involved the interviewing of staff working within the NHS with the role of supporting NHS innovation. A major finding of this study was that support was available for user-innovators within the NHS, from both NHS trusts and external organisations. A major potential source of support was from the NHS innovation hubs. Unfortunately, the exploratory study highlighted that much support for user-led innovation was focused predominantly on commercial exploitation of IP, with technology transfer processes, similar to those found in universities, becoming the norm for this support. The study raised the question of whether the prevailing technology transfer models of innovation support were appropriate for user-led innovation projects within the NHS.

Identify and investigate four NHS sites, in order to develop distinctive case studies of user-led innovation based on the perspectives of user-innovators.

The result of applying the methodology described in Chapter 3 was the development of four interpretive case studies. The cases are presented in Chapters 5, 6, 7 and 8. All four cases use a common structure to describe the purpose, process, events and context in which each innovation project took place. Each case report includes a descriptive element of the case and some analysis at the level of the individual project.

Use the case study findings to establish the enabling and inhibiting factors affecting user-led innovation.

Within Chapters 5, 6, 7 and 8 a range of issues were raised that illustrate the enabling and inhibiting factors affecting user-led innovation in the NHS. While many of these factors are directly related to the research questions, many were emergent from the research and are therefore included at the start of Chapter 9 as they inform a discussion of each of the research questions.

Based on the case study findings and theory within the existing literature, synthesise models that aid understanding of the nature and process of user-led innovation.

Chapter 9 reviews and draws general conclusions about each of the research questions. Several theoretical models are developed that underpin an improved understanding of user-led innovation. The models developed constitute some of the major contributions of this research and are summarised in the next section.

10.2 Major contributions made by the thesis

The research was guided by questions identified with the aim of gaining a better understanding of the phenomenon of user-led innovation with the UK NHS. Despite existence of anecdotal evidence that user-led innovation occurred, little was understood of the processes that underpinned it and whether the available support was effective. Furthermore, the modernisation agenda within the NHS had placed significant value on the exploitation of NHS-developed innovations, resulting in a raft of government policies. In answering the research questions this thesis has made a significant theoretical contribution in establishing user-led innovation as a distinct mode of innovation and creating a foundation for further research. In this conclusion, it is useful to reiterate how the thesis adds to current knowledge and potentially informs future innovation policy and practice in the NHS.

This research has established user-led innovation as a theoretically useful and coherently defined mode of innovation. The distinction drawn between supplier-led and user-led innovation made in Chapter 2, has been extended by identifying specific factors that characterise user-led innovation. It has been shown that user-led innovation in comparison with other generic models of supplier-led innovation, such as Rothwell's third-generation model of innovation (Rothwell 1994), share some common features especially with respect to the interaction between research-push and demand-pull. However, the organic process of user-led innovation does not exhibit the close coupling or sophisticated innovation management of the fourth and fifth generation models. However, the lack of sophistication exhibited by user-led innovation processes, in comparison to these models, needs to be balanced by its emergent nature and the differences in its ascribed purposes. The cases illustrate how the broadly-based purposes of user-led innovation extended to include innovation of

both hard and soft technology, and the institutional structures around their use. This is a very different focus to Rothwell's models that focused primarily on science and technology applied to the creation of commercial products; providing little insight into the institutional change required for successful innovation.

The diverse activities and interests of users was shown to be a distinguishing feature of user-led innovation, especially when compared to users within the lead-user (Hippel 2005) or open innovation (Chesbrough 2003) paradigms. The most significant difference being that within user-led innovation, user-innovators maintain significant power and control over the innovation process. This is not the case with lead-users or customers involved in open innovation where technology suppliers maintain overall control. This altered balance of power gives user-innovators much greater scope in defining the purpose and trajectory of their innovations. This is a significant step in democratising innovation and shifting power from technology suppliers to users. However, this simultaneously creates a risk that user-led innovation projects address sub-optimal goals or fail to recognise potential opportunities; user-led innovation projects are potentially limited by the cognitive limits of user-innovators working in isolation and the core rigidities of their organisations (Leonard-Barton 1992).

Despite the centrality of technology users within user-led innovation, the research suggests that it represents only a partially democratic or participative approach to technological innovation. This research has illustrated that user-innovators are often strong minded and maintained significant control of the development and evaluation of their innovations, though supported by their teams. This illustrates a distinct contrast with participative approaches to design and development. For example, within the information system literature, much emphasis has been placed on the importance of user participation in development (Lyytinen and Klein 1985; Stowell 1994). On the surface there is an illusion that user-innovators and their teams operate in a participative fashion, however the question remains as to the extent to which individuals are free to participate. In common with other disciplines such as development studies, the participation of users, aside from the roles taken by user-innovators, within user-led innovation is not immune from the power relationships and the "tyranny of participation" (Cooke and Kothari 2001). The power base of

clinicians in the cases exemplifies the risk that other members of the innovation team have limited influence on how the project develops.

The most significant and novel contribution to the understanding of healthcare technology innovation presented in this thesis is the development of an analysis of the relationship between healthcare technology and institutions, resulting in the development of the model of healthcare technology system. The model was necessary to explain the complex and dynamic nature of the user-led innovation cases but has significant implications for the wider study and management of healthcare technology.

The development of an institutional perspective is based around the application of Scott's analytical framework for institutions (2001:77) to healthcare technology. This has complemented and extended Orlikowski's model of technology (1992). Two benefits are gained from combining these two models. First, the synthesised model is more explicit about the nature of the institutional structures influencing healthcare technology. Second, the institutional perspective emphasises the independent existence of institutions from human agency and their trajectories of development over time. Thus, the synthesised model of a healthcare technology system proposed in this thesis integrates not just soft and hard technology, but also the interaction between structure and agency. Overall, this model provides a lens through which healthcare technologies can be specifically understood in terms of their institutional components. This is important as the healthcare sector, as illustrated by the cases, is one dominated by formal organisations, professional networks and institutionalised technologies.

The distinctive application of institutional theory to innovation in this thesis has focused on the organisational and sub-organisational levels of analysis, as compared to more macro levels of analysis, such as the organisational field (DiMaggio and Powell 1983; Scott 2001:83). This contrasts with institutional analyses of technological change that have been approached at other levels of analysis, for example in the electricity sector (Kunneke 2008). The resulting analysis has illustrated the role of proto-institutions in enabling locally developed skills to become institutionalised organisational capabilities, as an integral part of the user-led innovation process.

The implication of this analysis for user-led innovation is that when managing the diffusion of healthcare technology innovations it is imperative that action is taken to re-create any proto-institution formed during the innovation process. Hence, the successful diffusion of hard technologies created by user-led innovation is contingent on the wider institutionalisation of associated proto-institutions, in parallel to the codification and abstraction of the soft technologies. Further research should look specifically at how proto-institutions are recognised and where appropriate efforts made to diffuse them more widely.

The institutional view of a healthcare technology proposed here suggests that when evaluating user-led innovation projects, consideration should be given to the extent and maturity of any supporting proto-institutions that have developed. If sufficiently mature, consideration can then be given to how to achieve its widespread institutionalisation. The implication of this for management of user-led innovation in the NHS is that evaluation must be extended beyond simply valuing innovations in commercial terms. Where an effective user-led innovation is implemented effectively in part of the NHS, then its associated proto-institution has potential value to the wider NHS. The value of user-led innovations should therefore be viewed in terms of the: commercial value of IP associated with hard technology; intellectual capital associated with soft technology; and the revised institutional structures that support improved performance.

In summarising the conclusions of this research, the significance of proto-institutions within the phenomenon of user-led innovation cannot be understated. Proto-institutions should be recognised as distinctive and integral components of the healthcare technology systems created through user-led innovation. This research has shown how user-led innovation creates an environment that is conducive to the development and emergence of the sophisticated institutional frameworks required for implementation of novel technologies, by enabling mutual adjustment, accommodation and consensus building between stakeholders. These findings however, contrast with the NHS's IP-led approach to innovation management described in Chapter 4. The IP-led approach was criticised for placing IP exploitation and commercial technology transfer processes at the centre of NHS innovation policy. By focusing only on hard technology, the less easily codified products of innovation such as capability and proto-institutions were ignored. This research has shown that it is as important to manage the diffusion of proto-institutions, as much as it is to protect and exploit IP.

This in turn suggests that innovation policy in the NHS should be re-aligned to take account, not only of the hard and soft technologies developed by user-innovators, but also the institutional innovations that they create. Policy needs to recognise the systemic change that user-innovators are able to effect. Comprehensive support is still needed for nurturing and supporting the development of proto-institutions and their effective diffusion. Unfortunately, in the past the support structures within the NHS for innovation have been organised in a reductionist manner, with individual agencies taking responsibility for single pieces of the "innovation jigsaw". This has made it difficult to achieve an integrated and co-ordinated approach to managing user-led innovation. The policy changes stemming from the Darzi review (Reid 2009), that refocus innovation policy around clinician-led change and patient-centred service re-design, create an opportunity for improving the integration of services for supporting user-led innovation in the NHS. It is however still too early to assess how successful this policy change will be.

Chapter 4 highlighted the historical importance of technology transfer in both user-led innovation policy in the NHS and the operational processes through which it was managed by trusts. This represents a positive contribution to the management of user-led innovation and suggests that development of the triple-helix model of technology transfer (Etzkowitz and Leydesdorff 2000) to one with a fourth thread representing the role of technology users could be explored. The cases in this research however, have demonstrated the limitations of a technology transfer approach. A significant characteristic of the cases was the attention given to the successful implementation of the innovations. The most valuable products of the user-led innovation projects were often new ways of working and organising, rather than commercially exploitable IP. Technology transfer approaches provide only a partial solution to improving the management of innovations created within the NHS.

Finally, the major benefit of adopting this institutional view of healthcare technology is that it provides a lens on both the overall process of user-led innovation and sub-activities that support it, such as evaluation and diffusion of innovations. The research highlights the need to recognise the impact of user-led innovation projects on the whole healthcare technology system. This suggests that innovation policy needs to shift away from one that focuses only on the exploitable IP related to hard technology. A shift that needs to be reflected in the evaluation of user-led innovation

projects through their life-cycle. Similarly, the performance of agencies tasked with supporting innovation in the NHS needs to be based on wider range of parameters. Coarse indicators such as numbers of patents, licence agreements and business start-ups, provide very little indication of the extent to which agencies actually support user-led innovation projects. Especially when a potential benefit of NHS-developed innovations, is improvement of performance across the NHS, rather than just producing commercial products. Industrial partnerships are required to develop hard technologies so that they can be used within the NHS. However, the process of commercialising hard technology risks ignoring the challenge of diffusing associated soft technologies. Even more challenging is the extent to which localised institutional innovations are diffused to other parts of the NHS. This research has suggested a range of dimensions that have potential to provide a more holistic view of the success, both potential and achieved, of user-led innovation projects.

10.3 Changes to NHS innovation services as a result of the Darzi Review

Since this research was completed, the innovation support in the NHS has changed, with various priorities evolving. There is a significant contrast between the landscape in which the LUTM innovation started in 1999 and that experienced by innovators in 2009. The intervening years between the articulation of a vision for the reformed NHS (UK Government 2000) and Lord Darzi's review (Darzi 2008) have seen significant changes in assumptions about the NHS. Central to these changes has been a shift in belief about what services should be provided and how they should be delivered. This has lead to evolution in many areas of healthcare policy impacting on innovation. Some policies have been constructive in supporting user-led innovation. Other policies, such as the Payment By Results (PbR) introduced in 2003/4, have had unintended negative consequences for innovation in the NHS (Audit Commision 2008:66). It is therefore worth reviewing some of the most recent policy changes and assessing them in relation to the findings in this thesis.

This thesis mirrors many of the themes articulated in the Darzi review, especially with respect to how NHS clinicians and managers can lead innovation in the NHS. (This is a central tenet of Lord Darzi's strategy for change in the NHS.) A direct result of the Darzi review has been a range of

policy initiatives that aim to promote user-led innovation the NHS (Reid 2009; NSR Implementation Team 2009). These initiatives include creation of regional innovation funds; establishing a legal duty on strategic health authorities (SHA) to promote innovation; creating a system of innovation "challenge" prizes; and creation of a central database for evidence to support decision-making around innovation.

Establishing a legal obligation on SHAs to encourage and lead innovation is clearly a great step forward. On a practical level however, it still remains to be seen how SHAs will develop suitable capabilities to support innovation. Development of the necessary organisational capability is a significant challenge, requiring new structures and skilled staff. In the face of cuts in public-sector spending, the worst case will be that SHAs will carry out their obligations to the minimum acceptable level. It may transpire that SHA are too distant from emergent user-led innovation projects and the complex innovations to healthcare technology systems that they generate.

Development of regional innovation funds is also a long-needed development. In the past, innovation projects in trusts have been halted because it was not possible to spend money in one financial year in order to save money in subsequent years. The establishment of a £220m NHS innovation fund has potential to reverse this situation, enabling critical strategic investment in innovations. However, the relatively small value of the fund will mean that some worthwhile projects will still not be funded. A further risk is that funding will go to innovators with the necessary knowledge, power and influence to gain funding; groups who have always been relatively well placed to gain innovation funding. As discussed in this thesis, the process of evaluation relating to innovations has a significant political dimension and so in managing the payments from the innovation funds the danger is that money will be allocated to those capable of mastering the system rather than those with the truly significant innovation.

The political rhetoric towards innovation in the NHS certainly shifted during 2008-2009 with the emphasis shifting from IP exploitation to whole-system innovation of healthcare services. Both the Secretary of State for Health and the NHS Chief Executive were unequivocal about the need for healthcare innovation and its direct relevant to service quality and productivity. While in the past the *raison d'etre* for managing NHS innovation was to exploit IP, focus has now changed to how

innovation can create systemic improvement across the health system (HSJ 2009:1). This is an important shift as it recognises that challenge to innovation is not purely technical but is also about social and institutional innovation.

The range of new policies and the accompanying change in political rhetoric have pushed user-led innovation up the political agenda. The complexity of managing innovation in the NHS means it is unlikely to be solved by a few "silver bullet" policies. The complex interconnected system of organisations, professions and other stakeholders means that identifying the relevant levers for change is undoubtedly challenging. Any "solution" to the innovation problem in the NHS must have the necessary requisite variety (Ashby 1958; De Raadt 1987) to cope with this complexity. The post-Darzi response has seen the further development and multiplication of agencies responsible for innovation (NSR Implementation Team 2009). Thus existing agencies, such as the NHS innovation hubs, have now been augmented with other agencies such as the NHS Technology Adoption Centre to manage technology adoption. Similarly, establishment of Academic Health Science Centres (AHSCs), Health Education and Innovation Centres (HIECs) and biomedical research centres seek to increase the extent to which knowledge translation is improved in the NHS; increasing the speed at which research knowledge is embedded in clinical practice. The result has been that agencies relevant to a range of innovation activities do now exist and the criticism that that the NHS overemphasised commercial technology transfer processes (Savory 2006) may have been addressed. However, the creation of separate agencies, each with a specific focus, does not fully address the problem of how best to diffuse user-led innovations. In the UK, spending on the adoption and spread of innovations in the NHS has historically been very small, in comparison to spending on innovation creation (Barlow and Burn 2008:40).

10.4 Potential areas of future research

This research, in common with most other research projects, has raised further issues and questions. As such, this research creates a foundation for future research in this area, both with respect to practical application of this research, but also new opportunities for development of theory. The case studies raised several additional issues and questions relating to user-led

innovation that could not be addressed within the thesis. Future research could focus on these important themes. Six areas in particular would benefit from further investigation.

Applying the theory of user-led innovation in practice

This thesis has established user-led innovation as a distinctive form of innovation activity. Further work is now required to apply this new understanding to the support of user-led innovation within NHS trusts. The problem faced by the NHS has been that it is very difficult to identify projects, making it impossible to provide support, adjust them to meet more strategic objectives, or possibly even halt them to avoid waste of resource. In addition, work is needed that is oriented to building a pragmatic and relevant set of tools and techniques to allow NHS trust R&D departments, innovation hubs and other stakeholders of NHS innovation to identify and support user-led innovation projects. The activity model presented in this thesis has a potential to form the basis for an organisational audit tool, that builds on existing tools (Chiesa, Coughlan, and Voss 1996). This could be used to ensure that relevant, tailored, support is available for user-innovators in all six sub-systems of the model. Development of an audit tool lends itself to development through a programme of action research carried out jointly between academics and NHS innovation managers.

What role does the organisation play in supporting the knowledge management processes underpinning user-led innovation?

It was apparent that for all the cases in this research, a crucial process is the translation of knowledge from outside the user-innovators immediate working context. This was a complex process relying on a range of mechanisms including the formal education system, professional networks, and multi-disciplinary teams. Overall, the cases suggest that for organisations to be effective in supporting user-led innovation activity they will need a need to possess a suitable organisational capability in relation to knowledge translation (Savory 2006, 2009). Further research could be directed at building a better understanding of the organisational capabilities that might support knowledge translation processes within user-led innovation.

How do user-innovators act to diffuse their innovations beyond the initial context of development to other parts of the NHS or outside organisations?

It was apparent in the LUTM, ePAQ and PMS cases that significant efforts were needed by user-innovators to ensure that their innovations diffused beyond the initial development context. Several strategies were identified in the cases that illustrate how user-innovators used formal and informal mechanism for diffusing their ideas. Further research could consider how user-innovators act to codify and abstract their innovations in order to support their wider diffusion.

What entrepreneurial qualities do user-innovators in the NHS possess?

A major attribute of many of the user-innovators in the cases were their entrepreneurial qualities. Further research is needed to examine how the entrepreneurial qualities of user-innovators compare with other categories of entrepreneur e.g. business entrepreneurs, social entrepreneurs and intrapreneurs. This would be of particular importance to NHS agencies responsible for supporting and encouraging user-led innovation within the NHS. However, one of the potential pitfalls for projects lead by enthusiastic clinical staff is that as the project develops, the skill and knowledge requirements for leading the project will change. Typically, this may mean a shift from a clinical focus to a more technical or business focus. Many of the user-innovators in the case studies expressed concern that gaining the necessary business skills was challenging for them. This raises the question for projects as to when it is most appropriate for the original user-innovators in a project to hand over the project to staff with different skill sets. Further research is needed to examine the extent to which the leadership of entrepreneurial clinicians continues to benefit projects, once development moves away from its original context.

What factors affect the relationship between user-innovators and their industrial partners?

For a large proportion of user-led innovation projects, it is likely that at some point a private sector partnership will be needed. The creation of such partnerships is fraught with problems and their success may well be critical to the ultimate success of the innovation. User-innovators face a similar set of challenges to those of small hi-tech start-up firms when forming partnerships (Fraser, Minshall, and Probert 2005). Central to this problem are the respective perspectives of the user-

innovator and industrial partner, on the purpose and expectations enrolled in the partnership. Further research is needed into how these partnerships develop and what factors support or inhibit their success. This research would be relevant to agencies, such as NHS innovation hubs, for which building partnerships is a critical activity.

How successful is the wider adoption of user-led innovations and do they have any advantage over innovations produced through other processes?

It is tempting to assume that user-led innovations created within the NHS have significant advantages, over innovations developed outside the NHS, when implementing them within the wider NHS. It is possible that the close relationship between development and context of use will lead to healthcare technologies that have a strong match with the needs of the NHS. Research is however needed to assess whether user-led innovations from the NHS are any more effective in being adopted into the NHS. The question is therefore raised as to whether user-led innovations perform better than those developed through conventional routes. It may be that user-led innovations developed in the NHS have inherent strengths, due to their strong relationship with the NHS. In particular, user-led innovations from the NHS may be better in terms of:

- their fit with the culture, values and processes of the NHS;
- facilitating process re-design across primary and secondary care organizations;
- being more acceptable to NHS staff due to their NHS "brand";

Conversely, it is possible NHS user-led innovations may exhibit relative weaknesses, as compared to those developed through other mechanisms. For example:

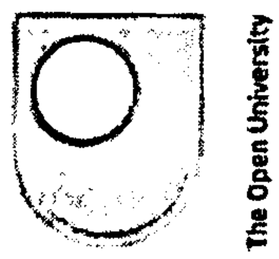
- competition between specialist centres within the NHS may inhibit adoption;
- not being backed up by an established healthcare brand;
- user-led innovations may be overly specific in their application and lack the flexibility to be used across several contexts; lack of fit with overarching NHS strategy or policy.

Significant topics for current NHS policy are the problems associated with adopting new technologies into the NHS (Greenhalgh et al. 2004; Darzi 2008). Further research is needed to

assess whether user-led innovations have any significant advantage when being adopted into the NHS.

Appendices

11.1 Appendix 1: Interview Schedule for NHS Staff



Managing Technological Innovation in the NHS

NHS Staff semi-structured interview schedule

During the interview, the development of the technological innovation will be referred to as "the project".

	Short personal introduction by interviewer and reiteration of the purpose of the interview and the basis on which the interview is carried out. Time should be allowed for clarifying any points not understood by the participant. It is important that the inherent limits to confidentiality of the research are made clear to the participant. This should also stress the participant's: • Right to withdraw without prejudice • Right to review summary of the interview notes • Right to decline audio recording of the interview
Q1	At the time of your involvement in the project, what was your job title and what did your work involve?
Q2	Tell me why the project was important to pursue? How were people initially convinced that it was a good idea? How did this view change during the course of the project? How formal was the initial feasibility assessment of the project?
Q3	Tell me about your involvement in the project? Over what period were you involved? What was your involvement? To what extent was the project part of your normal work role?
Q4	To what extent did the project follow a set of formal stages Who defined the stages? What were the stages? How was the project monitored and controlled? How helpful did you find this process?
Q5	If there was no formal process what were the main stages that it followed?
Q6	What were the significant events during the project? What were the high/low points? How did you feel at these high/low points? How do you feel these events affected the team?
Q7	What were the important relationships that affected the project? Within the project team? Strong supportive relationships to other parts of the NHS? Relationships outside the NHS? Were any organisational relationships unhelpful?
Q8	To what extent was the organisation (NHS) supportive of the project? What organisation initiatives/structures really helped What organisation initiatives/structures actually held back the project?
Q9	What could be done to improve the support of future projects of this type? At the level of the organisation? At the level of the individual?
	Closing remarks and thanks for the interview

Interview Schedule for NHS Staff
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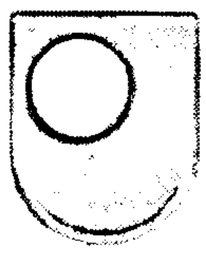
11.2 Appendix 2: Participant Information Sheet and Consent form (PIS/CF)



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Participant Information and Consent Form: Managing Technological Innovation in the NHS

You are invited to participate in a research project into technological innovation in the NHS. The chief investigator for the research is Clive Savory, Lecturer in Technology Management at the Open University based in Milton Keynes. The project will contribute to his PhD research into technological innovation in the NHS. He is not being paid for carrying out the research. Insights from this research may inform course development in the area of technology management at the Open University.

Project Aims

The research is focused on the way that innovations are managed from their initial invention to protection and commercialisation. The research will compare the intention and impact of formal processes and initiatives in the NHS with the experiences of inventors and innovators working in and with the NHS. By reviewing examples of successful innovations the research will develop case material on the actual innovation processes at work in the NHS. In reviewing the experience of NHS staff it will be possible to assess the impact of formal processes and initiatives. In addition the cases will also have potential to feed into a grounded model of good practice. This model could then in turn inform the organisation of future innovation processes.

The project will investigate the following questions:

- Do NHS organisations have strategies that support new internally generated technology projects based on inventions?
- Is there a formal technology project process that supports either individuals or teams to develop their inventions and if so what is it?
- How in practice are new technological innovations initially identified, evaluated, implemented and integrated into the organisation's existing processes?
- How effective is the use of existing knowledge and competences in building new technological innovations?
- What activities and processes support the effective use of the organisation's knowledge in building technological innovations?

Why have you been asked to take part in this research study?

The key questions which this research addresses are how innovation in the NHS comes about and the role which management has in supporting it? Though the main purpose of the NHS is care of patients, effective management of technological innovation has the potential long term benefits of both improving patient care and providing additional income streams for the NHS.

You have been approached to be included in this research study as you have either had a direct involvement in the successful development of a technological innovation or you are involved with an aspect of the innovation process in the NHS. You were initially identified as a potential participant by staff in the R&D department of the NHS trust in which you work. It is hoped that you will be able to provide a personal view of the way the innovations develop.

Potential Risks & Benefits

There are no significant risks associated with taking part in this study. In fact, the benefit of taking part in the study is that you will have the chance to review the way an innovation project has developed and express your own views on what helped or hindered its progress. The perspective on technological innovation that you contribute to the research will also be represented in published findings.

Research Procedures

Should you decide to participate in this research study, you will be asked to sign this consent form, once all your questions have been answered to your satisfaction.

This study consists of interviews with individual participants working for or with the NHS. The innovation projects in the study are based in several NHS centres in the UK. As part of the study you will be asked to take part in a face to face semi-structured interview lasting approximately 45 minutes. It is intended that the interview will be recorded as this will allow a more conversational style of interview. The main purpose of the interview will be to allow you recall your involvement in the innovation project and discuss key events and issues that affected it. Within a few weeks of your interview you will have the opportunity to see a summary of the interview. You will have the opportunity to clarify, amend or withdraw any statements that you have made. You will also be given the chance to participate in a short workshop in which the case study of the project is reviewed by all the people contributing to the case.

Confidentiality

The nature of this research project is such that there are inherent limits to the level of confidentiality that can be maintained for research participants. The case studies are to be based on specific innovations that are by definition distinctive. It is likely that other members of the NHS and wider healthcare sector will be able to identify the project and associated staff. Subsequently it is unrealistic for the researcher to be able to offer a guarantee of anonymity for any participants in the research.

The innovation projects in the study have been selected because they have been successful. For this reason it is hoped that participants will be happy to participate without remaining anonymous. You may however choose not to be either quoted verbatim or named in any published work based on the research.

It is also unlikely that specific innovations can be the subject of a case study without providing some detail of the innovation and its underlying technology. It is therefore important that participants are certain that any intellectual property associated with the innovation have been properly protected commercially and its details are free to be placed into the public domain. Should you be in any doubt about the extent to which details can be made public, you should consult with staff in the R&D department of the NHS trust in which you work.

Data collected in the interviews will be handled in compliance with the Data Protection Act (1998). Access to the raw data will be limited to the chief investigator and his PhD supervisor. As a member of staff at the Open University Clive Savory is covered by professional indemnity insurance while carrying out research..

Participation

Your participation is entirely voluntary. You are free to choose not to participate. Should you choose to participate, you can withdraw at any time.

Complaints

If you have cause to complain about any aspects of the research you should contact:

Dr Joyce Fortune
Head of Department

at the address on the head of this letter.

Participant Consent Form
Research Project: Managing Technological Innovation in the NHS

Please tick the appropriate boxes and sign at the bottom of both copies of the form. Then send both copies to the chief investigator at the address given below. You will then receive back one countersigned copy of the form.

I have had an opportunity to ask questions about my participation ☐ *(please tick if agree)*

I understand that I can withdraw at any time without prejudice ☐ *(please tick if agree)*

Should I withdraw from the research early, I am happy for any data collected prior to my withdrawal to continue to be used in the research. ☐ *(please tick if agree)*

I am happy for any interview I give to be recorded ☐ *(please tick if agree)*

I am happy for verbatim quotations to be used in published work ☐ *(please tick if agree)*

I am happy to be named in any published work ☐ *(please tick if agree)*

I understand that the chief investigator cannot guarantee that participants in the research will remain anonymous ☐ *(please tick if agree)*

I understand that insights and examples gathered during the research may be used in any teaching that the chief investigator undertakes ☐ *(please tick if agree)*

I have read this consent form and I understand what is being requested of me as a participant in this study. I freely consent to participate. I have been given satisfactory answers to my questions. The investigator provided me with a copy of this form.

Name of Participant (Printed)	Name of Researcher (Printed) Clive Savory
Name of Participant (Signed)	Name of Researcher (Signed)
Date.....	Date.....

Should you have questions or concerns before, during or after your participation in this study please contact the chief investigator using the contact details below.

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Mobile: 07855 553310
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NHS Staff information sheet.doc

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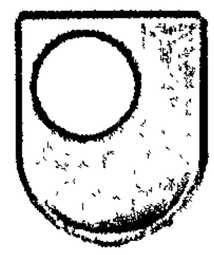
11.3 Appendix 3: Participant Interview Summary Approval Form



The Open University

Interview Summary

Participant: .....
Referred to as: .....
Interview date: .....

I confirm that the following notes of the interview with Clive Savory are accurate and I am happy for them to be used within any subsequent published work.

Signed: ...

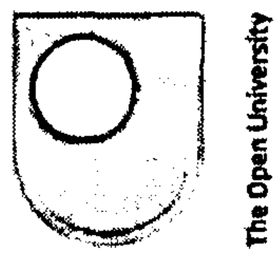
If there are any additional points, you would like to make, please include them in the box below or on a separate sheet

Please countersign each individual page of the summary and then return this page and the summary to:

Clive Savory
Department of Technology Management
Technology Faculty
The Open University
Walton Hall
Milton Keynes
MK7 6AA

Page 1 of 1

11.4 Appendix 4: NHS Technology Transfer Manager Questionnaire



Managing Technological Innovation in the NHS

NHS Innovation Hub Director semi-structured Interview schedule

	Short personal introduction by interviewer and reiteration of the purpose of the interview and the basis on which the interview is carried out. Time should be allowed for clarifying any points not understood by the interviewee. This should also stress the interviewee's: • Right of anonymity • Right to withdraw • Right to review summary of the interview notes • Right to decline audio recording of the interview
Q1	What is the role of the hub in relation to the NHS To what extent is the hub organisationally "part" of the NHS How does this affect the relationship with trusts and NHS employees How does this affect the relationship with other organisations such as university technology transfer companies
Q2	How is the hub funded and how does this affect the hub?
Q3	What types of innovation does the hub deal with and what are the rough proportions: Practise based innovation vs formal R&D Diagnostic vs therapeutic technologies Service delivery
Q4	What is the core process used for protecting and commercialising technologies and how does this differ for various technological innovations For service delivery innovations For practise based innovations
Q5	How are innovation initially screened and evaluated prior and during their development? How are innovations summatively assessed in terms of: Quality Relevance and potential for patient benefit? Effectiveness in gain benefit through translating into service?
Q6	To what extent is the work of the hub characterised as: Searching for pearls Growing pearls
Q7	To what extent is NHS culture: Consistent with the work of the hub? Antagonistic with the work of the hub
Q8	What are the weaknesses of the NHS in developing innovations
Q9	What processes would you hope to develop to support NHS innovation in the hub and in the NHS?
Q10	How effective is the NHS in managing knowledge to support its innovations?
Q11	To what extent do internal relationships between departments/functions support innovation
	Is it possible to follow up on any points that arise after the interview? Closing remarks and thanks for the interview

Interview Schedule for Hub Managers

References

Ali, Shaymaa Abdulreda, Peter Mossey, and Toby Gillgrass. 2006. "A study model based photographic method for assessment of surgical treatment outcome in unilateral cleft lip and palate patients". *Eur J Orthod* 28 (4):366-372.

Angle, Niren, and John J Bergan. 1997. "Chronic venous ulcer". *BMJ* 314 (7086):1019-.

Archer, Margaret Scotford. 1995. *Realist social theory : the morphogenetic approach.* Cambridge ; New York: Cambridge University Press.

———. 2003. *Structure, agency, and the internal conversation.* Cambridge, UK ; New York: Cambridge University Press.

Argyris, C. 1976. "Single loop and double loop models in research on decision making". *Administrative Science Quarterly* 21 (0):363-375.

Arora, Ashish, and Alfonso Gambardella. 1994. "The changing technology of technological change: general and abstract knowledge and the division of innovative labour". *Research Policy* 23 (5):523-532.

Ashby, R. 1958. "Requisite Variety and Implications for control of complex systems". *Cybernetica* 1 (0):83-99.

Atack, N, I Hathorn, M Mars, and J Sandy. 1997. "Study models of 5 year old children as predictors of surgical outcome in unilateral cleft lip and palate". *Eur J Orthod* 19 (2):165-167.

Audit Commission. 2008. "*The right result?: Payment by Results 2003-07*". London: Audit Commission

Audit Commission. 2006. "*Audit Commission Review of the NHS Financial Management and Accounting Regime*": The Audit Commission.

Baker, J. 1999. "*Creating knowledge creating wealth: Realising the economic potential of public sector research establishments. A report by John Baker to the Minister for Science and the Financial Secretary to the Treasury*". London, UK: HM Treasury.

Barley, Stephen R, and Pamela S Tolbert. 1997. "Institutionalization and Structuration: Studying the Links between Action and Institution". *Organization Studies* 18 (1):93-119.

Barley, Stephen R. 1986. "Technology as an Occasion for Structuring: Evidence from Observations of CT Scanners and the Social Order of Radiology Departments." *Administrative Science Quarterly* 31 (1):78.

Barlow, James, and Jamie Burn. 2008. "*All change please: Putting the best new healthcare ideas into practice*": Policy Exchange.

Barnes, Mike. 2000. "Welcome to Biotech Advantage!" *Biotech Advantage*, July, 2.

Bass, B.M., and B.J. Avolio. 1993. "Transformational leadership: a response to critiques". In *Leadership theory and research : perspectives and directions*, edited by M. M. Chemers and R. Ayman. San Diego: Academic Press.

Bell, Judith. 1993. *Doing your research project : a guide for first-time researchers in education and social science*. 2nd ed. Buckingham ; Philadelphia: Open University Press.

Benbasat, Izak, David Goldstein, and Melissa Mead. 2002. "The case research strategy in studies of information systems". In *Qualitative research in information systems : a reader*, edited by M. D. Myers and D. E. Avison. London ; Thousand Oaks, Calif.: SAGE.

Bessant, J. and Buckingham, J. 1993. "Innovation and organisational learning the case of computer aided production management". *British Journal of Management* 4 (4):219-234.

Bessant, John. 2005. "Enabling Continuous and Discontinuous Innovation: Learning From the Private Sector". *Public Money and Management* 25 (1):35-42.

Bessant, John, Sarah Caffyn, and Maeve Gallagher. 2001. "An evolutionary model of continuous improvement behaviour". *Technovation* 21 (2):67-77.

Bessant, John, and David Francis. 2005. "Transferring soft technologies: exploring adaptive theory". *International Journal of Technology Management & Sustainable Development* 4 (2):112.

Bhaskar, Roy. 1989. *Reclaiming reality : a critical introduction to contemporary philosophy*. London ; New York: Verso.

Bijker, Wiebe E. 1995. *Of bicycles, bakelites, and bulbs : toward a theory of sociotechnical change, Inside technology*. Cambridge, Mass.: MIT Press.

Bijker, Wiebe E., Thomas Parke Hughes, and T. J. Pinch. 1987. *The Social construction of technological systems : new directions in the sociology and history of technology*. Cambridge, Mass.: MIT Press.

Bijker, Wiebe E., and John Law. 1992. *Shaping technology/building society : studies in sociotechnical change, Inside technology*. Cambridge, Mass.: MIT Press.

Black, Nick. 2001. "Evidence based policy: proceed with care". *BMJ* 323 (7307):275-278.

Blackler, F. 1995. "Knowledge, knowledge work and organizations: An overview and interpretation". *Organization Studies* 16 (6):1021-1046.

Boisot, M. H. 1998. *Knowledge assets: Securing competitive advantage in the information economy*: Oxford University Press.

Borgmann, Albert. 1984. *Technology and the character of contemporary life : a philosophical inquiry*. Chicago: University of Chicago Press.

Bower, Jane. 2003. "Innovation in healthcare delivery". In *Service innovation : organizational responses to technological opportunities & market imperatives*, edited by J. Tidd and F. M. Hull. London: Imperial College Press.

Bozeman, B. 2000. "Technology transfer and public policy: a review of research and theory". *Research Policy* 29 (4-5):627-655.

BPS. 2004. *"A practical guide to the provision of Chronic Pain Services for adults in Primary Care"*. London: British Pain Society and the Royal College of General Practitioners.

Bradshaw, H. D., L. Hiller, A. G. Farkas, S. Radley, and S. C. Radley. 2006. "Development and psychometric testing of a symptom index for pelvic organ prolapse". *J Obstet Gynaecol* 26 (3):241-52.

Brown, John Seely, and P. Duguid. 1991. "Organizational learning and communities-of-practice: towards a unified view of working, learning and innovation". *Organization Science* 2 (1).

Bryman, Alan. 1996. "Leadership in organizations". In *Handbook of organization studies*, edited by S. Clegg, C. Hardy and W. R. Nord. London ; Thousand Oaks: Sage Publications.

Burgess, Robert G. 1984. *In the field : an introduction to field research, Contemporary social research series ; 8*. London ; Boston: Allen & Unwin.

Burrell, G. 1994. "The contribution of Jurgen Habermas". *Organisation Studies* 15 (1):1-19.

Bush, Vannevar. 1945. "*Science, the endless frontier. A report to the President*". Washington,: United States. Office of scientific research and development.

Cain, Mary, and Robert Mittman. 2002. "*Diffusion of innovation in health care*": California Healthcare Foundation.

Carlsson, Bo, Staffan Jacobsson, Magnus Holmen, and Annika Rickne. 2002. "Innovation systems: analytical and methodological issues". *Research Policy* 31 (2):245.

Carter, Bob, and Caroline New. 2004. "Introduction: realist social theory and empirical research". In *Making realism work : realist social theory and empirical research*, edited by B. Carter and C. New. London ; New York: Routledge.

Chesbrough, Henry William. 2003. *Open innovation : the new imperative for creating and profiting from technology*. Boston, Mass.: Harvard Business School Press.

Chiesa, V., P. Coughlan, and C. A. Voss. 1996. "Development of a technical innovation audit". *Journal of Product Innovation Management* 13 (2):105-136.

Christensen, C. M., R. Bohmer, and J. Kenagy. 2000. "Will disruptive innovations cure health care?" *Harvard Business Review* 78 (5):102.

Christensen, Clayton M. 2000. *The innovator's dilemma : when new technologies cause great firms to fail, The management of innovation and change series*. New York: HarperBusiness.

Clark, K. B. 1985. "The interaction of design hierarchies and market concepts in technological evolution". *Research Policy* 14 (5):235-251.

Cleghorn, GD, and LA. Headrick. 1996. "The PDSA cycle at the core of learning in health professions education." *The Joint Commission Journal on Quality Improvement* 22 (3):206-12.

Cockburn, Cynthia. 1981. "The Material of Male Power". *Feminist Review* (9):41-58.

Cohen, Michael D., James G. March, and Johan P. Olsen. 1972. "A Garbage Can Model of Organizational Choice". *Administrative Science Quarterly* 17 (1):1-25.

Cohen, W, and D Levinthal. 1990. "Absorptive capacity: a new perspective on learning and innovation". *Administrative Science Quarterly* 35 (1):128-153.

Colyvas, J., M. Crow, A. Gelijns, R. Mazzoleni, R. R. Nelson, N. Rosenberg, and B. N. Sampat. 2002. "How do university inventions get into practice?" *Management Science* 48 (1):61-72.

Cooke, Bill, and Uma Kothari. 2001. *Participation : the new tyranny?* London ; New York: Zed Books.

Cookson, Richard, David McDaid, and Alan Maynard. 2001. "Wrong SIGN, NICE mess: is national guidance distorting allocation of resources". *BMJ* 323 (7315):743-745.

Coombs, R., M. Harvey, and B. S. Tether. 2003. "Analysing distributed processes of provision and innovation". *Industrial and Corporate Change* 12:1155.

Cooper, R. G., S. J. Edgett, and E. J. Kleinschmidt. 2000. "New problems, new solutions: Making portfolio management more effective". *Research-Technology Management* 43 (2):18-33.

Cooper, Robert G. 2000. "Winning with new products: Doing it right". *Ivey Business Journal* 64 (6):54.

COREC. 2001. "*Governance arrangements for NHS Research Ethics Committees*": NHS Central Office for Research Ethics Committees.

———. 2004. "*Standard operating procedures for research ethics committees, Version 2*": NHS Central Office for Research Ethics Committees.

Craib, Ian. 1992. *Anthony Giddens*. London ; New York: Routledge.

Crinnion, John. 1991. *Evolutionary systems development : a practical guide to the use of prototyping within a structured systems methodology, Software science and engineering*. New York: Plenum Press.

Culyer, A. 1994. "*Supporting research and development in the NHS. A report to the minister for health by a research and development task force chaired by Professor Anthony Culyer*". London, UK: HMSO.

Darzi, Ara, and Sean Mackay. 2002. "Recent advances in minimal access surgery". *BMJ* 324 (7328):31-34.

Darzi, Professor Lord. 2007. "*NHS next stage review interim report*". London: NHS Next Stage Review Team.

———. 2008. "*High quality care for all: NHS next stage review final report*". London: NHS Next Stage Review Team.

Davis, Dave, Mike Evans, Alex Jadad, Laure Perrier, Darlyne Rath, David Ryan, Gary Sibbald, Sharon Straus, Susan Rappolt, Maria Wowk, and Merrick Zwarenstein. 2003. "The case for knowledge translation: shortening the journey from evidence to effect". *BMJ* 327 (7405):33-35.

De Raadt, J. 1987. "Ashby's Law of Requisite Variety: An Empirical Study". *Cybernetics and Systems* 19 (6):517-536.

Deed, R. 2002. "IP from NHS Trusts". *Biotech Advantage*, July, 15-16.

Denzin, Norman K. 1978. *The research act : a theoretical introduction to sociological methods*. 2d ed. New York: McGraw-Hill.

Department of Health. 2008. "*Treatment of heart attack national guidance: final report of the National Infarct Angioplasty Project (NIAP)*": DoH.

Deschamps, J P. 2003. "Innovation and Leadership". In *The international handbook on innovation*, edited by L. V. Shavinina. Amsterdam; Boston: Elsevier Science.

Dictionary, Collins. 1994. *Collins English dictionary*. 3rd ed. Glasgow: HarperCollins Publishers.

DiMaggio, Paul J., and Walter W. Powell. 1983. "The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields". *American Sociological Review* 48 (2):147-160.

Directive 2007/47/EC of the European Parliament.

Djellal, F., and F. Gallouj. 2005. "Mapping innovation dynamics in hospitals". *Research Policy* 34 (6):817-835.

Dodds, S. R. 2002. "Shared Community-Hospital Care of Leg Ulcers Using an Electronic Record and Telemedicine". *Int J Low Extrem Wounds* 1 (4):260-270.

Dodds, Simon. 2005. "Designing improved healthcare processes using discrete event simulation". *British Journal of Healthcare Computing and Information Management* 22 (5):14-16.

———. 2006. *Three Wins: service redesign through flow modelling*: Aeneas and Kingsham.

DoH. 1998. "*Policy framework for the management of intellectual property within the NHS arising from research & development*": Department of Health.

———. 2002. "*The NHS as an Innovative Organisation A Framework and Guidance on the Management of Intellectual Property in the NHS*". London, UK: Department of Health.

———. 2002. "*The NHS as an innovative organisation, a framework and guidance on the management of intellectual property*". London, UK: Department of Health.

———. 2004. "*Agenda for Change - Final Agreement*": Department of Health.

Drejer, Ina. 2004. "Identifying innovation in surveys of services: a Schumpeterian perspective". *Research Policy* 33 (3):551-562.

DTI. 2004. "*Knowledge transfer and public sector research establishments (PSREs)*". London, UK: Department of Trade and Industry.

Easterby-Smith, Mark, Richard Thorpe, and Andy Lowe. 2002. *Management research, SAGE series in management research*. London ; Thousand Oaks: Sage Publications.

Economic and Social Research Council. 2005. *Research Ethics Framework*. Swindon: ESRC.

Eden, C. 1988. "Cognitive Mapping". *European Journal of Operational Research* 36 (1):1-13.

Eden, C., and F. Ackermann. 2004. "Cognitive mapping expert views for policy analysis in the public sector". *European Journal of Operational Research* 152 (3):615-630.

Edgerton, David. 1999. "From innovation to use: Ten eclectic theses on the historiography of technology". *History & Technology* 16 (2):111.

Edmondson, Amy C., Richard M. Bohmer, and Gary P. Pisano. 2001. "Disrupted Routines: Team Learning and New Technology Implementation in Hospitals." *Administrative Science Quarterly* 46 (4):685.

Edquist, Charles. 2001. "Innovation policy - a systemic approach". In *The globalizing learning economy*, edited by D. Archibugi and B.-ê. Lundvall. New York: Oxford University Press.

Eisenhardt, K. M. 1989. "Building Theories from Case-Study Research". *Academy of Management Review* 14 (4):532-550.

Eisenhardt, K. M., and J. A. Martin. 2000. "Dynamic capabilities: What are they?" *Strategic Management Journal* 21 (10-11):1105-1121.

Eldridge NE, Woods SS, Bonello RS, Clutter K, Ellingson L, Harris MA, Livingston BK, Bagian JP, Danko LH, Dunn EJ, Parlier RL, Pederson C, Roselle GA Reichling KJ, and Wright SM. 2006. "Using the six sigma process to implement the centers for

disease control and prevention guideline for hand hygiene in 4 intensive care units". *Journal of General Internal Medicine* 21:s35-s42.

Ellul, Jacques, and Geoffrey William Bromiley. 1989. *What I believe*. Grand Rapids, Mich.

London: W.B. Eerdmans, Marshall Morgan and Scott.

Emirbayer, Mustafa, and Ann Mische. 1998. "What is Agency?" *American Journal of Sociology* 103 (4).

Engel, GL. 1977. "The need for a new medical model: a challenge for biomedicine". *Science* 196 (4286):129-136.

Etzkowitz, H., and L. Leydesdorff. 2000. "The dynamics of innovation: from National Systems and "Mode 2" to a Triple Helix of university-industry-government relations". *Research Policy* 29 (2):109-123.

Feenberg, Andrew. 2002. *Transforming technology : a critical theory revisited*. New York, N.Y.: Oxford University Press.

Ferlie, Ewan, Louise Fitzgerald, Martin Wood, and Chris Hawkins. 2005. "The nonspread of innovation: the mediating role of professionals". *Academy of Management Journal* 48 (1):117-134.

Fiedler, Fred Edward, and University of Illinois at Urbana-Champaign. Group Effectiveness Research Laboratory. 1963. *A contingency model of leadership effectiveness*. Urbana,: Group Effectiveness Research Laboratory, University of Illinois.

Fleck, James, and John Howells. 2001. "Technology, the Technology Complex and the Paradox of Technological Determinism". *Technology Analysis & Strategic Management* 13 (4):523-531.

Fleetwood, Steve. 2004. "An ontology for organisation and managment studies". In *Critical realist applications in organisation and management studies*, edited by S. Fleetwood and S. Ackroyd. London ; New York: Routledge.

Flood, R.L. 1999. *Rethinking the fifth discipline: Learning within the unknowable*. 1 ed: Routledge.

Forrest, Janet E. 1991. "Models of the Process of Technological Innovation." *Technology Analysis & Strategic Management* 3 (4):439.

Fortune, Joyce, and Geoff Peters. 2005. *Information systems : achieving success by avoiding failure*. Hoboken, NJ: Wiley.

Franke, Nikolaus, and Sonali Shah. 2003. "How communities support innovative activities: an exploration of assistance and sharing among end-users". *Research Policy* 32 (1):157-178.

Franks, Peter J., and Nick Bosanquet. 2004. "Cost-Effectiveness: Seeking Value for Money in Lower Extremity Wound Management". *Int J Low Extrem Wounds* 3 (2):87-95.

Franz, Charles , and Daniel Robey. 1984. "An investigation of user-led system design: rational and political perspectives". *Communications ACM* 27 (12):1202-1209.

Fraser, P., T. Minshall, and D. Probert. 2005. "Them and us - asymmetric dyads involving early-stage technology firms". Paper read at *The 27th R&D Management Conference 2005, 6-8 July. 2005.*, at Pisa, Italy.

Freeman, C. 1995. "The National System of Innovation in Historical-Perspective". *Cambridge Journal of Economics* 19 (1):5-24.

Freeman, Christopher. 1974. *The economics of industrial innovation*. Harmondsworth ; Baltimore: Penguin.

———. 1987. *Technology, policy, and economic performance : lessons from Japan*. London ; New York: Pinter Publishers.

Garud, R., and M. A. Rappa. 1994. "A Sociocognitive Model of Technology Evolution - the Case of Cochlear Implants". *Organization Science* 5 (3):344-362.

Garud, Raghu, and Peter Karnøe. 2001. *Path dependence and creation, LEA's organization and management series*. Mahwah, N.J.: Lawrence Erlbaum Associates.

Ghauri, A. S. K., M. C. Taylor, J. E. Deacon, M. R. Whyman, J. J. Earnshaw, and K. R. Poskitt B. P. Heather. 2000. "Influence of a specialized leg ulcer service on management and outcome". *British Journal of Surgery* 87 (8):1048-1056.

Gibbons, Michael, Camille Limoges, Helga Nowotny, Simon Schwartzman, Peter Scott, and Martin Trow. 1994. *The new production of knowledge : the dynamics of science and research in contemporary societies*. London ; Thousand Oaks, Calif.: SAGE Publications.

Giddens, Anthony. 1984. *The constitution of society : outline of the theory of structuration*. Cambridge Cambridgeshire: Polity Press.

Gill, John, and Phil Johnson. 1997. *Research methods for managers*. 2nd. ed. London: Paul Chapman.

Ginsberg, Liane S., Deborah. Tregunno, Peter G. Norton, and Ann L. Casebeer. 2006. "Patient dafety culture in health organizations: Whose culture is it it anyway?" In *Innovations in health care : a reality check*, edited by A. L. Casebeer, A. Harrison and A. L. Mark. Houndmills, Basingstoke, Hampshire ; New York: Palgrave Macmillan.

Glaser Barney, G., and L. Strauss Anselm. 1967. *The discovery of grounded theory : strategies for qualitative research*. Chicago ; New York: Aldine Pub. Co.

Godin, B. 2006. "The linear model of innovation - The historical construction of an analytical framework". *Science Technology & Human Values* 31 (6):639-667.

Goldberg, Andy. 2006. "Deliverance: Andy Goldberg on healthcare innovation". *Healthcare Equipment and Supplies*, January 2006.

Golden-Biddle, Karen, and Karen Locke. 1993. "Appealing Work: An investigation of how ethnographic texts convince". *Organization Science* 4 (4):595-616.

———. 1997. *Composing qualitative research*. Thousand Oaks, Calif.: Sage Publications.

Gomm, Roger, Martyn Hammersley, and Peter Foster. 2000. *Case study method : key issues, key texts*. London ; Thousand Oaks, Calif.: SAGE.

Gould, Stephen Jay. 1997. "The Panda's Thumb of Technology". In *Managing strategic innovation and change : a collection of readings*, edited by M. Tushman and P. Anderson. New York: Oxford University Press.

Granovetter, Mark S. 1973. "The Strength of Weak Ties". *American Journal of Sociology* 78 (6):1360-1380.

Greener, Ian. 2004. "Health Service Organization in the UK: a Political Economy Approach". *Public Administration - Oxford* 82 (3):657-677.

Greenhalgh, Trisha, Glenn Robert, Fraser MacFarlane, Paul Bate, and Olivia Kyriakidou. 2004. "Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations". *The Milbank Quarterly* 82 (4):581-629.

Grey, Joseph E, Keith G Harding, and Stuart Enoch. 2006. "Venous and arterial leg ulcers". *BMJ* 332 (7537):347-350.

Habermas, Jèurgen. 1971. *Knowledge and human interests*. Boston,: Beacon Press.

Hadjimanolis, Athanasios. 2003. "The barriers approach to innovation". In *The international handbook on innovation*, edited by L. V. Shavinina. Amsterdam ; Boston: Elsevier Science.

Hansen, M. T. 1999. "The search-transfer problem: The role of weak ties in sharing knowledge across organization subunits". *Administrative Science Quarterly* 44 (1):82-111.

Hargadon, Andrew. 2003. *How breakthroughs happen : the surprising truth about how companies innovate*. Boston, Mass.: Harvard Business School Press.

Harrison, Stephen, and Bruce Wood. 1999. "Designing Health Service Organization in the UK, 1968 to 1998: from Blueprint to Bright Idea and Manipulated Emergence". *Public Administration* 77 (4):751-769.

Hayes, Susan, and Simon Dodds. 2003. "Telemedicine: a new model of care". *Nursing Times* 99 (5):48-49.

Heidegger, Martin. 1977. *The question concerning technology, and other essays*. 1st ed. New York: Harper & Row.

Held, David, and John B. Thompson. 1989. *Social theory of modern societies : Anthony Giddens and his critics*. Cambridge [England] ; New York, NY, USA: Cambridge University Press.

Helfat, C. E., and M. A. Peteraf. 2003. "The dynamic resource-based view: Capability lifecycles". *Strategic Management Journal* 24 (10):997-1010.

Henderson, Rebecca M., and Kim B. Clark. 1990. "Architectural innovation: The reconfiguration of existing product technologies and the failure of..." In *Administrative Science Quarterly*: Administrative Science Quarterly.

Hiller, L., H. D. Bradshaw, S. C. Radley, and S. Radley. 2002. "A scoring system for the assessment of bowel and lower urinary tract symptoms in women". *BJOG* 109 (4):424-30.

Hiller, L., S. Radley, C. H. Mann, S. C. Radley, G. Begum, S. J. Pretlove, and J. H. Salaman. 2002. "Development and validation of a questionnaire for the assessment of bowel and lower urinary tract symptoms in women". *BJOG* 109 (4):413-23.

Hippel, Eric von. 1988. *The sources of innovation*. New York: Oxford University Press.

———. 2005. *Democratizing innovation*. Cambridge, Mass.: MIT Press.

HITF. 2004. *"Better health through partnership: a programme for action"*. London, UK: Health Industries Task Force, Department of Health.

Hobday, M. 2005. "Firm-level innovation models: Perspectives on research in developed and developing countries". *Technology Analysis & Strategic Management* 17 (2):121-146.

Hoffman, Andrew J. 1997. *From heresy to dogma : an institutional history of corporate environmentalism*. 1st ed, *The New Lexington Press management series*. San Francisco, Calif.: New Lexington Press.

Howells, J. 1997. "Rethinking the market-technology relationship for innovation". *Research Policy* 25 (8):1209-1219.

———. 1999. "Regional systems of innovation". In *Innovation policy in a global economy*, edited by D. Archibugi, J. Howells and J. Michie. Cambridge, England ; New York: Cambridge University Press.

Howells, John. 2004. *The management of innovation and technology : the shaping of the market economy*. London: SAGE.

HSJ. 2009. "Foreword: Securing the NHS future with innovation". *Health Service Journal Supplement*, 10th September 2009.

Huff, Anne Sigismund. 1990. *Mapping strategic thought*. Chichester ; New York: Wiley.

Hughes, T. 2006. "Nurses at the forefront of innovation". *International Nursing Review* 53:94-101.

Ihde, Don. 1993. *Philosophy of technology : an introduction*. 1st ed, *Paragon issues in philosophy*. New York: Paragon House.

Jepperson, Ronald. 1991. "Institutions, institutional effects and institutionalism". In *The New institutionalism in organizational analysis*, edited by W. W. Powell and P. DiMaggio. Chicago: University of Chicago Press.

Jones, Mathew. 1999. "Structuration theory". In *Rethinking management information systems: an interdisciplinary perspective*, edited by W. Currie and R. Galliers. Oxford ; New York: Oxford University Press.

Jones, Matthew. 2001. "An interpretive method for the formative evaluation of an electronic patient record system". Paper read at *8th European Conference on IT Evaluation, September 17-18 2001*, 2001, at Oriel College, Oxford, UK.

Jones, O., T. Edwards, and M. Beckinsale. 2000. "Technology Management in a Mature Firm: Structuration Theory and the Innovation Process". *Technology Analysis and Strategic Management* 12:177.

Kamien, M., and N Schwartz. 1975. "Market structure and innovation". *Journal of Economic Literature* 23 (1):1-37.

Kimberly, John R., and Michael J. Evanisko. 1981. "Organizational Innovation: The Influence of Individual, Organizational, and Contextual Factors on Hospital Adoption of Technological and Administrative Innovations". *Academy of Management Journal* 24 (4):689-713.

Kirkpatrick, Graeme. 2008. *Technology and social power*. New York: Palgrave Macmillan.

Kirkup, John. 2006. *The Evolution of Surgical Instruments: An Illustrated History from Ancient Times to the 20th Century*: Norman Publishing.

Klein, H. K., and M. D. Myers. 1999. "A set of principles for conducting and evaluating interpretive field studies in information systems". *Mis Quarterly* 23 (1):67-93.

Kline, Stephen J., and N. Rosenberg. 1986. "An overview of innovation". In *The Positive sum strategy: harnessing technology for economic growth*, edited by R. Landau and N. Rosenberg. Washington, D.C.: National Academy Press.

Kogut, B., and U. Zander. 1992. "Knowledge of the Firm, Combinative Capabilities, and the Replication of Technology". *Organization Science* 3 (3):383-397.

———. 2003. "A memoir and reflection: knowledge and an evolutionary theory of the multinational firm 10 years later". *Journal of International Business Studies* 34 (6):505-515.

Kranzberg, Melvin. 1986. "Technology and History: "Kranzberg's Laws"". *Technology and Culture* 27 (3):544-560.

Kunneke, Rolf W. 2008. "Institutional reform and technological practice: the case of electricity". *Ind Corp Change* 17 (2):233-265.

Langley, Ann. 1999. "Strategies for theorizing from process data". *Academy of Management Review* 24 (4):691-710.

Lansisalmi, H., M. Kivimaki, P. Aalto, and R. Ruoranen. 2006. "Innovation in healthcare: A systematic review of recent research". *Nursing Science Quarterly* 19 (1):66-72.

Lave, Jean, and Etienne Wenger. 1991. *Situated learning : legitimate peripheral participation, Learning in doing*. Cambridge England ; New York: Cambridge University Press.

Law, John. 1999. "Traduction/Trahison: Notes on ANT". *Working Paper - Centre for Science Studies Lancaster University*, http://www.cs.ucsd.edu/~goguen/courses/175/stslaw.html.

Lawrence, Thomas B., Cynthia Hardy, and Nelson Phillips. 2002. "Institutional effects of interorganizational collaboration: the emergence of proto-institutions". *Academy of Management Journal* 45 (1):281-290.

Layton, Edwin T., Jr. 1987. "Through the Looking Glass, or News from Lake Mirror Image". *Technology and Culture* 28 (3):607.

Lee, Allen S., and Richard L. Baskerville. 2003. "Generalizing Generalizability in Information Systems Research". *Information Systems Research* 14 (3):243.

Leonard-Barton, D. 1988. "Implementation as mutual adaption of technology and organisation". *Research Policy* 17 (5):251-267.

———. 1992. "Core Capabilities and core rigidities: a paradox in managing new product development". *Strategic Management Journal* 13 (0):111-125.

Leonard, Dorothy. 1995. *Wellsprings of knowledge : building and sustaining the sources of innovation*. Boston, Mass.: Harvard Business School Press.

Lettl, Christopher. 2005. "The emergence of radically new health care technologies: Inventive users as innovation networkers." *Technology & Health Care* 13 (3):169-183.

Lettl, Christopher, Cornelius Herstatt, and Hans Georg Gemuenden. 2006. "Users' contributions to radical innovation: evidence from four cases in the field of medical equipment technology". *R and D Management* 36 (3):251-272.

Lewin, Kurt. 1951. *Field theory in social science; selected theoretical papers*. [1st ed. New York,: Harper.

Little, Chuck, and Wendy B. Katzman. 2006. "Automated external defibrillators for layperson use". In *Advances in healthcare technology : shaping the future of medical care*, edited by G. Spekowius and T. Wendler. Dordrecht ; London: Springer.

Locke, John. 1689. "An essay concerning human understanding".

Loeser, J. D. 2000. "Pain and suffering". *Clinical Journal of Pain* 16 (2):S2-S6.

Lukes, Steven. 1974. *Power : a radical view*. London ; New York: Macmillan.

Lundvall, Bengt-Ake. 1992. *National systems of innovation : towards a theory of innovation and interactive learning*. London New York: Pinter Publishers; Distributed exclusively in the USA and Canada by St. Martin's Press.

Luthje, C. 2004. "Characteristics of innovating users in a consumer goods field: An empirical study of sport-related product consumers". *Technovation* 24 (9):683-695.

Lyytinen, Kalle J., and Heinz K. Klein. 1985. "The critical theory of Jurgen Habermas as a basis for a theory of information systems". In *Research methods in information systems : proceedings of the IFIP WG 8.2 Colloquium, Manchester Business School, 1-3 September, 1984*, edited by E. Mumford. Amsterdam ; New York: North-Holland ; Sole distributors for the U.S.A. and Canada Elsevier Science Pub. Co.

Malerba, Franco. 2004. *Sectoral systems of innovation : concepts, issues and analyses of six major sectors in Europe*. New York, N.Y.: Cambridge University Press.

Malinowski, Bronislaw. 1922. *Argonauts of the western Pacific*. London,: G. Routledge & sons.

Marinnova, Dora, and John Philliore. 2003. "Models of innovation". In *The international handbook on innovation*, edited by L. V. Shavinina. Amsterdam ; Boston: Elsevier Science.

Marmot, Michael G. 2004. "Evidence based policy or policy based evidence?" *BMJ* 328 (7445):906-907.

Mars, M., C. Ashermcdade, V. Brattstrom, E. Dahl, J. McWilliam, K. Molsted, D. A. Plint, B. Prahlandersen, G. Semb, W. C. Shaw, and R. P. S. The. 1992. "A 6-center international study of treatment outcome in patients with clefts of the lip and palate.3. dental arch relationships". *Cleft Palate-Craniofacial Journal* 29 (5):405-408.

Maynard, Alan, Karen Bloor, and Nick Freemantle. 2004. "Challenges for the National Institute for Clinical Excellence". *BMJ* 329 (7459):227-229.

Medipex. 2004. "R&D Managers Guidance Booklet: For managing intellectual property". UK: Medipex.

Metcalfe, J. S. 1995. "Technology Systems and Technology Policy in an Evolutionary Framework". *Cambridge Journal of Economics* 19 (1):25-46.

Metcalfe, J. S., A. James, and A Mina. 2005. "Emergent innovation systems and the delivery of clinical services: The case of intra-ocular lenses". *Research Policy* 34 (9):1283-1304.

Metcalfe, J. S., and J. Pickstone. 2006. "Replacing hips and lenses: surgery, industry and innovaton in post-war Britain". In *New technologies in health care : challenge, change, and innovation*, edited by A. Webster. Houndmills, Basingstoke, Hampshire ; New York, N.Y.: Palgrave Macmillan.

Miles, Matthew B., and A. M. Huberman. 1994. *Qualitative data analysis : an expanded sourcebook*. 2nd ed. Thousand Oaks: Sage Publications.

Mina, A, G Tampubolon, R Ramlogan, L Venetucci, A. McMeekin, and J. S. Metcalfe. 2004. "Problem sequences and innovation systems: emergence, growth and transformation of a medical sector". In *CRIC Discussion Paper No 67*. Centre for Research on Innovation & Competition: University of Manchester.

Mintzberg, Henry. 1993. *Structure in fives : designing effective organizations*. Englewood Cliffs ; London: Prentice Hall : Prentice-Hall International.

Mitcham, Carl. 1994. *Thinking through technology : the path between engineering and philosophy*. Chicago: University of Chicago Press.

Moffatt, C.J., P.J. Franks, D.C. Doherty, R. Martin, R. Blewett, and F. Ross. 2004. "Prevalence of leg ulceration in a London population". *QJM* 97 (7):431-437.

Moffatt, C.J., P.J. Franks, M. Oldroyd, Nick Bosanquet, Pearl Brown, Roger Greenhalgh, and Charles N McCollum. 1992. "Community clinics for leg ulcers and impact on healing". *BMJ* 305:1389-92.

Mohr, Lawrence B. 1982. *Explaining organizational behavior*. 1st ed, *The Jossey-Bass social and behavioral science series*. San Francisco: Jossey-Bass.

Moore, Mark H. 2005. "Break-Through Innovations and Continuous Improvement: Two Different Models of Innovative Processes in the Public Sector". *Public Money and Management* 25 (1):43-50.

Morison, Elting Elmore. 1966. *Men, machines, and modern times*. Cambridge, Mass.,: M.I.T. Press.

Mowery, D. C., B. N. Sampat, and A. A. Ziedonis. 2002. "Learning to patent: Institutional experience, learning, and the characteristics of US university patents after the Bayh-Dole Act, 1981-1992". *Management Science* 48 (1):73-89.

Nag, Rajiv, Kevin Corley, and Dennis Gioia. 2003. "Innovation tensions: Chaos, structure, and managed chaos". In *The international handbook on innovation*, edited by L. V. Shavinina. Amsterdam ; Boston: Elsevier Science.

Nelson, Richard R. 1990. "Capitalism as an engine of progress". *Research Policy* 19 (3):193-214.

———. 2001. "Observations on the Post-Bayh-Dole Rise of Patenting at American Universities". *The Journal of Technology Transfer* 26 (1 - 2):13-19.

NHS Connecting for Health: Integrated Service Improvement Programme. 2006. "*Benefits Review: Leg Ulcer Telemedicine service at Good Hope Hospital NHS Trust*": NHS Connecting for Health: Integrated Service Improvement Programme.

NHS Innovations. 2004. "*NHS Innovations Annual Report 2003/2004*". London, UK: NHS Innovations.

NHS Institute for Innovation and Improvement. 2005. "*NHS Institute for Innovation and Improvement: Priorities for 2005/06*". London, UK: Department of Health.

NICE. 2005. "*Lung Cancer: The diagnosis and treatment of lung cancer. Guideline 24*". London: National Instiute for Clinical Excellence.

———. 2006. "*CG40 Urinary incontinence: full guideline* ". London: National Instiute for Clinical Excellence.

Nonaka, Ikujirâo, and Hirotaka Takeuchi. 1995. *The knowledge-creating company : how Japanese companies create the dynamics of innovation*. New York: Oxford University Press.

Northrup, Jon. 2005. "The pharmaceutical sector". In *The business of healthcare innovation*, edited by L. R. Burns. Cambridge, UK ; New York: Cambridge University Press.

Nowotny, H., P. Scott, and M. Gibbons. 2003. "'Mode 2' revisited: The new production of knowledge - Introduction". *Minerva* 41 (3):179-194.

Nowotny, Helga, Peter Scott, and Michael Gibbons. 2001. *Re-thinking Science: knowledge and the public in an Age of Uncertainty*. 1 ed. Cambridge, UK: Polity.

NSR Implementation Team. 2009. "*High quality care for all: Our journey so far*": Department of Health.

Nugent, Helen. 2008. "Heart attack response plan 'would save hundreds more'". *The Times*, October 20, 2008, 13.

Oates, John. 2002. "Ethical frameworks for research". In *Doing postgraduate research*, edited by S. Potter. London ; Thousand Oaks, Calif.: SAGE Publications in association with the Open University.

OECD, and EUROSTAT. 2005. *Oslo manual : guidelines for collecting and interpreting innovation data*. 3rd ed. Paris, France: OECD Publishing.

Office of Science and Technology. 2000. "*The Government response to the Baker Report: "Creating Knowledge, Creating Wealth:" Realising the economic potential of public sector research establishments*": HM Treasury.

Orlikowski, W. 1992. "The duality of technology: rethinking the concept of technology in organisations". *Organization Science* 3 (2):398-427.

Orlikowski, W. J. 2000. "Using technology and constituting structures: A practice lens for studying technology in organizations". *Organization Science* 11 (4):404-428.

Orlikowski, W. J., and J.J. Baroudi. 2002. "Studying information technology in organsations: research approaches and assumptions". In *Qualitative research in information systems : a reader*, edited by M. D. Myers and D. E. Avison. London ; Thousand Oaks, Calif.: SAGE.

Orr, Julian E. 1996. *Talking about machines : an ethnography of a modern job, Collection on technology and work*. Ithaca, N.Y.: ILR Press.

Pettigrew, Andrew M. 1990. "Longitudinal field research on change: theory and practice". *Organization Science* 1 (3):267-292.

———. 1992. "The character and significance of strategy process". *Strategic Management Journal* 13:5-16.

Piatier, A. 1984. *Barriers to innovation*. London ; Dover, N.H.: F. Pinter.

Pinch, T. J., and W. E. Bijker. 1984. "The Social Construction of Facts and Artifacts - or How the Sociology of Science and the Sociology of Technology Might Benefit Each Other". *Social Studies of Science* 14 (3):399-441.

Pisano, G. P. 1996. "Learning-before-doing in the development of new process technology". *Research Policy* 25 (7):1097-1119.

Pisano, G. P., R. M. J. Bohmer, and A. C. Edmondson. 2001. "Organizational differences in rates of learning: Evidence from the adoption of minimally invasive cardiac surgery". *Management Science* 47 (6):752-768.

Polanyi, M. 1958. *Personal knowledge: Towards a post-critical philosophy*. 1 ed: Routledge.

Pope, Catherine, Glenn Robert, Paul Bate, Andree Le May, and John Gabbay. 2006. "Lost in Translation: A Multi-Level Case Study of the Metamorphosis of Meanings and Action in Public Sector Organizational Innovation". *Public Administration* 84 (1):59-79.

Potter, Stephen. 2002. *Doing postgraduate research*. London ; Thousand Oaks, Calif.: SAGE Publications in association with the Open University.

Price, Cathy. 2006. "Managing pain management: Setting up an effective pain service in Southampton". *Bulletin 36, The Royal College of Anaesthetics*:p.1830-1831.

———. 2008. *Managing Pain Management: lecture given by Dr Cathy Price, Consultant in Pain Management for the Southampton University Hospitals NHS Trust, to the*

North British Pain Association Spring Scientific Meeting in Edinburgh on Friday 18th May, 2007 [Powerpoint presentation] 2007 [cited 6 June 2008 2008]. Available from http://www.slideshare.net/epicyclops/managing-pain-management/.

Price, Cathy, and Jane Swales. 2004. "Working within a primary care trust - ramifications for a pain service". *The British Pain Society Newsletter* (Summer):22-23.

Radley, S., and O. Brown. 2005. "Does prolapse surgery address the symptoms that concern women?" *Hosp Med* 66 (3):158-62.

Radley, S. C., and G. L. Jones. 2004. "Measuring quality of life in urogynaecology". *BJOG* 111 Suppl 1:33-6.

Radley, S. C., G. L. Jones, E. A. Tanguy, V. G. Stevens, C. Nelson, and N. J. Mathers. 2006. "Computer interviewing in urogynaecology: concept, development and psychometric testing of an electronic pelvic floor assessment questionnaire in primary and secondary care". *BJOG* 113 (2):231-8.

Raftery, James. 2006. "Review of NICE's recommendations, 1999-2005". *BMJ* 332 (7552):1266-1268.

RCN. 1998. *The managment of patients with venous leg ulcers, Clinical Practice Guidelines*. York, UK: Royal College of Nursing Institute.

Reason, P, and H Bradbury, eds. 2000. *Handbook of Action Research: Participative inquiry and practice*. 1 ed. London: Sage.

Reason, P. 1999. "Integrating action and reflection through co-operative inquiry". *Management Learning* 30 (2):207-226.

Reid, Graham. 2009. *"Innovation for a healthier future - briefing pack"*: Department of Health.

Roback, Kerstin, Per-Olof Gaddlin, Nina Nelson, and Jan Persson. 2007. "Adoption of medical devices: Perspectives of professionals in Swedish neonatal intensive care". *Technology & Health Care* 15 (3):157-179.

Roberts, C.T., G. Semb, and W.C. Shaw. 1991. "Strategies for the advancement of surgical methods in cleft lip and palate". *Cleft Palate-Craniofacial Journal* 28:141-149.

Roberts, Karlene, and Martha Grabowski. 1996. "Organisations, technology and structuring". In *Handbook of organization studies*, edited by S. Clegg, C. Hardy and W. R. Nord. London ; Thousand Oaks: Sage Publications.

Roethlisberger, F. J., and George F. F. Lombard. 1977. *The elusive phenomena : an autobiographical account of my work in the field of organizational behavior at the Harvard Business School*. Boston, Cambridge, Mass.: Division of Research, Graduate School of Business Administration distributed by Harvard University Press.

Rogers, Everett M. 2003. *Diffusion of innovations*. 5th ed. New York: Free Press.

Rogers, H, K Silvestor, and J Copeland. 2004. "NHS Modernisation Agency's way to improve health care". *British Medical Journal* (328):463.

Rosenberg, Nathan. 1982. *Inside the black box : technology and economics*. Cambridge Cambridgeshire ; New York: Cambridge University Press.

Rothwell, Roy. 1992. "Developments Towards the Fifth Generation Model of Innovation." *Technology Analysis & Strategic Management* 4 (1):73.

———. 1994. "Towards the Fifth-generation Innovation Process." *International Marketing Review* 11 (1):7.

Rothwell, Roy, and Walter Zegveld. 1985. *Reindustrialization and technology*. Armonk, N.Y.: M.E. Sharpe.

Rushmer, R., D. Kelly, M. Lough, J. E. Wilkinson, and H. T. O. Davies. 2004. "Introducing the learning practice - I. The characteristics of learning organizations in primary care". *Journal of Evaluation in Clinical Practice* 10 (3):375-386.

Sakkab, Nabil Y. 2002. "Connect Develop Complements Research Develop at PG". *Research-Technology Management* 45:38-45.

Samad, a, Susan Hayes, and S. R. Dodds. 2002. "Telemedicine: an innovative way of managing patients with leg ulcers". *British Journal of Nursing* 11 (6):(Supp): S38-S52.

Samad, a, Susan Hayes, Lorraine French, and S. R. Dodds. 2002. "Digital imaging versus conventional contact tracing for the objective measurement of venous leg ulcers". *Journal of Wound Care* 11 (4):137-140.

Sandy, J, A Williams, S Mildinhall, T Murphy, D Bearn, B Shaw, D Sell, B Devlin, and J Murray. 1998. "The Clinical Standards Advisory Group (CSAG) Cleft Lip and Palate Study". *J. Orthod.* 25 (1):21-30.

Sarason, Yolanda. 1995. "A model of organizational transformation: the incorporation of organizational identify into a structuration theory framework". *Academy of Management Proceedings*:51.

Savory, C. 2006. "Does the UTTO model of technology transfer fit public sector healthcare services?" *International Journal of Innovation and Technology Management* 3 (2):171-187.

———. 2006. "Knowledge Translation Capability and Public-Sector Innovation Processes". Paper read at *International Conference on Organizational Learning, Knowledge and Capabilities, 20th - 22nd March 2006*, 20th - 22nd March 2006, at University of Warwick, Coventry, UK.

———. 2006. "Translating knowledge to build technological competence". *Management Decision* 44 (8):1052-1075.

———. 2009. "Building knowledge translation capability into public-sector innovation processes ". *Technology Analysis & Strategic Management* 21 (2):149-171.

Schon, Donald A. 1967. *Technology and change; the new Heraclitus*. New York,: Delacorte Press.

Schumpeter, Joseph Alois. 1934. *The theory of economic development; an inquiry into profits, capital, credit, interest, and the business cycle, Harvard economic studies. vol. XLVI*. Cambridge, Mass.,: Harvard University Press.

Scott, W. Richard. 2001. *Institutions and organizations*. 2nd ed, *Foundations for organizational science*. Thousand Oaks, Calif.: Sage Publications.

Shah, Syed Ghulam Sarwar, and Ian Robinson. 2006. "User involvement in healthcare technology development and assessment: Structured literature review". *International Journal of Health Care Quality Assurance* 19 (6).

———. 2007. "Benefits of and barriers to involving users in medical device technology development and evaluation". *International Journal of Technology Assessment in Health Care* 23 (01):131-137.

Shaw, W. C., J. R. Sandy, A. C. Williams, and H. B. Devlin. 1996. "Minimum standards for the management of cleft lip and palate: Efforts to close the audit loop". *Annals of the Royal College of Surgeons of England* 78 (2):110-114.

Siegel, Donald S., David Waldman, and Albert Link. 2003. "Assessing the impact of organizational practices on the relative productivity of university technology transfer offices: an exploratory study". *Research Policy* 32 (1):27-48.

Simon, Deborah A, Francis P Dix, and Charles N McCollum. 2004. "Management of venous leg ulcers". *BMJ* 328 (7452):1358-1362.

Slappendel, Carol. 1996. "Perspectives on Innovation in Organization". *Organization Studies (Walter de Gruyter GmbH & Co. KG.)* 17 (1).

Smith, Adam. 1981. "An Inquiry Into the Nature and Causes of the Wealth of Nations, Vol.1 [1776]". In *Part of: The Glasgow Edition of the Works and Correspondence of Adam Smith, 7 vols.*, ed R. H. Campbell and A. S. Skinner. Place Published: Indianapolis: Liberty Fund. http://files.libertyfund.org/files/220/Smith_0141.02.pdf (accessed 2008-09-23).

Souitaris, Vangelis. 2003. "Determinants of technological innovation: current research trends and future prospects". In *The international handbook on innovation*, edited by L. V. Shavinina. Amsterdam ; Boston: Elsevier Science.

Stahl, James E., Joseph P. Vacanti, and Scott Gazelle. 2007. "Assessing emerging technologies:The case of organ replacement technologies: Volume, durability, cost". *International Journal of Technology Assessment in Health Care* 23 (03):331-336.

Stake, Robert. 2000. "Case studies". In *Handbook of qualitative research*, edited by N. K. Denzin and Y. S. Lincoln. Thousand Oaks, Calif.: Sage Publications.

Stogdill, Ralph M. 1974. *Handbook of leadership; a survey of theory and research.* New York,: Free Press.

Stowell, F. and West, D. 1994. *Client led design*: McGraw Hill.

Strauss, Anselm, L., and Juliet Corbin. 1998. *Basics of qualitative research : techniques and procedures for developing grounded theory.* Thousand Oaks, Calif. ; London: Sage Publications.

Suchman, Lucille Alice. 1987. *Plans and situated actions : the problem of human-machine communication.* Cambridge Cambridgeshire ; New York: Cambridge University Press.

Swamidass, P. M., and A. Nair. 2004. "What top management thinks about the benefits of hard and soft manufacturing technologies". *IEEE Transactions on Engineering Management* 51 (4):462-471.

Swan, J. 1997. "Using cognitive mapping in management research: Decisions about technical innovation". *British Journal of Management* 8 (0):183-198.

Szulanski, G. 1996. "Exploring internal stickiness: Impediments to the transfer of best practice within the firm". *Strategic Management Journal* 17:27-43.

———. 2000. "The process of knowledge transfer: A diachronic analysis of stickiness". *Organizational Behavior and Human Decision Processes* 82 (1):9-27.

Teece, D. J. 1998. "Capturing value from knowledge assets: The new economy, markets for know-how, and intangible assets". *California Management Review* 40 (3):55.

Teece, D. J., G. Pisano, and A. Shuen. 1997. "Dynamic capabilities and strategic management". *Strategic Management Journal* 18 (7):509-533.

Teece, David J. 1986. "Profiting from technological innovation: Implications for integration, collaboration, licensing and public policy". *Research Policy* 15 (6):285-305.

———. 2000. *Managing intellectual capital : organizational, strategic, and policy dimensions*. Oxford ; New York: Oxford University Press.

Teich, Albert H. 2003. *Technology and the future*. 9th ed. Belmont, CA: Thomson/Wadsworth.

Tether, B. 2004. "Do services innovate (differently)?" In *CRIC Discussion Paper No 66*. Centre for Research on Innovation & Competition: University of Manchester.

Tether, B. S., and J. S. Metcalfe. 2003. "Horndal at Heathrow? Capacity creation through co-operation and system evolution". *Industrial and Corporate Change* 12:476.

Thomke, S., and E. von Hippel. 2002. "Customers as innovators - A new way to create value". *Harvard Business Review* 80 (4):74-81.

Tidd, Joseph, and Frank M. Hull. 2003. *Service innovation : organizational responses to technological opportunities & market imperatives, Series on technology management ; v. 9*. London: Imperial College Press.

Trist, E.L. 1981. "The evolution of sociotechnical systems as a conceptual framework and as an action research program". In *Perspectives on organization design and behavior*, edited by A. H. Van de Ven and W. F. Joyce. New York: Wiley.

Tushman, Michael L., and Philip Anderson. 1986. "Technological Discontinuities and Organizational Environments". *Administrative Science Quarterly* 31 (3):439-465.

Tyre, M. J., and E. von Hippel. 1997. "The situated nature of adaptive learning in organizations". *Organization Science* 8 (1):71-83.

UK Government. 2000. "*The NHS Plan, A plan for investment, a plan for reform*". London: HMSO.

Van De Ven, Andrew H. 1992. "Suggestions for studying strategy process: a research note". *Strategic Management Journal* 13:169-188.

Van de Ven, Andrew H. 1999. *The innovation journey*. New York: Oxford University Press.

Vincenti, Walter G. 1990. *What engineers know and how they know it : analytical studies from aeronautical history, Johns Hopkins studies in the history of technology ; [new. ser., no. 11]*. Baltimore: Johns Hopkins University Press.

von Hippel, E. 1994. "Sticky Information and the Locus of Problem-Solving - Implications for Innovation". *Management Science* 40 (4):429-439.

von Hippel, Eric. 2007. "Horizontal innovation networks--by and for users". *Ind Corp Change* 16 (2):293-315.

Von Korff, Michael, Russell E Glasgow, and Michael Sharpe. 2002. "ABC of psychological medicine: Organising care for chronic illness". *BMJ* 325 (7355):92-94.

Voss, C. A. 1984. "Technology push and need pull: A new perspective". *R&D Management* 14 (3):147-151.

Waddell, Gordon. 1987. "A new clinical model for the treatment of low-back pain". *Spine* 12 (7):632-644.

Walsham, Geoff. 1995. "Interpretive case studies in IS research: nature and method". *European Journal of Information Systems* 4 (0):74-81.

———. 1999. "Interpretive evaluation design for information systems". In *Beyond the IT productivity paradox*, edited by L. Willcocks and S. Lester. New York: Wiley.

———. 2001. *Making a world of difference : IT in a global context*. Chichester: Wiley.

———. 2002. "Interpretive case studies in IS research". In *Qualitative research in information systems : a reader*, edited by M. D. Myers and D. E. Avison. London ; Thousand Oaks, Calif.: SAGE.

———. 2006. "Doing interpretive research". *European Journal of Information Systems* 15:330.

Walsham, Geoff, and S. Sahay. 1999. "GIS for district-level administration in India: Problems and opportunities". *Mis Quarterly* 23 (1):39-65.

Ward, J. 1990. "A portfolio approach to evaluating information systems investments and setting priorities". *Journal of Information Technology* 5:222-231.

Ward, John, and Elizabeth Daniel. 2006. *Benefits management : delivering value from IS & IT investments, John Wiley series in information systems*. Hoboken, NJ: Wiley.

Weaver, Gary R., and Dennis A. Gioia. 1994. "Paradigms Lost: Incommensurability vs Structurationist Inquiry". *Organization Studies (Walter de Gruyter GmbH & Co. KG.)* 15 (4).

Webster, Andrew. 2007. *Health, technology and society : a sociological critique*. Basingstoke: Palgrave Macmillan.

Weick, K. E., and K. M. Sutcliffe. 2003. "Hospitals as cultures of entrapment: A reanalysis of the Bristol Royal Infirmary". *California Management Review* 45 (2):73.

Weick, K.E. 1995. *Sensemaking in organisations*. 1 ed: Sage.

Weick, Karl E. 2001. *Making sense of the organization*. Oxford, UK ; Malden, MA: Blackwell Publishers.

Wenger, Etienne. 1998. *Communities of practice : learning, meaning, and identity, Learning in doing*. Cambridge, U.K. ; New York, N.Y.: Cambridge University Press.

Williams, A. C., D. Bearn, S. Mildinhall, T. Murphy, D. Sell, W. C. Shaw, J. J. Murray, and J. R. Sandy. 2001. "Cleft lip and palate care in the United Kingdom - The Clinical Standards Advisory Group (CSAG) study. Part 2: Dentofacial outcomes and patient satisfaction". *Cleft Palate-Craniofacial Journal* 38 (1):24-29.

Willmott, Robert. 1997. "Structure, Culture and Agency: Rejecting the Current Orthodoxy of Organisation Theory". *Journal for the Theory of Social Behaviour* 27 (1):93-123.

Wilson, Charles B. 2006. "Adoption of new surgical technology". *BMJ* 332 (7533):112-114.

Winner, Langdon. 1985. "Do artifacts have politics?" In *The Social shaping of technology : how the refrigerator got its hum*, edited by D. A. MacKenzie and J. Wajcman. Milton Keynes ; Philadelphia: Open University Press.

Worthington, F. 2004. "Management, change and culture in the NHS: rhetoric and reality". *Clinician in Management* 12 (2):55-67.

Yanof, Jeffrey, and Michael Kuhn. 2006. "New technology for image-guided therapy". In *Advances in healthcare technology : shaping the future of medical care*, edited by G. Spekowius and T. Wendler. Dordrecht ; London: Springer.

Yin, Robert K. 2003. *Case study research : design and methods*. 3rd ed, *Applied social research methods series ; v. 5*. Thousand Oaks, Calif.: Sage Publications.

Zahra, S. A., and G. George. 2002. "Absorptive capacity: A review, reconceptualization, and extension". *Academy of Management Review* 27 (2):185-203.

Zander, U. and Kogut, B. 1995. "Knowledge and the speed of transfer and imitation of organisational capabilities: an empirical test". *Organization Science* 6 (1):76-92.

Zhang, Qingyu, and William J Doll. 2001. "The fuzzy front end and success of new product development: a causal model". *European Journal of Innovation Management* 4 (2).

Zuboff, Shoshana. 1988. *In the age of the smart machine : the future of work and power.* New York: Heinemann Professional.