

Why and How New Technologies Fail or Succeed to Embed in Routine Health Services:

Lessons from the Introduction of Telehealth Home Monitoring

Victor Vuni Joseph

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The candidate confirms that the work submitted is his own, except where work which has formed part of jointly authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

A jointly authored publication was referenced in Chapter 4 of the thesis, which addressed key challenges and factors for success of telehealth projects. The jointly authored publication is entitled: *Key challenges in the development and implementation of telehealth projects*, and it was authored by Victor Joseph, Robert M West, Darren Shickle, Justin Keen, and Susan Clamp. The article was published in the Journal of Telemedicine and Telecare, 2011; 17:71-77. The candidate carried out the work contained in the publication, and wrote the draft article. The rest of the authors provided comments on the draft article.

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Abstract

Title: Why and how new technologies fail or succeed to embed in routine health services: Lessons from the introduction of telehealth home monitoring.

Background: New technologies were introduced in Doncaster to enable people with long-term illness self-manage their conditions and to reduce health care costs.

Aim: To investigate why telehealth home monitoring embeds in routine healthcare setting.

Methods: A case-study research method was used, drawing on lessons from (1) a randomised controlled trial; (2) observational study (before and after uncontrolled evaluation); and (3) qualitative study capturing the views of the stakeholders using semi-structured interviews. The study was informed by Normalisation Process Theory (NPT). The case-study research was carried out in accordance with approach advocated by Yin (2009).

Results: The evidence shows that factors related to evaluation design, the technology, and staff could not be excluded as possible explanations for the performances of telehealth home monitoring. There was limited evidence to support the fact that factors related to geographical setting and patient groups provided possible explanation for the difference in the uptake of the new technology. Randomised controlled trial (RCT) showed poor uptake of telehealth, while evidence from service evaluation showed that telehealth was embedding in routine healthcare use in Doncaster.

Conclusions: The interaction of factors related to evaluation design, technology, and staff cannot be rejected as causal factors for success or failure of new technologies to embed in routine healthcare setting. On the other hand, the evidence available could not allow the hypotheses related to setting and patients' group to be accepted as to why new technologies fail or succeed in routine practice. The evidence suggests that telehealth home monitoring was embedding in routine healthcare use in Doncaster.

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Abbreviations

A&E	Accident and Emergency (in hospital)
AT	Assistive Technology
BP	Blood Pressure
BT	British Telecom
C/W/S	Consultation per week per site
CASP	Critical Appraisal Skills Programme
CCG	Clinical Commissioning Group
CCHT	Care Coordination Home Telehealth
CCRN	Comprehensive Clinical Research Network
CDM	Chronic Disease Management
CENTRAL	Cochrane Central Register of Controlled Trials
CHD	Coronary Heart Disease
CHF	Congestive Heart Failure
CI	Confidence Interval
CLRN	Comprehensive Local Research Network
CONSORT	Consolidated Standards Of Reporting Trials
COPD	Chronic Obstructive Pulmonary Disease
COREQ	Consolidated Criteria for Reporting Qualitative studies
CSO	Clinical System Organiser (telehealth system)
DALLAS	Delivering Assistive Living Lifestyle at Scale
DEPOSE	Design, Environment, Procedures, Operators, Suppliers and materials, and Environment.
DH	Department of Health
DMBC	Doncaster Metropolitan Borough Council
DSR	Directly Standardised Rate
DTPB	Doncaster Telesolution Programme Board
EBR	Evidence Based Review

e-Health	Electronic Health
e-HIT	e-Health Implementation Toolkit
FEV1	Forced Expiratory Volume in one second
EQ5D	EuroQol 5-Dimension questionnaire
GAD-7	Generalised Anxiety Disorder 7-items questionnaire
GP	General Practitioner (doctor)
HbA1c	Haemoglobin A1c (Glycated haemoglobin)
HES	Hospital Episode Statistics
HMIC	Health Management Information Consortium
Ho	Null Hypothesis
HR	Hazards Ratio
HRG	Healthcare Resource Group
ICCP	Integrated Community Care Pathway
ICD-10	International Classification of Disease version 10
ICP	Integrated Care Platform
ICT	Information and Communication Technologies
IMD	Index of Multiple Deprivation
ITPOSMO	Information, Technology, Process, Objectives and values, Staff and skills, Management and structure, and Other resources
ITT	Intention To Treat
ITU	International Telecommunication Union
KI	Karnofski Index
LA	Local Authority
LDL	Low Density Lipoprotein
LES	Local Enhanced Service
LoS	Length of (hospital) Stay
LR	Logistic Regression
LTC	Long Term Condition
MeSH	Medical Subject Headings

MLHF	Minnesota Living with Heart Failure
NCD	Non-Communicable Disease
NCHOD	National Clinical and Health Outcomes Database
NHS	National Health Service (in UK)
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NPM	Normalisation Process Model
NPT	Normalisation Process Theory
NRES	National Research Ethics Service
NRF	Neighbourhood Renewal Fund
NSF	National Service Framework
ONS	Office for National Statistics
OR	Odds Ratio
PASA	Purchasing and Supply Agency (part of NHS)
PAT	Portable Appliance Testing
PCT	Primary Care Trust
PhD	Doctor of Philosophy
PHE	Public Health England
PHIU	Public Health Intelligence Unit
POTS	Plain Old Telephone System
QALY	Quality Adjusted Life-years
QOF	Quality Outcome Framework
QoL	Quality of Life
R&D	Research and Development
RCT	Randomised Controlled Trial
RDASH	Rotherham, Doncaster and South Humber Mental Health Foundation Trust
REC	Research Ethics Committee
RR	Risk Ratio

RWG	Respiratory Working Group
SF-36	Short-Form 36 items questionnaire
SIGN	Scottish Intercollegiate Guidance Network
SGRQ	St George's Respiratory Questionnaire
SHA	Strategic Health Authority
SMT	Senior Managers Team
SpO2	Pulse Oximeter Oxygen Saturation
SR	Systematic Review
STROBE	Strengthening the Reporting of Observational studies in Epidemiology
SYCLRN	South Yorkshire Comprehensive Local Research Network
TCS	Transforming Community Service
TELECCOM	Referring to pragmatic randomised controlled trial in this thesis entitled: Effects of Tele health on patients with COPD in the Community)
TRoPH	Trial Register for Promoting Health intervention
UCL	University College London
U-health	Ubiquitous healthcare
VHA	Veteran Health Administration
WHO	World Health Organisation
WSD	Whole System Demonstrator

Chapter 1: Introduction

This chapter introduces the thesis by outlining (1) the purpose of the thesis; (2) the original research questions, aim, and objectives; (3) the final research questions, aim, objectives, and hypotheses; and (4) the structure of the thesis.

1.1 The purpose of the thesis

This thesis is about why and how new technologies fail or succeed to embed in routine healthcare practice. In particular, the thesis looks at telehealth as an example of new technologies, which is used in the delivery of healthcare at a distance. This understanding is important to promote the uptake of worthwhile new technologies in routine use. The purpose of the study is to help new technologies that are considered to be cost-effective or otherwise deemed worthwhile to embed in routine health service delivery in the future in order to improve access to health service, reduce hospital admissions, save costs of delivering healthcare, improve quality of life, and save lives.

Telehealth technologies are being introduced in healthcare systems either as pilot projects or as part of routine service deliveries from around the world, including Britain. However, the level of uptake of these technologies varied; with some failing to embed in routine practice while others succeeding to do so. For example, a pilot of telehealth in Carlisle in the North West of England (Britain) which began in 2006 had to be halted after a short period of implementation (personal communication). Similarly, an initially ambitious scheme in North Yorkshire (England), which aimed to utilise 2000 telehealth kits for patients with long-term conditions also failed to achieve the recruitment target envisaged

(Evanstad, 2013). The healthcare organisations in North Yorkshire managed to recruit only 645 patients (of the expected 2000) by February 2013, and five of the six Clinical Commissioning Groups (CCGs) refused to engage (Evanstad, 2013). The North Yorkshire scheme was part of a 5-year bigger Government programme in England to get 3 million people to use telehealth by 2017 (3MillionLives, 2012). This contrasts with lessons from the Veterans Health Administration (VHA) in the United States of America (USA), where telehealth appeared to have embedded in routine delivery of health service and over 50,000 patients were receiving telehealth service by 2011 (Cruickshank, 2012).

Telehealth home monitoring, or otherwise referred to as remote patient monitoring, in this thesis has been defined by the author as follows:

“Remote patient monitoring is the remote exchange of patients’ data where patients measure their vital signs (oxygen saturation level in their blood (SpO₂), pulse, breathing, or blood pressure), and answer symptoms questions from their home and the data is transmitted via internet to a healthcare professional who monitors the patients’ data and institutes appropriate management actions.” Adapted from (Steventon et al., 2012)

The role and potential benefits of new technologies, such as telehealth, in the delivery of healthcare at a distance had been identified in a number of published literatures. For example, Wanless (2002) argued that in order to secure a long-term financially sustainable future delivery of high quality healthcare, and health outcomes for the British population, it was essential to engage the population fully in prevention and self-care agenda using assistive technologies such as

telehealth (Wanless, 2002). Some of the claimed potential benefits of telehealth technologies in the delivery of healthcare included: enabling users to gain control of their health conditions and to remain independent, efficient use of limited healthcare resources, such as reduction of hospital admissions, and saving the lives of people (Audit Commission, 2004, Steventon et al., 2012, Ekeland et al., 2010, Jones and Brennan, 2002, Department of Health, 2005a). There are, however, uncertainties around effectiveness and cost-effectiveness of some of these new technologies in routine delivery of healthcare on a range of health conditions and/or disease areas, and the evidence base for these remains inconclusive (Ekeland et al., 2010, Hailey, 2005, Steventon and Bardsley, 2012). Chapter 4 of this thesis assesses the evidence of effectiveness and cost-effectiveness of telehealth. There is also a poor understanding of why and how some of the technologies fail while others succeed when introduced in routine healthcare practice (Sheikh et al., 2011).

Areas of potential gaps that new technologies can be used to address include self-care or remote care for people with long-term conditions (LTC). Examples of LTC include patients suffering from heart disease, cancers, chronic respiratory diseases, and diabetes among others. LTCs are a major public health problem, and they cause 36 million (63%) deaths globally each year (World Health Organisation, 2011). In Britain alone, 1 in 3 (17.5 million) of the population are considered to have a LTC (Department of Health, 2001). With ageing population, especially in the western world, more people live longer and are likely to suffer from LTCs. Therefore, the prevalence of LTCs is expected to increase. Self-care and telehealth are considered to play an important role in the management of people with LTCs. This should be viewed in light of current

healthcare challenges faced by healthcare organisations where there are limited healthcare resources, and difficulties in accessing healthcare (Department of Health, 2005a).

1.2 How the research aims and objectives evolved

The aims and objectives of the PhD research evolved over time. Initially, the aim of the research was to assess the effectiveness of telehealth. However, this was later changed to investigating why new technologies fail or succeed to embed in routine healthcare practice. The reason for the change of focus was that the pragmatic randomised control trial reported in Chapter 5 was considered to be unlikely to yield valid results in assessing the effectiveness of telehealth due to a number of reasons, including the difficulties in recruiting participants into the trial. The detail challenges encountered in conducting the pragmatic trial are discussed in Chapter 5.

1.2.1 The original research question, aim, and objectives

The idea of introducing telehealth in Doncaster came about following attendance by the author, at a conference in South Yorkshire (England) on the management of LTCs in 2006. At the conference, the emerging experience of telehealth in an English district in the North West of England was presented and discussed. Subsequently, further discussion took place in Doncaster at the local Respiratory Working Group, chaired by the author, where telehealth was discussed following a presentation by invited healthcare workers who were involved in piloting telehealth in Carlisle, North West England. The pilot scheme at Carlisle suggested that telehealth was effective in reducing hospital

admissions among patients with chronic obstructive pulmonary disease (COPD), based on observational study (before-after uncontrolled service evaluation).

Following a successful application to the Neighbourhood Renewal Fund (NRF) for assistive technology grant, it was decided to pilot the use of telehealth in Doncaster, focusing on patients with COPD. Given, the potential bias in evaluation of similar telehealth projects, such as the one in Carlisle, the steering group in Doncaster, led by the author, decided to evaluate the telehealth service using a pragmatic randomised controlled trial (RCT) in order ensure a robust assessment of its effectiveness.

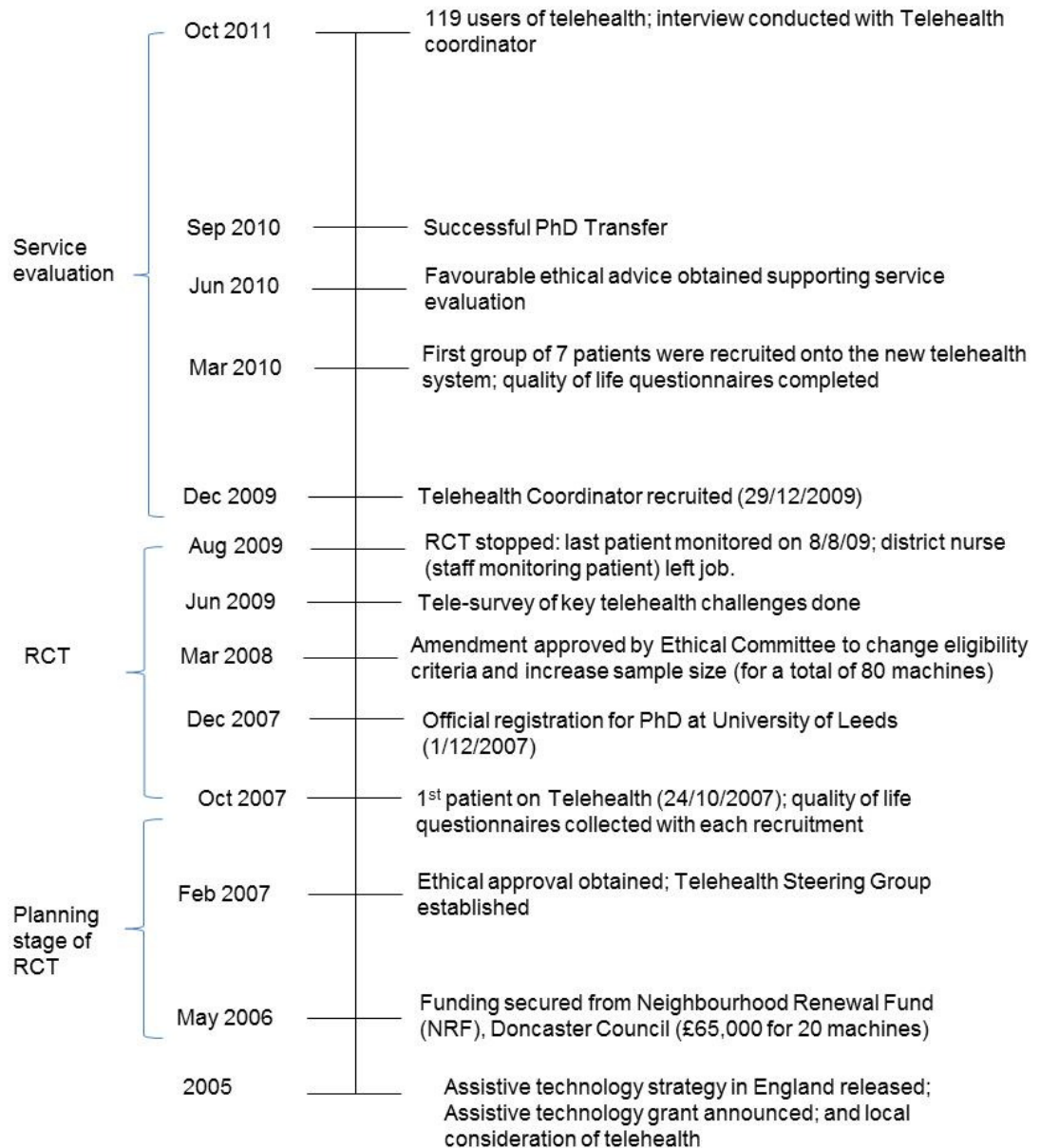
The original research was conceived, planned and conducted as a pragmatic trial between 2006 and 2009. The research commenced as a trial in Doncaster, a district healthcare setting in England (UK), as part of a service development. New technologies, like telehealth, emerged as part of a solution to address the problem of long-term conditions. It was being promoted then in the UK to improve health outcomes for patients, and to reduce healthcare costs associated with hospital admissions (Audit Commission, 2004). In order to test these claims, the pragmatic trial was adopted. The research was conceived in 2006, and it received favourable ethical approval in February 2007. The first patients started on the trial in October 2007. The research focused on patients with COPD, as an example of patients with LTC. The intention was to extend telehealth service subsequently to all other patients with LTCs if it was shown to be effective and cost-effective. The aim of the research was to address the question of effectiveness and cost-effectiveness of telehealth for patients with

COPD who were living in the community, after previous hospital admission due to the disease. It was envisaged that the trial would provide information for local health policy makers on the future options for commissioning of health service in relation to telehealth. The trial was subsequently adopted as a PhD project, with a formal registration with the University of Leeds, School of Medicine, on the 1st of December 2007.

The timeline for the research, covering both the pragmatic trial and observational study period is shown in Figure 1.1. The service evaluation period for this research was from March 2010 when the first patients were started on the new telehealth service to October 2011. The telehealth service, however, continued after October 2011.

Figure 1.1: Timeline of undertaking the research work on telehealth

May 2006 to October 2011



The original research question, aim, objectives and hypotheses, were reported in the initial PhD Transfer Report (October 2009), and are outlined below.

1.2.1.1 Original research question

The original research question of the trial was:

What effects will telehealth monitoring have on people with COPD, the care they receive and resources required to maintain that care?

1.2.1.2 Aim

The original aim of the study was to assess the effectiveness and cost-effectiveness of telehealth monitoring for patients with COPD.

1.2.1.3 Objectives

The following original objectives were formulated:

1. To quantify the impact of telehealth monitoring on emergency hospital admissions rates from COPD.
2. To determine acceptability of telehealth to patients with COPD and staff.
3. To quantify the impact of telehealth on patients' quality of life.
4. To assess the costs of telehealth monitoring on the workload of primary care workers and emergency admissions in relation to COPD patients.
5. To assess the practicalities (key challenges) of implementing telehealth monitoring.
6. To determine the categories of COPD patients that benefitted most from telehealth, from among those with 2 or more hospital admissions in the previous 12 months compared to those with one previous hospital admissions in the previous 12 months.

7. To investigate which of the markers or combination of markers of state of respiratory health (vital signs and questions) were best for predicting the need for intervention to address any problem early.

The trial was stopped prematurely. The reason for the stoppage was that there was no staff member available to monitor patients on telehealth service. It was also felt that the trial was prematurely implemented. An initial period of piloting the trial before its actual implementation would have highlighted some of the challenges. This would have informed a better implementation of the trial. Both staff and patients were considered not to be at equipoise. Despite the trial being able to recruit to the minimum number planned, it was unlikely to yield valid outcomes due to a number of biases encountered in the trial.

1.2.2 The final research questions, aim, objectives and hypotheses

The stoppage of the trial gave opportunity for Doncaster Primary Care Trust (PCT) to prepare and address some of the key challenges faced in recruiting patients and engaging community nurses in the implementation of telehealth service. The challenges that were addressed included the recruitment of a dedicated Telehealth Coordinator; and the removal of strict eligibility criteria associated with the pragmatic trial. This was done with consultation of community nurses at Telehealth Delivery (Steering) Group. The study was transformed from a pragmatic RCT to a service evaluation. The service evaluation was an observational study and in a sense a cohort study where patients were remotely monitored over time through telehealth service. It had two parts: the quantitative part, which assessed embeddedness of telehealth service and the details are reported in Chapter 6; and a qualitative part, which

focused on capturing the views of staff and patients who were involved in the observational study and it is reported in Chapter 7. The primary goal of the thesis, therefore, changed from assessing the effectiveness of telehealth, to investigating why and how telehealth embeds or not in routine health service (Chapter 7). The service development expanded to include patients with other LTCs, such as heart failure, COPD and diabetes; and not only those with COPD, as it was the case in the pragmatic trial.

Even though the pragmatic trial was stopped, the author maintained an interest in doing PhD and new technologies. The objective for a PhD was pursued by investigating embeddedness of telehealth service through the observational study. The reason for the focus of the research on telehealth service was that there was still commitment by the organisation (Doncaster PCT) to roll out telehealth service. The organisation had already funded for a wider roll out of telehealth service. The author was leading the implementation of telehealth service for Doncaster PCT.

Usually as part of standard service evaluation in the British National Health Service (NHS) such as in the PCTs, the level of service evaluation of intervention in health service context was not as detailed as it is presented here for a PhD. What the PhD level of evaluation added to the evaluation of telehealth in Doncaster was the critical appraisal of available evidence on telehealth, theoretical context to help with interpretation of the results, and critical assessment of potential sources of bias that might have influenced the outcomes of the evaluation. The end product of the evaluation included

knowledge generated to support practitioners and research in helping new technologies embed in routine healthcare practice.

In 2010, a revised thesis plan (PhD Transfer Report, July 2010) was produced. The reason for the change of the thesis plan was that the prospect of recruiting the expected number of participants into the pragmatic RCT was considered to be less likely. There was a low uptake in recruitment experienced at the time, against an expected revised target of 80 participants, which was double the number initially planned. There were difficulties encountered in the process of recruitment, as a result, the trial was eventually stopped. It was therefore, felt necessary to revise the PhD thesis plan. The revised thesis plan focused on the investigation of why telehealth embedded or not in routine healthcare practice. It was not restricted to patients with COPD, but extended to patients with other LTCs, such as heart failure, and diabetes.

The final research questions, aim, objectives and hypotheses were based on those agreed at the PhD transfer viva. They addressed why telehealth embeds or not in routine healthcare. The term “new technology” was used instead of “telehealth” as a generic label in order enable lessons learned to be generalised to other new technologies in healthcare. Issues to do with embedding (such as factors related to staff and organisational management, patient groups, etc.) appear to be similar for telehealth as they are with other new technologies. This is shown by examples of new technologies such whole body scanners when they were first introduced (Stocking and Morrison, 1978), and lessons learned from recent telehealth implementation in practice (May and Finch, 2009, May et al., 2011).

In order to investigate why and how new technologies embed or not in routine use, a case study research method was used, as recommended by Yin (2009), by developing prior hypotheses and sub-questions. Evidence was drawn from throughout the chapters of the thesis to answer the research questions. Case study research methods allowed various sources of data to be used to try to answer the research questions (Yin, 2009).

According to Yin (2009), a case study was technically defined as follows:

- 1) *“A case study is an empirical inquiry that*
 - *Investigates a contemporary phenomenon in depth and within its real-life context, especially when*
 - *The boundaries between phenomenon and context are not clearly evident.*
- 2) *The case study inquiry:*
 - *Copes with the technically distinct situation in which there will be many more variables of interest than data points, and as one result;*
 - *Relies on multiple sources of evidence, with data needing to converge in a triangulating fashion, and as another result;*
 - *Benefits from the prior development of theoretical propositions to guide data collection and analysis.”*

The case study approach synthesizes the evidence generated in the thesis in Chapter 8, entitled “Synthesis”.

The final research questions, aim, objectives and hypotheses are outlined below.

1.2.3.1 *The research questions*

The final primary research question was: *Why does a new technology embed or not in a routine health service?*

In order to address this research question, five sub-questions were formulated covering service design, technology, patient group, staff, and setting. The five sub-questions are outlined below:

1. **Setting:** Is there something about Doncaster that made it more difficult to operate a randomised controlled trial (RCT) versus a service evaluation?
2. **Technology:** Are there factors associated with the new technology¹ used in the RCT versus the ones used in the observational study that made a difference in uptake of the new technology?
3. **Patients' group:** Are there factors related to the patients' group recruited for the RCT as opposed to the observational study that made the difference in uptake of the new technology?
4. **Staff:** Are there factors associated with staff involved in the RCT, as opposed to the observational study that made a difference in uptake of the new technology?

¹ The term new technology is generic and it encompasses the whole of the intervention (the service) and not just the physical equipment (see also Chapter 3 on definition and description of telehealth service).

5. **Evaluation:** Are there factors associated with RCT methodology approach, as opposed to observational study that made a difference in uptake of the new technology?

1.2.3.2 *The research hypotheses*

The following hypotheses were developed, to aid data collection and to confirm or eliminate possible explanations, according to Yin's case study research method (Yin, 2009):

1. Doncaster is significantly different in its experience of uptake of new technology compared to other districts in England.
2. There were factors associated with the new technology used in the RCT versus the ones used in the observational study that made a difference in the uptake of the new technology.
3. There were factors related to the patients' group recruited for the RCT as opposed to the observational study that made the difference in the uptake of the new technology.
4. There were factors associated with staff involved in the RCT, as opposed to the observational study that made a difference in the uptake of the new technology.
5. There were factors associated with the RCT methodology approach, as opposed to observational study that made a difference in the uptake of the new technology.

1.2.3.3 *The research aim*

The aim of the study was to investigate why new technologies fail or succeed to embed in routine health service delivery.

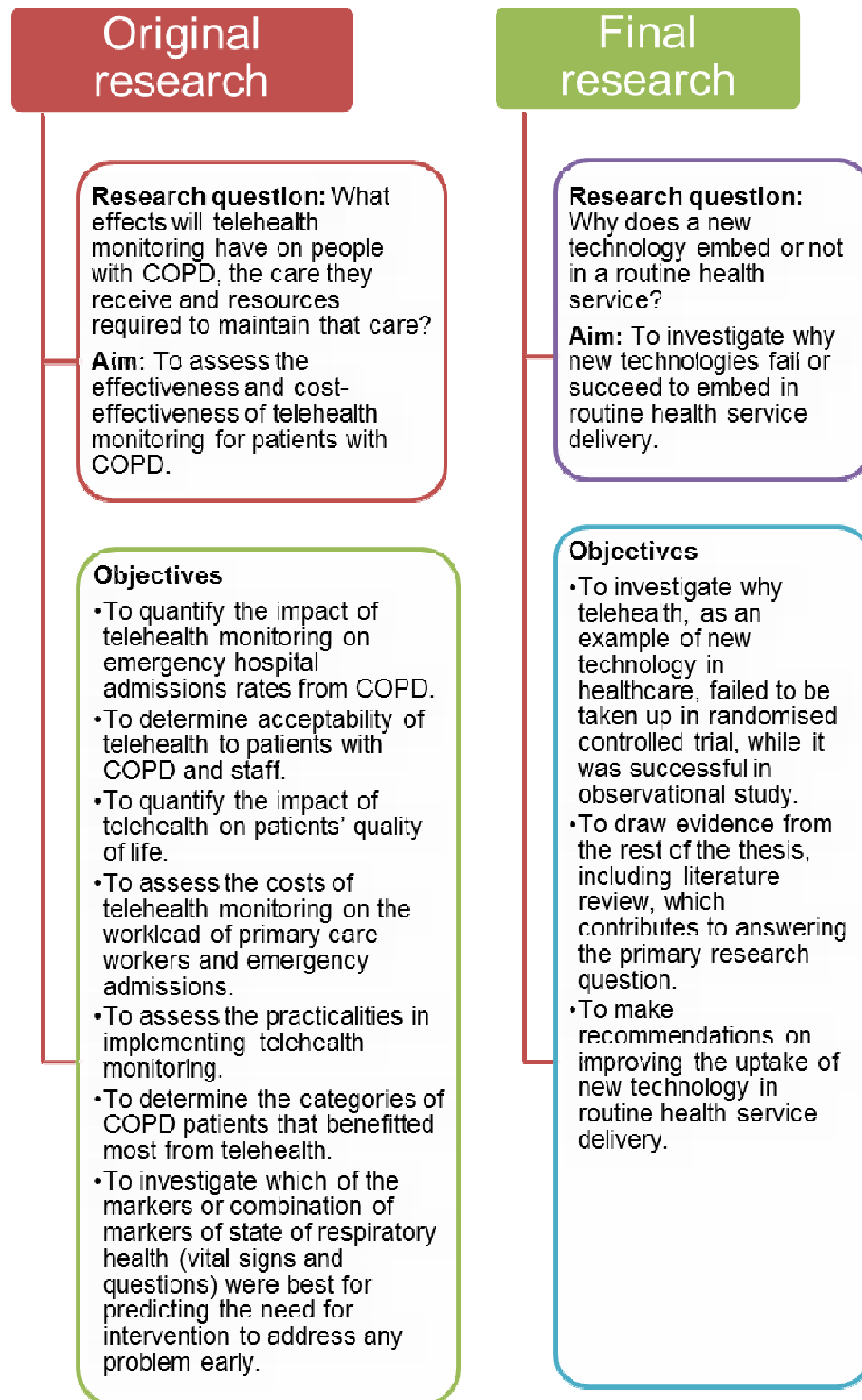
1.2.3.4 *The research objectives*

The objectives of the research were:

1. To investigate why telehealth, as an example of new technology in healthcare, failed to be taken up in randomised controlled trial, while it was successful in the observational study.
2. To draw evidence from the rest of the thesis, including literature review, which contributes to answering the research question.
3. To make recommendations on improving the uptake of new technology in routine health service delivery.

A diagrammatic representation of the changes in the research aims and objectives is shown in Figure 1.2.

Figure 1.2: Original and final research aim and objectives



1.3 The structure of the thesis

The thesis is structured into nine chapters. Chapter 1 introduces the thesis. Chapter 2 outlines the theoretical framework used in the thesis; the normalisation process theory (NPT). This is set in the context of other competing theoretical frameworks (Design-Reality Gap, and Theories of Practice) related to implementation of information systems and practices. As the focus of this thesis is about implementation of new technologies, theories related to implementation practices were selected and presented for comparison. The key criterion for the choice of theoretical framework was based on ability to help in answering the research question. Both Design-Reality Gap and Theories of Practice were considered to be abstract and high level theories. They were not specific enough to address the research question. In contrast, NPT was considered to be specific and focused and found to help in addressing the research question. Therefore, NPT was chosen as the appropriate theoretical framework to guide the work on the thesis.

Chapter 3 describes the background information relevant to the research, which includes a description of Doncaster as the study setting, its health profile, and research activities in the area. It provides a definition and descriptions of telehealth service used in the study. The background information helps to set the scene and context for the thesis.

In Chapter 4, a literature review of telehealth is presented, which assesses its effectiveness, cost-effectiveness, and practical challenges encountered in developing and implementing telehealth project. The literature review focused

mainly on systematic review articles. Even though the focus of the thesis changed to investigating why new technologies fail or succeed in routine practice, it was considered relevant to know whether or not they were worthwhile to embed in routine use. The literature review further addresses challenges related to implementation of telehealth in order to understand factors that determines successful implementation of telehealth service. The chapter concludes by examining factors for increasing uptake of participants in trials by drawing lessons from failed trials.

Chapter 5 presents the findings of the pragmatic trial that assessed the effectiveness and cost-effectiveness of telehealth service, despite its premature stoppage. It was found that telehealth made no difference in reducing hospital admission rates among patients with COPD, and it was not cost-effective. The limitations and implication of the trial are discussed.

Chapter 6 reports the findings of uptake of telehealth service as part of the observational study. Uptake of telehealth service by participants was used as a quantitative measure of embeddedness. The findings suggest that telehealth service was embedding in routine health service in Doncaster. The chapter also addresses compliance of patients to telehealth home monitoring. There was high compliance with telehealth usage, but the rates of red alerts were also very high, which brings into questions the reliability of telehealth home monitoring service. Patients were satisfied with the service.

Chapter 7 presents qualitative research findings of why and how new technologies fail or succeed to embed in routine health service. This was based on the observational study participants and staff. A thematic analysis was

carried out and it presented the key themes emerging from the research that provided possible explanations as to why telehealth performed the way it did in the study setting. Factors related to staff, technology, service design, and patients were considered to provide possible explanations as to why and how telehealth performed the way it did in routine healthcare practice.

Chapter 8 synthesizes all the findings of the research undertaken in the thesis. Syntheses were carried out in the context of NPT, which is described further in Chapter 2. The chapter concluded that factors related to the technology, staff and the methodological approach of evaluating the service could not be excluded as possible reasons why new technologies fail or succeed in routine service. There was limited evidence to accept hypotheses related to setting and patients' group as explanations for the performance of new technologies in routine practice.

The final chapter of the thesis (Chapter 9) provides a reflection on (1) the extent to which the research questions, aim, and objectives were met; (2) the author's own learning, (3) the author's roles and areas of potential conflicts, and (4) statements of original contributions to knowledge.

Chapter 2: Theoretical Frameworks

2.1 Introduction

In the previous chapter, an introduction to the thesis was made. The introductory chapter acknowledged the challenges faced in the early stage of the PhD research. The focus of the research changed when it was decided that the pragmatic randomised controlled trial (RCT) would not go ahead as planned. The primary goal of the pragmatic trial was to assess effectiveness of telehealth. However, it was realised that due to challenges encountered in the implementation, the trial was not going to yield valid results. The new focus of the thesis is therefore about embeddedness of telehealth in routine service. A conceptual framework was developed in order to guide the PhD research with fieldwork and later in the interpretation of the findings. The appropriate theoretical framework is used later in the thesis for the following purposes:

- (a) To understand what happened in Chapters 5 (the pragmatic trial) and 6 (the service evaluation study) related to uptake of telehealth. The theory is used to work out how to investigate, and make sense of, what went well and not so well as far as embedding of telehealth was concerned in routine practice;
- (b) To guide the conduct of qualitative interviews reported in Chapter 7; and
- (c) To make sense of the totality of the findings of the thesis, in Chapter 8 where the findings are synthesised.

There are many theoretical frameworks in the published literature on the subject of implementation and effects of information technologies (IT), both in health

care and more generally. It was not possible to review all of them; therefore, three of the theoretical frameworks were chosen that were considered to be broadly representatives of the literature. The three theoretical frameworks were: (1) Design-Reality Gap (DRG) model (Heeks et al., 1999); (2) Theories of Practice (ToP) (Orlikowski, 2008, Orlikowski, 2000, Feldman and Orlikowski, 2011); and (3) Normalisation Process Theory (NPT) (May and Finch, 2009).

Design-Reality Gap model was selected because it represents a large body of literature that came out of management and business schools and had been used in information technology (IT) systems (Heeks et al., 1999, Heeks, 2006, Heeks, 2008). Meanwhile, *Theories of Practice* was chosen because it is a sociological framework that had been widely cited in health care and in other areas in recent years (Orlikowski, 2009, Orlikowski, 2008). The reason for selecting NPT was because it represents a theoretical framework on implementation of new technology and it addresses issues related to embedding (May and Finch, 2009). NPT has been widely used in healthcare.

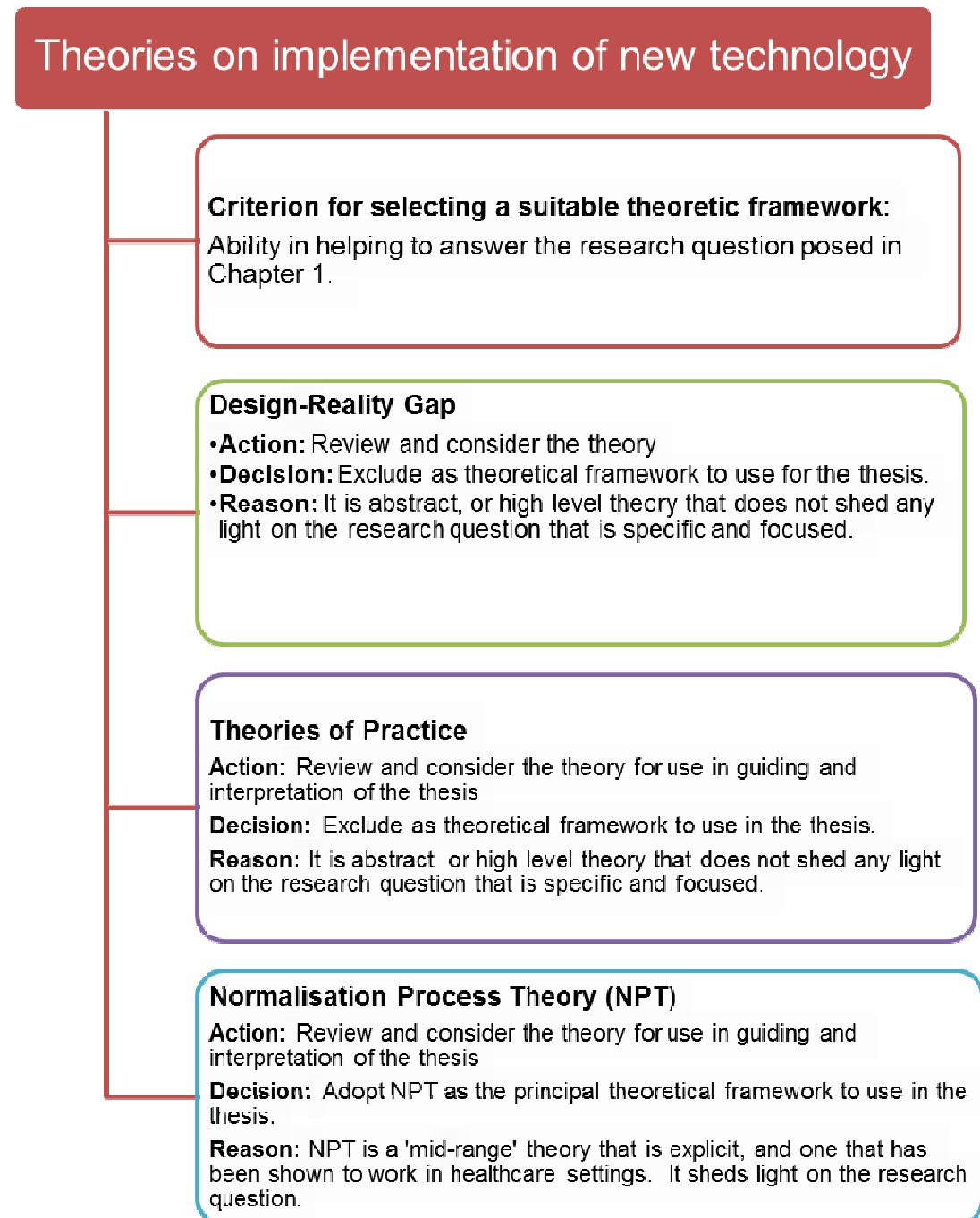
The key criterion set for determining appropriateness of a theoretical framework is the ability to help in addressing the research question posed in Chapter 1.

Both *Design-Reality Gap model* and *Theory of Practice* were considered to be high-level and abstract theories and did not shed light on the specific and focused research question. On the other hand, NPT appeared to be specific and most relevant in helping to answer the research question.

Therefore, NPT was chosen as the theoretical framework used throughout this thesis to guide the conduct, and interpretation of the study. An overview of the

three theoretical frameworks is given in Figure 2.1, which outlines the decisions made to exclude two of them and to adopt one; and the reasons for doing so.

Figure 2.1: Theoretical frameworks considered and the one selected for the study



In the sections below, the three theoretical frameworks are further described, and their relevance to this research work is examined in terms of their usefulness and limitations in contextualising and interpreting the findings of the thesis.

2.2 Design-Reality Gap (ITPOSMO) model

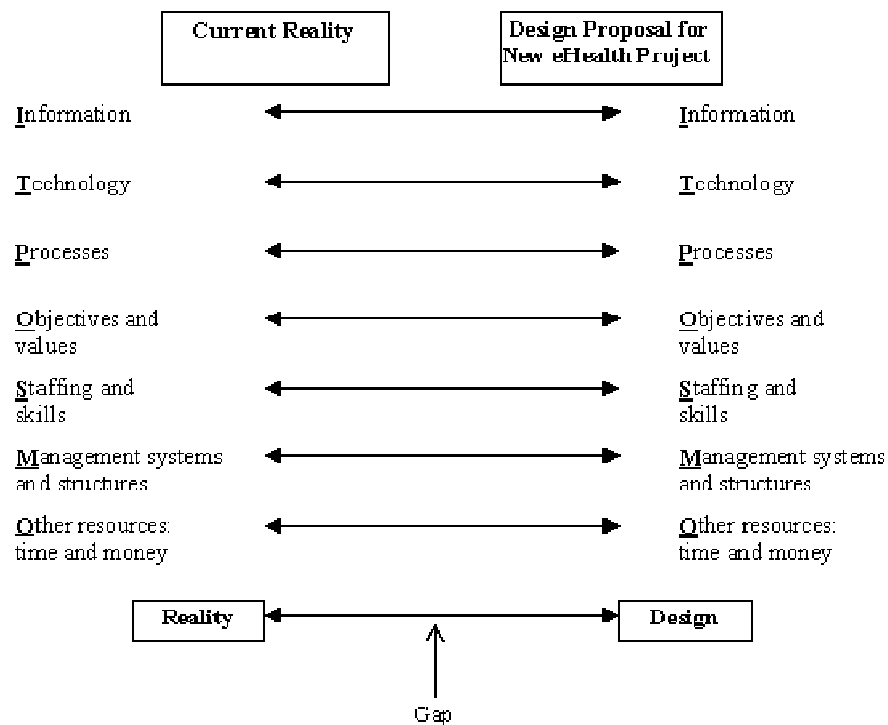
Heeks and colleagues argued that failure or success of health information system (HIS) could be evaluated or predicted by examining the gap that exists between design (project proposal) and current reality factors of a project (Heeks, 2006, Heeks et al., 1999, Heeks, 2008). In this regard, they developed a seven-dimensional model covering the following areas: Information (e.g. quantity, quality, flow etc.); Technology (e.g. computer hardware, software etc.); Process (e.g. decision-making, and actions); Objectives and values (e.g. objectives of medical and non-medical staff and other stakeholders); Staffing and skills (staff numbers, skills, and knowledge); Management and structures; and Other resources (e.g. investment, and time). These dimensions were summarised into an acronym referred to as ITPOSMO, representing each of the seven dimensions in the model (Figure 2.2). They argued that the smaller the design-reality gap, the more likely an information system would succeed; conversely the wider the gap the likely it was to fail. They developed a rating scale of 0-10 for each dimension to measure the gap between reality and design with 0 being no gap; 5 representing some degree of difference; and 10 being major gap between design and reality. A maximum of 70 score was expected for all the seven dimensions. Projects that scored between 57-70 were considered to be most likely to fail; 43-56 might well fail, 29-42 might

partially/totally fail; 15-28 might partially fail; and those with score of 0-14 might well succeed (Hawari and Heeks, 2010).

An example of design-reality gaps involving public and private hospitals in relation to “staff and skills” was given. Public hospitals tended to have fewer nursing staff and fewer technology-related staff in comparison to private hospitals (Heeks et al., 1999).

Figure 2.2: Design-Reality Gap: The ITPOSMO model and its seven dimensions

Source: (Heeks, 2008)



Heeks *et al.* (1999) offered the following definitions of failures and successes of health care information system, while acknowledging that such definitions were fraught with degrees of subjectivity:

Total failure: “a system never implemented or in which a new system is implemented but immediately abandoned.”

Partial failure: “an initiative in which major goals are unattained or in which there are significant undesirable outcomes.”

Sustainability failure: “an initiative that succeeds initially but then fails after a year or so.”

Replication failure: “an initiative that succeeds in its pilot location but cannot be repeated elsewhere.”

Success: “an initiative in which most stakeholder groups attain their major goals and do not experience significant undesirable outcomes.”

Design-Reality Gap model provides some useful perspective in contextualising and interpreting the findings of this research. Its advantages include the following:

- (1) It offers opportunity for systematic assessment of several dimensions, when examining technology and human interaction;
- (2) The model provides mechanisms for quantifying the likelihood of success or failure of implementing a new technological project;
- (3) The model also helps to contextualise success or failure of a study, based on definitions of successes or failures offered by the authors (Heeks et al., 1999, Heeks, 2008); and
- (4) An additional strength of the model was its simplicity in examining the dimensions against Design-Reality Gap, with potential for adding any

dimension deemed necessary by stakeholders. The model had also undergone field trials in a number of IT systems (Hawari and Heeks, 2010).

However, there are a number of potential problems in the application of Design-Reality Gap in routine practice. They include the following:

- (1) The true “design-reality” gap may not be clearly known at the time of assessment; hence such initial assessment or prediction could be inaccurate resulting from uncertain proposals.
- (2) The model does not offer assessment of relative merit (weight) of each dimension against each other, given that several elements could be at play in the model. Certain elements of the model might carry more weight than others in determining success or failure of an initiative. In addition, the effects of interaction of each dimension with one another had not been taken into account in deriving the overall likelihood of success or failure.
- (3) The model also has potential methodological limitations in how it assessed design-reality gap, including problems with subjectivity in assessing gaps, issues with definitions of successes, failures and inherent subjectivity involved, sensitivity of the tool, and “floor/ceiling” effects of the tool.
- (4) Examples of field practice where Design-Reality Gap had been applied could not be found where second generation telehealth were used. Most of the fields in which the model was applied were limited to information technology systems such as computer network or computerised coloscopy system (Heeks, 2006, Heeks et al., 1999).

Therefore, the Design-Reality Gap theoretical framework did not meet the criterion set in Figure 2.1, because it was considered to be a high level theory that was abstract and lacked focus in helping to answer the research question posed in Chapter 1.

2.3 Theories of Practice

Theories of Practice (ToP) is a broad field of theoretical framework, which has been widely used by scholars in the field of social science and its usage had been extended to information technology (Feldman and Orlikowski, 2011). Orlikowski (2008, 2009) argued that technology became meaningful if it interacted with people resulting into what she termed as *technologies-in-practice* and the below quotes summarises *Theories of Practice*:

“As humans interact with technological artifacts they constitute a technology-in-practice through their recurrent use of the technologies. However, their actions are at the same time shaped by the technologies-in-practice they have enacted in the past. Thus, in their on-going and situated action, actors draw on structures that have been previously enacted (both technologies-in-practice and other structures) and in such action reconstitute those structure.” (Feldman and Orlikowski, 2011)

Feldman and Orlikowski (2011) identified three main principles of ToP. The first principle stipulates that the actions undertaken by people in particular contexts have consequences in influencing their social life (*every day actions were consequential*). For example, the authors (Feldman and Orlikowski, 2011) noted

that the development of painting was driven by the high quality of paintings that the public demanded.

The second principle states that it is false theory to categorise elements into two independent groups or dichotomies. The principle asserts that there are some inherent relationships between phenomena. The principle rejects viewing elements in dichotomies, such as: objective and subjective, body and mind, structure and agency, cognition and action, etc.

The third principle of ToP states that no phenomenon is considered to be independent of each other; which was referred to by the authors as *rationality of mutual constitution* (Feldman and Orlikowski, 2011). For example, it was observed that the relationships between social order (structures, institutions, etc.) were constantly influenced by agencies (human or technologies). Orlikowski (2000) highlighted that the consequences of technology-in-practice could result in (a) reinforcing the social status quo; (b) changes in practice and system; or (c) integration of technologies into social life (Orlikowski, 2000).

Feldman and Orlikowski (2011) argued that ToP offers two important uses for researchers: firstly, it provides the basis for powerful theoretical generalisation; and secondly, it has the capacity to offer important practical implications for practitioners, in explaining and guiding actions.

Orlikowsky (2009) acknowledged that it was not possible to guarantee a perfect translation of technological plan and design into its running code in the real world; nor exert any control over whether or how other people used the

technology and the possible unintended consequences of the technology in practical use.

In essence, the ToP rested on the concept that social processes influenced the design and implementation of new technology and similarly, new technology also influenced social processes (Keen et al., 2012, Orlikowski, 2008).

ToP was not chosen as the most suitable theoretical framework to use for the thesis because it did not meet the criterion set in Figure 2.1, in helping to answer the research question of the thesis.

2.4 Normalisation process theory

Normalisation Process Theory (NPT) is a theoretical framework that deals with implementation of new technologies and practices and how they get normalised or embedded into every day practice of individuals and groups (Finch et al., 2012). NPT helps researchers to explore three main areas of interest in relation to implementation and embedding of new technologies (May and Finch, 2009). The theory proposes that:

- (1) Practices are embedded if they fit with the organisational structure and the social contexts; and by individuals and groups involved working together;
- (2) There are four stages through which practices become embedded in practices. These stages are coherence, cognitive participation, collective action and reflexive monitoring (Finch et al., 2012, May and Finch, 2009). What May and Finch (2009) meant by *coherence* was how people found a practice useful. They considered *cognitive participation* to be the

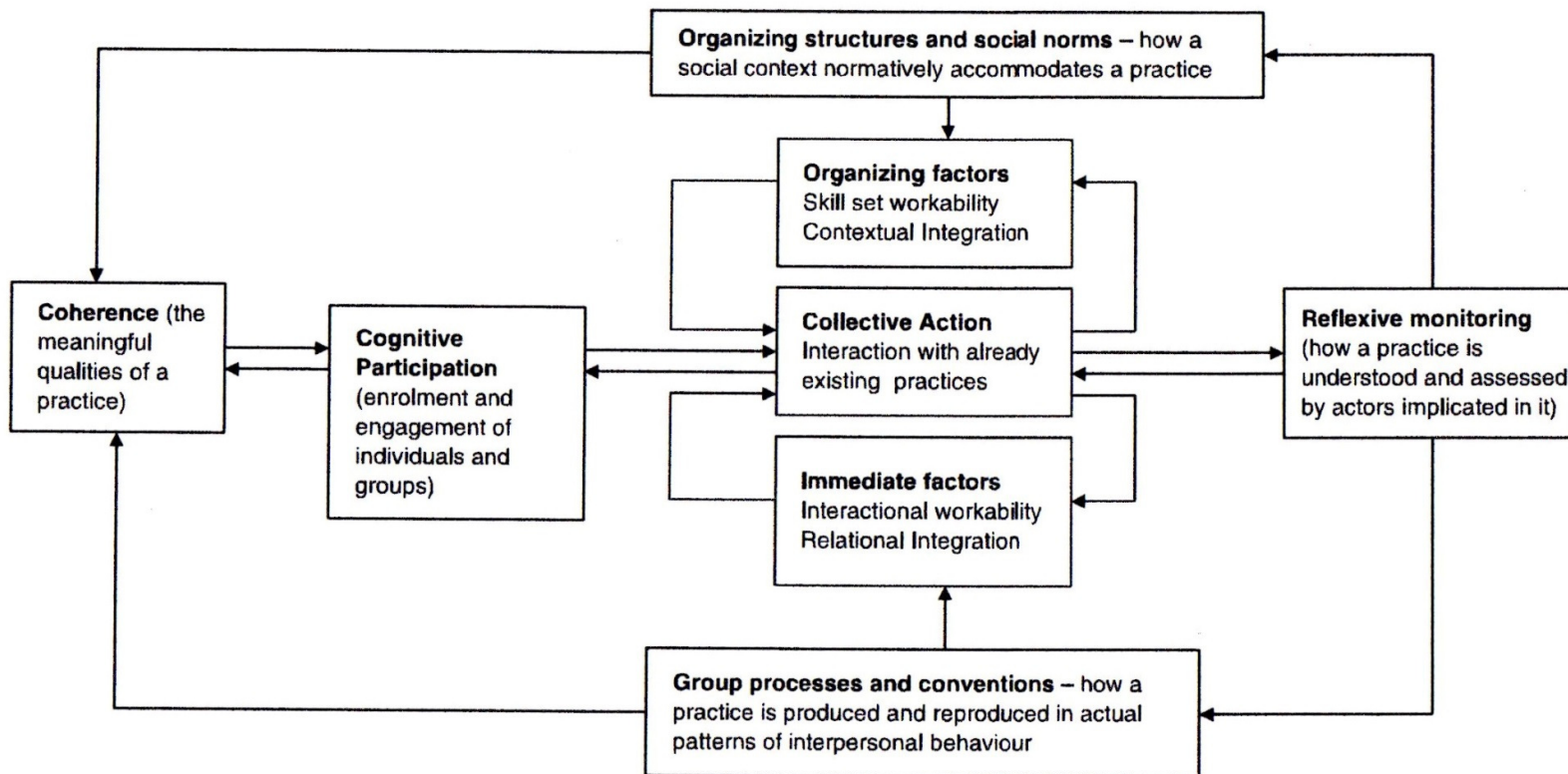
enrolments and engagement of people to do a particular work; while *collective action* was about efforts put in doing the work, which might include resistance, subversion, affirmation and compliance. Collective action encompassed (1) how people did the work e.g. professional-patient interaction (interactional workability); (2) how practice was mediated and understood among the network of people related to it (relational integration); (3) how work was distributed and conducted based on division of labour (skill-set workability); and (4) how the work was incorporated within the social context (contextual integration) (May and Finch, 2009). Reflexive monitoring was described by the authors as the continuous evaluation of implementation process by participants.

(3) Embedding is a continuous process of investment of efforts by the people involved in implementation of a practice.

Each of the four stages of NPT raises a number of questions for researchers to consider, such as, those related to the exact nature of work that needs to be done, who does it, how, and the value placed by those who are involved in doing it (May and Finch, 2009). Figure 2.3 shows how the components of the theory are related to one another.

Figure 2.2: Model of the components of normalisation process theory

Source: (May and Finch, 2009), page 541.



2.4.1 NPT propositions

There are 12 propositions that constitute NPT (May and Finch, 2009) and these are summarised in Table 2.1.

Table 2.1: Propositions of Normalisation Process Theory (NPT)

Source: Adapted from (May and Finch, 2009)

DOMAIN	PROPOSITIONS
Coherence	<ol style="list-style-type: none"> 1. <i>“Embedding is dependent on work that defines and organizes a practice as a cognitive and behavioural ensemble. (1.1)”</i> 2. <i>“Embedding work is shaped by factors that promote or inhibit actors’ apprehension of a practice as meaningful. (1.2)”</i> 3. <i>“The production and reproduction of coherence in a practice requires that actors collectively invest meaning in it. (1.3)”</i>
Cognitive participation	<ol style="list-style-type: none"> 4. <i>“Embedding is dependent on work that defines and organises the actors implicated in a practice. (2.1)”</i> 5. <i>“Embedding work is shaped by factors that promote or inhibit actors’ participation. (2.2)”</i> 6. <i>“The production and reproduction of a practice requires that actors collectively invest commitment in it. (2.3)”</i>
Collective action	<ol style="list-style-type: none"> 7. <i>“Embedding is dependent on work that defines and operationalizes a practice. (3.1)”</i> 8. <i>“Embedding work is shaped by factors that promote or inhibit actors’ enacting it. (3.2)”</i> 9. <i>“The production and reproduction of a practice requires that actors collectively invest efforts in it. (3.3)”</i>
Reflexive monitoring	<ol style="list-style-type: none"> 10. <i>“Embedding is dependent on work that defines and organizes the everyday understanding of a practice. (4.1)”</i> 11. <i>“Embedding work is shaped by factors that promote or inhibit appraisal. (4.2)”</i> 12. <i>“The production and reproduction of a practice requires that actors collectively invest in its understanding. (4.3)”</i>

2.4.1 Justification of choosing NPT over other theories

The focus of this research is around the implementation of new technologies and whether or not they embed in routine healthcare practice and how they do so. It is for this reason that NPT is considered to be the most appropriate framework to use (Murray et al., 2011, Winblad et al., 2009). Its usefulness has been proven in field studies in the healthcare system in a number of countries and in similar context, as in this research, involving telehealth service (Murray et al., 2011, Winblad et al., 2009). Therefore, NPT has been chosen to help guide the conduct of this research and to explain its findings.

Design-Reality Gap model is not chosen as the preferred theoretical framework because of its focus on examining gaps between proposed and current situations. It was not focused enough to help in addressing the research question posed in Chapter 1.

Compared with Theories of Practice (ToP), NPT is considered a better option because of its direct relevance to implementation of new technologies and field trials. Although ToP has a long history and origin of use in sociology, its application in the field of implementation of new technologies such as telehealth has been relatively limited. In addition, the three propositions of ToP are considered to be limited in providing a full explanation on why new technologies embed in routine practice.

By using NPT to help explain the research, the validity of the theory is also being tested. Therefore, NPT is the principal theoretical framework chosen for

the thesis. It helps to explain the findings of the research, as well as test its application in this research.

Chapter 3: Background Information

3.1 Introduction

The first chapter of the thesis covers introduction to the whole thesis, while the second chapter describes the theoretical framework that will be used later on in the thesis. The introductory chapter explores the evolution of the research questions, aims and objectives over the course of the thesis. The initial focus of the thesis was on assessing effectiveness and cost-effectiveness of telehealth. However, the focus subsequently changed to investigating why and how new technologies embed or not in routine practice. Chapter 2 explores theoretical frameworks from the fields of management, information system, and sociological studies. The three theoretical frameworks considered were: Design-Reality Gap, Theories of Practice, and Normalisation Process Theory (NPT). The latter was subsequently chosen to understand what happened in the pragmatic trial (Chapter 5) and observational study (Chapters 6 and 7); and to make sense of all the findings of the thesis. NPT was chosen as the theoretical framework because of its usefulness in helping to understand why practices embed or not in routine healthcare.

The objectives of this chapter are:

1. To provide background information and contexts to help in the understanding of the research presented in this thesis;
2. To contribute evidence towards answering the following research question:

Is there something about Doncaster that made it more difficult to operate a randomised controlled trial (RCT) versus a service evaluation? (See Chapter 1)

3. To define and describe telehealth service, as used in Doncaster.

The chapter is structured as follows:

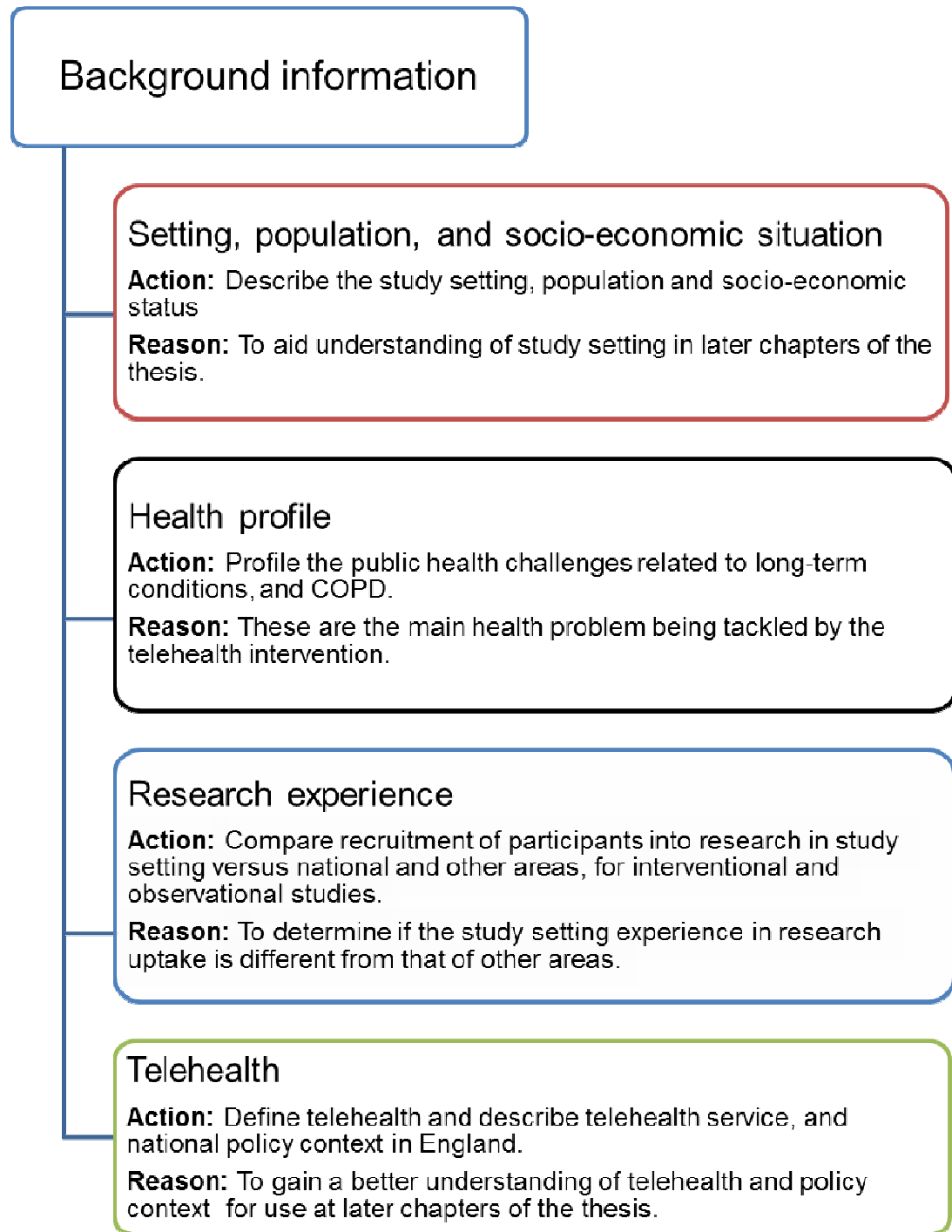
- Study setting (Doncaster), its population, and socio-economic status;
- Local health profile, long-term conditions(LTCs), chronic obstructive pulmonary disease (COPD) – the disease area that was the focus of pragmatic trial reported in Chapter 5;
- Local health services structure and commissioning responsibility;
- Research experience in the study setting compared with national and neighbouring areas, including recruitment into research studies;
- Telehealth: definitions, policy contexts and description of the service.

The study setting is one of five research sub-question of the thesis. The study setting is also important in the pragmatic trial, and the observational study. The local health service structure helps in understanding the commissioning and provision of health services in the study setting. In Chapters 6 and 7 where the observational study is reported, all the participants suffered from long-term conditions (LTCs). There are different types of diseases that can be classified as LTCs, such as high blood pressure, heart disease, chronic respiratory diseases, including COPD, diabetes, etc. COPD, one of the LTCs, was the focus of the pragmatic trial covered in Chapter 5. Telehealth is the key intervention in the whole work of this thesis. Its definition, policy context and

description are provided here. Later on in the thesis (Chapters 4-8), the effectiveness and cost-effectiveness of telehealth is assessed using literature review (Chapter 4), pragmatic trial (Chapter 5), and observational study (Chapter 7). Syntheses of the findings in the whole of the thesis are carried out in Chapter 8 in an attempt to answer why new technologies embed or not in routine practice. Reflections on the thesis are captured in Chapter 9. Therefore, the background information reported in this chapter is relevant to subsequent chapters of the thesis.

An overview of Chapter 3 is shown in Figure 3.1.

Figure 3.1: Background information relevant to the thesis



3.2 Setting

3.2.1 Location

Doncaster is one of the local authorities (LAs) in England (Britain), located in the North of the country within the County of South Yorkshire. The geographical area that constitutes the local authority in Doncaster is the same as that of the then Doncaster Primary Care Trust (PCT), a healthcare commissioning organisation that was abolished on the 1st of April 2013. The major cities close to Doncaster are Sheffield in the West, Leeds in the North West, Hull in the East, and Nottingham in the South. Doncaster Metropolitan Borough Council (DMBC) covers an area of 219 square miles (567 square kilometres) (Doncaster Primary Care Trust, 2007).

Doncaster is a town in transformation to be a city with an International Airport (Robin Hood Airport) within its territory and a range of other local developmental initiatives (Doncaster Strategic Partnership, 2005).

3.2.2 Population

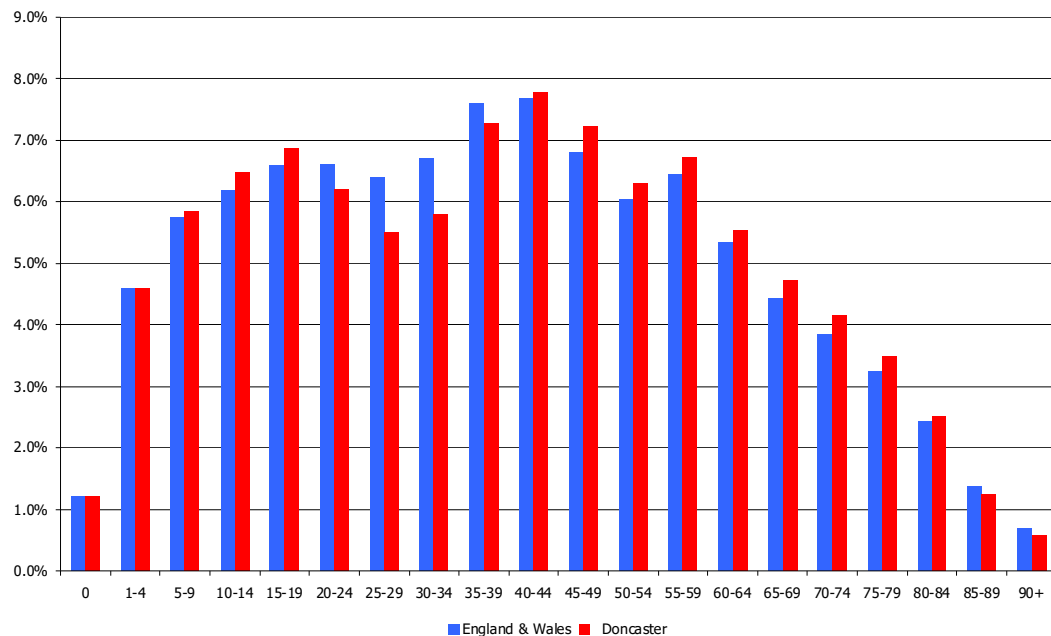
The headline figures from 2011 Census indicated that the population of Doncaster had risen to 302,400 from the previous census in 2001 which put the population of the town at 288,000 (Office for National Statistics, 2012).

Doncaster Primary Care Trust was responsible for providing healthcare for patients registered with general practitioners (GPs) in Doncaster. In April 2006, there were around 305,000 people who were registered with GPs in Doncaster. They included around 3.4% (10,500) of the population who resided outside

Doncaster in the neighbouring local authorities (Doncaster Primary Care Trust, 2007).

The age structure of the population of Doncaster was generally similar to that of England & Wales, with the exception of a notable lower proportion of young people aged 20-34 year-olds, which was thought to be due to those going out of the area for higher education or in search of employment (Figure 3.2).

Figure 3.2: Population age structure (%): England & Wales and Doncaster



Source: ONS (2004).

In decades to come, it is widely recognised in Britain and most other developed countries that the problem posed by the ageing population was likely to increase, and it would pose a significant challenge to service providers, including health and social care service providers for older people (Stroetmann et al., 2003).

The distribution of age-sex structure of Doncaster's population was generally similar between males and females, with the exception of older population where there were fewer males than females (Figure 3.3).

Figure 3.3: Age and sex population structure of Doncaster



Source: Public Health Intelligence Unit, Doncaster PCT (2007).

According to the 2001 National Census, Doncaster recorded less black and minority ethnic population (2.3%) than that observed in England (9.1%), with a range of people from various religious backgrounds represented in Doncaster, although predominantly of Christian faith (79.6%).

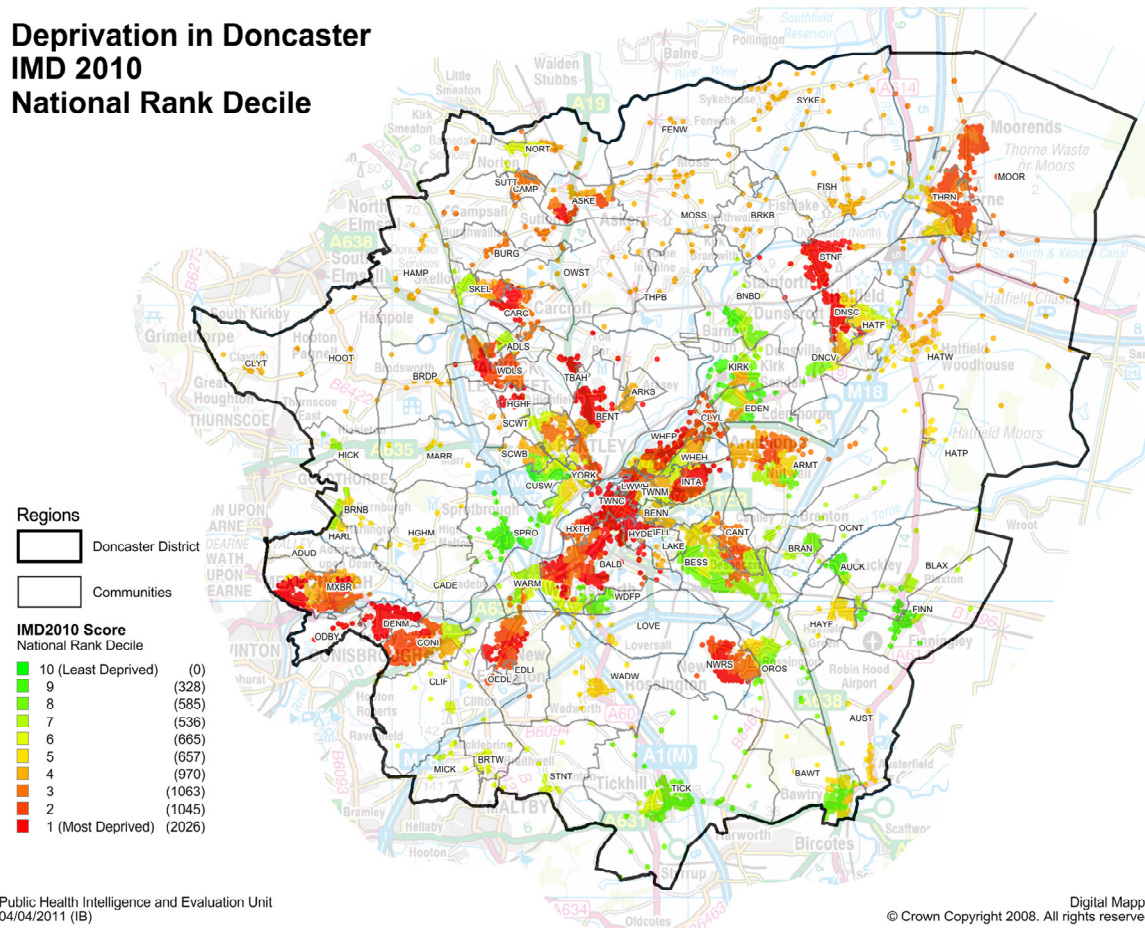
3.2.3 Socio-economic status

According to the official Government's Index of Multiple Deprivation (IMD) 2010 for England, Doncaster was considered as a deprived local authority area, with an average deprivation score of 29.76, and ranking as 39th most deprived local authority (out of 326 local authorities) in England – [rank of 1 was the most

deprived] (Department of Communities and Local Government, 2011). Within Doncaster, the level of deprivation varied among the geographical communities in the districts (Figure 3.4). Doncaster is a former coalmining area and experienced a high rate of unemployment.

Figure 3.4: Communities in Doncaster by levels of deprivation

**Deprivation in Doncaster
IMD 2010
National Rank Decile**



Public Health Intelligence and Evaluation Unit
04/04/2011 (1B)

Digital Mapping Solutions from Dotted Eyes
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Source: Public Health Intelligence Unit, NHS Doncaster.

3.3 Health profile: the burden of long-term conditions

The World Health Organisation (WHO) defined chronic diseases as “*diseases of long duration and generally slow progression*” (WHO, 2011). The Department of Health in England considered a chronic disease as a “*condition that cannot be cured but can be managed through medication and/or therapy*” (Department of Health, 2001). Although there was no definitive list of long-term conditions (LTCs), the following diseases were considered to be part of them: heart disease, stroke, cancer, chronic respiratory diseases such as COPD, and diabetes (Department of Health, 2001, World Health Organisation, 2011).

According to the WHO report entitled: *Global status report on non-communicable disease 2010* (World Health Organisation, 2011), of the 57 million deaths that occurred worldwide in 2008, 63% (36 million) were due to non-communicable diseases (NCD). The report showed that 80% of the NCD occurred in low- and middle-income countries and the trend was projected to overtake that of communicable diseases, maternal, perinatal and nutritional diseases as the leading cause of deaths by 2030.

In Britain, there were around 17.5 million adults living with LTCs in 2001 (Department of Health, 2001). According to the same report, LTCs were more prevalent among the British older people with as much as two-thirds to three-quarters of all people over the age of 75 years old were thought to suffer from at least one LTC. In 2005, the Government produced a strategy document on LTCs called *National Service Framework (NSF) for Long-term Conditions* in

order to improve the health and care of people with LTCs (Department of Health, 2005b).

3.3.1 The prevalence of LTCs in Doncaster

In Doncaster, one in five people (22%) lived with long-term conditions (n=63,000), according to the 2001 UK Census data; and the standardised illness ratio was 25% higher than that expected for England and Wales (Table 3.1). LTCs affect both sexes and all age groups.

Evidence from population prevalence of LTCs in Doncaster from disease registers held by general practitioners (GPs) showed the extent of prevalence of LTCs in primary care (Table 3.2). Although there was discrepancy between expected and observed prevalence in some disease areas, what was clear was that the list of LTCs was composed of non-communicable diseases and lifestyle behaviours that were harmful to health e.g. smoking (26.8%) and obesity (16.4%). Among the LTCs, the prevalence of COPD was 2.6% (7,637); heart failure 1.1% (3,139); hypertension 15.4% (44,638); and diabetes 6.5% (14,989) (Table 3.2).

The prevalence model used for calculating the disease prevalence above had been derived by Public Health Observatory in England based on national rates of the diseases, which took into account levels of deprivation at local areas.

Table 3.1: Number of household persons with limiting long-term illness
Doncaster and national and neighbouring comparison

AREA	Number	Percent of population	Standardised illness ratio	Number for Males				Number for Females			
				Age group				Age group			
				Under 65	65-74	75 & over	All ages	Under 65	65-74	75 & over	All ages
England & Wales	9,019,242	17.6	100.0	2,569,861	858,884	785,910	4,214,655	2,512,936	921,814	1,369,837	4,804,587
England	8,369,174	17.3	98.5	2,379,296	794,510	733,244	3,907,050	2,329,385	854,786	1,277,953	4,462,124
Yorkshire & Humber	920,892	18.9	107.0	266,704	90,226	77,420	434,350	252,596	98,118	135,828	486,542
Barnsley MCD	53,179	24.6	138.8	17,291	5145	3824	26,260	15,192	5379	6348	26,919
Doncaster MCD*	63,227	22.4	125.8	19,513	6556	4928	30,997	17,482	6725	8023	32,230
Rotherham MCD	53,615	21.8	124.4	16,366	5310	4059	25,735	14,966	5777	7137	27,880
Sheffield MCD	101,208	20.1	113.6	28,811	9617	8649	47,077	27,239	10,785	16,107	54,131

*MCD = Metropolitan County District

Source: The Information Centre for Health and Social Care. Compendium of Clinical and Health Indicators / Clinical and Health Outcomes Knowledge Base (www.nchod.nhs.uk or nww.nchod.nhs.uk) (accessed online on 18th August 2009; data based on 2001 Census).

Table 3.2: Long-term condition on disease registers held by GP practices in Doncaster

Long-term condition	Practice Population	Expected Prevalence		Observed Prevalence (QMAS data)		Difference between expected and observed (%)
		n	%	n	%	
Hypertension	290687	71144	24.5	44638	15.4	37.3
Obesity	235710	53686	22.8	38629	16.4	28.0
Asthma (treated in the previous year)	290687	26679	9.2	20418	7.0	23.5
Coronary Heart Disease (CHD)	290687	15191	5.2	13986	4.8	7.9
Chronic Kidney Disease	227653	13387	5.9	14797	6.5	-10.5
Diabetes and Mellitus	231703	13094	5.7	14989	6.5	-14.5
Chronic Obstructive Pulmonary Disease	290687	6949	2.4	7637	2.6	-9.9
Hypothyroidism	290687	5808	2.0	8751	3.0	-50.7
Stroke and Transient Ischaemic Attack	290687	5586	1.9	6478	2.2	-16.0
Learning Disabilities	290687	4970	1.7	1139	0.4	77.1
Heart Failure	290687	4282	1.5	3139	1.1	26.7
Atrial Fibrillation	290687	3833	1.3	4753	1.6	-24.0
Dementia	290687	3659	1.3	1510	0.5	58.7
Palliative Care	290687	3180	1.1	343	0.1	89.2
Cancer	290687	2066	0.7	3660	1.3	-77.2
Treated Epilepsy	227653	1995	0.9	2314	1.0	-16.0
Mental Health (Psychotic Disorders)	290687	1162	0.4	2001	0.7	-72.2
Depression (and Diabetes or CHD)	290687	n/a	-	25509	8.8	-
Smoking	290687	n/a	-	77936	26.8	-

Data source: Doncaster PCT, Quality Outcome Framework (QOF) data, April 2009.

3.3.2 The prevalence of COPD in Doncaster

As shown in Table 3.2, Doncaster had 7,637 (2.6%) patients with COPD on its primary care disease registers held by GP practices in 2009. An analysis of a subset of COPD patients that were part of a locally enhanced service (LES) for COPD at the time further showed that of the 5,897 cases categorised for disease severity, 60% were mild, 29% were moderate, and 11% were severe COPD. The prevalence of COPD and its severity increased with increasing age as shown in Table 3.3.

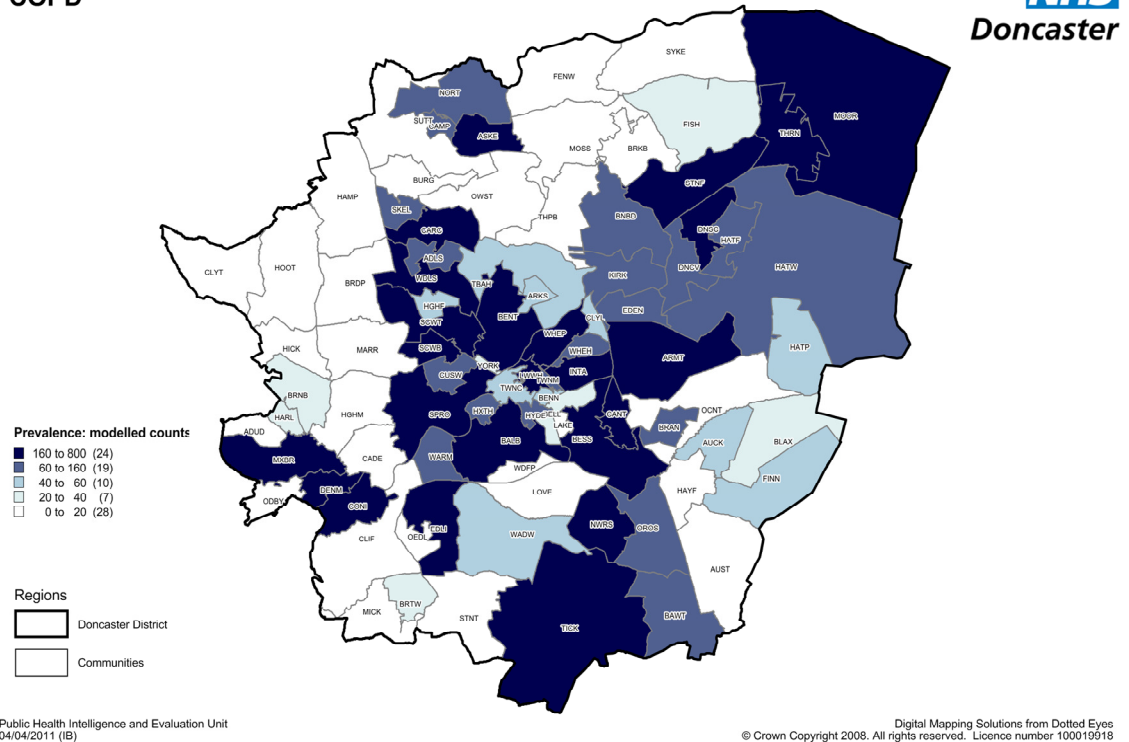
Table 3.3: Prevalence of COPD by age groups and disease severity
Prevalence among GP practices population in Doncaster on 01/01/2010

Variables	Numerator (cases)	Percentage	95% CI
AGE			
All ages:	5897	2.28	(2.23, 2.34)
All ages (expected):	11239	3.85	(3.78, 3.92)
<65 years	1938	0.91	(0.87, 0.95)
65-74 years	1886	8.16	(7.81, 8.52)
75+ years	2073	9.77	(9.38, 10.18)
SEVERITY			
All COPD	5897	2.28	(2.23, 2.34)
Mild	3530	1.37	(1.32, 1.41)
Moderate	1735	0.67	(0.64, 0.70)
Severe	632	0.25	(0.23, 0.26)
AGE & SEVERITY			
<65 years:			
Mild	1246	0.58	(0.55, 0.62)
Moderate	512	0.24	(0.22, 0.26)
Severe	180	0.08	(0.07, 0.10)
65-74 years old:			
Mild	1094	4.74	(4.47, 5.02)
Moderate	581	2.52	(2.32, 2.73)
Severe	211	0.91	(0.80, 1.04)
75+ years:			
Mild	1190	5.61	(5.30, 5.93)
Moderate	642	3.03	(2.80, 3.27)
Severe	241	1.14	(1.00, 1.29)

The pattern of disease distribution within Doncaster varied across the communities therein (Figure 3.5), which was consistent with the known pattern of local levels of deprivation (Figure 3.4).

Figure 3.5: COPD modelled prevalence counts by communities in Doncaster

COPD



Source: Public Health Intelligence and Evaluation Unit, Doncaster PCT (2011)

Note: The corresponding areas of deprivation are shown in Figure 3.4

3.3.3 Life expectancy and mortality

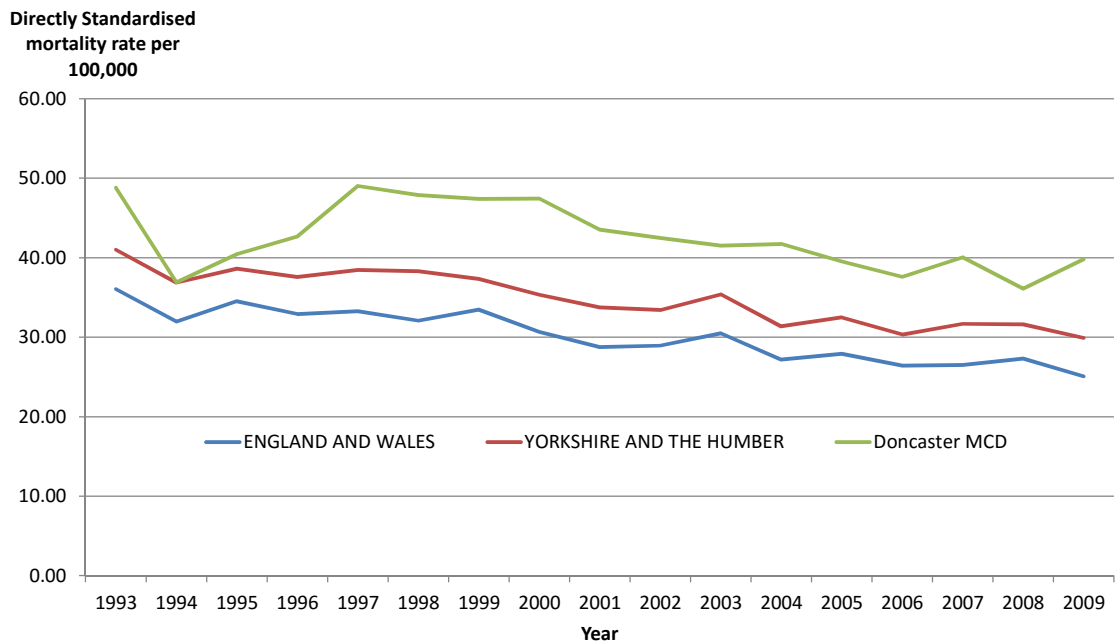
Life expectancy at birth in Doncaster was 75.1 years for males, and 79.8 years for females, (compared to 76.5 for males; and 80.8 for females in England), according to Public Health Profile for Doncaster carried out in 2008 (Doncaster PCT, 2008). Life expectancy at birth continued to increase steadily for both males and females in both Doncaster and England & Wales, although it was lower in Doncaster compared to that of England & Wales (Doncaster PCT, 2008).

All-cause mortality rate was significantly higher in Doncaster than that seen in England and Wales. The main causes of mortality were from cancers and circulatory diseases (including coronary heart disease), and COPD (Doncaster PCT, 2008).

From 1993 to 2009, death rates from COPD showed a gradual decline in England and Wales, Yorkshire and the Humber, and in Doncaster. However, the mortality rate from COPD in Doncaster remained higher than that of the regional average and that of England & Wales (Figure 3.6).

Figure 3.6: Mortality trend from bronchitis, emphysema and other COPD.

Directly standardised mortality rates (DSR) from bronchitis, emphysema and other COPD (ICD9 490-492, 496 adjusted; ICD10 J40-J44): 1993-2009, all persons.

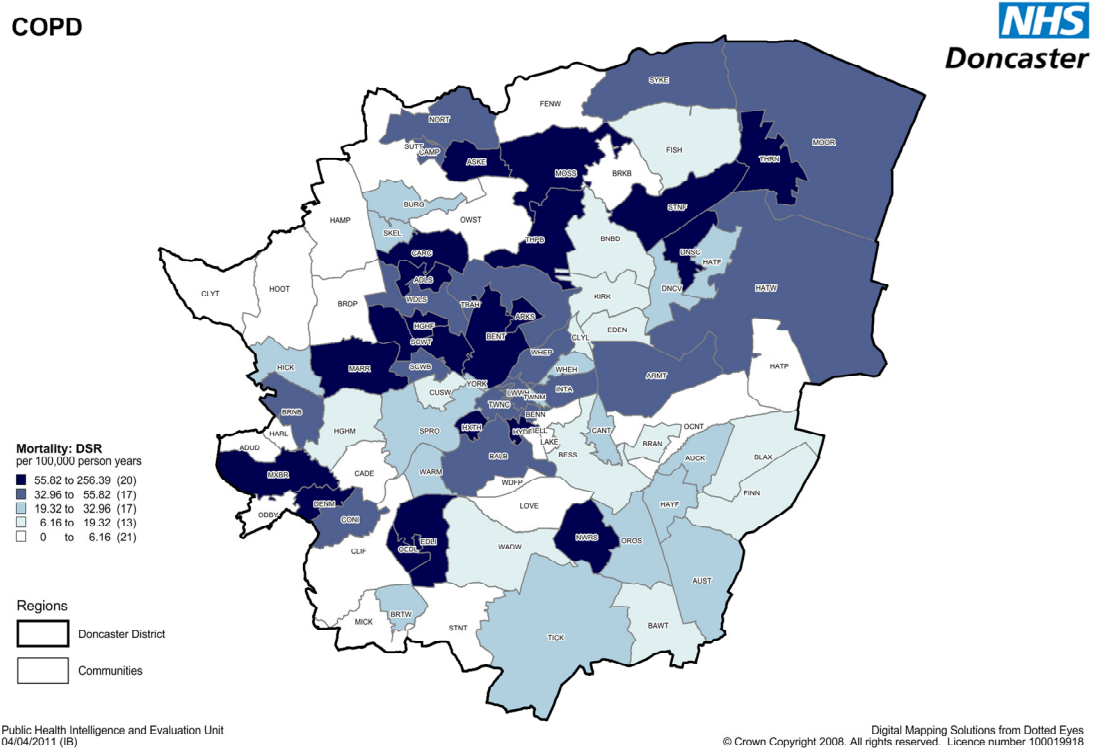


Source of data: The NHS Information Centre for health and social care.
 Compendium of Clinical and Health Indicators / Clinical and Health Outcomes
 Knowledge Base (www.nchod.nhs.uk or nww.nchod.nhs.uk)

The distributions of mortality rate from COPD among geographical communities in Doncaster are shown in Figure 3.7, which shows evidence of concentration of deaths in most deprived areas.

Figure 3.7: COPD Mortality by communities in Doncaster.

Directly standardised mortality rate (DSR) from COPD by communities in Doncaster (5 year 2005-2009).



Source: Public Health Intelligence and Evaluation Unit, Doncaster PCT (2011)

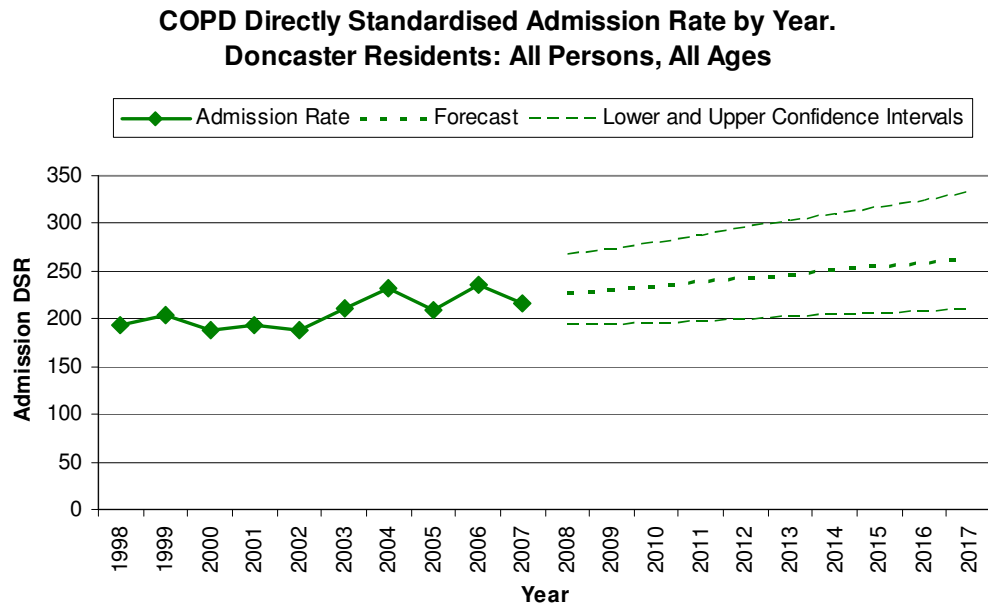
Note: The corresponding areas of deprivation are shown in Figure 3.4.

3.3.4 Hospital admissions: COPD

Hospital admissions from COPD posed a significant challenge to Doncaster PCT due to the increasing yearly trend in admission rate and its associated

healthcare costs. The rate of hospital admissions from COPD was projected to increase in the future, if the existing trend continued (Figure 3.8).

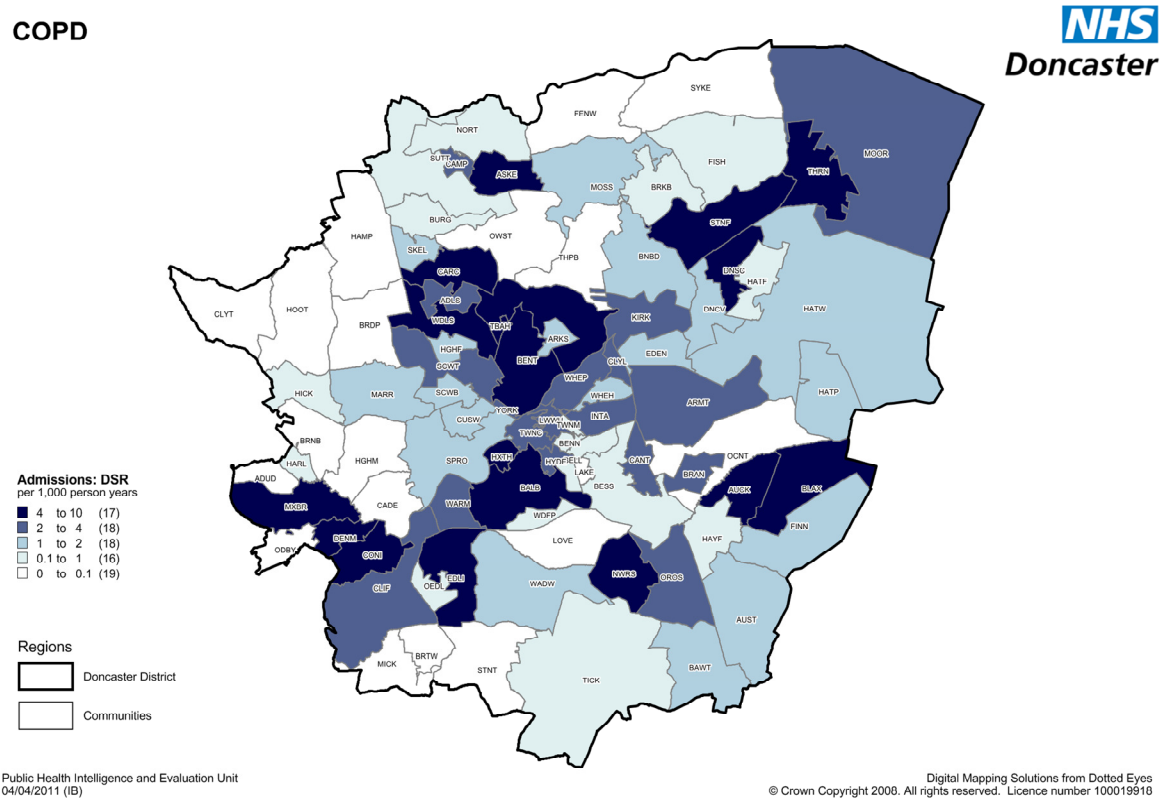
Figure 3.8: Directly standardised rate (DSR) of hospital admission from COPD



Source: Public Health Intelligence and Evaluation Unit, Doncaster PCT (2011)

The pattern of distribution of hospital admissions over a three-year period (2009-2011) by geographical communities in Doncaster showed that hospital admissions were concentrated in particular communities in the borough (Figure 3.9), that were also considered to be deprived.

Figure 3.9: Map of COPD admissions directly standardised rate (DSR)
Distribution by communities in Doncaster (3 year: 2007-2009)



Source: Public Health Intelligence and Evaluation Unit, Doncaster PCT (2011)

3.3.5 Commissioning of local health service

At the time of undertaking this research (2006-2012), the strategic responsibilities for the delivery of health services and improvement of public's health in Doncaster rested with Doncaster PCT. Doncaster PCT was responsible for commissioning health services at various levels in Doncaster: community-based (e.g. district nursing, school nursing, health visitors, etc.) secondary and tertiary health care services both at hospital settings. Its annual health budget was over £0.5 billion in 2010/11. Doncaster PCT had 46 GP

practices, 36 community pharmacies, 66 Optometry practices and 47 dental practices in 2011. It commissioned secondary healthcare services from the following main local hospital providers: Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster and South Humber Mental Health NHS Foundation Trust, Sheffield Teaching Hospitals NHS Trust, and Rotherham NHS Foundation Trust (Doncaster PCT, 2008). The main tertiary hospital providers for Doncaster patients were the Royal Hallamshire Hospital in Sheffield, part of Sheffield Teaching Hospitals; and the Leeds Teaching Hospitals in Leeds.

However, on 1 April 2013 changes to the National Health Service (NHS) re-organisation came into force in England following the enactment of Health and Social Care Act 2012 (Crown Copy Right, 2012). The Act saw the abolition of PCTs, and the creation of Clinical Commissioning Groups (CCGs) to take over some the responsibilities for commissioning secondary care (hospital) services. It also transferred public health functions to local authorities, and created Public Health England (PHE) whose duties was to improve and protect the health of the people of England and to support public health in local authorities. The Act also created NHS England whose responsibilities included commissioning of primary care services and specialised health services.

3.4 The experience of Doncaster in research

3.4.1 Objectives and source of data

This section provides backgrounds to later chapters in addressing the research question related to poor uptake into the pragmatic randomised controlled trial

and to determine if the poor uptake of recruitment into the RCT was associated with the design of the study; and the experience of Doncaster in undertaking research. The section addresses the following research question:

Is there something about Doncaster that made it more difficult to operate a randomised controlled trial (RCT) versus a service evaluation?

The objective of this section was to investigate the experience of Doncaster in undertaking research compared with other similar areas in England. The local experience in Doncaster of recruiting study subjects into national portfolio studies was examined and comparison was made with other PCTs in England. Comparison of approval of research study by local research ethics committee was collated for research activities covering several years.

South Yorkshire Comprehensive Local Research Network (CLRN) office was contacted for comparative data of recruitments of subjects into portfolio studies for Doncaster PCT and other PCTs in England. Data was requested with a breakdown of observational and interventional studies. Analysis was carried out on recruitment into research studies for all PCTs; including Doncaster PCT. Additional data was obtained from the local research ethics committee in Doncaster, based on approval of research studies.

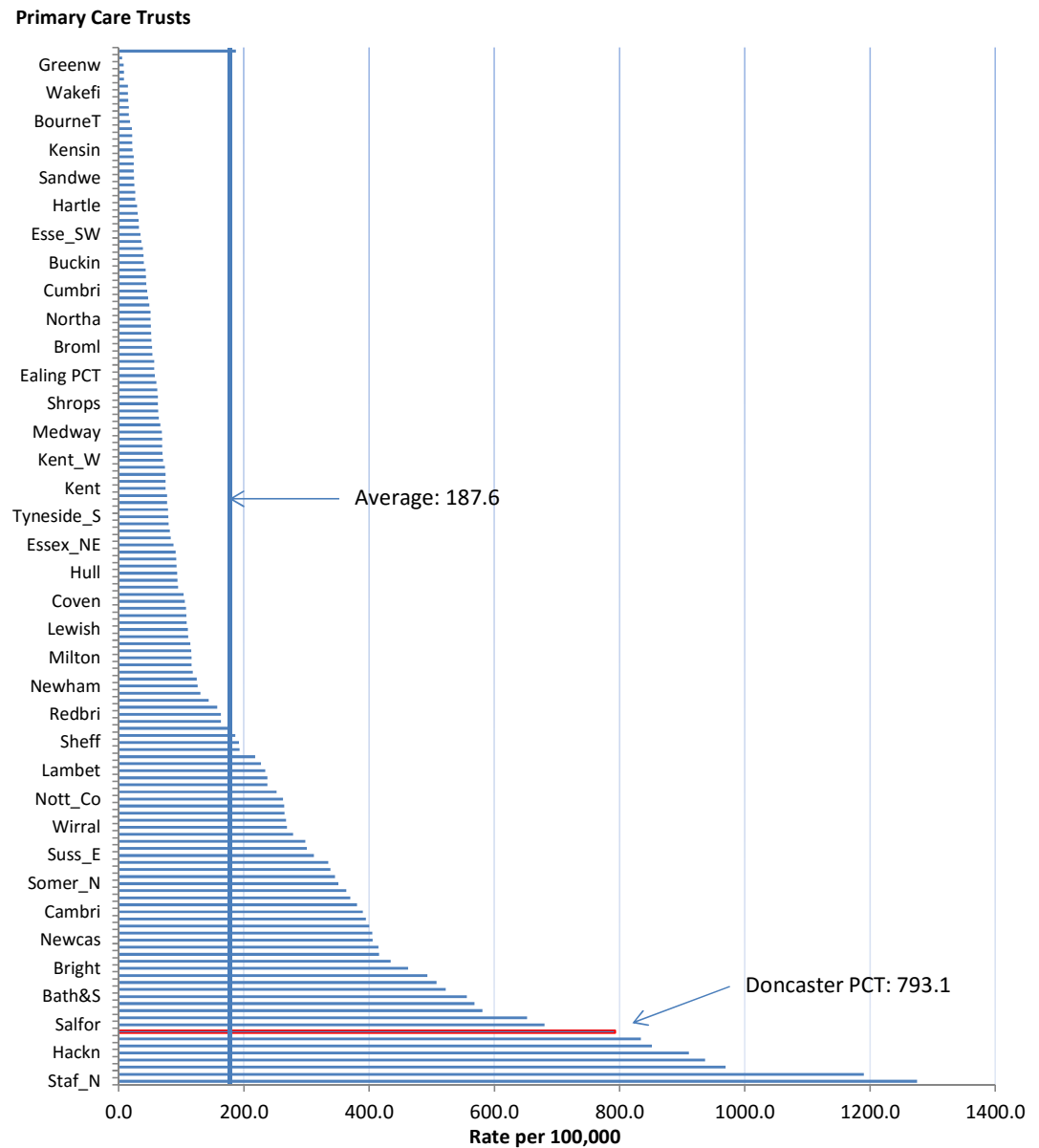
Population for the PCTs was obtained from the population estimate for 2009 from the National Office for Statistics (ONS) in England. This population estimate was used to calculate the recruitment rate into portfolio studies per 100,000 for each PCT in the country.

3.4.2 Results of recruitment into portfolio studies

Of the 146 PCTs in England during the financial year from 1 April 2010 to 31 March 2011, Doncaster ranked as the 8th top PCT with the highest total recruitment of participants into national portfolio studies. The rate of total recruitment of participants in Doncaster PCT was 793.1 per 100,000 population, in comparison with the average of all the PCTs (187.6 per 100,000), (Figure 3.10).

Figure 3.10: Recruitment of participants into portfolio studies

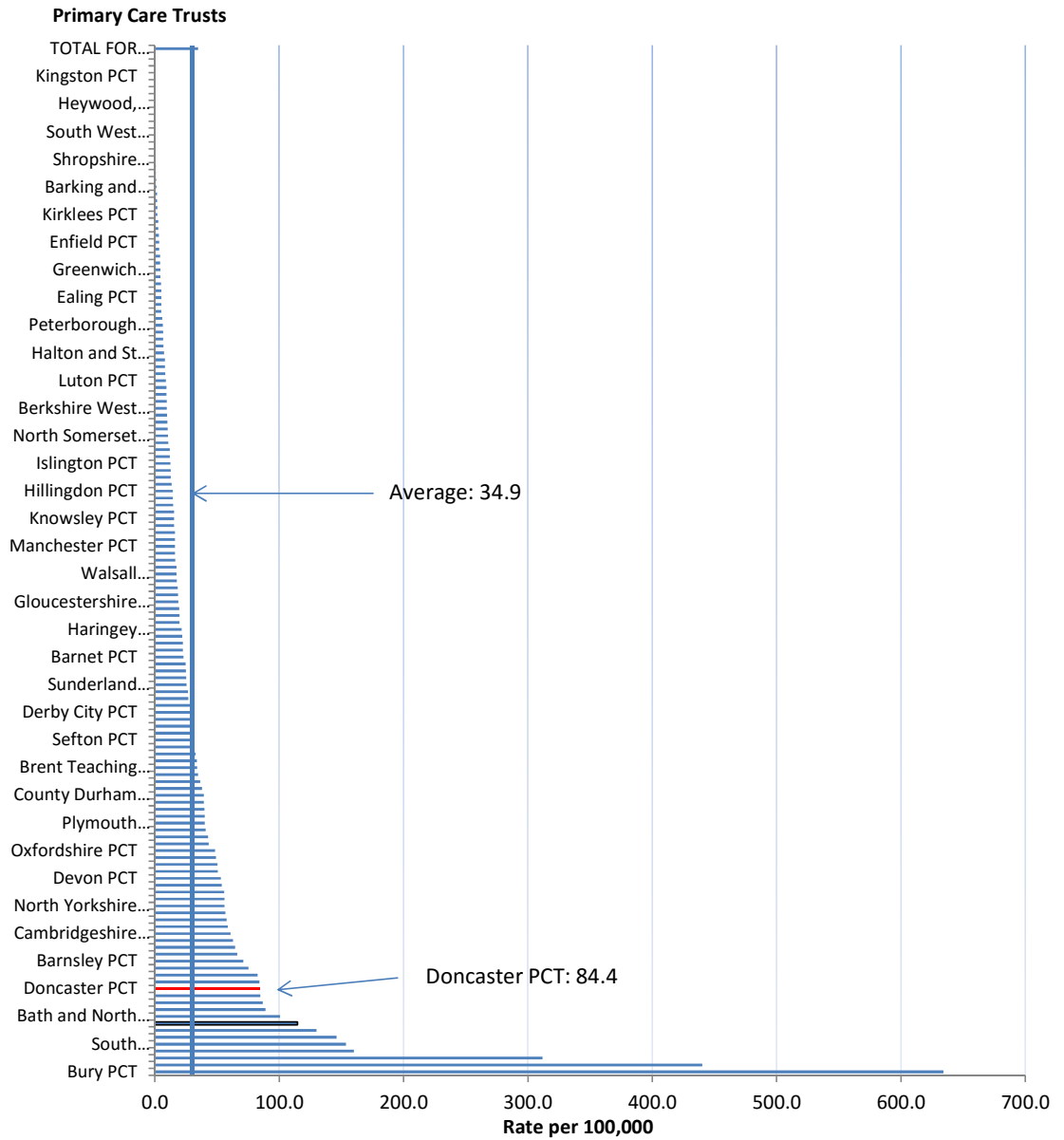
Rates per 100,000 population, Doncaster versus all PCTs in England, 2010/2011 (n=146 PCTs).



Recruitment rates per 100,000 population into portfolio study were categorised according to the degree of increasing complexity as follows: (1) large studies (simple studies with over 10,000 subjects); (2) observational studies; and (3) interventional studies. A comparison of recruitment rates into interventional

studies between participants in Doncaster and all the 146 PCTs was made. It showed that Doncaster recruitment rate into interventional study was 84.4 per 100,000, which was more than double that of the average for all the PCTs (34.9 per 100,000). Doncaster PCT ranked as the 13th highest PCT (of the 146 PCTs) in recruiting into interventional studies in comparison with all PCTs in England (Figure 3.11).

Figure 3.11: Recruitments of participants into interventional studies
 Rate per 100,000 population for Portfolio studies: Doncaster vs. all PCTs in England, 2010/2011 (n=146 PCTs).



The experience of researchers in Doncaster in recruiting participants into portfolio research studies between 2008/09 and 2010/11 also showed that the average number of participants per interventional study was 30 compared to 156 for observational studies (Table 3.4).

Table 3.4: Recruitments into various types of studies in portfolio research
Doncaster: 2008 to March 2011

Type of study	No. of Portfolio studies	Number of participants recruited			
		2008/09	2009/10	2010/11	Total
Interventional studies: number	6	3	41	138	182
Average rate of participants per study (interventional study)	n/a	1	7	23	30
Observational studies: number	13	329	91	1602	2022
Average rate per study (observational study):	n/a	25	7	123	156
Total number of cases in all studies:	19	333	139	1763	2234
Average rate per study (total):	n/a	18	7	93	118

Note: Data obtained from South Yorkshire CLRN, 28th March 2011.

In comparison with some neighbouring districts in South Yorkshire, the number of recruitment was higher in Doncaster. The exception to Doncaster was Sheffield which had higher number of research activities, and it had two universities and a teaching hospital; it also had a high volume of research activities (Table 3.5).

Doncaster Primary Care Trust achieved its target for participants' recruitment into portfolio study for the year 2010/11, although the local provider, Doncaster and Bassetlaw Hospitals (DBH) did not achieve its target (Table 3.6).

Table 3.5: Number of participants recruited into Portfolio studies

South Yorkshire CLRN by intervention (Int.) and observational (obs.) studies, 2008-2011

Trust	2008-09			2009-10			2010-11*		
	Int. studies	Obs. studies	Total	Int. studies	Obs. studies	Total	Int. studies	Obs. studies	Total
Barnsley PCT	0	155	155	53	71	124	130	808	938
Doncaster PCT	3	329	332	41	91	132	94	1602	1696
Rotherham PCT	0	67	67	3	42	45	13	1260	1273
Sheffield PCT	1839	157	1996	870	446	1316	443	321	764

* Up to 4th April 2011

Table 3.6: Recruitment into portfolio studies against allocated target by area for year 2010/11 in South Yorkshire

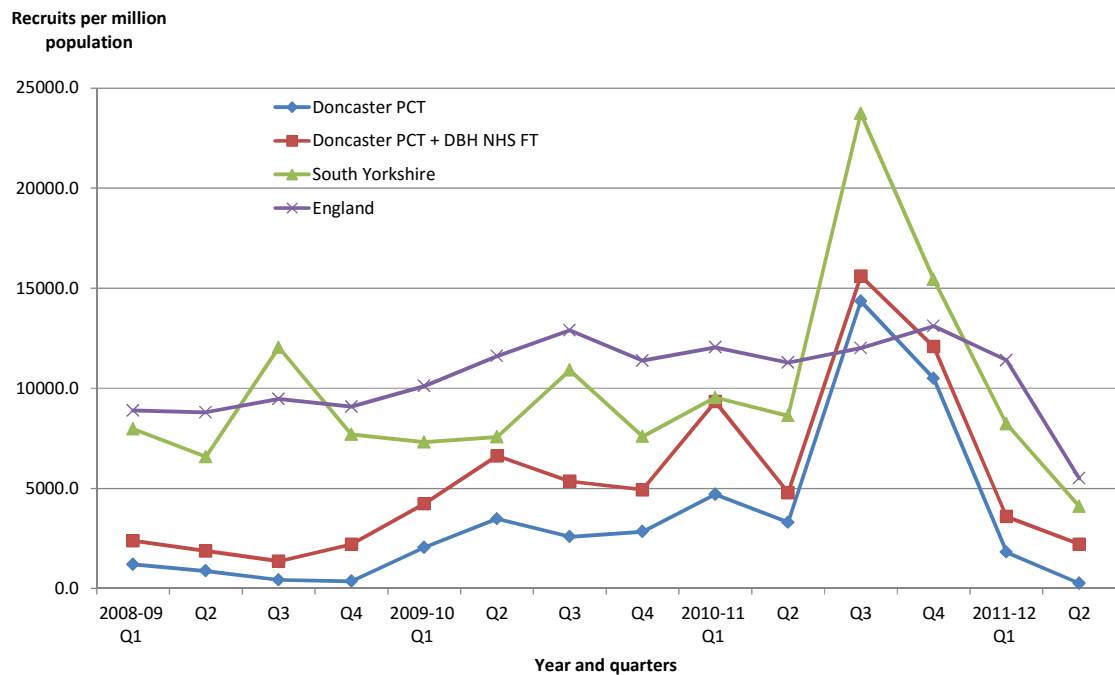
TRUSTS	Total number of recruitment for year 2010/11	Target of recruitment for 2010/11	Remarks
Barnsley Hospital	287	245	Target met or exceeded
Barnsley PCT	1140	84	Target met or exceeded
Doncaster & Bassetlaw Hospitals	331	845	Target missed by >5%
Doncaster PCT	2238	169	Target met or exceeded
Rotherham PCT	1702	50	Target met or exceeded
RDASH Mental Health	36	52	Target missed by >5%
Sheffield Children's	317	328	Target missed by <=5%
Sheffield Health & Social Care	161	55	Target met or exceeded
Sheffield PCT	1006	1132	Target missed by >5%
Sheffield Teaching Hospitals	4682	4044	Target met or exceeded
The Rotherham NHS FT	604	413	Target met or exceeded
South Yorkshire	12504	7417	Target met or exceeded

3.4.3 Time-trend of recruitment into portfolio studies

Complexity weighted recruitment per million population increased steadily in Doncaster over the years from 2008/09 to 2010/11. Recruitment peaked in the third and fourth quarters of 2010/11. However, in comparison with the recruitment observed in South Yorkshire as a whole and England, Doncaster recruitment was low in the first two years when CLRN was established. In 2010/11, the research activities in Doncaster reached a level that was comparable to that observed in England (Figure 3.12).

Figure 3.12: Complexity-weighted recruits per million populations

Doncaster PCT; Doncaster PCT & Doncaster and Bassetlaw Hospitals;
South Yorkshire CLRN; and England; 2008/09 to 2011/12



Data source: South Yorkshire CLRN

The SY CLRN had dedicated research nurses embedded in each districts to support recruitment. There was reported evidence that having a dedicated staff

on site was essential for recruitment of participants into research study, as reported by one of the research nurses (SYCLRN, 2010):

“X Trust [hospital provider in South Yorkshire] is 95 over recruitment on a relatively small number of targeted cases. Jenny [not the real name of staff] reported that X Trust’s success was because the research nurse team, which has made a huge impact on recruitment in X Trust over the past few months, work on site.”

There was no dedicated research nurse in Doncaster for the implementation of telehealth project. The two nurses that were allocated for the telehealth implementation during the pragmatic trial period did not have protected time to undertake the required work.

3.4.4 Non-Portfolio studies in Doncaster

The data on approval of research studies by the Local Research Ethics Committee in Doncaster during the period from 2005 and 2011 showed that 80% of the studies were non-RCT studies and 20% were RCTs (Table 3.7).

Table 3.7: Non-portfolio research activities in Doncaster

Based on recorded studies held by Doncaster PCT that had local research ethics committee approval

Start year	Non-RCT		RCT		Total	
	n	%	n	%	n	%
2005	6	66.7	3	33.3	9	100.0
2006	26	72.2	10	27.8	36	100.0
2007	11	57.9	8	42.1	19	100.0
2008	19	90.5	2	9.5	21	100.0
2009	14	93.3	1	6.7	15	100.0
2010	24	85.7	4	14.3	28	100.0
2011	16	94.1	1	5.9	17	100.0
Total	116	80.0	29	20.0	145	100.0

Note: 19 studies with details unknown were not included in the above tables; studies were recorded to have started from March 2005 to September 2011.

3.5 Telehealth service

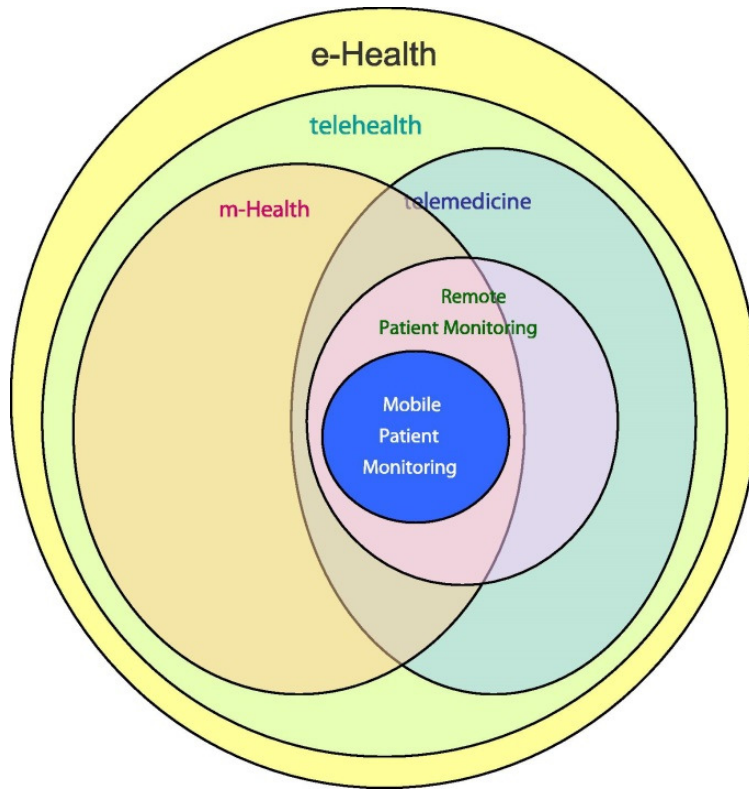
Against the background of the burden of LTCs in Doncaster, and the opportunity offered by the introduction of assistive technology by the Government (Department of Health, 2005a), Doncaster PCT decided to pilot the use of telehealth service for the care of patients with LTCs. This section explores what telehealth is and it describes telehealth service introduced in Doncaster. The section describes telehealth service, as one of the interventions to support self-care for people living with LTCs, taking patients with COPD as an example to focus on. Telehealth, as used in this study, focuses on remote patient monitoring (part of telehealth). The contexts of remote patient monitoring in England and in Doncaster are also described.

3.5.1 Definition of telehealth and remote patient monitoring

This section aims to provide the context to help in understanding telehealth. There is much confusion in the published literature in relation to definitions of telehealth and related terms. This confusion has resulted from the use of terminologies that are either too broad (e.g. e-Health), which makes comparison of study results difficult; or the use of different terms (e.g. telehealth, telemedicine or telehealthcare or telemonitoring) for similar technological interventions.

It is important to place telehealth and related definitions in the wider context of electronic health (e-Health). This context is best illustrated by Figure 3.13 (Pawar et al., 2012), in which telehealth is considered as a subset of e-Health. Under the entity of telehealth, Pawar and colleagues (2012) regarded remote patient monitoring (similar to the type used in the study setting in Doncaster for this research), as being part of telemedicine (Pawar et al., 2012).

Figure 3.13: Remote patient monitoring as a subset of telehealth and e-health



Source: (Pawar et al., 2012)

This research is about remote patient monitoring as it involved the remote home monitoring of patients in their own homes by healthcare professionals.

E-Health encompasses medical informatics, public health and business application of delivering healthcare using internet and related technologies (Eysenbach, 2001, Pawar et al., 2012). Such a wide remit of e-health has made evaluation and comparison of related interventions a major challenge to researchers and practitioners in the field. Telemedicine can be considered as a subset of telehealth, as shown in Figure 3.13. Attempts to differentiate between the two had often resulted in more confusion. Even the World Health

Organisation (WHO) agreed that the term telehealth was much broader than telemedicine, and it regarded telehealth as a preferred terminology to use because it addressed public health agenda; education for health, public and community health, health systems development and epidemiology (World Health Organisation, 2003, Pawar et al., 2012, Darkins and Cary, 2000).

Examples of telehealth technological devices ranges from telephone alone or in combination with other devices, videophone, computer, mobile phone, still image video phones, radio, fax, internet (Grigsby et al., 2005, Wootton et al., 2006).

The telehealth work involved in this study entailed regular monitoring of patients in their own home by community nurses. Steventon et al (2012) offered a definition of telehealth remote home monitoring that was used as part of Whole System Demonstrator (WSD) in England, and it closely reflected the remote home monitoring used in this research:

“Telehealth involves the remote exchange of data between a patient and healthcare professionals as part of the patient’s diagnosis and healthcare management.” (Steventon et al., 2012), p2.

The limitation of the definition of remote patient monitoring offered by Steventon and colleagues (Steventon and Bardsley, 2012) was that it did not describe the types of information collected for self-management, and patients’ diagnoses were not part of the local telehealth service in Doncaster. The type of telehealth remote home monitoring used in Doncaster was similar to that in the WSD in that it involved monitoring patients’ blood pressure and blood sugar to support self-management of patients (Cartwright et al., 2013).

In light of the limitation of definition described by Steventon and colleagues (2012), a modified definition of remote patient monitoring, which reflected the service in this research, was advanced by the author of this thesis, as follows:

“Remote patient monitoring is the remote exchange of patients’ data where patients measure their vital signs (oxygen saturation level in their blood (SpO2), pulse, breathing, or blood pressure), and answer symptoms questions from their home and the data is transmitted via internet to a healthcare professional who monitors the patients’ data and institutes appropriate management actions.” Adapted from (Steventon et al., 2012)

This definition of remote patient monitoring is used throughout this thesis in reference to the type of telehealth service employed in this research, including literature review. Therefore, in this thesis, where the term telehealth is used, it refers to remote patient monitoring. Unless otherwise stated, the use of term telehealth also refers to telehealth service (Section 3.5.3).

3.5.2 The policy contexts of remote patient monitoring

The role of new technology in England, in the delivery of future high quality health care, was set out in a 20-year vision report produced by Sir Derek Wanless in 2002. Wanless (2002) described the best option for improving the future health of the nation in England as that of full level of engagement by the population with preventive and self-care using new technologies. He described this option as a *fully engaged scenario*, in comparison to other options of “*do nothing*” or *partial engagement* by the population with preventive agenda (Wanless, 2002). In 2005, the Government’s strategy on assistive technology *Building Telecare in England* (Department of Health, 2005a) started to

implement this vision by offering initial grant of £80 million to local authorities in England. The Department of Health defined telecare as:

“...the continuous, automatic and remote monitoring of real-time emergencies and lifestyle changes over time in order to manage the risks associated with independent living.” (Ellis, 2008a)

An example of telecare that was operated by Doncaster Council was a pendant alarms system that older people at risk of falls could wear on the neck. When the alarms were pressed after a fall, it would alert staff members who remotely monitor the alarms generated. Although majority of the Government's £80 million grant allocated in 2005 was for telecare, some local authority areas working in partnerships with the NHS (National Health Service in Britain), used it for piloting telehealth service.

The Whole System Demonstrator (WSD) was another major cluster randomised controlled trial (RCT) study funded by the Department of Health in England in 2008 to investigate the effectiveness and cost-effectiveness of telehealth, at a cost of £31 million (Ellis, 2008b). The role played by telehealth was also recognised by the Audit Commission as having the potential to provide better and less expensive care, while promoting self-care and patients' independence (Audit Commission, 2004). In 2011/12, an initiative called *Delivering Assistive Living Lifestyles at Scale (DALLAS)* was launched, which aimed to target 3-5 clusters of communities (each cluster aimed to recruit 10,000 users): one in Scotland and the others in England. These communities were to be given assistive living technologies, and some of these technologies would be telehealth (Technology Strategy Board, 2011). The project was budgeted at £23

million; with £5m funding from the Scottish Government and £18m from England.

On the 6th of December 2011, the British Prime Minister, David Cameron, gave a speech at the Financial Times (FT) Global Pharmaceutical and Biotechnology Conference in London where he affirmed his Government's determination to roll out telehealth to 3 million people in England:

“Just look at our approach to tele-health – telemedicine – getting new technology into patients' homes so they can be monitored remotely. We've done a trial, it's been a huge success and now we're on a drive to roll this out nationwide with an aim to improve three million lives over the next five years with this technology.” (Cameron, 2011)

The importance which the Government attached to investment in technology in health was further reflected in the speech by the Chancellor of the Exchequer on 28 May 2012 in which he committed £180 million, as part of life science strategy announced by the Prime Minister in December 2011 (Osborne, 2012b). The Chancellor, in a later speech (9 November 2012), also gave the support of the government to the scientific community to realise the social and economic benefits of several areas of new technologies, including those in health (Osborne, 2012a). Some examples of the technologies in health cited by the Chancellor included sport vest worn by footballers that measured heart beats of players, which could enable coaches to monitor their players (pioneered in Spain); and the use of robots in medicine. Although this might seem unrelated to telehealth, what it suggested was that the future technologies are likely to be those that are incorporated into day-to-day activities of ordinary people. The broad eight areas of the new technologies that the Government pledged its

support for included: efficient computers (data revolution), synthetic biology, regenerative medicine, advance material science, robotic and automatic system; agri-science, and satellite application (Osborne, 2012a).

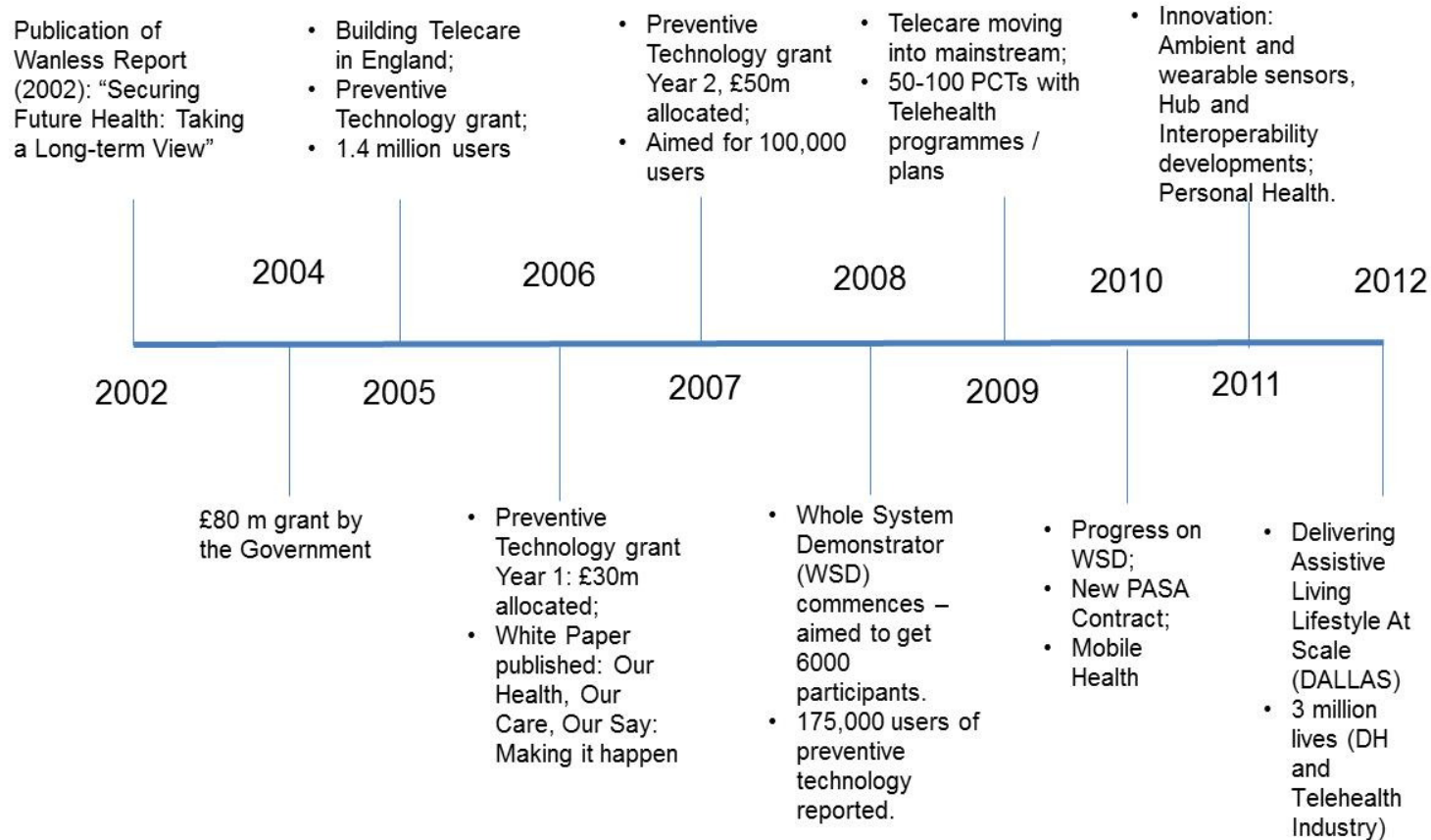
The purposes of the Government's drive for new technology in health appeared to be not only about improving the quality of life of people using these technologies, but also to have commercial edge globally:

"Now this will make an extraordinary difference to people. Diabetics will be taking their blood sugar levels at home and having them checked remotely by a nurse; heart disease patients will have their blood pressure and pulse rates checked without leaving their home at all. This is dignity and convenience and independence for millions of people. And it's not just a good healthcare story; it's going to put us miles ahead of other countries commercially too as part of our plan to make our NHS a driver of innovation in UK life sciences." (Cameron, 2011)

In January 2012, the Department of Health in England signed a Concordat with the UK telehealth and telecare industry for rolling out telehealth and telecare in the health and social care with the aim of improving the lives of 3 million people in England over a 5-year period: 2012-2017 (Department of Health, 2012). Part of this drive could be attributed to the determination of the telehealth and telecare industries to find markets for selling their new technologies in health and social care, coupled with keen interest among some researchers to see that the technologies got implemented.

The history of telehealth in England between 2002 and 2012 is summarised in Figure 3.14.

Figure 3.14: The history of telehealth and telecare in England



Adapted from (Clark, 2009, Biddle and Chahaian, 2011)

3.5.3 Description of telehealth service (system)

The devices used for the telehealth during the pragmatic trial in Doncaster between 2007 and 2009, was the Genesis Monitor model (Figure 3.15a below), which was the size of a radio alarm clock. It had blood pressure cuff, pulse oximeter, weighing machine, and thermometer as peripheral devices, which were connected to the base unit. Patients with COPD used the weighing machine only at the start (or when determined by a nurse), but they monitored daily their vital signs, which included blood pressure, pulse and body temperature. The base unit was connected to a landline telephone from where readings from the machines were transmitted to a central monitoring location in a health centre located in Thorne area of Doncaster. Patients without functional landline telephones could not use the machine at this time and were excluded, as per pragmatic trial's exclusion criteria.

Figure (3.15a): Telehealth Equipment: Genesis Monitor (Model), 2007



An improved model (RTX Model) (Figure 3.15b) used during the service evaluation study period, which came into use about two years later following the introduction of Genesis Monitor, had wireless features utilising blue tooth technologies for its peripheral devices. The blue tooth technologies enabled some of the machines to operate without the need to connect to landline telephones. Patients without landline telephone who were deemed eligible for the study were given these new devices, unlike in the pragmatic trial.

Figure (3.15b): Remote patient monitoring machine (RTX3371 Model), 2010



The following vital signs could be captured via the device: blood pressure (systolic and diastolic), oxygen saturation (SpO₂), heart beat (pulse) per

minute, weight (kilogramme). A peripheral device for measuring blood glucose levels was also available for patients with diabetes. The parameters of the vital signs were set by healthcare professional for individual patients, taking into account recommended national guidelines by the National Institute for Health and Care Excellence (NICE) in England. Any breach of parameters set for each vital sign generated a red alert, which required a healthcare worker to investigate and take appropriate course of action.

In addition, there was a bank of questions that could be chosen by healthcare workers to ask patients on a regular basis, if required. The Genesis Monitor (older device) had a bank of 51 questions. An example of such questions was:

“Are you experiencing more difficulty breathing today compared to a normal day?”

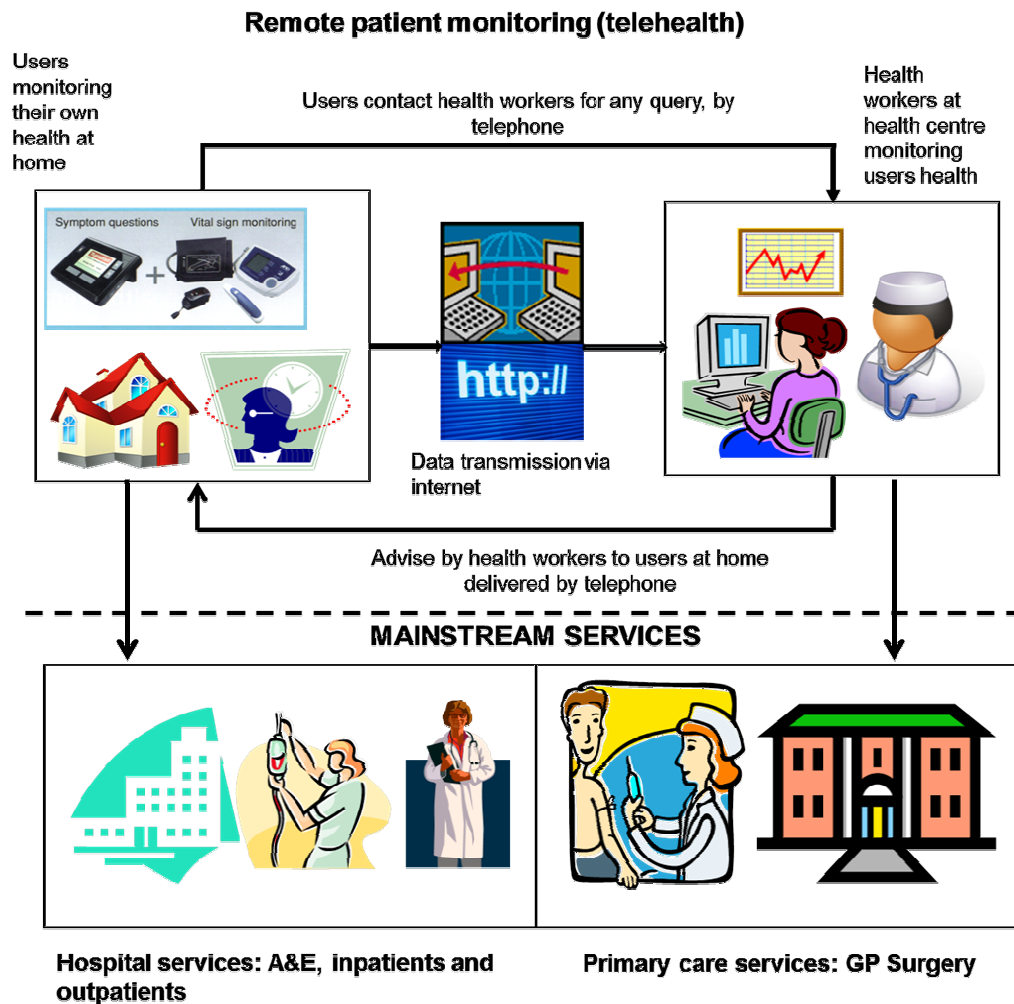
Detail of the questions used in the pragmatic trial is found in Chapter 5. They were asked to all patients in the trial. However, during the service evaluation study, the questions were optional, and were not the same as those used during the trial.

While the focus on telehealth service appeared to be around the technology (“The Black Box”) that measured vital signs and answered some symptoms questions, there were in fact multiple interventions that could be identified in a telehealth service (system). These included the following: (1) the technology itself used for remote patient monitoring (“The Black Box”), including the associated internet communication system and data transmission to a monitoring centre; (2) telephone contacts between

healthcare professionals and users; also described in the literature as the plain old telephone system (POTS) that was used for exchanging real-time information (Sheikh et al., 2011); and (3) advice by appropriate healthcare professionals to users, including actions on implementing management plan. Recognition of these interventions (wider contexts) is important to the understanding of how telehealth service (system) operates. The author's perspective on diagrammatic representation of telehealth service with the different components is shown in Figure 3.16.

Figure 3.16: A depiction of how telehealth service works

Enabling communication between a patient and a healthcare professional (author's perspective)



As shown in Figure 3.16, users of telehealth service took their vital signs: blood pressure, level of oxygen saturation (SpO₂), heart rate, temperature; and they also answered symptom questions through the technology. While users were able to measure their vital signs and answer symptoms questions, however, they were not able to access historical data about themselves. They could observe and note the vital signs readings at the time of undertaking the measurements. The data was transmitted remotely via internet to a web-based storage where healthcare professionals gained

access to the data using secure user names and passwords to specified sites and patients under their care, subject to the level of authorisation granted to them by a designated staff that had the overall responsibility.

The community nurses reviewed the patients' vital signs readings and any response to individually tailored questions only from Monday-Friday during working hours from 09:00 hours to 17:00 hours. The system was not considered to be for emergency use, and if there was any urgent matters outside working hours, patients were advised to contact usual emergency services. Hence, any readings that patients might have performed during out of hours, including weekends, were only responded to by the nurses during working hours, Monday-Friday. The expectation was that patients would take their vital sign readings and answer symptom questions twice a day; in the morning and in the evening at agreed time between the patient and their healthcare worker.

According to the four classes of telehealth described by Cartwright and colleagues (2013), the first generation telehealth had non-reactive data collection (store and forward) where providers did not respond immediately; in the second generation of telehealth patient data was transferred for decision making purpose, but there was some delays by health service providers as the system operated during office hours. While third generation telehealth was characterised by constant analytical and decision making components with 24 hours per day and seven days a week operation; and finally the fourth generation was an extension of the third generation involving more complex surgical and medical procedures (Cartwright et al.,

2013). The Doncaster telehealth was considered to be a second generation telehealth service.

3.5.4 Selection process of preferred supplier of telehealth service

The implementation of telehealth service in Doncaster could be categorised into two main phases: the pilot phase (in which 20 devices were purchased); this was where the RCT study design was used. It was intended that additional 60 devices were going to be used during the pragmatic trial phase, but this did not happen. The second phase (or service evaluation) was the roll out phase (where the existing 80 devices were replaced with newer ones and additional 100 devices were purchased bringing a total of 180 commissioned telehealth devices). The first telehealth service involving the pragmatic trial was commissioned in 2007/2008, while the roll out phase was commissioned in 2009/2010, with phased implementation over a two-year period.

A committee was formed to consider the specification required for procuring the right telehealth technology. The committee consisted of nine members including community nurses, project manager for assistive technology, information technology manager, information governance representative, commissioning manager for physical disability and sensory impairment; and a public health consultant.

Potential suppliers of telehealth were invited to tender through the NHS Purchase and Supply Agency (PASA) framework, in line with Department of Health procurement rules in England. The invitation contained information with questionnaires that were completed by the suppliers. The questionnaire

asked for information on (1) cost of telehealth machine, (2) equipment and data storage, (3) service support and help facilities, (4) training, and (5) experience of the suppliers in delivering telehealth to users. These five areas were weighted in the assessment as follows: cost – 40%; equipment – 30%; training - 10%; service, support and help facilities – 10%; and experience – 10%. Each of these components had detail elements that were assessed by the panel before arriving at their final score.

The suppliers were invited for a demonstration day, and later for a formal interview lasting for a whole day, with each supplier being interviewed for about one hour by a panel of PCT staff. The panel consisted of seven members from different disciplines, and they included: project manager, IT manager, community matrons, and public health. The process of selection of the preferred supplier was as follows: first the nine potential suppliers were invited, of which six applied; four of them were subsequently interviewed; and finally one was chosen as the preferred supplier.

Individual members of the panel separately scored each supplier's performance against the five dimensions described above. The scores were then collated to derive the panel overall scores. A separate meeting of the panel was held to discuss the combined scores of the panel. The panel finally chose Tunstall as the preferred supplier of telehealth service in Doncaster.

When it was felt that more than 20 devices might be needed for telehealth service, a business case was made for additional 60 devices. As the additional telehealth was expanding on existing telehealth programme, it

was not deemed necessary to undertake a new process of procurement. Hence, the additional 60 devices were purchased from Tunstall. Ethical approval was sought and obtained for the amendment to increase the number of machine in use in the RCT.

During 2009/10, it was decided to roll out telehealth service in Doncaster following the pragmatic trial. However, it was felt necessary to undertake a tender process, similar to the one described at the pragmatic trial period. It was realised that the existing devices that were in use were already outdated, even though they were less than two years in use. One of the requirements for potential suppliers was to replace existing devices in use with newer ones. Tunstall emerged as the preferred choice of supplier.

3.6 Summary

This chapter describes the relevant backgrounds to the research and provides information to address some of the research questions, posed in the introduction of the thesis. Doncaster is a health district (PCT), coterminous with the local authority, and it is located in South Yorkshire (in the North of England). It had a population of 302,400 and was considered to be a deprived area. Long-term conditions are a major public health problem in Doncaster in terms of high disease prevalence, morbidity and mortality burden. Locally, one in five people suffered from a long-term condition such as heart disease, diabetes, respiratory disease, cancer, etc.

It has been shown that Doncaster had a more favourable research experience in relation to recruiting subjects into research activities when compared with other PCTs in England and within the same county of South

Yorkshire. Evidence shows that majority of the research activities were for observational studies (non-RCT), than interventional studies (RCTs).

Telehealth service was considered to have a role in managing patients with LTCs. It involved the delivery of healthcare at a distance. Telehealth service in this thesis means remote patient monitoring, and a full definition has been offered in this chapter. Telehealth service can be described as consisting of multiple intervention; the device, telephone service, and professional advice. The device was capable of monitoring patients' vital signs (blood pressure, level of oxygen saturation in the blood [SpO₂], pulse rate, weight, etc.) and answering individually tailored sets of questions.

Chapter 4: Literature Review on the Effectiveness and Cost-Effectiveness of Telehealth Services

4.1 Introduction

The first three chapters of the thesis provided an introduction, theoretical framework and backgrounds to the research. The first chapter outlined the evolution of the research aims and objectives from that of initially assessing effectiveness of telehealth to investigating why and how new technologies embed or not in routine practice. In the second chapter, the principal theoretical framework, normalisation process theory (NPT), was identified and described. The third chapter described relevant backgrounds information to the research, which included the study setting, demographic characteristics, health profiles, research experience in the study setting, and a description of telehealth services used in the study setting.

Figure 4.1 describes the focus of the current chapter, which assesses the evidence of effectiveness and cost-effectiveness of telehealth services. In addition, it describes evidence from the literature on the implementation of new technologies and failed trials. Throughout the chapter, reference will be made to Figure 4.1 and the relevant numbered boxes.

There were two groups of patients of interest in relation to assessing the evidence of effectiveness and cost-effectiveness of telehealth services. One group of patients was broad and included those with long-term conditions

(LTCs), as shown in Boxes 1a.i and 1b.i. They were the potential target group for telehealth service, as described in Chapter 1.

The second group was patients with chronic obstructive pulmonary disease (COPD). The latter group is a subset of systematic reviews assessing the effectiveness and cost-effectiveness of telehealth service among patients with LTCs, as shown in Boxes 1a.iii and 1b.iii of Figure 4.1. This group of patients was chosen because they were identified and targeted for telehealth service when the service was first introduced in Doncaster, the study setting. The headline findings of effectiveness and cost-effectiveness of telehealth service for patients with COPD are in Box 1c.ii.

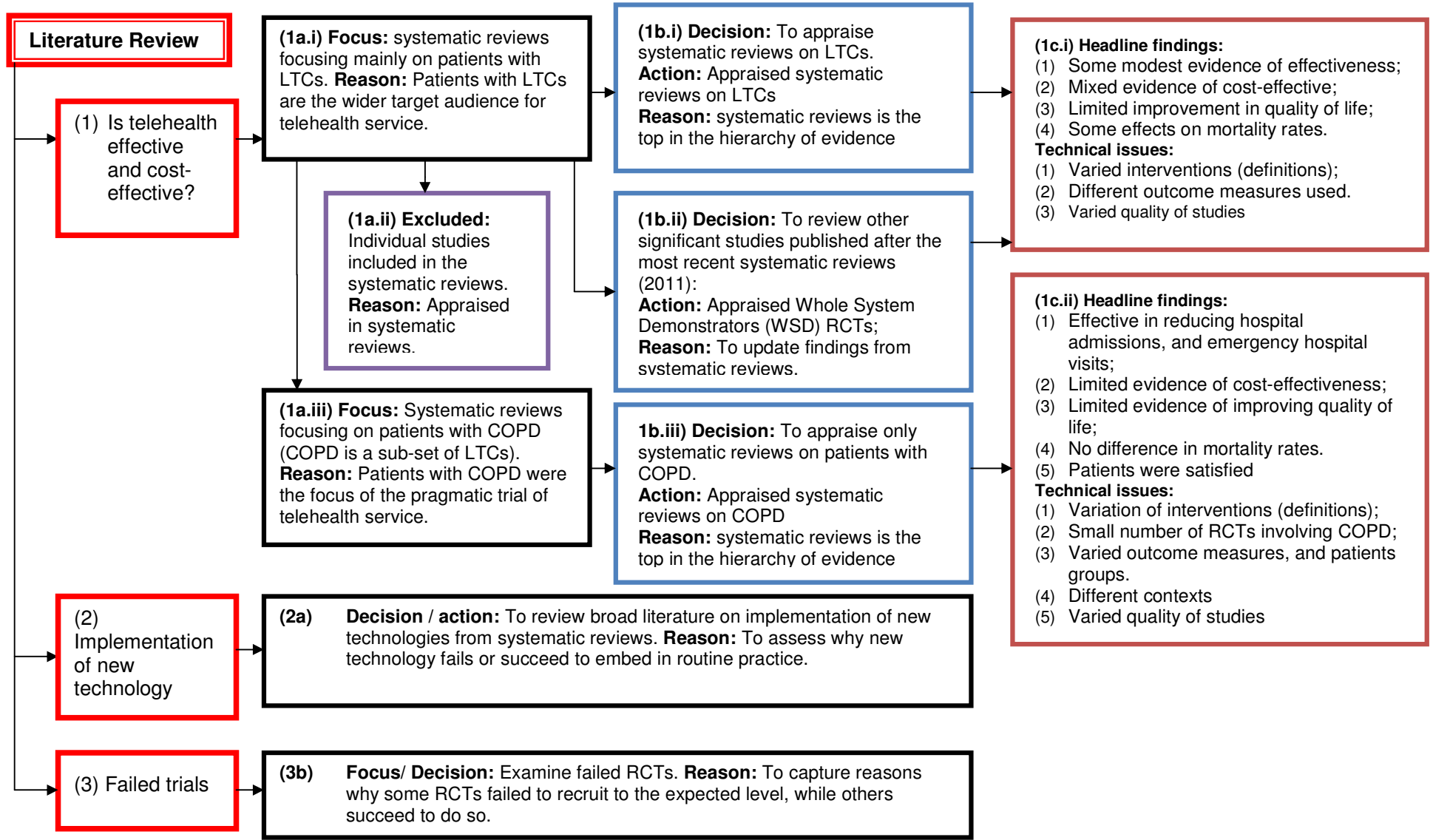
As the focus of the thesis changed, to investigating why new technologies fail or succeed to embed in routine practice, a review of the literature on implementation of new technology was undertaken (Boxes 2 and 2a). The final part of the review assessed the evidence from the literature related to factors associated with the successes and failures of pragmatic randomised controlled trials (RCTs) (Boxes 3 and 3a). This section is relevant later on in the thesis in helping to contextualise what went wrong in the pragmatic trial that is reported in Chapter 5 and how recruitment into trials could have been improved.

Therefore, the objectives of this chapter are:

1. To assess the evidence of effectiveness and cost-effectiveness of telehealth services in managing patients with long-term conditions (LTCs) in general, and COPD in particular.

2. To identify factors which determine the success or failure to implement a telehealth service in routine practice.
3. To identify factors why RCTs fail to recruit to their target sample sizes.

Figure 4.1: Literature review systematic reviews on effectiveness and cost-effectiveness of telehealth: decisions, actions and reasons



4.2 Methods

4.2(1a.i and 1b.i): Is telehealth effective and cost-effective?

The focus of this first part of the literature review was to find systematic reviews on effectiveness and cost-effectiveness of telehealth services. The following search question was formulated to aid the search of articles:

“What is the evidence of effectiveness and cost-effectiveness of telehealth services among patients with long-term conditions (LTCs) in routine healthcare use?”

Evidence of cost-effectiveness was sought, but there was very little evidence about costs, and the literature review focused on effectiveness of telehealth in practice.

The search strategy included the use of the following terms: telehealth or telemedicine, or home telemonitoring, AND effectiveness, AND cost or cost analysis, AND chronic diseases. Employing features in the medical subject headings (MeSH), articles covered under the searched terms and related terms were included in the search of bibliographic databases.

The following sources of databases were searched: (1) evidence based medicine reviews, which contained Cochrane reviews, and Cochrane-style reviews; and (2) Medline, with a focus on systematic reviews articles.

The original search was conducted in 2012, capturing systematic reviews articles from 1991 up to 2012. The search was later updated in order to identify new articles published between 2012 and 2015. The evidence based

medicine reviews databases that were originally searched included the following:

- Cochrane Database of systematic reviews: 2005 to May 2012,
- American College of Physicians (ACP) Journal Club: 1991 to May 2012,
- Database of Abstracts of Reviews of Effects: 2nd Quarter 2012,
- Cochrane Central Register of Controlled Trials: May 2012,
- Cochrane Methodology Register: 2nd Quarter 2012,
- Health Technology Assessment: 2nd Quarter 2012,
- NHS Economic Evaluation Database: 2nd Quarter 2012.

The updated literature search of articles published between 2012 and 2015 included the following databases: Web of Science core collection; BIOSIS Previews; BIOSIS citation index; Data citation index; KCI – Korean Journal Database; Medline; and SciELO (Scientific Electronic Library Online) citation index.

The original literature search of Medline was performed on 14th February 2012, involving Ovid Medline (1996 to February Week 1, 2012) with full search history shown in Annex 1.1, Table A1.1. This is shown as an example of database that was searched. The updated literature search history for the period 2012 and 2015 carried out in Web of Science is shown in Annex 1.1, Table A1.2

The systematic reviews were updated with pragmatic trials articles from the WSD telehealth project (Steventon and Bardsley, 2012, Henderson et al.,

2013, Cartwright et al., 2013, Steventon et al., 2014) (Box 1b.ii of Figure 4.1).

4.2(1a.ii) Exclusion and inclusion criteria

The inclusion criteria for articles were: (1) systematic review articles; (2) articles related to patients with long-term conditions; (3) the intervention used closely reflected the definition of telehealth service as defined in Chapter 3; and (4) articles that addressed effectiveness or cost-effectiveness of telehealth service.

Articles were excluded if they: (1) did not meet the operational definition of telehealth stated above; (2) were not related to a long-term condition; (3) they were not systematic reviews (except the WSD pragmatic trial articles, given the status of the trial, being so large and undertaken in the NHS in England); and (4) they did not address effectiveness or cost-effectiveness of telehealth service.

4.2(1a.iii) Patients with COPD

From among the systematic review articles assessing effectiveness and cost-effectiveness of telehealth services for patients with LTCs, a subset of these related specifically to patients with COPD. This subset was appraised separately under a section on COPD in this chapter.

The studies were appraised using an appropriate critical appraisal tool – the Critical Appraisal Skills Programme or CASP tool (Public Health Resource Unit (England), 2006b, Public Health Resource Unit (England), 2006a). For the systematic reviews, there were 15 questions in the CASP tool that were

used to assess the quality of each study, and they explored the focus of the review, the validity of the results, their application in practice and generalisation. Each question was scored as follows: 2 = yes (where it was fully answered); 1 = somewhat (where it was partially answered); and 0 = no or can't tell (where the question was not answered). At the end of appraisal of each systematic review article, a total score was derived; the maximum score was 30. The total score out of 30 was expressed as a percentage to enable broad comparison with other systematic reviews. Appraised articles were assigned a low score if the total score was <60.0%; 60.0 – 74.0% was moderate; and 75.0% or more was high quality. Interpretation of the conclusions of each study was made by considering the total score and assigning an overall assessment, based on SIGN evidence-based criteria for assessing quality of study outlined in Table 4.1.

Table 4.1: Overall assessment of quality of study

Code	Description
++	All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.
+	Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.
-	Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.

Source: (SIGN, 2011), p55.

The framework for assessing quality of studies by SIGN (2011) was also used in assessing the quality of articles reviewed. The reason for this choice was based on the fact that the framework has been used widely, for example by NICE, as part of its evidence-based recommendations.

Articles from the WSD pragmatic RCTs were appraised using relevant CASP tool for trials, and a similar process was used to that of appraising the systematic reviews.

4.2(2) Implementation of new technology

The search words employed for undertaking literature search on implementation of new technology were “*Telehealth or telemedicine and challenges or success factors*”.

Articles on the implementation of new technology related to key challenges for successes and failures of telehealth projects were identified from a range of sources, including systematic reviews captured in the above search. Specific searches that were carried out included specialist websites for telemedicine, Medline, Web of Science, EMBASE, evidence based reviews and internet google search. The references of the articles were screened for relevant papers on implementation of new technology. Further search for books on telehealth was conducted at the University of Leeds Library and the NHS Library service in Doncaster. Searches for specialist telehealth centres, included those in the UK and elsewhere in the world; Norway (The Norwegian Centre for Integrated Care and Telemedicine, 2009), Scotland (Scottish Centre for Telehealth, 2009), (NHS Institute for Innovation and Improvement, 2009), and England (Swinfen Charitable Trust, 2009).

The focus of the literature search was to identify systematic review articles.

4.2(3) Failed trials

Literatures on failed trials were identified through my own professional networks, from Health Technology Assessment (HTA) Programme web sites and articles, [the HTA is part of the UK National Institute for Health Research (NIHR)], Google search, and retrieval of relevant articles from the systematic review list of references. All the databases covered under the Web of Science were included in the search, including Medline, Web of Science core collection, BIOSIS citation index, BIOSIS Previews, Data citation index, KCI – Korean Journal Database, and SciELO citation index (Table 4.3). From Web of Science, articles that were related to, or cited the primary article, were screened to identify other potential new systematic review articles. The focus was to identify systematic reviews articles. The search terms used included “failed trials” or “failed RCTs” or “failed randomised controlled trials” (Table A1.3 in the Annex 1.1).

4.3 Results

4.3(1) Is telehealth effective and cost-effective?

4.3(1b.i) Effectiveness and cost-effectiveness of telehealth service among patients with LTCs: findings from systematic reviews

The original search of evidence-based medicine databases identified 12 articles, and the Medline search yielded 25 review articles, making a total of 37 potential systematic review articles. Of these, 24 were excluded and the

reasons for their exclusion are set out in Figure 4.2a, leaving 13 articles that were included in the literature review.

Figure 4.2a: (Original search) Systematic review articles related to effectiveness and cost-effectiveness of telehealth service for patients with long term conditions: 1991 to 2012

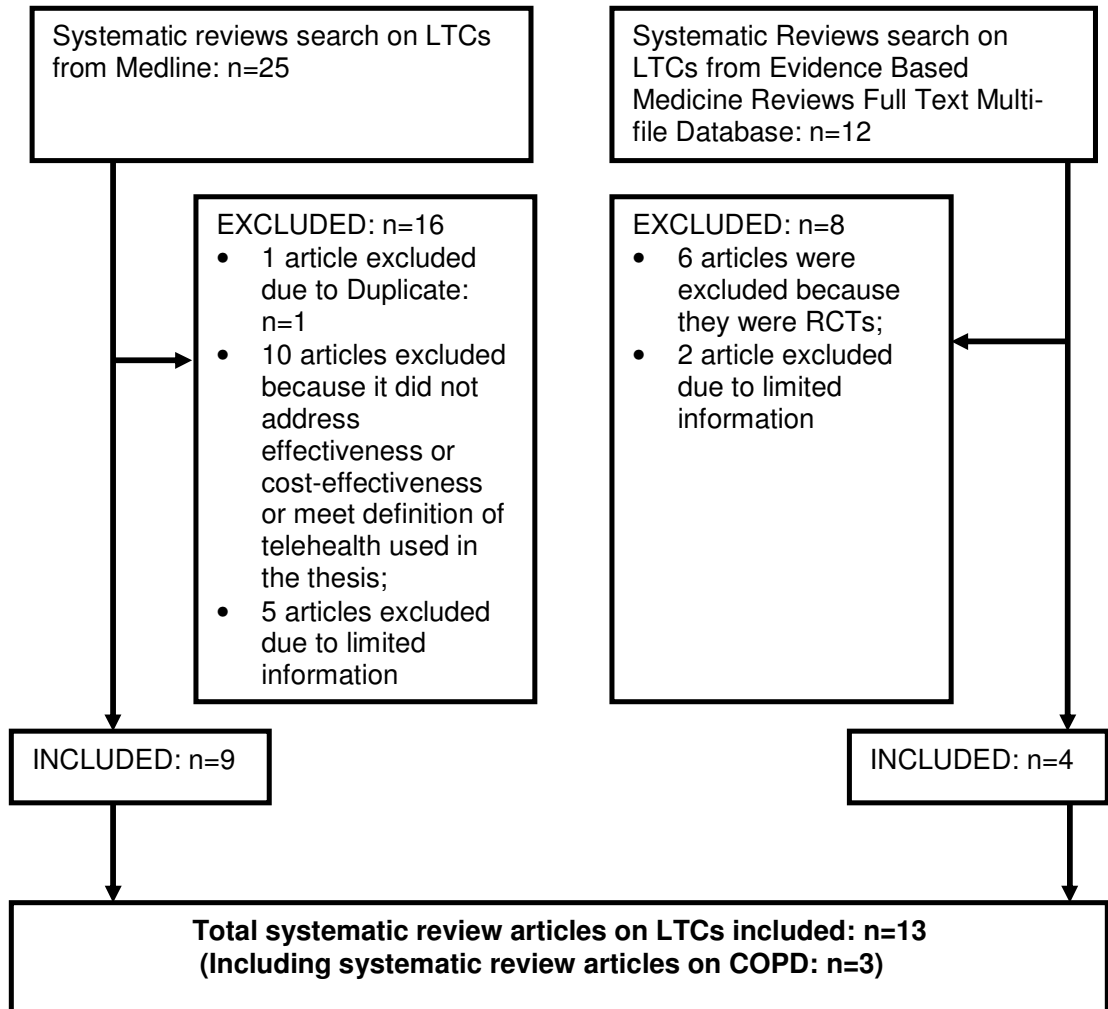
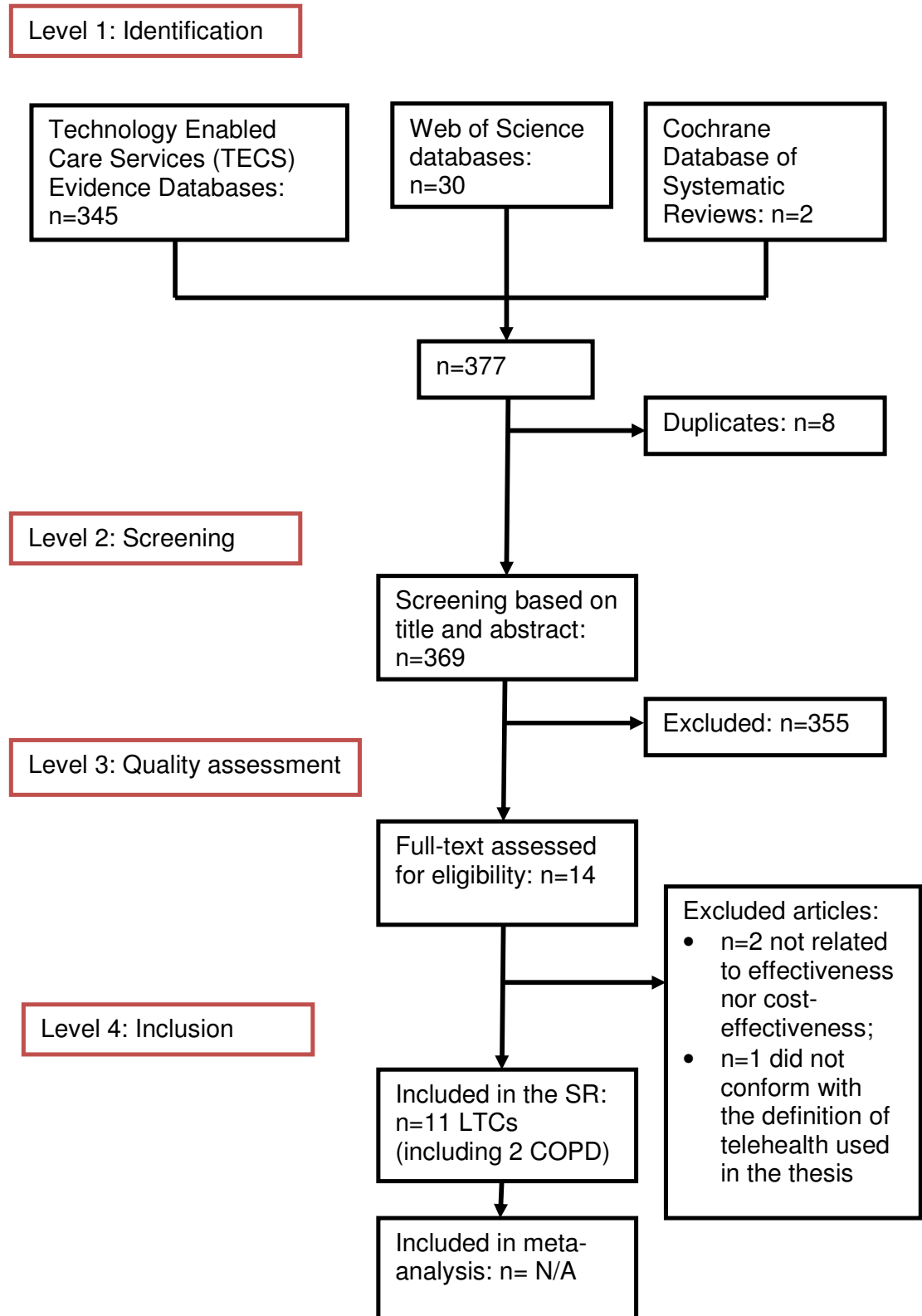


Figure 4.2b: (Updated search) Selection process of systematic review articles on telehealth:

Update from 2012 to 2015 (11 July 2015)



The updated literature found 377 potential systematic review articles, and 11 systematic reviews were included in the appraisal that related to all long term conditions (LTCs), including two articles that focused on COPD (Figure 4.2b). The two articles on COPD were appraised in the relevant section of the chapter for COPD, while the 9 articles were assessed under the section on LTCs.

The original (n=13) and the updated literature search (n=11) made up a total of 24 systematic review articles that were included in the review on effectiveness and cost-effectiveness of telehealth service. The updated literature search was used to update the original literature review findings and adjust the overall conclusions of the chapter in light of most recent evidence.

The qualities of the nine systematic reviews are shown in Table 4.2.

Table 4.2: Summary of appraisal of systematic review articles on effectiveness and cost-effectiveness of telehealth for patients with LTCs (excluding COPD): based on updated literature search

Systematic review articles and their appraisal scores: 2 = Yes; 1 = somewhat; 0 = No or can't tell									
QUESTIONS	(Purcell et al., 2014);	(Pando r et al., 2013);	(Laver et al., 2013)	(Kotb et al., 2015)	(Bergmo, 2014)	(Merriel et al., 2014)	(Kitsiou et al., 2015)	(Huang et al., 2015)	(Xiang et al., 2013)
REVIEW FOCUS									
1. Did the review address a clearly focussed issue?	2	2	2	2	2	2	1	2	2
2. Did the review assess a clearly focussed technology?	2	2	1	2	1	1	1	1	1
3. Did the authors look for the appropriate sort of papers?	2	2	2	2	1	2	2	2	1
VALIDITY OF REVIEW RESULTS									
4. Do you think the important, relevant studies were included?	1	2	1	2	2	1	1	1	2
5. Did the review's authors do enough to assess the quality of the included studies?	2	2	2	2	1	2	1	2	1
6. Were the studies accurately described?	2	2	2	2	2	2	2	1	2
7. Are the results of individual studies reported in a clear and meaningful way or just listed with no real flow?	2	2	1	1	2	2	2	2	2
8. If the results of included have been combined, was it reasonable to do so? (overall result presented from more than one study or	0	1	1	1	0	2	1	2	2

Systematic review articles and their appraisal scores: 2 = Yes; 1 = somewhat; 0 = No or can't tell)

QUESTIONS	(Purcell et al., 2014);	(Pando r et al., 2013);	(Laver et al., 2013)	(Kotb et al., 2015)	(Bergmo, 2014)	(Merriel et al., 2014)	(Kitsiou et al., 2015)	(Huang et al., 2015)	(Xiang et al., 2013)
meta-analysis)									
9. Did the review demonstrate awareness of its own limitations?	2	2	1	0	2	2	1	1	0
RESULTS									
10. Does the review present an overall result?	0	2	1	2	0	2	1	2	2
11. How precise are the results?	0	1	2	2	1	2	2	2	2
APPLICABILITY									
12. Implications for policy makers and or those considering implementing such technologies? Appropriate based on findings?	2	2	0	1	1	1	1	2	2
13. Are the results generalisable beyond the confines of the setting in which the work was originally conducted?	1	1	0	1	1	1	0	1	1
14. Were all important outcomes considered?	1	1	1	1	1	1	1	1	1
15. Are you able to assess the benefit versus harm and costs?	2	2	1	1	1	1	1	1	1
CASP Total Score (%)	21/30 (70.0)	26/30 (93.3)	17/30 (56.7)	22/30 (73.3)	18/30 (60.0)	24/30 (80.0)	19/30 (63.3)	23/30 (76.7)	22/30 (73.3)

Note: A study with a total score of <60.0% was considered of low quality; 60.0 – 74.0% was moderate; and 75.0% or more was high quality.

4.3.1.1 *Telehealth and LTCs*

The findings from systematic review articles on effectiveness and cost-effectiveness of telehealth varied. A systematic review of systematic reviews published in 2011 included 162 articles published between 1997 and 2010 (Sheikh et al., 2011). The main conclusion was that there was limited evidence of effectiveness of e-Health for improving patients' outcomes. For specific disease areas, the authors found that telehealth was effective in reducing hospital admissions in cases with severe asthma, severe COPD, and diabetes. For severe cases of asthma, the odds ratio (OR) for hospital admission over 12-months period was reported to be 0.21 (95% CI: 0.07, 0.61); significantly lower hospital admissions among users of telehealth compared to the control group. The evidence around improving quality of life was found to be weak for patients with asthma [mean difference in Juniper's Asthma quality of life of 0.08 (95% CI: 0.01, 0.16); minimum clinical importance difference was 0.5]. Similarly, the case for cost-effectiveness of telehealth was uncertain (Sheikh et al., 2011). The authors also reported that many patients were satisfied with telehealth, and patients accepted telehealth more readily if it was offered in addition to face-face consultations rather than instead of it. Another review found that the levels of patients' satisfaction with telehealth were consistently well over 80% and frequently at 100% when the relationships between patients with staff were explored. Satisfaction was also high among patients on how they felt about consultation with staff, including the technical aspects of telehealth (Williams et al., 2001).

Ekeland and colleagues (2010) also undertook a systematic review of reviews, which involved 80 review articles published between 2005 and 2009. They appeared to have posed a focused question to conduct a review of reviews on the impacts and cost of telehealth services. The definition that they used for what constituted telehealth was broad, and it included all information and communication technologies (ICT) used in health care and internet-based interventions for health and social care. As a consequence, the reviews were heterogeneous in nature, and they were unsuitable for combination in a forest plot. The qualities of many studies included were low, and limited information on CASP total scores was presented. Of the 61 articles assessed by the authors, they found 20 (32.7%) review articles which concluded that telehealth was effective, 19 (31.1%) studies found the evidence of telehealth to be promising but inconclusive, and 22 (36.1%) which concluded that there was limited and inconsistent evidence of the effectiveness of telehealth (Ekeland et al., 2010). The disease areas covered in the systematic reviews included chronic heart failure, respiratory conditions (i.e., COPD and asthma) and diabetes. From this systematic review (Ekeland et al., 2010), it can be deduced that there was mixed effectiveness of telehealth for managing patients with LTCs, with some limited evidence of effectiveness of telehealth service. The authors recommended that future studies should focus on the themes of economic analyses, patients' perspectives, larger studies such as controlled interventions, and to consider telehealth interventions to be complex interventions.

A Cochrane systematic review on asthma found that telehealth resulted in non-significant increase in the odds of emergency department visits over a 12-months' period, with odds ratio (OR) of 1.16 (95% CI: 0.52, 2.58) (McLean et

al., 2010). The authors found a significant reduction in hospital admission over a 12-months' period: OR 0.21 (95% CI: 0.07, 0.61). This review asked a focused question: "*to assess the effectiveness of telehealth interventions in people with asthma*". The study was well conducted, with clear inclusion and exclusion criteria. It contained tests for heterogeneity, based on meta-analysis results, and it showed that the key studies upon which the main conclusions were drawn were homogeneous. The application of findings to other settings remained questionable due to a number of factors, including the precise nature of the interventions used, the local contexts, and the challenges posed by complex interventions.

4.3.1.2 *Telehealth and cardiovascular disease / heart failure*

A meta-analysis of telehealth interventions for patients with heart failure found risk ratio (RR) compared to usual care for all-cause mortality to be 0.66 (95% CI: 0.5, 0.81); all-cause hospital admission RR was 0.91 (95% CI: 0.84, 0.99); and the RR for hospital admission related to chronic heart failure was 0.79 (95% CI: 0.76, 0.94) (Anker et al., 2011). The authors reviewed 11 RCTs, involving 2710 participants in the review. The findings in the meta-analysis were similar to that carried out by Inglis and colleagues (2010) on patients with heart failure who reviewed 25 RCTs involving 8,323 participants (Inglis et al., 2010).

Another systematic review consisting of 13 reviews assessed the effectiveness of telemonitoring for managing patients with cardiovascular disease (Purcell et al., 2014). The systematic review was of a high quality (total appraisal score of 75%), and the authors' assessment showed that 9 out of the 13 articles reviewed were considered to be Level 1 in the hierarchy of evidence

(systematic review of RCTs). The main outcomes measures of the systematic review were: (1) blood pressure and medication used as a marker of hypertension management; and (2) mortality, hospital admissions, quality of life, cost, and acceptability of telehealth for heart failure. The authors reported that all the review articles found benefits associated with telemonitoring, although the level of benefit varied, and none of them reported negative effects of telemonitoring or harm to patients. The authors concluded that telemonitoring had the potential to reduce the burden related to hypertension and heart failure in primary care. The main limitations of the review were that the outcomes measured varied among studies; the definitions of telemonitoring also differed from one study to the other, and as the review focused only on systematic reviews, some large trials were reported to have been excluded. The excluded trials might have negative results, posing potential source of bias. The review recommended that future research needed to investigate how and why telemonitoring interventions work to improve health outcomes (Purcell et al., 2014).

The effectiveness of telehealth in primary prevention of cardiovascular disease (CVD) in the community was assessed in a separate systematic review by Merriel et al. (2014). The review involved 13 trials with a combined total of 10,057 participants. They found no clear evidence of overall risk reduction (based on Framingham 10-year CVD risk) among patients on telehealth intervention (standard mean difference of -0.37%, 95% CI: -2.08%, 1.33%). Similarly, there were no statistically significant differences in reduction of individual risk factors for systolic blood pressure, total cholesterol, high density lipoprotein, and smoking between the telehealth and the control groups. The

telehealth interventions used varied, and most of the studies were conducted in setting in developed countries, hence their generalisation to low- and developing countries were limited.

Meanwhile, a Health Technology Assessment report published in 2013 examined clinical effectiveness and cost-effectiveness of home telemonitoring for heart failure patients who were recently discharged from hospital (Pandor et al., 2013). They found a statistically non-significant benefit of remote monitoring during office hours in reducing all-cause mortality by 24% (hazard ratio [HR] of 0.76, 95% credible interval (CrI): 0.49, 1.18); and by 51% when monitored 24 hours per day, seven days a week (24/7), HR 0.49, 95% CrI: 0.20, 1.18). Similarly, there were non-statistically significant reductions in all-cause hospital admissions observed in telemonitoring group with medical support during office hours by 25% (HR 0.75, 95% CrI: 0.49, 1.10) and by 19% (HR 0.81, 95% CrI: 0.33, 2.00) when monitored 24/7. No change was observed for patients who received usual care (structured telephone support): HR 1.06, 95% CrI: 0.44, 2.53). Findings on cost-effectiveness are separately presented in the relevant Sub-section 4.3.1.5.

Xiang et al. (2013) undertook a meta-analysis to examine the effectiveness of telehealth for patients with chronic heart failure (CHF). They identified 33 trials with a combined total of 7530 participants. The main findings of the meta-analysis were that there was a reduction in all-cause mortality (relative risk [RR] of 0.76, 95% CI: 0.66, 0.88); hospital admissions related to CHF (RR 0.76, 95% CI: 0.61, 0.85) and length of hospital stay (-1.41, 95% CI: -2.43, -0.39). The meta-analysis was judged to be of a moderate quality (73.3%). The telehealth

technologies used in this review appeared to be broadly similar. It was difficult to generalise the findings of the review beyond limited developed countries such as US, UK, and a few European countries where the original individual studies were conducted.

Comparative effectiveness of different forms of telehealth interventions was undertaken involving 30 trials with a total of 10,193 participants (Kotb et al., 2015). Kotb and colleagues found that telemonitoring reduced the odds of all-cause mortality (Odds Ratio [OR] 0.80, 95% CI: 0.66, 0.96); and hospital admissions due to heart failure (OR 0.64, 95% CI: 0.39, 0.95) when it was compared to usual care. The authors also found that using electrocardiographic data also significantly reduced hospital admissions due to heart failure (OR 0.7, 95% CI: 0.52, 0.98). The study was considered to be of a moderate quality (73.3%).

Kitsiou et al. (2015) undertook a systematic review with a meta-level synthesis to determine the effectiveness of home telemonitoring for patients with heart failure. They found reduction in all-cause mortality among intervention groups (RR ranged from 0.64 to 0.86) compared to usual care. The effects were statistically significant among heart failure patients who were stable and had been recently discharged from hospital within 28 days for all-cause mortality (RR 0.66, 95% CI: 0.54, 0.81); and all-cause hospital admissions (RR 0.67, 95% CI: 0.42, 0.97). However, the qualities of the individual studies included in the review were low. Kitsiou (2015) argued that future research agenda on telehealth should move away from whether or not it was effective, to addressing what features of telehealth were considered to be effective, for which patients,

under what circumstances, how long and why. They supported further research into how and why telehealth worked or not in particular context, and the interaction of human behaviour and outcomes of telehealth.

4.3.1.3 Diabetes

The effects of telehealth for the glycaemic control among patients with type 2 diabetes was investigated in a systematic review involving 18 trials and 3798 participants (Huang et al., 2015). Four of the articles were assessed as being of high quality, nine were moderate, and five were low. The authors found that there was a mean reduction of HBA1c, a measure of glycaemic control, by -0.54 (95% CI: -0.75, -0.34; $p < 0.005$). However, the findings may not be generalisable to non-Asian settings, as the trials included were mainly from Asia, and there was limited description of telehealth interventions that were used.

4.3.1.4 Stroke

A Cochrane systematic review assessed the effectiveness of tele-rehabilitation service for managing patients with stroke in order to improve their ability to perform activities of daily living (Laver et al., 2013). The review included 10 trials, which had a total of 993 participants. The authors found no improvement in activities of daily living among the intervention groups using tele-rehabilitation compared to usual care (standard mean difference of 0.00, 95% CI: -0.15, 0.15). The review is of a moderate quality and includes studies that were considered by the authors to be of poor quality and heterogeneous. The

intervention used in the trials varied, making generalisation of the findings difficult.

4.3.1.5 QALYs and cost-effectiveness

One systematic review study involving patients with diabetes concluded that telehealth had the potential to be cost-effective for delivering diabetic retinopathy screening (Jones and Edwards, 2010). However, the review was not able to present cost comparison figures in a meta-analysis, and the poor methodologies of the studies that were reviewed limited the generalisation of the findings. Meanwhile, Polesena and colleagues (2009) undertook an economic evaluation of telehealth in the management of chronic diseases based on published studies between 1998 and 2008, involving 22 studies (including 6 systematic reviews) and 4871 patients. They concluded that telehealth had the potential to reduce costs (Polisena et al., 2009). Due to the methodological limitations of the studies included, the authors concluded that the evidence available was only suggestive of cost-effectiveness of telehealth. An earlier systematic review (2002) was not able to find evidence to establish cost-effectiveness of telehealth because none of the studies reviewed undertook cost utility analysis (Whitten et al., 2002).

Studies on quality adjusted life-years (QALYs) are limited in the published literature in relation to telehealth. Bergmo (2014) undertook a systematic review to examine QALYs and cost-effectiveness. The review included 17 economic evaluation studies that measured outcomes using a range of quality of life tools: EuroQol-5D (EQ5D), SF-6D, Quality of Wellbeing (QWB), and Health Utility Index (HUI). The review found small but positive gain in mean QALYs

associated with the use of telehealth (range: 0.001 to 0.118). However, the findings on cost-effectiveness was mixed; with six studies reporting statistically significant benefit of cost-effectiveness, three studies did not find QALYs gained to be statistically significant, four studies did not report confidence intervals nor p-values, and three did not report differences in QALYs.

A Health Technology Assessment (HTA) systematic review of cost-effectiveness of telehealth published in 2013, found that telemonitoring during office hours was cost-effective compared with usual care; with an estimated incremental cost-effectiveness ratio (ICER) of £11,873 per quality adjusted life years (QALY) compared to £228,035 per QALY for usual care (structured telephone support human-to-human contact) (Pandor et al., 2013). In the UK, the threshold set by the National Institute for Health and Care Excellence (NICE) for determining an intervention to be cost-effective was £20,000 to £30,000. Below this threshold, an intervention is considered to be cost-effective, while those above this are deemed as not cost-effective. The review was appraised as being of high quality (26/30, 90.3%). However, the interventions used in the study varied. In addition, the cost-effectiveness was based on assumption that the cost assumption was constant over time, this might not be the case as lessons from the WSD pragmatic trial showed that the first three months' experience of hospital admission were different from the rest of the trial period (Steventon et al., 2012).

A summary of assessment of confidence in the conclusions reached by the authors of the systematic reviews can be found in Table 4.3.

Table 4.3: Summary of evidence from systematic reviews on effectiveness and cost-effectiveness of telehealth for patients with LTCs (other than COPD)

Author (year)	Disease area	Authors' main conclusions	% CASP Total Score (Max. = 30)	Overall assessment (SIGN, 2011)*
<i>Cardiovascular disease / heart failure systematic reviews</i>				
(Purcell et al., 2014) – SR of SRs	Cardiovascular disease (CVD)	Telemonitoring had the potential to enhance primary care management of CVD by improving patient outcomes (blood pressure, all-cause and heart failure related hospital admissions, all-cause mortality, and improved quality of life) and reducing health costs.	70.0% (21/30)	+
(Merriel et al., 2014)	Cardiovascular disease	There was some evidence suggesting that telehealth might be effective in reducing specific individual risk factors for CVD. No strong evidence for the effectiveness of multifactorial telehealth programmes for primary prevention.	80.0% (24/30)	+
(Xiang et al., 2013)	Chronic heart failure (CHF)	Telehealth demonstrated clinical effectiveness in reducing all-cause mortality, CHF-related hospital admissions and length of stay.	73.3% (22/30)	++
(Kotb et al., 2015)	Heart failure	Structured telephone support and telemonitoring significantly reduced the odds of deaths and hospital admissions due to heart failure.	73.3% (22/30)	++
(Kitsiou et al., 2015)	Heart failure	Home telemonitoring intervention improved survival rates and reduced risk of heart failure-related hospital admissions.	63.3% (19/30)	-
(Pandor et al., 2013)	Heart failure	There was statistically non-significant reduction in all-cause mortality; and cost-effectiveness analyses suggested that home telemonitoring during office hours was an optimal strategy.	90.3% (26/30)	++
<i>Miscellaneous</i>				
(Huang et al., 2015)	Diabetes	Telehealth showed significant improvement in glycaemic control in type 2 diabetes.	76.7% (23/30)	+

Author (year)	Disease area	Authors' main conclusions	% CASP Total Score (Max. = 30)	Overall assessment (SIGN, 2011)*
(Laver et al., 2013)	Stroke	There was insufficient evidence of effectiveness of tele-rehabilitation for managing patients with stroke	56.7% (17/30)	-
(Bergmo, 2014)	QALYs	There was small but positive gain in QALYs; and mixed evidence of cost-effectiveness.	60.0% (18/30)	-

*Note:

- ++ All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.
- + Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.
- Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.

4.3(1b.ii) Update from WSD pragmatic RCTs

The WSD was the largest RCT undertaken in England at the time of writing this thesis. The objective of the RCT was to assess the effectiveness of telehealth services. Four of the published papers from the WSD pragmatic trials are reviewed here. The papers addressed the effectiveness of telehealth in relation to hospital admissions and mortality (Steventon et al., 2012), impact on quality of life (Cartwright et al., 2013), cost-effectiveness (Henderson et al., 2013), and effects on patients with type 2 diabetes (Steventon et al., 2014). All the trials were individually appraised using CASP tool designed for trials.

The WSD study, Steventon et al. 2012, had 3,230 participants with LTCs that consisted of 1,525 COPD patients (47.2%), the rest being patients with diabetes or heart failure. The telehealth interventions used in this study included pulse

oximeter, glucometer, weighing scales, and symptom questions. The study design used cluster randomisation, with GP practices as units of randomisation. The authors admitted there was the possibility of selection bias due to awareness by recruiters of allocation groups. Although the authors aimed for comparable baseline characteristics of their participants, in practice, the intervention groups were younger, and had fewer patients with COPD and heart failure. Emergency admissions at baseline, prior to start of telehealth, were fewer in the intervention group than they were in the control group and this persisted into the first quarter of the trial.

If the first quarter findings of the study were to be excluded in the analyses, the authors noted that none of the main outcome findings of the study would have been statistically significant. The patients and staff were not blind to the trial intervention. The study found a statistically significant reduction in hospital admission in favour of the intervention group with an odds ratio (OR) of 0.82 (95% CI: 0.70–0.97, $p=0.017$), which was just at the statistically significant margin; and mortality was 4.6% in intervention group versus 8.3% in the control group (OR=0.54, 95% CI: 0.39–0.75), significantly lower in the intervention group. There was no statistically significant cost difference between the groups, although some marginal benefit was attributed to the intervention group.

Findings from a cost-effectiveness study showed that the incremental cost per quality adjusted life years (QALY) was £92,000, which was well above the recommended NICE upper threshold of £30,000 per QALY (Henderson et al., 2013). It was unclear how data was handled in the analysis stage for some patients, as the authors noted that 17 patients were randomised into usual care

but ended up receiving telehealth; while 6 patients who were randomised into telehealth did not receive telehealth service (Henderson et al., 2013).

Similarly, the WSD trial that examined the effects of telehealth on quality of life and psychological outcomes found no significant difference between the two arms of the trial (Cartwright et al., 2013). The interventions used and how they were implemented varied in the three trial sites in England, depending on the patients' clinical condition and clinician assessment. The authors used generic quality of life measures, but could have considered using some specific disease quality of life measures such as those for heart failure (Minnesota Living with Heart Failure) and COPD (St George's Respiratory Questionnaire).

One of the most recent papers from the WSD pragmatic trial, published in 2014, reported the effects of telehealth on glycaemic control for patients with type 2 diabetes (Steventon et al., 2014). It found that the level of glycaemic control was 0.21% lower in patients who were in the telehealth group than those in usual care (95% CI: 0.04%, 0.38%; $p = 0.013$). The authors acknowledged that improvement was modest but conceded that it was unlikely to produce significant patients benefit. There were 513 patients in the trial with type 2 diabetes and 300 of them were selected for the intervention. There was potential for selection bias and not all patients' characteristics were similar between the two arms of the trial in respect of sex, age, and prior medication prescription experience.

A summary of the scores of the trials from the WSD project are shown in Table 4.4.

Table 4.4: Summary of appraisal score of trials on telehealth against CASP tool for appraising RCTs:

The effects on health outcomes for patients with LTCs.

Questions	Score: 2 = Yes; 1 = Somewhat; 0 = No or can't tell.			
	Trial 1: (Steventon and Bardsley, 2012)	Trial 2: (Cartwright et al., 2013)	Trial 3: (Henderson et al., 2013)	Trial 3: (Steventon et al., 2014)
(A) Are the results of the review valid?				
1. Did the trial address a clearly focused issue?	2	2	2	2
2. Was the assignment of patients to treatments randomised?	1	2	1	2
3. Were all of the patients who entered the trial properly accounted for at its conclusion?	2	2	1	2
Is it worth continuing?	Yes	Yes	Yes	Yes
Detailed questions				
4. Were patients, health workers and study personnel 'blind' to treatment?	1	0	1	1
5. Were the groups similar at the start of the trial?	2	2	2	1
6. Aside from the experimental intervention, were the groups treated equally?	1	2	1	2
(B) What are the results?				
7. How large was the treatment effect?	1	2	2	1
8. How precise was the estimate of the treatment effect?	2	2	1	2
(C) Will the results help locally?				
9. Can the results be applied in your context? (Or to the local population?)	1	1	1	1
10. Were all clinically important outcomes considered?	1	1	2	1
11. Are the benefits worth the harms and costs?	1	0	2	1
TOTAL SCORE: Maximum: 2 x 11= 22 (%)	15 (68.2%)	16 (72.7%)	15 (68.2%)	16/22 (72.7%)

Note: All the four trial articles were from WSD project.

Synthesis of trials on telehealth and its effects on patients with LTCs is summarised in Table 4.5.

Table 4.5: Synthesis of trials involving telehealth for patients with LTCs

Trial reference, country, and sample size	Main conclusions, Intervention and duration	Total CASP score	Overall assessment (SIGN, 2011)*
(Steventon et al., 2012) – WSD, UK, n=3230	Conclusions: Telehealth was associated with lower mortality and emergency admission rates (for patients with COPD, heart failure, and diabetes). Intervention: pulse oximeters, glucometer, weighing scales. Duration: 12 months.	15/22 (68.2%)	+
(Henderson et al., 2013), UK, n=1573	Conclusions: Telehealth did not seem to be cost-effective addition to standard support and treatment for patients with COPD, heart failure, and diabetes (cost per QALY was £92,000). The probability for achieving cost-effectiveness was 61% (at £30,000 per QALY – NICE threshold for cost-effectiveness) if the cost of the equipment were to reduce and there was increased working capacity. Intervention: pulse oximeters, glucometer, weighing scales. Duration: 12 months.	15/22 (68.2%)	+
(Cartwright et al., 2013), UK, n=1573	Conclusions: Home based telehealth did not improve quality of life or psychological outcomes for patients with COPD, diabetes, or heart failure over 12 months. The findings suggested that concerns about potentially deleterious effect of telehealth were unfounded for most patients. Intervention: pulse oximeters, glucometer, weighing scales. Duration: 12 months.	16/22 (72.7%)	+
(Steventon et al., 2014)	Conclusion: Telehealth led to modest improvement in glycaemic control among people with type 2 diabetes, as measured by HbA1c, over 12 months. Intervention: glucometer	16/22 (72.7%)	+

*Note: + = some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.

In conclusion, the evidence from the WSD pragmatic trials showed that telehealth services appeared to be effective in reducing hospital admissions. However, the trial found that overall telehealth was not cost-effective, and it did not improve quality of life of patients with LTCs. The study suggested that the concerns about the deleterious effects of telehealth were unfounded. The trials also suggested that telehealth was associated with a modest reduction in mortality rates among patients with LTCs. Telehealth had limited effects in improving glycaemic control among patients with diabetes.

4.3(1c.i) Headline findings related to LTCs

Table 4.5 provides a summary of the evidence on effectiveness and cost-effectiveness of telehealth (headline findings described in Figure 4.1, Box 1c.i.).

Table 4.5: Summary of evidence of effectiveness of telehealth

Outcome measures	Long-term conditions		
	SRs	RCTs: WSD	Overall assessment
(1) Hospital admissions	Reduced only for some LTC (COPD, diabetes, and heart disease)	Reduced	Limited evidence
(2) Quality of life	Limited effect	No effect	No effect
(3) Mortality	Reduced mortality for COPD, and diabetes, and heart failure	Reduced	Limited evidence
(4) Cost-effectiveness	Mixed	Not cost-effective	Not cost-effective
(5) Patients' satisfaction	Satisfied	Satisfied	Satisfied
(6) Clinical markers: e.g. HBA1c, BP, and cholesterol	Improved	Improved	Improved
(7) Use of health and social care services	n/a	No effect	No effect

The syntheses of the evidence from systematic reviews and update from WSD pragmatic trial, suggest that there was some evidence of effectiveness of telehealth in reducing hospital admissions and mortality among patients with some LTCs, such as, heart failure, diabetes, asthma, and COPD. Telehealth had limited impact on quality life but patients appeared to be generally satisfied with it. The evidence on cost-effectiveness of telehealth was mixed. However, there were technical issues related to different interventions, outcome measures, and variation in quality of the studies appraised in the systematic reviews. These pose some limitations in generalising the findings of the articles.

4.3(1b.iii and 1c.ii) Systematic reviews focusing on evidence of effectiveness and cost-effectiveness of telehealth service for patients with COPD

There were a total of six systematic review articles on COPD; four from the original literature search, and two from updated search. Five of the systematic reviews were quantitative and dealt with the effectiveness of telehealth services. They are reviewed in this section.

One systematic review article was a qualitative study, and it was about implementation of telehealth. The qualitative paper is appraised under the Section 4.3(2) related to the implementation of new technology.

4.3(1c.iii) Summary of evidence from systematic review and COPD

A summary score of the appraisal of the quantitative systematic reviews are shown in Table 4.6 below.

Table 4.6: Summary of systematic reviews on effectiveness of telehealth for patients with COPD

Author (year)	Authors' main conclusions	CASP Total Score (Max. = 30)	Overall assessment (SIGN, 2011)*
(McLean et al., 2011)	Telehealthcare in COPD appeared to have an impact on the quality of life of patients and the number of times patients attended emergency departments. Telehealth made no difference to mortality rates.	22/30 (73%)	+
(Polisena et al., 2009)	Telehealth had the potential to reduce costs, but its impact from a societal perspective was uncertain.	17/30 (57%)	+
(Polisena et al., 2010)	Home telehealth was found to reduce rates of hospitalisation and emergency department visits; mortality rates were greater in the telehealth group.	18/30 (60%)	+
(Cruz et al., 2014)	There was limited evidence of the effectiveness of home telemonitoring to reduce healthcare utilisation and improve health-related outcomes in patients with COPD (Cruz et al., 2014).	12/30 (40%)	-
(Udsen et al., 2014)	Lower average cost per patients was found in the telemonitoring group compared to usual care, but the quality of studies was poor.	21/30 (70%)	+

*Note:

- + Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.
- Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.

(1) Effectiveness of telehealth for patients with COPD

McLean et al. (2011) undertook a Cochrane systematic review of telehealth services for patients with COPD. The authors found clinically significant increases in quality of life, as measured by St Georges Respiratory

Questionnaire (SGRQ), [mean difference of -6.57 (95% CI: -3.62, 0.48); minimum clinically significant difference was defined as a change of -4.0] (McLean et al., 2011). It can be noted that the 95% CI of mean difference in quality of life suggested that telehealth made no difference in quality of life. The review also showed that there was significant reduction in hospital emergency department attendance over 12 months period (odds ratio (OR) of 0.27 (95% CI: 0.11, 0.66)); and an odds ratio for more than one hospital admission within 12 months was 0.46 (95% CI: 0.33, 0.65). Mortality was not found to be statistically different between the intervention and controlled groups: OR=1.05 (95% CI: 0.63, 1.75). The review found that patients were generally satisfied with telehealth services.

The number of studies included was 21, representing 1,004 patients. The main limitation of the review is that the definition of telehealth used varied and it encompassed various interventions e.g. telephone, videoconferencing, and 'store and forward' technologies (spirometry). This poses a challenge in comparing the effects of the studies to the interventions used. An assessment against the CASP systematic review criteria shows that the review overall score was 22/30 (73%) – moderate quality, as shown in Table 4.7. An example of the appraisal of the review against the appropriate CASP tool is shown in Annex 1.2 (McLean et al., 2011). Similar appraisals were undertaken for all the systematic reviews.

Table 4.7: Summary score of systematic reviews on COPD studies

QUALITY ASSESSMENT QUESTIONS	Systematic reviews reference number (see below) and their appraisal scores (keys): 2 = Yes, 1 = Somewhat; 0 = No or can't tell				
	1	2	3	4	5
REVIEW FOCUS					
1. Did the review address a clearly focussed issue?	2	1	2	2	2
2. Did the review assess a clearly focussed technology?	1	1	2	1	1
3. Did the authors look for the appropriate sort of papers?	2	2	2	1	1
VALIDITY OF REVIEW RESULTS					
4. Do you think the important, relevant studies were included?	2	2	2	1	1
5. Did the review's authors do enough to assess the quality of the included studies?	2	2	2	2	1
6. Were the studies accurately described?	1	1	1	2	2
7. Are the results of individual studies reported in a clear and meaningful way or just listed with no real flow?	1	1	1	1	1
8. If the results of included studies have been combined, was it reasonable to do so? (overall result presented from more than one study or meta-analysis)	1	0	0	2	0
9. Did the review demonstrate awareness of its own limitations?	2	2	1	1	1
RESULTS					
10. Does the review present an overall result?	2	2	1	2	0
11. How precise are the results?	2	0	1	2	0
APPLICABILITY					
12. Implications for policy makers and or those considering implementing such technologies? Appropriate based on findings?	2	1	1	1	0
13. Are the results generalizable beyond the confines of the setting in which the work was originally conducted?	0	0	0	1	0
14. Were all important outcomes considered?	1	1	1	1	1
15. Are you able to assess the benefit versus harm and costs?	1	1	1	1	1
CASP TOTAL SCORE: numerator/denominator (%)	22/30 (73%)	17/30 (57%)	18/30 (60%)	21/30 (70%)	12/30 (40%)

Note: References number: 1 = (McLean et al., 2011); 2 = (Polisena et al., 2009); 3 = (Polisena et al., 2010); 4 = (Udsen et al., 2014); and 5 = (Cruz et al., 2014)

Polisena et al. (2010) reviewed evidence on the effectiveness of telehealth for patients with COPD. They included nine studies with a combined population of 858 patients. The review addressed a focused issue related to effectiveness of telehealth for patients with COPD, and it also focused on 'second generation' telehealth (similar to the type used in this thesis). Seven of the nine studies were RCTs, while the other two studies were observational studies (one prospective study and the other a pre-post study).

The authors did not undertake a meta-analysis, given that they found variation in the characteristics of the control groups, study designs, and differing clinical outcomes. The findings on hospital admissions, based on two RCTs, showed that there were low proportions of hospitalisation in a group that received telephone support compared with usual care: 46% versus 66%, $p=0.003$ in one study; and 32% versus 51%, $p=0.01$ in another study. On the other hand, the findings on bed-days of care were mixed, with some studies reporting low reduction following the intervention, while others reporting higher rates of bed days of care. Hospital emergency department visits were reported to be lower among the telehealth group than the group receiving usual care. Two studies did not find any difference in quality of life, while another two studies concluded that telehealth improved patients' quality of life.

Cruz *et al.* (2014) undertook a systematic review of effectiveness of home telemonitoring in reducing hospital admission and improving quality of life for patients with COPD. They analysed nine studies (7 RCTs and 2 non-RCTs) with varying duration of follow up ranging from two to 12 months. The quality of the

systematic review article was assessed as medium (70%) using critical appraisal score tool for systematic reviews. A meta-analysis found that the risk ratio of hospitalisation was statistically significantly lower, at 0.72 (95%CI: 0.53, 0.98); p-value = 0.03; and the mean change in quality of life, as measured by St. George's Respiratory Questionnaire, also showed statistically significant improvement: -0.53 (95% CI: -0.97, -0.09); p=0.02 (Cruz et al., 2014). The main limitations of the review were limited number of articles included in the review, and for those articles that were included; the studies were of small sample sizes ranging from 30 to 165 participants. The duration of the studies were also short: three articles followed patients for less than six months; five articles followed patients for 6-9 months; and one article managed to follow patients for 12 months. On the basis of the findings of the review, there was limited evidence to support the use of home monitoring in routine practice.

(2) Economic evaluation of telehealth and COPD

A systematic review by Polisena et al (2009) assessed the cost-effectiveness of telehealth for patients with chronic disease, including COPD. The review identified 22 original studies (14 RCTs, four case-control studies, and four pre-post studies), with a combined total number of 4871 participants. Only three of the studies focused on COPD patients. The technology assessed varied, and included telephone-based care, remote patient monitoring (vital signs monitoring), and video-based telecare. There were limited description of the technologies used, and no information on compliance. The findings of the review were heterogeneous, and therefore not combined, due to different

patients' population groups, study designs, interventions, and comparison groups.

The authors concluded that most studies found that telehealth saved costs, from the perspective of healthcare system and insurers, but they acknowledged the low quality of original studies. The findings could not be generalised due to the heterogeneity of the studies reviewed, different settings in which the studies were conducted, and different patient groups and interventions. There was limited information on benefits, harms and costs of telehealth reported by individual study authors. It was likely that some of the costs were not fully accounted for in the reviews, especially those from carers' and patients' perspectives, which were also important. CASP scores are shown in Tables 4.6 and 4.7; it was scored as being of low quality (17/30 or 57%).

Polisena *et al.* (2009) recommended that future cost-effectiveness studies into telehealth should consider including (1) events rates; and (2) deaths from long-term conditions. While for short-term programmes, they proposed including surrogate markers of clinical outcomes such as glycaemic control (HbA1c) for diabetes; forced expiratory volume in one second (FEV1) for COPD; and systolic blood pressure for heart failure patients; or quality of life of patients.

Meanwhile, Udsen *et al.* (2014) conducted a systematic review of cost and cost-effectiveness of telehealth for patients with COPD. They reviewed six articles, consisting of a combine total of 559 patients. The articles included in the review were assessed by the authors to be of poor quality: five of the six articles were assessed as poor and one was considered to be of moderate quality. All the six articles included in the review reported lower average cost per patient among

those on telehealth compared to the usual care. Given the poor quality of the systematic review (overall appraisal score of 40%) the findings were not generalisable to inform routine healthcare practice.

4.3(2) Implementation of new technology

This section assesses the evidence drawn from systematic reviews related to factors influencing successful implementation and embedding of new technologies in routine practice.

A systematic review undertaken by Bartoli et al. (2009) investigated the types of telemedicine applications and the related organisational models used and their impacts in embedding telehealth service in routine practice. The review included 40 studies (16 quantitative and 24 qualitative studies). The review had a clear aim but did not provide details of how data were analysed, nor gave explicit descriptions of the methods used in the studies included in the review. Despite the above limitations of the review, the key findings summarised below were valuable in this thesis, in understanding issues related to implementation of new technologies and why they succeed or fail to embed in routine clinical practice.

The review identified three layers of organisational relationships which could impact on the implementation of telehealth, and these involved (1) hospital specialist and primary care physicians; (2) clinical teams and patients; and (3) nurses and hospital specialists. The key organisational factors influencing implementation were (Bartoli et al., 2009):

- Tension in agreeing a common goal (shared vision) between collaborative partners, between primary and secondary care and the need for shared vision and inter-agency working;
- The need to re-design work programme to adapt to patients' needs in the new technology service;
- The difficulties of 'mainstreaming' a new service;
- The effect of new technology on relationships between nurses and doctors;
- The attitudes of clinical staff to the new technology, including their concerns about the safety of the equipment, and general confidence in it;
- Technology being perceived as a threat. It was sometimes thought to undermine the credibility of nurses, and might take over nursing tasks, and threatened jobs.

The authors' main conclusion was that technology might be regarded simultaneously as an opportunity and a threat. There was a need to reconsider organisational structures in order to realise the benefits of new technologies.

Bartoli et al. (2009) suggested that areas for future research in the implementation of telehealth should focus on (1) redistributions of staff roles, (2) change of work processes, and staff productivity; and (3) performance introduced by different telehealth services.

A systematic review of reviews by Sheikh and colleagues identified at least 16 systematic reviews related to implementation and adoption of new technology in healthcare. They acknowledged the limited theoretical frameworks in the field of implementation of new technology; however, they highlighted the importance of

technical, human, and organisational factors. Based on the body of literature from systematic reviews, they concluded that the key factors for success or failure of implementation of new technological service depended on: (1) user involvement; (2) showing early benefit of the technology; (3) close fit with organisation priorities and process; (4) training and support; and (5) effective leadership, and change management (Sheikh et al., 2011). They recommended that there was a need for further research where the above factors could be addressed in contexts of organisations. A number of future research questions and further practical issues for implementation of new technology were identified by the authors. These included potential dependency on cold technology versus warm human interaction; ease of operation of the technology by patients and staff; and the issues of data generated, including security and privacy. They also raised practical issues related to the need for major changes to roles and responsibilities and work flows in healthcare organisations if new technologies were to be successfully implemented. The fear by health professional, such as doctors, of being sued for medical negligent was also highlighted as potential barriers, as the British Medical Association placed obligations for doctors to undertake physical examinations of their patients (Sheikh et al., 2011).

The Norwegian Centre of Telemedicine carried out a systematic review to determine characteristics of successfully implemented telemedicine programmes, and it identified six main categories of factors of interests (Obstfelder et al., 2007). These were: (1) defining health needs and challenges; (2) recognising the benefit of telemedicine; (3) seeing it as a solution to political and/or medical issues (e.g. equal access to healthcare); (4) collaboration

between promoters and users; (5) addressing the issues regarding organisational and technical arrangements; and (6) considering the future operation of the service, including future financing of telehealth (Obstfelder et al., 2007).

Gorst *et al.* (2014) undertook a systematic review of the barriers and facilitators of telehealth service which determined why patients with heart failure and COPD refused or withdrew from telehealth service. They found three main themes that explained barriers to implementation of telehealth service: (1) technology related (technical problems such as equipment failure, technology anxiety, and technical support that patients needed); (2) telehealth process (believing telehealth to be unnecessary, difficulty remembering – the need to remind patients, and repetitive process that users found boring or monotonous); and (3) healthcare services (patients preferred in-person care). On the other hand, the main themes that summarised facilitation of implementation of telehealth were: (1) health management (improved self-care, improved health knowledge, effective health management when patients perceived telehealth to save lives); (2) health services (improved access to care, feeling happy and confident with health professional advice, telehealth perceived to be better than in-person care); (3) patient variables (convenient, and peace of mind); and (4) technology-related where the patients found the technology to be easy to use.

4.3(3) Failed randomised controlled trials

Research has shown that a third of trials managed to recruit less than 75% of planned subjects; and that reluctance of clinicians was a greater obstacle to successful completion of trial than reluctance of patients (Rendell et al., 2007).

Rendell *et al.* (2007) investigated factors that were considered as incentives or disincentives to clinicians to participate in recruiting patients into trial studies. They found that motivation was more important than simply being acquainted with the researchers. The review identified concerns expressed by clinicians about randomisation process, which was not considered to be selecting the intervention they perceived to be beneficial for their patients. The other factors hindering recruitment into trials were having too stringent criteria. Participation of academic research group was viewed to be a positive factor in helping to increase recruitment to research studies (Rendell *et al.*, 2007). The authors also identified concern about damage to doctor-patient relationship which was considered to be a potential disincentive to participation in research.

Further evidence from the literature to help understand why some trials fail to recruit participants to expected level came from the findings of a report by Health Technology Assessment or HTA (Campbell *et al.*, 2007). The report examined factors associated with good and poor recruitment into multicentre trials. The authors found that of the 114 trials reviewed, less than one third (31%) successfully recruited participants to their original target. Factors identified for successful recruitment into trial are outlined in Table 4.8 (Campbell *et al.*, 2007).

Table 4.8: Factors influencing successful recruitment into trials

<i>Having dedicated trial manager</i>
<i>Being a cancer or drug trial</i>
<i>Having intervention only available inside the trial</i>
<i>Using newsletters and mailshots to communicate about the trial</i>
<i>Trials addressing clinically important questions</i>
<i>Investigators were held in high esteem</i>
<i>Trials were grounded in existing clinical practice</i>
<i>Need of patients were considered to be well served in the trial</i>
<i>Clear delineation of roles, which released the research collaborators from workload related to the trial participation.</i>
<i>Feelings of pride in taking part in the trial.</i>
<i>Good ground work and excellent communication</i>
<i>Training about trial intervention and processes</i>
<i>Team building</i>
<i>Trial flexible and robust enough to adopt to changes</i>
<i>Funders monitoring progress of the trials</i>
<i>Use of business model (framework) to recruit participants into the research: (i) building brand value; (ii) product and market planning; (iii) making the sale; and (iv) maintaining engagement.</i>

Source: (Campbell et al., 2007)

A similar review of trials funded by both Health Technology Assessment and the UK Medical Research Council (MRC) between 2002 and 2008, found that 55% of trials managed to recruit to their original target, and 78% managed to recruit to 80% of their set target (Sully et al., 2013). The authors suggested that trials with power of 80% were less likely to achieve their recruitment target compared with those with 90% of power.

The importance of conducting a formal pilot before undertaking an RCT is highlighted in a systematic review by McDonald et al (2006). The researchers found that in 53% of trials that had undertaken formal pilots, they resulted in changes to trial design, recruitment strategy, written materials to patients and staff, inclusion criteria, and recruitment targets (McDonald et al., 2006). They suggested strategies for improving recruitment into trials, such as sending out newsletters, making regular contacts, producing information leaflets, changing

inclusion criteria or amending the research protocol, and doing presentations to appropriate target audience, among others (McDonald et al., 2006), see Table 4.9.

Table 4.9: The most common strategies for improving recruitment
(McDonald et al., 2006)

<i>Strategies</i>	
1)	<i>Newsletters, mail shots, flyers (to clinical staff and/or patients)</i>
2)	<i>Regular visits / phone calls to wards / sites / practices</i>
3)	<i>Posters / information leaflets in clinics / wards / notes</i>
4)	<i>Amending inclusion criteria and protocol</i>
5)	<i>Presentations to appropriate groups e.g. at consultant meetings / community based physiotherapists etc.</i>
6)	<i>Resource manual for site staff / trained staff in disease area / procedures being investigated / role play exercises / study day / workshops for recruiters</i>
7)	<i>Advertisement / articles in newspapers / journals; radio interviews</i>
8)	<i>Presentations at national / international meetings</i>
9)	<i>Employed extra staff</i>
10)	<i>Investigators' / recruiting staff meetings</i>
11)	<i>Training / information videos</i>
12)	<i>Incentives for recruiters e.g. prize draw, chocolates etc.</i>
13)	<i>Trial material revised / simplified / customised for specific sites</i>
14)	<i>Visits to centres by Principal Investigators / senior members of study group</i>
15)	<i>Repeated contact by phone or letter to individuals / sites</i>
16)	<i>Increased or changed time points when information provided to potential participants</i>
17)	<i>Supportive statements from opinion leaders</i>

Meanwhile, systematic review by Fletcher et al. (2012) identified the following specific actions that clinicians could do to improve recruitment into trials: using qualitative methods embedded in trials; communicating trial methods; educating staff and patients to remove any misunderstanding about trial methods; and finally reinforcing the benefits of trials to both staff and patients (Fletcher et al., 2012).

A Cochrane review of strategies to improve recruitment to RCTs found three strategies to be statistically significant: (1) having telephone reminders to non-responders (odds ratio 1.95; 95%CI: 1.04, 3.66); (2) using opt-out rather than opt-in recruitment approach (relative risk [RR] 1.39; 95% CI: 1.06, 1.84); and (3) open design of trial where participants knew which arm of the trial they would be (RR 1.22; 95% CI: 1.09, 1.36) (Treweek et al., 2011). There were ethical issues related to the use of opt-in approach for recruitment but it was considered by the authors to be more acceptable when used to contact participants in order to obtain their consent rather than use it as a means to consent participants into trials. Similarly, the authors acknowledged potential for bias in adopting open design trials due to lack of blinding. The Cochrane review was appraised as being of high quality (total score of 23/30 or 76.7%). It included 45 eligible trials with a total of 41,239 participants.

Another review aimed at increasing recruitment of palliative care patients found cluster consent, opt-out consent, contact of participants before arrival, and memory aid for patients with dementia to be effective recruitment strategies into trials (Boland et al., 2015). However, this review was considered to be of a poor quality (total score of 13/30 or 43.3%). The review included 15 articles; 13 of which were RCTs.

4.4 Conclusions

The evidence from the systematic reviews shows that there is limited evidence of the effectiveness of telehealth services for patients with LTCs. However, for some specific disease areas such as COPD, heart failure, severe asthma and diabetes, there is evidence of modest effectiveness in reducing hospital

admissions and mortality. Patients seemed to be generally satisfied with telehealth services. Evidence of cost-effectiveness of telehealth was mixed, and the impact on quality of life was limited.

Factors that determine success or failure of implementation of new technology included a combination of human, technical and organisational ones. Some of the organisational factors included having a common vision, redesign of work programmes, mainstreaming the service, enhancing relationship among professionals and their attitudes to new technology. The involvement of users in the implementation of new technology was considered to be important, along with provision of training for staff, and having effective leadership. Some of the main barriers and facilitators to implementation of telehealth were related to the technology and its processes, and the way in which health service was delivered to patients.

Lessons from failed trials suggest that there are a number of factors that can influence successful recruitment into trials. These factors include: having formal pilots of trials, communicating the trial methods, designing study sample size with 90% power to detect effects, improving clinician-patient relationship, educating staff and patients about the methods and benefits of the trial, adopting cluster consent and opt-in consent, having open trial design where participants knew before-hand the treatment they were going to receive, telephone reminders, and embedding qualitative methods into the study. Observing these factors and building them into trial designs and processes could improve recruitment into trials and reduce the likelihood of them failing to recruit to the expected target sample size.

Chapter 5: Effects of Telehealth on Patients with COPD in the Community (TELECCOM Study): A Pragmatic Randomised Controlled Trial

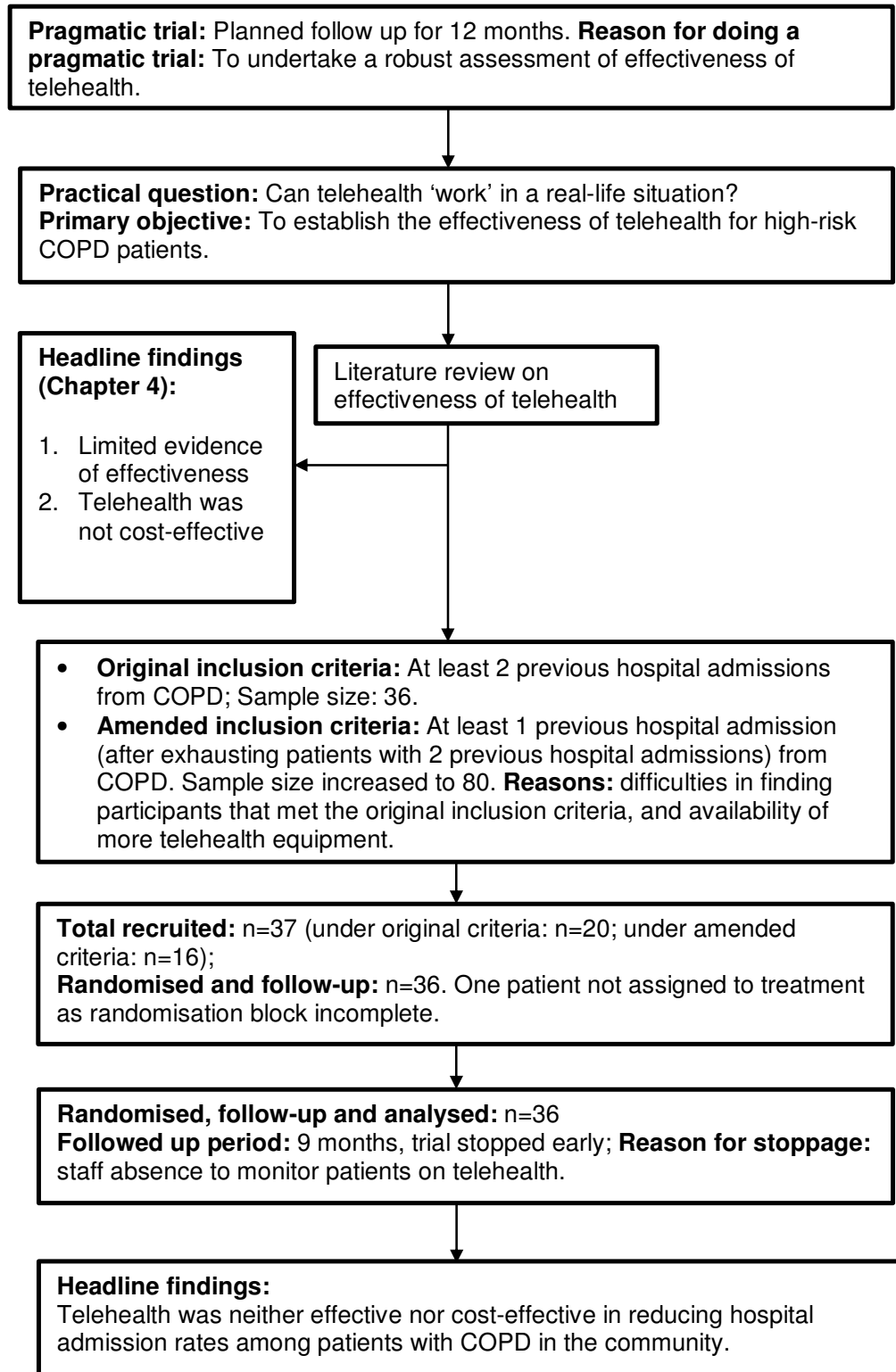
5.1 Chapter introduction

This chapter reports the trial conducted to evaluate the effectiveness of a telehealth service for chronic obstructive pulmonary disease (COPD) patients, living in the Doncaster community and at high risk of emergency hospital admission.

Note that sub-section headings will reflect the numbering in the CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist for reporting randomised controlled trial (RCT) in peer-review publications (CONSORT, 2012). This is to assist the reader and demonstrate that all guidelines for reporting of this trial have been adhered to.

A flow chart summarising key actions undertaken, reasons for the key actions, and headline findings in Chapter 5 is shown in Figure 5.1.

Figure 5.1: Pragmatic trial assessing the effectiveness of telehealth: key actions and decisions (Chapter 5)



5.2 Introduction to the trial

5.2.2a Background

A review of the literature is provided in Chapter 4. The trial reported in this chapter was initiated before the literature review was completed. At the start of the trial however it was clear that there was insufficient good quality evidence to show the efficiency of telehealth for COPD patients in the community.

The setting of the trial is Doncaster, which is described in Chapter 3. Doncaster Primary Care Trust (PCT), the funder, wished to establish the effectiveness of telehealth for patients with COPD and in particular if the addition of a telehealth service could reduce the number of emergency admissions to hospital for those patients at highest risk. The aim was to answer the practical question: “can telehealth ‘work’ in a real-life situation?” The trial was a pragmatic one.

It is noted, just as the trial was pragmatic; the running of the trial was much influenced by the needs of the PCT. For example, the target sample size was increased when more funding became available, and the trial was stopped prematurely when staffing issues arose and the objectives from the PCT changed.

5.2.2b Objectives and hypotheses

At the start of the trial, the primary objective was to establish the effectiveness of telehealth for high-risk COPD patients. A secondary objective was to establish cost-effectiveness of that telehealth service.

The null hypothesis was that the rate of emergency hospital admissions would not be affected by the telehealth service. The alternative hypotheses were that, either the rate would be lower and consequently telehealth shown to be effective, or that the rate would be higher and thus harm associated with telehealth.

5.3 Methods

5.3.3a Trial design

The initial design of the trial was a pragmatic randomised controlled trial with two arms: one active arm where patients received the telehealth service for monitoring COPD; and one control arm where monitoring was as usual. That is, where patients received routine primary care services (e.g., access to their general practitioners (GPs) and community nursing service) and hospital services (accident and emergency department, inpatient admissions, and outpatient departments). A more detail description of the intervention and usual care is provided in Chapter 3 (see Section 3.5.3, and Figure 3.15).

The allocation ratio was 1:1 for selection of patients into the control and intervention arms of the trial, as this was the most efficient method. As the trial was relatively small, block randomisation of four cases, allocating two to each arm randomly, was used to ensure a balance of participants to each arm of the study. The protocol stipulated that patients were free to withdraw from the study at any time.

It is important to note that a cluster randomised trial was considered. A number of authors had highlighted advantages and disadvantages of cluster

randomised trial, which included costs, ethical issues and consents, risk of contaminations and external validity among others (Edwards et al., 1999, Sanson-Fisher et al., 2007, Mazar et al., 2007, Campbell et al., 2007). There are many aspects of the cluster RCT that would have contributed to clearer evidence for or against a telehealth service. For example, the clusters would have been the centres where all patients received telehealth or monitoring as usual. This would have been easier to administer as all staff within a centre would deliver the same care model. Also, staff would have been aware that telehealth was being implemented in other centres and this may have reduced staff resistance to the change of service. Such a trial would have been far larger than the one implemented here as several centres would have been needed. Randomisation would have been at the centre level and to provide convincing evidence around 20 centres would have needed to be involved. This size of trial was far beyond the resources available to Doncaster PCT and would have required collaboration with other PCTs. In addition, before such a cluster RCT could have been proposed there would need to be extensive pilot work completed.

At the trial design stage, an option for a cross-over trial was also considered, in which the intervention (Group 1) and control (Group 2) arms would be monitored for the first six months. With Group 1 receiving telehealth service and Group 2 receiving standard care. After the first six months, the intervention and control arms would be switched over (cross-over). This would mean that during the second six months, Group 1 would receive standard care while Group 2 would receive the intervention (telehealth service).

The advantages of this option are that it would minimise variation between patients, as each patient would have been in both intervention and control arms of the trial; and there was an opportunity for analysing two sets of intervention and control groups. There are however a number of limitations of the cross-over trial. Firstly, the trial would take place during different time periods (seasons) of the year, since the trials would be for six months each. It is known that the exacerbation of patients with COPD is worse in winter months. Therefore, the experiences of the trial groups during winter months would be adversely affected than those during other seasons of the year. Secondly, it is likely that, as telehealth service included elements of educating patients about self-care, some of the effects of intervention might persist beyond the first six months of the trial and into the second cross-over stage as control group. Thirdly, six months was not considered to be long enough to be able to determine the long-term use of telehealth, as it was envisaged that patients would use telehealth services as long as they wished to support themselves with self-care. There was also the ethical dilemma of what to do if patients found the telehealth service helpful and consequently wanted to continue using it. Fourthly, unlike drug trials, the logistics of swapping intervention from one group to another would be potentially very challenging. The installation of the telehealth devices is time-consuming and this design would double the effort required in terms of staff capacity.

5.3.3b Changes to design

There were a number of changes to the trial that occurred after it had been initiated. Details of the changes are provided in the relevant sections below.

The changes were:

1. Change to the sample size and to the size of the effect that was to be detected. When further funding became available, the sample size was increased so that the trial had better power to detect smaller effect sizes.
2. There were changes to the telehealth equipment when a new model was developed by the suppliers.
3. The inclusion criteria were modified (Table 5.1a) following difficulties in identifying eligible patients and recruitment.
4. The proposed analysis was changed following the change in the distribution of the outcome variable, which arose from the relaxation of the inclusion criteria.
5. The trial was stopped following staffing issues and a change of focus from Doncaster PCT, who funded the research.

5.3.4a Participants

Potential participants for the trial were identified from hospital admission records or hospital episode statistics (HES) data that was available at Doncaster Primary Care Trust (PCT).

The trial inclusion criteria focused on identifying patients with COPD who had two previous hospital admissions, were on general practice register, living in Doncaster and registered with a GP in Doncaster and were confirmed still alive

at the time of recruitment. These inclusion criteria were used for selecting patients who were recruited onto the trial from 24th October 2007 to 16th July 2008.

During the trial, it was planned to increase the sample size of the study to 80 from the initial number of 36 participants, as funding for more telehealth machines became available. With the proposed changes in sample size, it also became necessary to consider relaxing the inclusion criteria related to the number of previous hospital admissions from COPD from the initial two previous hospital admissions to at least one previous hospital admission. The proposed change in inclusion criteria received ethical approval on the 5th March 2008. Based on the amended inclusion criteria, 16 participants were recruited (8 in the intervention, and 8 in the control arm of the trial).

5.3.4a.1 *Eligibility criteria*

In total, 37 participants consented to take part in the trial and 36 of them were randomised. One patient was recruited but not allocated to a treatment. The trial was stopped when that one patient was the first of a block of four awaiting randomisation. The inclusion criteria (original and amended versions) are stated in Table 5.1a; and the number recruited under the two criteria can be found in Table 5.1b.

Table 5.1a: Amendments to original inclusion criteria into the trial

Inclusion criteria	Remarks
1. The person has had 2 or more COPD emergency admissions (ICD-10 codes J40, J41, J42, J43, J44 or J47) to hospital in the last 12 months from the day selection takes place.	Original inclusion criteria
2. The person has had a diagnosis of COPD as defined by NICE guidelines and had care optimised by an appropriate health care professional. The person must be on a General Practitioners (GP) COPD Register.	Original inclusion criteria
3. The patient is confirmed as alive and residing in Doncaster.	Original inclusion criteria
4. The patient must have the capacity to use the equipment.	Original inclusion criteria
5. After exhausting cases from primary pool that meet inclusion criteria 1-4; cases will be included that had 1 previous COPD admission in the last 12 months.	Amended inclusion criteria

Table 5.1b: Recruitment into the trial according to original and amended criteria

	Intervention	Control	Total
Original criteria	10	10	20
Amended criteria	8	8	16
Total	18	18	36

Patients were excluded if: (1) they did not have the physical or mental capability to operate telehealth machine or did not have carers that could enable them to operate the telehealth machine, this was determined by a community nurse at

the recruitment stage; (2) they were not on the GP COPD register; (3) they were registered with a Doncaster GP but were not living in Doncaster; and (4) they had no landline telephone. An initial list of patients, obtained from hospital admission records, was checked against the primary care patient registration system (also referred to nationally as the Exeter System) to exclude those who had died between their last hospital admission and the time of screening for eligibility into the trial.

5.3.4b Settings and locations

The Chief Investigator (author) generated a list of eligible patients for the community matron to use in order to obtain consent.

The setting of the study is the borough of Doncaster in the County of South Yorkshire, England (see Chapter 3). The sample was patients living in their own homes, who were registered with a GP in Doncaster, as well as being a resident of Doncaster. The telehealth service was monitored by staff from a central location, based at one community health centre in the Thorne area of Doncaster (England). A room at the health centre was used as a store for the telehealth machines that were not in use.

Patients commenced telehealth as part of the trial on 24th October 2007, and the trial was stopped on the 8th August, 2009.

5.3.5 Intervention

The intervention is a telehealth service, consisting of a telehealth monitoring device (Genesis Monitor), supported by staff who monitor the readings of

patients. A one-year contract for repair or replacement of any of the machines that were not working in the patients' homes was established prior to the trial. The control group had access to standard healthcare (routine access to primary care services; and hospital services such as accident & emergency services) that was also available to the intervention group. A description of the local telehealth service is given in Chapter 3.

Patients in the intervention group had a telehealth machine installed in their homes by a community nurse, after performing a demonstration of how to operate the machine. Patients then measured their vital signs (blood pressure, pulse rate using blood pressured cuff, temperature, and level of oxygen saturation using a pulse oximeter) and nine selected questions that patients answered by pressing a "yes" or "no" button on the telehealth device (Table 5.2). The records of these readings were transmitted through the internet to a central location in a dedicated office based at the same health centre, described above; where nurses could access them, using special user name and password, and monitor them from a computer connected to the internet.

Table 5.2: Selected questions on telehealth device (Genesis Monitor)

1. Are you experiencing more difficulty breathing today compared to a normal day?
2. Have you been using your inhalers more than usual?
3. Have you had to limit your activities more than usual?
4. Have your ankles been swollen more than usual?
5. Have you noticed a decrease in your appetite?
6. Has your mood been more depressed this week compared to a normal week?
7. Have you been to the Accident & Emergency this week?
8. Has your doctor added, deleted, or changed any of your medications this week?
9. Did you have an unexpected visit to your doctor this week?

Measurements of vital signs (blood pressure, blood oxygen saturation or SpO₂, heart rate, and temperature) and responses to selected questions were set to be taken twice a day; one in the morning when patients woke up and the other in the evening before patients went to bed. This was done at the same time every day, as agreed upon by the patients and the nurse. Each measurement usually took less than five minutes, but could take longer depending on individual circumstances and level of experience in using the equipment.

Hospital admission records were obtained from hospital episode statistics (HES) through Doncaster PCT. Actual tariff cost of hospital admissions were obtained for each patient from the HES data. The cost of the telehealth

machine, as purchased in 2007, was used in performing cost-effectiveness analysis. Bed-days were obtained from the HES data.

Information on mortality was obtained from three sources: (1) records on the telehealth system, as patients who died were noted by community nurses who monitored those on telehealth; (2) HES data, which indicated when patients died in hospital; (3) verification against public health mortality file data (all deaths that occurred in Doncaster up to the time of analysis), which was obtained from the Public Health Directorate of Doncaster Primary Care Trust.

Quality of life questionnaires (St George's Respiratory Questionnaire (SGRQ), and Karnofski Index) were completed at baseline and were planned to be undertaken subsequently after 6- and 12-month intervals. The 6- and 12-month quality of life questionnaires were not able to be followed up for all the patients as the study was prematurely stopped. Analysis was made based on the information collected at baseline for the quality of life questionnaire. Basic demographic information on patients was also collected at baseline.

Interviews with patients were planned towards the end of the study. However, these did not take place because the RCT was prematurely stopped. However, interviews were subsequently carried out as part of observational study and the findings are reported in Chapter 7. The purpose of the interviews was to capture the views of patients and staff on their experience in relation to telehealth service.

Patient compliance data related to telehealth was obtained from the telehealth system at the central computer that received all patients' data.

5.3.6a Outcomes

5.3.6a.1 Primary and secondary outcomes

Primary outcome

The main outcome measure of the trial was rates of hospital admission due to COPD measured in number per year of follow up.

The follow-up period was calculated by using patient-years of follow up as the denominator. Those who were followed for 12 months or less were analysed based on hospital admission experience over the period of follow up (in years). Similarly, for those who used telehealth for over 12 months, the denominator was the patient-years of follow up. The end period was determined by the date when patients were discharged from telehealth service or when they refused to take part or when they died. For example, a patient who spent nine months on the trial was considered to have 0.75 person-years of follow up (9/12).

Secondary outcomes

Secondary outcomes of the study included:

- whether or not participants were admitted to hospital;
- mean hospital admission, length of hospital stay, and costs and their 95% CI;
- lengths of hospital stay per year of follow-up;
- mortality rates;
- costs (hospital admissions and telehealth machine) per year of follow-up;

- quality of life as measured by Karnofsky Index and SGRQ based on changes at six months and twelve months of follow-up;
- compliance rate to telehealth monitoring measured against expected receipt of telehealth readings of twice per day per person or readings per week per person;
- challenges encountered in the implementation of telehealth related to staff, technology, patients recruitment as the study progressed based on observation, and views from staff and patients;
- safety of telehealth as measured by mortality rates in both arms of the trial, equipment failure or malfunction leading to inaccurate measurements of health outcomes, and level of red alerts generated from the telehealth device and how they are responded to by community nurses;
- patients' experience of telehealth in the trial as measured by levels of satisfaction using structured questionnaires and semi-structured interviews.

5.3.6b Changes to outcomes

As the trial was discontinued, there were a number of changes; data collection was stopped prematurely and analysis was performed up to the time of discontinuation instead of the anticipated full 12 months of follow-up. This meant that quality of life was only measured fully at baseline, but the intended assessment using quality of life questionnaires at six months and twelve months of follow-up could not be completed. The rates of hospital admissions, length of hospital stays, and costs of hospital admissions were assessed at a shorter

time period, based on actual time of follow-up as a result of discontinuation (person-years of follow up), than it was originally anticipated. Level of satisfaction by patients by means of structured questionnaires and semi-structured interviews could not be undertaken, as these were intended to be carried out towards the end of the study.

5.3.7a Sample size estimation

Initial sample size estimation

The initial sample frame for calculating the sample size of the study was derived from all patients who had emergency hospital admission from COPD with primary diagnostic codes of International Classification of Diseases version 10 (ICD 10: J40, J41, J42, J43, J44 or J47) and who were registered with a GP in Doncaster during the period of October 2005 to September 2006. A preliminary analysis showed that 73% of patients with COPD had only one previous hospital admission related to their disease, while the remainder (27%) had two or more previous hospital admissions (Table 5.3).

Table 5.3: Number of emergency hospital admissions from COPD (ICD 10: J40, J41, J42, J43, J44 or J47) in Doncaster, October 2005 to September 2006; based on 549 patients.

Number of hospital admissions	Total Patients	%
1	401	73.0
2	83	15.1
3	30	5.5
4	19	3.5
5 or more	16	2.9
Total Admissions	549	100.0

Data source: Information Unit, Doncaster Primary Care Trust (PCT)

The evidence in Table 5.3 shows that there were a total of 148 (27.0%) patients that had two or more emergency hospital admissions from COPD during a one-year period. The proportions of male and female patients who were admitted to hospital from COPD were 49.3% (n=73) and 50.7% (n=75) respectively. For patients with two or more admissions in a twelve month period, the average hospital admission was 2.97, with a standard deviation of 1.55.

Various models were proposed based on the potential average number of admissions per person that could be reduced (Table 5.4) in order to achieve a cost-effectiveness (value for money) threshold. The model estimated that in order to break even over a one-year period, the rate of COPD admissions that needed to be avoided was at least 1.33 (44.3%) average per person per year, a reduction from 3.0 to 1.67 admissions on average. Based on this assumption, three possible models were constructed, covering a five-year period. It was anticipated that the telehealth machine could be used beyond the 12 months of the study period. Assumptions of cost modelling were based on 2007 cost (in pounds sterling or £) of hospital admission from COPD of more than two days at £2,302; and the cost of telehealth machine at the time was £2,483 and its on-going annual maintenance fees was £582 per machine (Table 5.4).

Table 5.4: Models of potential savings (£) from investment in telehealth

Analysis per patient over a 5-year period

Models	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Model 1:						
Cumulative number of hospital admissions	2.0	4.0	6.0	8.0	10.0	30.0
Estimated costs: 3 to 2 admissions	£763	£97	-£1,998	-£5,522	-£10,475	-£17,135
Model 2:						
Cumulative number of hospital admissions	1.5	3.0	4.5	6.0	7.5	23
Estimated costs: 3 to 1.5 admissions	-£388	-£3,356	-£8,904	-£17,032	-£27,740	-£57,420
Model 3:						
Cumulative number of hospital admissions	1.0	2.0	3.0	4.0	5.0	15.0
3 to 1 admission	-£1,539	-£6,809	-£15,810	-£28,542	-£45,005	-£97,705

Note: Negative cost denote saving (cost-benefit); while positive cost denotes loss (cost of investment in telehealth is more than the cost from admissions prevented).

Based on benefits realisation projection, shown above, it was estimated that if telehealth were to be cost-effective (break-even), the mean hospital admissions reduction to be achieved should be at least 1.5 (from 3.0 at baseline to 1.5 after telehealth intervention; 50% reduction in hospital admissions). A minimum sample size to enable this effect to be achieved was determined to be 18 patients in each arm of the study (Table 5.5, option 3).

Table 5.5: Sample size calculations: mean hospital admissions rate per year

Options	mu1	mu2	Difference in Mean	Sample size per study arm (n1=n2)
1	3.0	2.0	1.0	38
2	3.0	1.7	1.3	23
3	3.0	1.5	1.5	18

Note: μ_1 = mean of population 1 – mean admissions per year from COPD admissions in the control group; μ_2 = mean of population 2 - mean admissions per year from COPD admissions in the intervention group.

Note that, for this sample size, the outcome (rates of admission) was taken to be a continuous measure. This may not be normally distributed. The average of several measurements can be distributed close to a normal distribution and a t -test is appropriate. It is worth noting that the mean is double the standard deviation which provides reassurance that a t -test is appropriate.

Sample size for an unpaired two-sample student t -test was calculated (using StatsDirect computer software for calculating sample size) based on the following statistical variables: alpha = 0.05; power = 0.8; difference between means = 1.5; standard deviation = 1.55; control per experimental subject = 1; and degrees of freedom = 34. Therefore, the sample size for the trial was selected to be 36 patients, as shown in Option 3 of Table 5.5.

A provision for recruiting additional 11% patients ($n=4$ or two extra participants in each arm of the trial) was planned in the study protocol (so that the trial was to have a total of 40 participants). The additional four participants were to cover for potential drop-out from the trial. However, this additional number was not recruited.

Revised sample size estimation

When further funding became available, the same assumptions described in Table 5.5 were still held, with the exception that patients with at least one previous hospital admission would be included at this time. Option 1 of Table

5.5 was chosen as the basis for the revised sample size with 38 participants in each arm of the trial (total of 76 participants). Allowance was made for drop-out, bringing the planned total number in the revised sample size estimation to 80. The inclusion criteria for the revised sample size estimation are shown in Table 5.1a.

5.3.7b Stopping rules

It was determined, in the study protocol, that the trial would be stopped if: (1) the equipment was found to be unsafe; (2) the integrity of the equipment and data was unreliable; and (3) a large number of patients withdrew from the study. The Steering Group would assess this, as and when the situation arose and it would take appropriate decisions and actions. No interim analyses of the trial were planned or performed.

5.3.8a Randomisation method

The method used to generate the random allocation of participants was carried out by means of an excel software programme. A macro programme was used for the random allocation process of participants, which selected from a list of even numbers half of them into intervention group. The randomisation into the intervention and control groups was carried out in blocks of four cases, based on the number of patients that consented at the time and were ready to be allocated into the trial. A list was created consisting of even numbers of patient identification numbers. The random allocation process using excel software was first tested on dummy numbers not related to the trial, and it was successful in randomly selecting half of the patients for the intervention arm of the trial. Using

similar process, random allocations were made from a list of even number, when randomisation command was activated, half of the cases were selected, and they were assigned as belonging to the intervention arm of the trial, while the remaining ones were assigned to the control group.

5.3.8b Randomisation type

The trial was designed primarily to determine the effect of telehealth between the intervention and control groups, and simple random sampling in blocks of four was chosen to ensure good balance between the trial arms. Although the author was aware of the potential differences in patients' characteristics, such as sex, age, ethnicity, and geographical location, these were not used for stratification: it was hoped that randomisation would balance these characteristics. Undertaking stratified random sampling would have increased the complexity of the study, and possibly the duration of recruitment.

5.3.9 Allocation concealment

Randomisation was concealed by carrying out central randomisation away from the community nurses who were responsible for implementing service delivery for the patients who might be allocated to control or intervention arms of the trial. The author undertook the central randomisation from a different site (at PCT headquarter), and informed the community nurses (based in the community setting) of the results of the allocation. The randomisation was therefore concealed from the clinical staff involved in the patients care. The staff who undertook randomisation did not know the patients.

5.3.10 Randomisation implementation

Patients who met the eligibility criteria were contacted by a district nurse to obtain consent and those who consented were randomised by the Chief Investigator (the author of this thesis). The district nurses were informed by the Chief Investigator regarding which patients were to be assigned to the intervention arm (thus receiving telehealth service) and which ones were to continue receiving standard care (control group) after randomisation. The district nurses enrolled the patients onto telehealth by undertaking the installation of the machines, following consent by the patients.

5.3.11 Blinding

Blinding was not possible since it was not practical for staff and participants involved in the trial to be blinded as to who was, and was not, receiving the telehealth intervention after randomisation.

After randomisation, patients were made aware that they could withdraw from the study at any time without giving any reason, as stipulated in the protocol. All cases that used telehealth for any duration were included in the analysis on the basis of intention to treat (ITT).

5.3.12 Statistical methods

Summary statistics (mean and rates) were calculated for intervention and control groups of the trial using STATA (statistical) software (version 11). The 95% confidence intervals (CIs) were calculated using Bootstrap resampling method using statistical computer programme called *Statistics101* (Grosberg,

2014). Grosberg (2014) described Bootstrap as a statistical technique, used to derive unknown population parameters, such as mean or confidence interval by resampling from the original sample infinite number of times. Each time the resample is drawn, it is replaced and the process repeated as many times as required (Grosberg, 2014). In this way, Grosberg argued that the mean and 95% CI of the unknown population could be derived. The advantage of using Bootstrap statistics to calculate 95% CI is that it does not rely on the distribution of the data being normal (Grosberg, 2014). There was evidence from the trial's data that the distribution of the data was skewed, thus justifying the use of Bootstrap for calculating 95% CI.

The initial analysis was to undertake the hypothesis testing by applying a *t*-test for the difference in the mean rates of hospital admission between the two groups (intervention and control). This was amended when it was discovered that admission rates were much lower in both groups. There was the possibility that the assumption that the means were normally distributed might be violated. That is, with lower means the rates are more heavily skewed. To ensure validity of the test, the two-sample Wilcoxon rank-sum (Mann-Whitney) test was undertaken instead. There would be a small reduction in power compared to a *t*-test should the normal assumption be valid but validity is ensured with a rank-sum test.

Secondary analyses were performed using Pearson's chi-square test for statistically significant differences in binary outcomes between the study subgroups: participants admitted to hospital or not. All analyses were performed using intention to treat (ITT).

Why a non-parametric test was used

As stated in the sample size calculation, the assumption of normality for the *t*-test depended on the mean being relatively large compared to the standard deviation. With time, the mean number of hospital admission dropped.

When the sample size calculation was carried out, a student *t*-test was assumed, since the distribution of the group means would be close to a normal distribution. Upon collecting data during the trial, it was revealed that the data were more skewed (asymmetric) and so the means were unlikely to be normally distributed (see Figures 5.2 and 5.3 under results). An alternative non-parametric test was considered to be the most appropriate one to use instead of the *t*-test. The alternative non-parametric test used was Wilcoxon rank-sum test (also called Mann-Whitney U test) for independent samples. This might have resulted in a minor loss of power.

5.4 Results

5.4.13a Participant flow

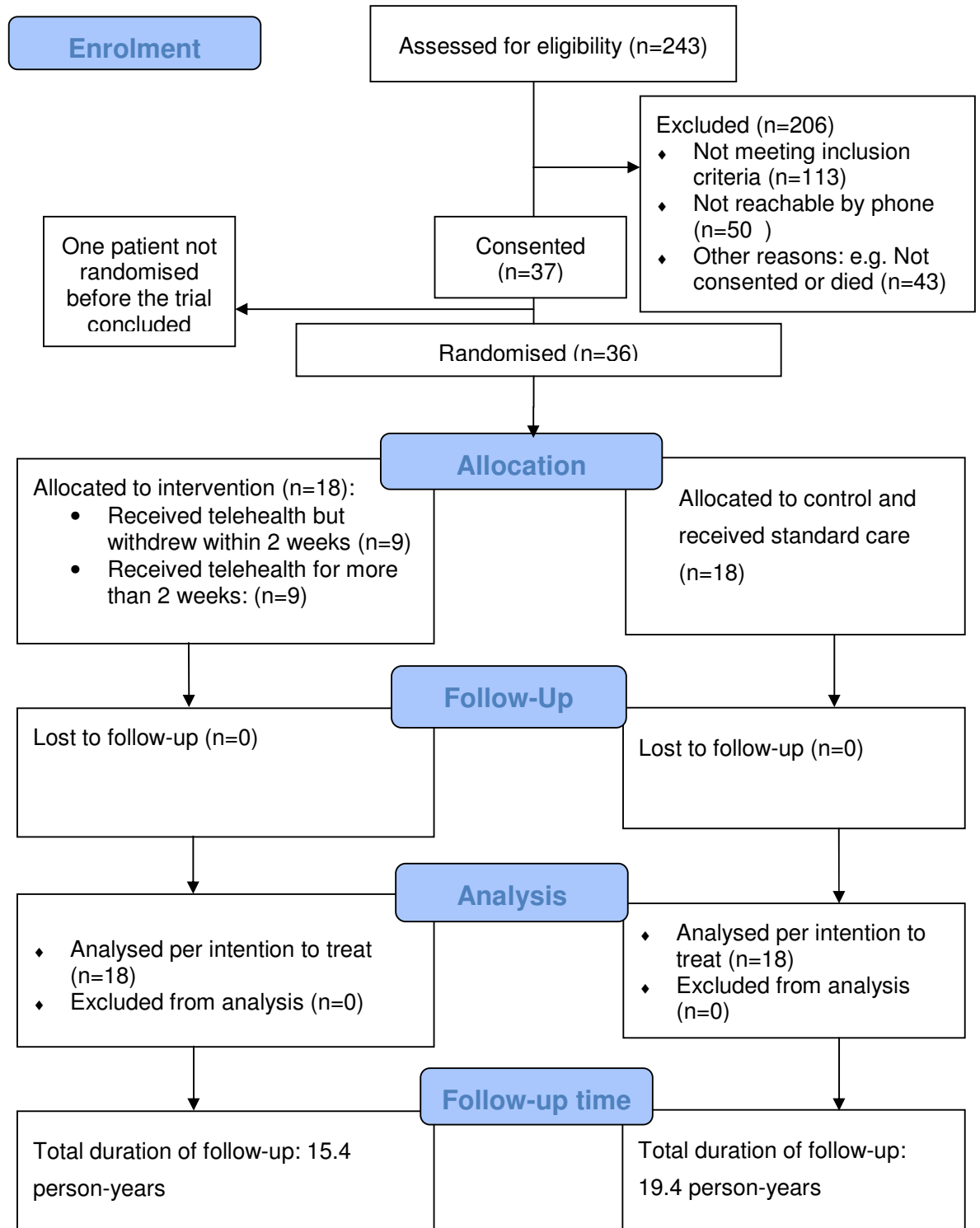
A total of 243 cases were screened for eligibility into the trial. They were derived from hospital admission data held by Doncaster PCT. Of these, 206 were excluded because: (a) they did not meet the inclusion criteria (n=113); (b) were not reachable by phone in order to make contact for consent (n=50); and (c) other reasons (n=43). Consent was obtained from 37 patients. As randomisation was carried out in blocks, 36 cases were randomised. One patient could not be randomised because the study was stopped prematurely

and additional patients could not be recruited. A flow diagram, which describes the recruitment process, is found in Figure 5.2.

For the 36 cases that were randomised into the trial: 18 were assigned to the control group and 18 to the intervention group. Of the 18 cases that were assigned to the intervention group, nine used telehealth for less than two weeks, while the remainder used telehealth for a duration ranging from two weeks to 1.3 years. The 18 cases assigned to the intervention group were followed up and analysed. Similarly, in the control group all the 18 cases were also followed up and analysed.

A flow diagram, showing number of cases assessed for eligibility, to inclusion in the analysis, is shown in Figure 5.2 below, as recommended in the CONSORT 2010 statement for reporting of randomised controlled trials.

Figure 5.2: Flow diagram of the recruitment process into RCT
Randomisation and analysis of the trial (CONSORT 2010 Flow Diagram)



5.4.13b Losses and exclusions

All cases were accounted for in the follow-up process, hence there was no loss to follow up. Analysis was carried out based on period of follow up, using intention to treat (ITT). There was no exclusion from the analysis of those who were allocated to the trial.

5.4.14a Recruitment period

Recruitment into the telehealth trial commenced in August 2007 and the first patient recruited received the intervention in October 2007. Recruitment and follow-up continued until August 2009 when the trial was discontinued prematurely.

5.4.14b Stopping the trial

The immediate reason that led to the trial being halted was that the sole remaining nurse, out of the original two nurses, left the job. As a result, it was deemed unsafe to continue the service without a nurse to monitor the patients. After the trial was stopped, the telehealth service was re-started after staff issues were addressed, but the service was evaluated in a different way, see Chapters 6 and 7.

Further details of stopping are provided in Section 5.7 below.

5.4.15 Baseline data

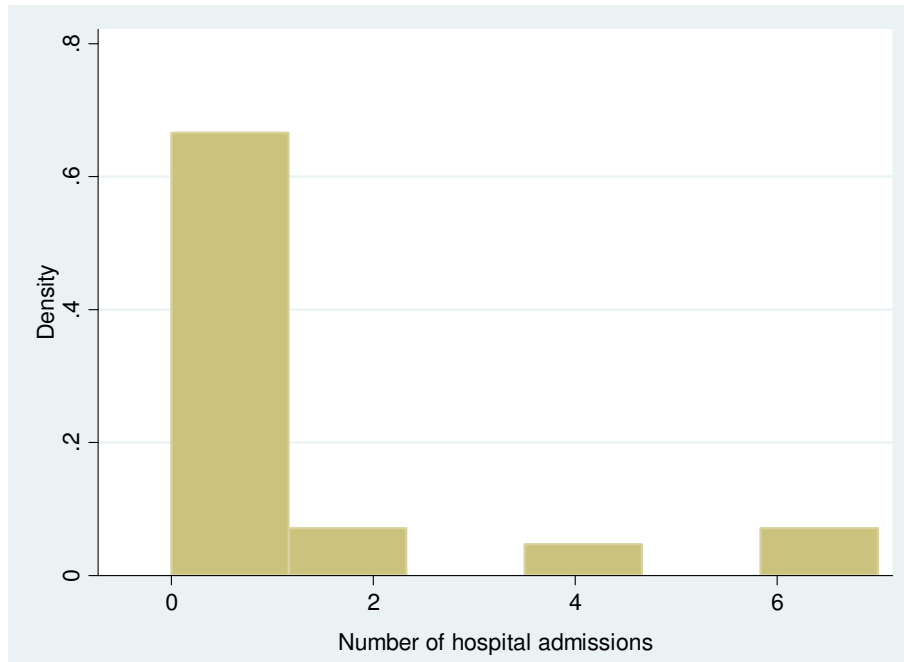
All 36 patients randomised and followed up were analysed. Of the 36 cases analysed, there were equal numbers; 18 (50.0%) in each arm of the trial. The

baseline characteristics of patients in the intervention and control groups were broadly similar in respect to age, sex, number of comorbidities, previous hospital admissions and length of stay in the previous 12 months; and also quality of life, as measured by Karnofski Index (KI) and St George's Respiratory Questionnaire (SGRQ). The intervention group however was slightly older compared to the control group and the baseline mean hospital admission rate and length of hospital stay were also lower in the intervention than the control group (Table 5.6). The baseline mean score on KI was 49.2 in the intervention group compared with 38.0 in the control (the higher the Index the better was the quality of life); while the corresponding total scores on SGRQ were 71.9 (intervention group) and 75.3 (control group); (the higher the score, the worse health outcome) respectively (Table 5.6).

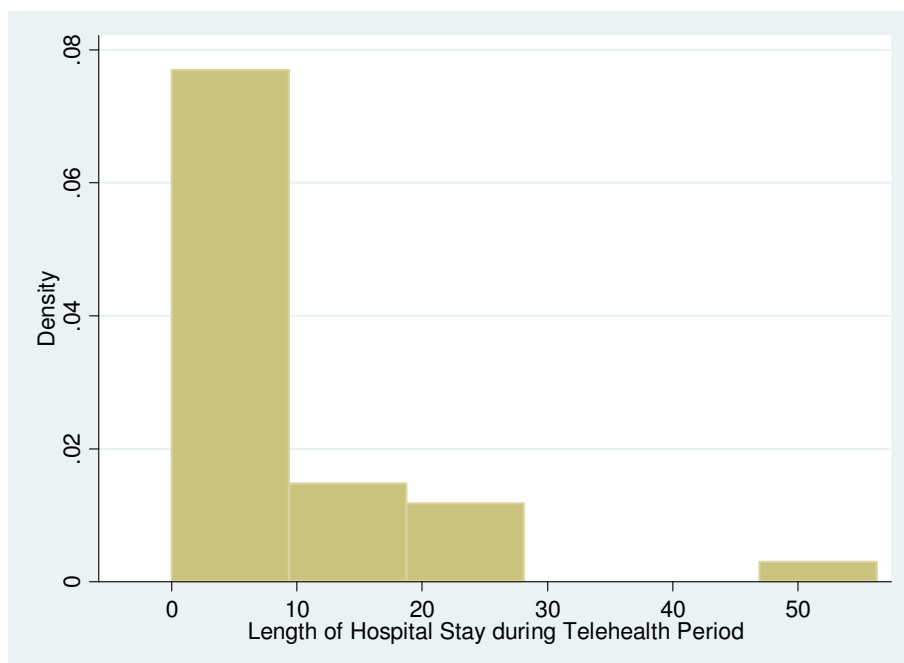
Table 5.6: Baseline characteristics of intervention and control groups

Variables	Intervention	Control
Number of cases (%)	18 (50.0)	18 (50.0)
Mean age in years (95% CI)	73.9 (70.3, 77.5)	67.7 (63.0, 72.4)
Sex:		
Male: n (%)	10 (27.8)	8 (22.2)
Female: n (%)	8 (22.2)	10 (27.8)
Mean number of comorbidities (95% CI)	6 (3, 8)	7 (5, 9)
Mean number of hospital admissions 12 months before the trial (95% CI)	1.11 (0.44, 1.94)	1.89 (1.11, 2.72)
Mean length of hospital stay (days) 12 months before the trial (95% CI)	5.83 (2.00, 10.39)	15.11 (8.50, 22.78)
Karnofski Index(KI):		
Number of cases	12	15
Score: mean (95% CI)	49.2 (36.0, 62.3)	38.0 (26.7, 49.3)
St Georges Respiratory Questionnaire (SGRQ):		
Number of cases:	13	13
Symptoms score: mean (95% CI)	74.2 (63.7, 84.8)	79.2 (71.1, 86.6)
Activity score: mean (95% CI)	87.2 (78.7, 95.8)	88.8 (83.3, 94.4)
Impact score: mean (95% CI)	62.9 (48.9, 77.0)	66.4 (55.2, 77.6)
Total score: mean (95% CI)	71.9 (61.5, 82.3)	75.3 (61.5, 82.3)

Analysis of the data showed that 25 of 36 patients (69.4%) did not experience any hospital admission, and the frequency of those that had one to seven hospital admissions tailed off in single digits. This showed that hospital admissions were skewed, far more than initially anticipated (Figure 5.3), thus requiring the use of non-parametric tests e.g., Wilcoxon rank-sum test (Mann-Whitney U test).

Figure 5.3: Distribution of hospital admissions among the study population

Similarly, the distribution of length of hospital stay (days) was also skewed (Figure 5.4).

Figure 5.4: Histogram of length of hospital stay (days) during the trial

5.4.16 Numbers analysed

There were 36 patients analysed, with 18 participants in each one of the intervention and control groups, as originally assigned.

5.4.17 Outcomes

5.4.17.1 Primary outcome: hospital admissions

During the trial period, there were 16 (43.2%) hospital admissions in the intervention arm of the study in comparison with 21 (56.8%) in the control group. The total duration of follow-up was 15.4 years for the intervention group, while it was 19.4 year for the control group. The mean hospital admission rate per year of follow-up per person was 1.04 (95%CI: 0.59, 1.69) in the intervention group, and the equivalent rate for control group was 1.08 (95% CI: 0.67, 1.65); p-value = 0.547 (p-value performed using Wilcoxon rank-sum test, while 95% CI was calculated using Bootstrap resampling method as described above). There was no statistically significant difference in hospital admission rates between the two arms of the trial (Table 5.7).

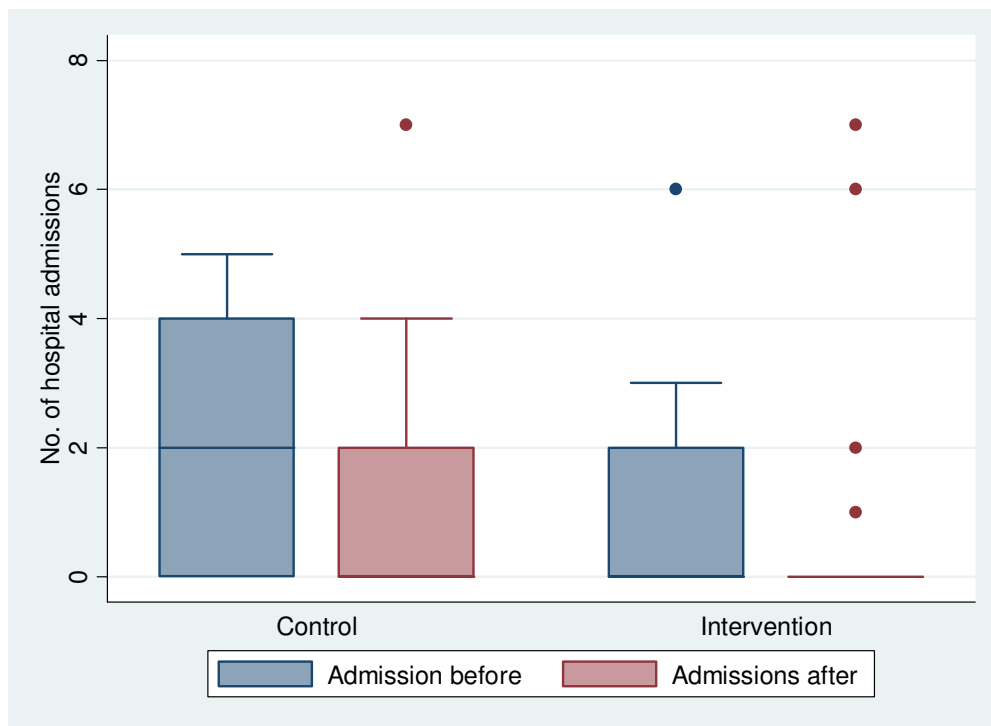
Table 5.7: Outcome of hospital admission rate per year of follow-up

Variables	Intervention	Control	P-value*
Number of cases	18	18	
Years of follow-up	15.4	19.4	
Hospital admissions:			
Total number of admissions	16	21	
Admissions rate per year of follow up (95% CI)	1.04 (0.59, 1.69)	1.08 (0.67, 1.65)	0.55

*P-value: derived from two-sample Wilcoxon rank sum (Mann-Whitney) test

A box plot of hospital admissions before and after the trial showed that hospital admissions appeared to be reduced in the intervention group compared to the control group (Figure 5.5).

Figure 5.5: Hospital admissions before and after the trial (box plot)



Note: The box plot has a box with upper end (75th percentile) and lower end (25th percentile) with a median (line). The whisker represents upper adjacent value (there can also be lower adjacent value, which is not available in this figure). The dots represent outliers.

During the trial the mean hospital admission rate per year reduced by only 6.3% (from 1.11 to 1.04) in the intervention group, while the control group experienced a reduction of 42.9% (from 1.89 to 1.08).

5.4.17.2 Secondary outcomes

Hospital admission as a binary outcome

Analysis of participants admitted, or not admitted, to hospital (binary outcomes), using Pearson chi-squared test showed that there was no statistically significant difference in the two study arms ($p=0.278$). There were 7 cases (19.4%) admitted to hospital in the control group, while in the intervention group, the number was 4 (11.1%), (Table 5.8).

Table 5.8: Pearson chi-squared test: admitted or not by study group

Admitted to hospital	Study groups				Total	
	Control		Intervention		n	%
	n	%	n	%		
No	11	30.6	14	38.9	25	69.4
Yes	7	19.4	4	11.1	11	30.6
Total	18	50.0	18	50.0	36	100.0

Note: Pearson $\chi^2(1) = 1.1782$, $p = 0.278$

Hospital bed days

The rate of mean hospital length of stay (bed-days) per year of follow-up per person was 5.99 (95% CI: 1.73, 11.32) in the intervention group, while the mean rate in the control group was 7.23 (95% CI: 2.27, 13.23), based on bootstrap statistical analysis described above in Section 5.3.12. There was no statistically significant difference in lengths of hospital stay rate between the control and intervention group (p -value = 0.57) (Table 5.8).

Costs

The total cost (limited to hospital tariff cost and cost of telehealth machine and its communication) was £83,986 in the intervention group compared with £43,419 in the control group. The mean total cost per patient-year was three times more in the intervention group at £6706 (95% CI: £3595, £10,537), in comparison to £2,605 (95%CI: £807, £4805), in the control group; *p*-value 0.005.

Deaths

There were a total of 15 deaths (41.7%) that occurred during the trial; which translated into 1.21 deaths per year of follow-up. Eight deaths (22.2%) occurred in the intervention group, and death rate per year of follow up was 0.52 (95%CI: 0.22, 1.02). There were seven deaths in the control group (19.4%), which was equivalent to death rate of 0.36 (95% CI: 0.14, 0.74) per year of follow-up.

There was no statistically significant mortality experience between the two arms of the trial (Table 5.9), although there was slightly higher mortality in the intervention group.

Table 5.9: Main health outcomes from the trial

Lengths of hospital stay (bed-days), costs, and mortality rates

Variables	Intervention		Control		P-value*
Number of cases	18		18		
Years of follow-up	15.4		19.4		
Lengths of hospital stay (days):					
Total number	98		127		
%	43.6		56.4		
Mean lengths of stay rate per person-year (95% CI)	5.99	(1.73, 11.32)	7.23	(2.27, 13.23)	0.5666
Costs (GB £) [admission + telehealth machine]:					
Amount (£)	83,986		43,419		
Mean total cost (£) per person-year (95% CI)	6706	(3585, 10,537)	2,605	(807, 4805)	0.0050
Mortality:					
Number (%)	8	(22.2)	7	(19.4)	
Rate of death per person-year of follow-up (95% CI)	0.52	(0.22, 1.02)	0.36	(0.14, 0.74)	0.7389

*Note: *P-value: derived from two-sample Wilcoxon rank-sum (Mann-Whitney) test

Quality of life

Since the trial was stopped before the planned completion time, the quality of life questionnaires were completed at baseline and no meaningful number of questionnaires was completed at 6th and 12th months' interval as originally envisaged. Therefore, change in quality of life could not be performed, based on the tools selected: Karnofski Index, and St George's Respiratory Questionnaire.

Compliance with telehealth monitoring

Records of nine cases (four females and five men) who received telehealth monitoring for a minimum period of 0.3 years (3.6 months) and a maximum of 1.3 years (15.6 months) were examined for compliance. These nine cases encompassed all participants, for whom telehealth monitoring was used for a longer time period. Patients who only used telehealth monitoring for a brief period (for example 14 days) and gave it up were excluded from telehealth compliance data analysis, because they did not have any meaningful computer records of telehealth monitoring data to analyse for purpose of understanding compliance of patients with telehealth service. . However, they were included in other analysis on the basis of intention to treat. Fourteen days was agreed as a cooling period in which patients could try telehealth service to determine whether or not they wanted to continue

The average age of users of telehealth home monitoring was 77 years old (72 years old for females; and 81 years old for males). The combined time of patients data monitored was 9.1 years, or 3,309 days. Two readings were expected per day (from Monday – Friday), and a total of 6618 readings were

expected. A total of 5724 readings were actually transmitted and received, representing a compliance rate of 86.5%. The compliance rate per person was equivalent to 1.7 readings (consultations) per day; or 12.1 readings (consultations) per week. The proportion of red alerts was 82.6% (n=4,726) of the readings generated (Table 5.10).

Table 5.10: Compliance with telehealth home monitoring

Experience of cases in Doncaster (note: cases with more readings received than was expected were considered to have complied fully, i.e. 100.0%, even though reading received was more than that expected)

Sex	Age (yrs.)	Duration years of follow-up	Actual days monitored	Readings Received	Red Alerts	% of Red Alerts	Expected readings calculated	Compliance Rate%	Consultation rate per day	Consultation rate / person / week
Female	69	0.8	285	629	382	60.7	570	100.0	2.2	15.4
Female	78	1.2	423	328	203	61.9	846	38.8	0.8	5.4
Female	80	1.3	478	950	814	85.7	956	99.4	2.0	13.9
Female	63	1.1	384	715	564	78.9	768	93.1	1.9	13.0
Male	79	0.3	113	209	164	78.5	226	92.5	1.8	12.9
Male	108	1.1	407	821	777	94.6	814	100.0	2.0	14.1
Male	75	1.1	409	589	513	87.1	818	72.0	1.4	10.1
Male	66	1.1	416	755	752	99.6	832	90.7	1.8	12.7
Male	76	1.1	394	728	557	76.5	788	92.4	1.8	12.9
All Females	72	4.3	1570	2622	1963	74.9	3140	83.5	1.7	11.7
All Males	81	4.8	1739	3102	2763	89.1	3478	89.2	1.8	12.5
All Persons	77	9.1	3309	5724	4726	82.6	6618	86.5	1.7	12.1

5.19 Harms

There were eight deaths (8/18) in the intervention group and seven deaths (7/18) in the control group, as shown in Table 5.9. Mortality rate per year of follow up was 0.52 (95% CI: 0.22, 1.02) in the intervention group, and the rate in the control group was 0.36 (95% CI: 0.14, 0.74).

A major concern was related to the high rate of red alerts that were reported through the telehealth monitoring system, which was 82.6% of all the readings. This resulted in increased contacts with patients. Some of these contacts were necessary, while others were not. The potential harm from the red alerts was that they could be ignored since they were so frequent. Some of the red alerts arose from the fact that the questionnaires selected were not specific enough to detect deterioration in patients' situation at the time of answering the questions. Consequently, patients often would return a response that yielded red alerts for a whole week (Table 5.2). Another reason for the red alerts was that staff did not have much experience in setting realistic red alerts that reflected the patients' individual situations, but were guided more by national guidelines from the National Institute for Health and Care Excellence (NICE) for COPD.

There were no harms directly reported as a result of using telehealth by patients. One patient reported concern around his readings not being picked up by the district nurse, when the latter was on leave.

5.5 Discussion

5.5.20 Limitations

The study had a number of challenges and limitations which became more evident as the trial progressed. Ultimately the trial was stopped. Details of these limitations are provided below.

Some inconsistencies in the methods of recruitment are worth highlighting, although they did not affect the study arms differently due to the randomisation process undertaken. These inconsistencies related to: (1) differences in population frame used for the sample size estimation and for recruitment to the trial; and (2) different time frame between when study sample were identified and the baseline period before commencing on telehealth service. Hospital admissions at the time of sample size calculation proved to be different from when the actual study sample frame was derived. The data for calculating the sample size was much older (October 2005 to September 2006) than that used for recruiting participants into the trial, which captured patients during 2007. After participants were identified from the sample frame, there had been time lag of a couple of months before they were recruited into the study. This time lag was taken up for the necessary preparatory work, such as, undertaking staff training and consenting patients into the trial before recruiting participants into the trial. The time lag shifted the “baseline” period of the trial, which was taken as 12 months before starting on the trial from that when the study frame was identified. Therefore, participants with two or more hospital admission during the sample frame period when they were selected into the trial, might no longer

have similar level of previous hospital admission during the 12 months period when they actually started on the trial (baseline period).

Since the actual baseline hospital admissions were lower than those originally anticipated, the economic model described in Table 5.4 is invalid. The cost-benefit model (Table 5.4) relied on the assumption that the mean hospital admission per year per person was three, but the findings from the trial showed that the mean hospital admission per person per year was only 1.11 in the intervention group and 1.89 in the control, with no statistically significant difference between the study groups (Table 5.6). Evidence from different sample study frame showed that the average hospital admission reduced, even without any telehealth interventions, suggesting a possible regression to the mean.

The change in inclusion criteria, from two previous hospital admissions from COPD to at least one previous hospital admission in the past 12 months, introduced some element of potential bias in the trial in detecting the effects of the intervention. However, through randomisation, the two arms of the trial were treated in the same way despite the change in inclusion criteria. The trial was originally planned to recruit 36 cases (Option 3, Table 5.5) and it achieved that number. The amended criteria were for a planned increase of study sample size to 80 participants, which did not come to fruition as the trial was halted prematurely.

During the trial, the actual baseline mean hospital admissions were similar: 1.11 (95% CI: 0.44, 1.94) for the intervention group and 1.89 (95% CI: 1.11, 2.72) for control groups. There was a large fall in the admission rates after recruitment in

both groups, thus suggesting that concerns about bias in randomisation process was false. The large reduction in admission rates observed is similar to a regression to the mean (RTTM) effect. This effect was very much larger than anticipated. The conditions during the trial were therefore very different to the conditions before the trial. This demonstrates the need for an RCT rather than a pre- and post-study design. The RTTM effect is also much larger than any anticipated treatment effect. As this is a source of considerable extra variation, the trial should be redesigned. Since the admission rate was lower and much of the variation in rate was further reduced due to the RTTM effect, the outcome measure had very different properties to that anticipated at trial design. If circumstances arise where another trial of telehealth is appropriate, then these influences should be factored into the redesign.

The change in statistical test used (non-parametric test instead of student *t*-test) might have resulted in lower power of the study and the potential for benefit was reduced. Therefore, the trial was less likely to detect an effect.

Given the option, some of the staff would have expectation and preference to give telehealth to their selected patients. From a research point of view, no one was at *equipoise* (including staff and patients); there was inherent belief that telehealth was effective, thus holding a biased position in favour of telehealth. Patients on telehealth might have reassurance that they were being monitored and therefore could down-grade their symptoms and not seek hospital care, unlike those receiving standard care. This assurance might be false for some patients, as there were a lot of red alerts generated from the telehealth monitoring system and their validity was uncertain. It was made clear to patients

however, that if they felt the need for emergency health care (Accident & Emergency or A&E in the hospital), they should make that contact, as the telehealth service was not an emergency service.

From a healthcare organisation point of view, Doncaster PCT was willing to invest in piloting telehealth because it believed in its potential health benefit. To minimise bias in allocation of participants, randomisation was carried out by different administrative staff to those who were not part of the clinical nursing team. Hence, the nursing staff did not influence in the selection of who should be allocated to the intervention arm of the trial to receive telehealth.

It was possible, that some staff might have carried out compensatory work with controlled arm of the trial, especially drawing on lessons learned from the intervention group. Nursing staff also considered their primary role as preventing hospital admission, and they perceived telehealth as a threat to their job. Therefore, some of the nursing staff may have preferred it to fail in showing any potential health benefit. It was also possible, that healthcare professionals interacting with trial participants could have influenced patients' behaviour, for example, they might have influenced when the patients sought hospital admissions. There was little firm evidence obtained that potential compensatory behaviour took place among the clinical staff, in the form of trying harder with control group participants. On the contrary, it was felt that the high rates of red alerts might have diverted the attention of nurses away from providing routine care, including care to those in the control arm of the trial. For participants in the control group, it was likely that enrolment into the trial might have increased their awareness about telehealth, but there was no evidence that it resulted in

modification of their behaviour to improve their health. Although the trial was small with only 36 patients, it would have been greatly preferable to run a pilot trial before embarking on the main trial. Looking back, the conditions for a fair pragmatic trial were not in place at the time; a good pilot with process evaluations would have uncovered the limitations encountered in this trial. This would have identified lessons learned by others related to failed trials (Rendell et al., 2007) and factors influencing the conduct of successful trials (Campbell et al., 2007), as summarised in Table 5.11, which would have enhanced the quality of the trial.

The premature discontinuation of the trial meant that the full outcomes initially planned could not be realised as part of the trial findings, including effects of telehealth on hospital admission, quality of life, and patients' satisfaction.

The timeline of this PhD, which commenced after the trial began, meant that there were additional secondary analyses introduced, such as, Wilcoxon ranked-sum test, including logistic regression. Before enrolment onto the PhD, this was not clearly determined. With the commencement of PhD study, additional knowledge was gained in how to analyse the findings of the trial, using Stata software (version 11). The pragmatic trial helped to address the question of whether telehealth is effective in the real world of routine healthcare delivery, (Roland and Torgerson, 1998) that is, in a Primary Health Care Trust in Doncaster (England), where policy makers wanted to implement telehealth.

Analysis was carried out based on intention to treat (ITT). This meant that participants who were allocated into the two arms of the trial, during any time period, were included in the final analysis. This included participants who were

assigned to the intervention arm of the trial and used telehealth for less than two weeks.

The fact that half of the intervention participants (9/18) withdrew within two weeks of commencing on telehealth, weakened the validity of the trial. This shows that, for patients recruited through the RCT, adherence to telehealth was poor.

The scale of red alerts generated was too high; 82% in this study. The high level of red alerts could be a reflection of lack of confidence by practitioners in setting the right vital sign parameters; and the problem of the selected questions that were initially thought to be relevant for patients with COPD. Most clinicians relied on guidelines, which did not reflect the conditions of individual patients. A red alert meant that healthcare professionals had to make contact with the patients, thus generating more work. With limited capacity in the workforce, the increased workload might be additional source of frustration for staff, and a possible reason why they ended up leaving work on the telehealth service. The nurses were not fully released to do the telehealth service work, they were doing it in addition to their main district nursing duties. With the high rate of red alerts (82%), this suggests that the level of contacts between patients using telehealth service and their healthcare professionals was also more frequent than patients in the control arm of the study. The increased contacts with the intervention group could potentially divert attention from control groups, thus raising potential safety concerns to those receiving standard care. As the red alert rate was so high, staff could become complacent

and might ignore the red alerts, thus posing a potential safety concern too among those using the telehealth service.

There was some concern that telehealth might have provided a false sense of security to some patients, who felt they were being monitored by healthcare staff when in fact the staff concerned were actually not actively monitoring patients. However, this concern was not substantiated. Apart from rare occasions, the nurses appeared to be dedicated in ensuring that the alerts were monitored during office hours and they took appropriate action. It was identified as a key gap, as part of risk in the service to have a sole nurse running the service, as oppose to a team to provide assurance of business continuity of telehealth service. This lesson was translated into the future development of service, which is reported in the observational study (Chapters 6 and 7).

It was also found that hospital episode statistics (HES) was a poor source for recruiting participants into a trial due to out-of-date records or cases that could not be easily contacted. Recruiting patients while they were in hospital would have been a more efficient method.

The costs of telehealth service were recognised to be much greater than that of the machine and hospital admissions alone. Other costs not featured in the analysis could include staff cost and costs to patients and carers. What the findings show is that the actual cost of delivering telehealth service would have been much higher than that found in the trial, making telehealth service even less cost-effective in the form it was used during the trial.

The strength of the trial was that it assessed the effectiveness of telehealth in a real world situation at the time when there was limited, good quality evaluation on the subject (Chapter 4). RCTs are regarded as the gold standard in hierarchy of evidence (SIGN, 2011). On this basis, it was considered justifiable to conduct a pragmatic RCT to determine the effectiveness of telehealth. The aim and objectives of the trial were clear.

5.5.21 Generalisability

The main findings of the study show that there is little evidence for effectiveness of telehealth in reducing hospital admission rates; significance tests did not show any difference between hospital admissions experience between control and intervention groups despite the admission rates being lower in the intervention arm of the trial.

The trial showed that, even without considering the cost of staff time, telehealth was already not cost-effective. The mean cost (pounds sterling or GBP-£) for the intervention group was £7,544 compared to £2,604 in the control group (three times higher in the intervention than the control group). If the real cost of telehealth service (machines plus all the service around it, including staff costs) were considered, telehealth as used in this trial, would have been even less cost-effective.

The study also adds to our understanding of (1) how patients complied in using telehealth, including the fact that nine of the 18 patients only used telehealth for less than two weeks suggesting that patients might have disliked the machine;

and (2) the dynamics between patients and staff in relation to remote home monitoring, and in particular the concerns about the high rate of red alerts.

It is often a challenge to try and translate the findings from research studies into the real world, as acknowledged in the literature. Complex interventions are often difficult to replicate due to difficulties in identifying the actual 'ingredients' that were responsible for the outcomes achieved (Campbell et al., 2000).

5.5.22 Interpretation

The findings from the trial show that there is little evidence of reduced hospital admission rates among patients with COPD, who were living in the community. The null hypothesis was accepted, which stipulated that telehealth made no difference in hospital admission rates among patients with COPD. Similarly, there was no impact of telehealth usage on lengths of hospital stay among participants in the trial. Mortality rates were similar in both arms of the trial, while the results showed that telehealth was not cost-effective. The findings of the trial, which demonstrated that telehealth had no effects on hospital admission rates, mortality rates, and was not cost-effectiveness are similar to some of the literature review findings reported in Chapter 4.

The Whole System Demonstrator (WSD), one of the world's largest RCTs on telehealth to-date, found an odds ratio (OR) from hospital admission to be 0.82 (95% CI: 0.70 to 0.97), only marginally protective for telehealth (Steventon et al., 2012). The findings of the WSD was heavily influenced by admissions records in the first three months of the trial, if this initial three months were excluded the study would not have been able to claim any positive findings

reported. A separate economic evaluation of the WSD showed that the cost per quality adjusted life years (QALY) for patients on telehealth was £92,000; three times more than the upper limit recommended by NICE (Henderson et al., 2013). The WSD also showed that telehealth was not cost-effective. In this pragmatic trial, it was found that the cost per year of follow-up in the telehealth group was three times more expensive than that in the control group. If all relevant costs were taken into account, telehealth would be even less cost-effective.

There were no consistencies in the published literature on mortality outcomes. Although the WSD appeared to find significant difference in mortality in favour of the telehealth group (Steventon et al., 2012), other studies showed no significant difference in mortality between the intervention and control groups (McLean et al., 2011, de Toledo et al., 2006, Vitacca et al., 2009).

On the other hand some positive findings were reported from a number of systematic reviews on telehealth among COPD patients, including hospital admissions odds ratio of 0.46 (95% CI: 0.33 to 0.65) (McLean et al., 2011); and Sorknaes and colleagues found hospital admissions hazard ratio (HR) of 0.25 (95% CI: 0.09, 0.69) among COPD patients (Sorknaes et al., 2011).

This chapter has provided a platform for work reported in the next two chapters, which focus on exploring why new technology embeds or not in routine practice, drawing on the experience from this chapter.

5.6 Other information

5.6.23 Registration

The trial received ethical approval from South Humber Local Research Ethics Committee, reference number 06/Q1105/64 (details in Annex 2.1).

At the time of conducting the trial, information about registration with the Trial Register of Promoting Health Interventions (TRoPHI) was unknown to the author (even though the register was in place then) and therefore it was not considered at the time of the trial; as a result the trial was not registered on TRoPHI. The requirement of registration of the trial was not mandatory, and no recommendation was made by the Research Ethics Committee for the trial registration, which could have prompted the author to register the trial.

5.6.24 Protocol

A copy of the trial protocol was submitted as part of NHS Research and Development application online on 24 January 2007. A copy of the application submitted is available from the author.

5.6.25 Funding

Funding for this study was secured from Neighbourhood Renewal Fund (NRF), totalling £65,000 (sixty-five thousand pounds), which comprised of £30,000 for capital costs (to purchase the telehealth machines) and £35,000 was allocated for revenue costs (including connection / communication fees and staff costs).

Following a competitive tender process (described in Chapter 3 on telehealth), a successful supplier (Tunstall) was chosen from among eight suppliers (Docobo, RSL Steeper, Initial Attendo, Tunstall, Fold Telecare, Philips Medical, Pro-wellness, and TSB GB Telematic).

The telehealth machine did not change during the trial. There was a plan in 2009 to replace the initial machines but this did not happen until 2010, when the trial had stopped. The rapid development of technology can be seen to be one of the challenges in evaluating telehealth but was not the case here. The wider roll out of telehealth service was funded by Doncaster PCT.

5.7 Lessons from other failed trial: the pragmatic trial in context

The trial planned to recruit 36 participants and it achieved that target. However, the trial could not be followed up for the anticipated 12 months' period and had to be stopped. The immediate reason that led to the stoppage of the trial was that the only remaining nurse left the job and there was no nurse to monitor the telehealth service. It was therefore deemed unsafe to continue with the service as it was. The underlying reason was that the trial was considered to be premature; it should have been preceded by a pilot to assess the process outcomes. This would have uncovered a lot of the issues related to staff, technology, and patients. Lessons learnt from the pilot could have strengthened the conduct of the pragmatic trial.

It was the plan to increase the sample size of the trial from 36 to 80 participants, but this did not happen due to factors related to recruitments, and changes to the technologies, among others.

Research has shown that a third of trials managed to recruit less than 75% of planned subjects; and that reluctance of clinicians was a greater obstacle to successful completion of trial, than reluctance of patients (Rendell et al., 2007). A review by Rendell et al. (2007) investigated factors that were considered as incentives or disincentives to clinicians to participate in recruiting patients into studies. They found that motivation was more important than simply being acquainted with the researchers (Rendell et al., 2007). In this pragmatic trial, the clinicians involved were largely not acquainted with the researcher; instead, some of the nurses who were considered to be more acquainted with the researcher resisted participating in telehealth. The reason they gave, included the view that some patients were not suitable as they were end-of-life or palliative patients. They also considered that any funds available could be used for alternative causes such as recruiting more nurses rather than for procuring telehealth devices. There were fears also expressed by community nurses that telehealth, if shown to be successful, might replace nursing jobs. There was similarity in the findings in this trial to that of the review by Rendell et al. (2007) related to potential increased workload to clinicians resulting from recruitment of participants. The potential increase in workload during the trial could be from red alerts generated from telehealth. Rendell et al. (2007) review also identified the same concern expressed by clinicians about randomisation process, which was not considered to be selecting the intervention clinicians perceived to be beneficial for their patients selected for the trial. This was one of the reasons for local resistance to participate in this pragmatic trial on telehealth. The other factors that were also experienced in this trial, also reported in the review (Rendell et al., 2007), were related to too stringent criteria. There was lack of

availability of dedicated staff in recruitment of participants. Participation of an academic research group was viewed to be a positive factor in helping to increase recruitment to research studies (Rendell et al., 2007). However, this trial did not have participation of an academic research group as such, but it was linked to an academic institution through PhD supervised study programme at the University of Leeds, Institute of Health Sciences being undertaken by this author. Another concern identified by Rendell and colleagues was about damage to doctor-patient relationship which was considered to be a potential disincentive to participation in research. In this trial, it was found that where doctors (GPs) were not fully aware of the telehealth service and they did not know what to do in case they were contacted by a community matron; they were less likely to engage positively with the patients. Some patients withdrew from the trial for fear of not damaging their relationship with their doctor, when they found that the GP were negative about telehealth service.

Another review evidence from the literature to contextualise findings of the trial came from the findings of a report by Health Technology Assessment (Campbell et al., 2007), which examined factors associated with good and poor recruitment into multicentre trials. The authors found that of the 114 trials reviewed, less than one third (31%) successfully recruited participants to their original target. The pragmatic trial reported in this chapter managed to recruit to the original target. However, it did not recruit to the amended protocol target of 80 participants due to stoppage of the trial. Factors identified for successful recruitment into a trial included those summarised in Table 5.11, and these were contextualised for the pragmatic trial into factors met and unmet in the course of the trial (Campbell et al., 2007).

Table 5.11: Factors influencing successful recruitment into trials

Source: (Campbell et al., 2007)

<p>Factors met in this trial (TELECCOM study)</p> <ul style="list-style-type: none"> • Having intervention only available inside the trial • Trials addressing clinically important questions • Need of patients were considered to be well served in the trial • Trials were grounded in existing clinical practice • Funders monitoring progress of the trials • Feelings of pride in taking part in the trial. • Investigators were held in high esteem
<p>Factors not met or limited evidence in this trial (TELECCOM study)</p> <ul style="list-style-type: none"> • Trial flexible and robust enough to adopt to changes • Having dedicated trial manager • Being a cancer or drug trial • Using newsletters and mailshots to communicate about the trial • Clear delineation of roles, which released the research collaborators from workload related to the trial participation. • Team building • Training about trial intervention and processes • Good ground work and excellent communication • Use of business model (framework) to recruit participants into the research: (i) building brand value; (ii) product and market planning; (iii) making the sale; and (iv) maintaining engagement.

A lot of the factors identified in Table 5.11 were lacking in the trial. Although there was Assistive Technology Manager recruited to post at the beginning of the trial, this was only temporary. The employment contract ended and the individual left the job before all participants were recruited into the trial.

Telehealth service, as an intervention, was available for those inside the trial.

The trial was neither for cancer nor drug trial. Communication could have been

improved, and there was no arrangement made for neither newsletter nor mailshots to communicate with clinicians, including GPs, to inform them about the trial. However, there was a GP represented in a steering group for the project.

The investigators were local clinicians / public health leaders in their respective fields, and the initiative of the trial was considered to be in the best interest of patients. Despite efforts to agree roles of collaborators in the trial, to ensure workloads were not unnecessarily increased, this was not realised; as line managers of the community nurses maintained normal duty in addition to that of the trial. No qualitative data was gathered at this stage of the trial in order to determine participants' feelings towards the project, because the trial was stopped prematurely. Some training was delivered to staff but this was considered to be inadequate. An update of the project progress was provided to the organisation management of Doncaster Primary Care Trust, including mitigation measures being considered at the time. The original inclusion criteria offered little flexibility in carrying out the trial. No business model approach was used to try to recruit participants into the trial. It is possible that this would have improved recruitment and identified resource gaps early, to allow them to be addressed. From the above analysis, it appears that the performance of the pragmatic trial, in terms of staff factors, recruitment of participants, and factors related to the technology, could have been improved if some of the factors above were considered and addressed, within the limitation of the resources available at the time.

5.8 Clarification of methods and findings in a separate publication

This section provides clarification on why logistic model was used by the author in a separate publication and the ethical implications of post-hoc outcomes.

The findings of the trial and that of a separate observational study had been published in a book chapter (Joseph, 2013). The article concluded that telehealth was effective in reducing hospital admissions among patients with COPD, heart failure and diabetes. The analysis of the trial, which focused on patients with COPD, was performed using hospital admission and logistic regression modelling. Since the trial was small, randomisation may not have balanced all factors between the two arms. Thus, an analysis with adjustment for baseline factors, using logistic regression modelling, would be reasonable and might also give further understanding of the impact of factors on the outcome. For the book chapter, the RCT protocol, which is usually preferred for reporting in the academic literature, had been adhered to. The results show a non-statistical significant reduction in hospital admission rates, while logistic regression analysis showed a statistically significant reduction in hospital admissions (odds ratio of 0.80; 95%CI: 0.01, 0.81; p -value 0.03). The logistic regression model performed could be considered as a post-hoc analysis, in view of the fact that it was not explicitly stated in the study protocol. The use of post-hoc outcome analysis had been recognised as an important analytical tool in research (Elliott, 1996). There are however limitations of the use of post-hoc

analysis (Elliott, 1996, Stefansdottir et al., 2013), as well as its associated ethical implications (Leung, 2011).

Logistic regression analysis could have been included at the design stage of the trial, but this was considered after registration for the PhD programme (see PhD study line in Chapter 1, Figure 1.3). Following expert statistical advice and further training received in handling statistical analyses for the trial, as part of PhD study, this was able to be undertaken.

The justification for the use of logistic regression, as post-hoc analysis, includes the fact that it focuses on hospital admissions as categorical variables, viewing analysis from the angle of whether or not patients with COPD were admitted to hospital. It was considered to be an appropriate and important analysis to perform. Future research in this area should include this analysis as part of the hypothesis (*a priori* hypothesis – pre-specified).

The limitation of the use of logistic regression analysis, as a post-hoc analysis, is that it can be criticised for attempting to find particular outcomes or relationship, which had been referred to as data fishing, mining or dredging (Smith and Shah, 2002). In the case of the trial, the post-hoc analysis could be accused of actively trying to find evidence of reduction in hospital admissions in relation to the use of telehealth. The chance of finding false statistical significant results is increased where multiple tests are carried out. It is possible that the logistic regression findings of the trial could uncover false statistically significant results, especially given the small sample size. The post-hoc findings from the trial using logistic regression model should be considered as exploratory only: as providing *potential associations*, rather than *testing whether telehealth is*

effective. The overall conclusion of the article (Joseph, 2013), is based not only on the findings of the trial, but also on the findings from the observational study, which was conducted separately and included different patients population (patients with COPD, heart failure and diabetes). In the observational study, the regression model was pre-specified as an analysis tool to predict the effects of the intervention on hospital admissions and other secondary health outcomes.

The ethical implication of post-hoc outcomes is that presenting the finding as though they are *a priori* (pre-specified) is likely to breach the ethical conduct of research (Leung, 2011). Leung (2011) suggested two options to remedy the challenge, either researchers could delete the rejected hypotheses or modify the hypotheses based on empirical findings. In this chapter, the number of hospital admissions is a pre-specified outcome, and there are multiple approaches used in performing the analyses.

5.9 Chapter conclusions

Telehealth, as used in the trial, was neither effective nor cost-effective in reducing hospital admission rates among high risk patients with COPD living in the community. Compliance with telehealth home monitoring was high among patients with COPD. However, the rates of red alerts generated from telehealth were also very high, which could increase workload of staff and posed safety concerns.

Chapter 6: Assessing Embeddedness of Telehealth Service in Routine Practice: A Service Evaluation

6.1 Introduction

The previous two chapters of this thesis addressed the effectiveness of a telehealth service in reducing hospital admissions among other health outcomes. This was achieved by reviewing the literature, and conducting a pragmatic randomised controlled trial (RCT). The current chapter is dedicated to assessing embeddedness of a telehealth service in routine healthcare practice.

Embeddedness is defined as the process of “making practices routine elements of everyday life” (May and Finch, 2009). Along with social organisation of work (implementation), and sustainability of embedded practices in social context (integration); embeddedness forms part of Normalisation Process Theory (NPT) (May and Finch, 2009), which was described in Chapter 2.

Implementation of innovation, such as new technology, involves a range of activities, from making adoption commitment to when an innovation either became routine in an organisation, or when it ceased to be new or was abandoned (Linton, 2002). Linton (2002) further noted similar attitudes among staff involved in implementation of innovation, which were characterised by avoidance, compliance, or skilled use of a new technology.

Embeddedness is important in helping to understand why innovation, such as implementation of new technologies, fails or succeeds in routine health services. The factors, which determined embeddedness of new practices in relation to NPT were described previously, in Chapter 2.

6.1.1 Backgrounds and rationale

The pragmatic trial on telehealth was stopped prior to its planned completion. The reasons for stoppage were outlined in Chapter 5. Fundamentally, it became apparent that there were many factors in the trial that were contributing to making it less likely to achieve valid results. These factors were not fully anticipated at the time, including the challenges related to staff, recruitment of participants, and the technology, among others. Analysis following the trial revealed little evidence that the telehealth service made any difference in hospital admission rates among community-dwelling patients with COPD, and there was also little evidence regarding its cost-effectiveness.

The service evaluation (observational study) was a new phase of implementation of telehealth following the stoppage of the pragmatic trial. The strict eligibility criteria and randomisation process associated with the trial were removed. Less onerous eligibility criteria for inclusion in the study and follow-up of patients were adopted as part of the service evaluation.

The main purpose of the current chapter is to understand why new technologies embed or not in routine practice, rather than to assess the effectiveness of telehealth. At this stage, lessons were learned from the pragmatic trial that could be transferred to the service evaluation, to improve the implementation of telehealth. There was also the need to observe how telehealth operated rather than to impose an artificial environment similar to that of the trial for the staff and patients in particular. A simpler and faster means of evaluation based on a greater number of patients receiving telehealth was needed, and the service evaluation offered this flexibility.

There is no accepted quantitative measure of embeddedness in the published literature. It has been identified that acceptance of telehealth by users is an important factor in the implementation of a telehealth service (Broens et al., 2007, Joseph et al., 2011). A systematic review by Gorst et al. (2014) used acceptance rate as a measure of uptake rate of telehealth service. They found that the uptake of telehealth among patients with heart failure and COPD was 67.9% (640/942) (Gorst et al., 2014). Therefore, it was decided to use the uptake rate of telehealth as a quantitative measure of this aspect of embeddedness for the service evaluation study. The overall uptake rate (67.9%) found by Gorst et al. (2014) was used as the standard to judge embeddedness and to pose hypotheses tests.

6.1.2 Objectives

The main objective of this chapter is to assess the embeddedness of a telehealth service in routine healthcare practice.

Other secondary objectives are to assess compliance of patients with telehealth home monitoring and the associated levels of red alerts; and to assess patients' levels of satisfaction with the service.

The primary difference between Chapter 5 and Chapter 6 are in the following areas: (1) Chapter 5 assessed the effectiveness of telehealth service, while Chapter 6 assesses uptake of a telehealth service; (2) the evaluation designs of the service are different, along with selection of participants; and (3) patient groups are also different. The evaluation design in Chapter 5 was a pragmatic trial focusing on patients with COPD, while Chapter 6 is a service evaluation

involving patients with long-term conditions (e.g. COPD, heart failures, and diabetes, among others).

6.1.3 Hypotheses

The null hypothesis was that the uptake rate of the telehealth service would be 67.9%; similar to that observed in the systematic review (Gorst et al., 2014).

The alternative hypothesis is that the uptake of the telehealth service would differ from 67.9%; with a lower rate suggesting the lack of uptake and therefore embeddedness of the telehealth service; and a higher uptake of telehealth service would support the case for embeddedness.

It was hypothesised that the telehealth service would embed in routine health service in this service design. Embeddedness of telehealth service would be demonstrated if:

Primary outcome

1. There is a statistically significant increase in the proportion accepting telehealth service over the whole study period.

Secondary outcomes

2. Generalised linear modelling shows a high acceptance rate of the telehealth service over time.
3. Compliance rates (percentage of readings received versus expected) with the telehealth service are the same or better than that observed in the pragmatic trial (86.5%).

4. The rates of red alerts generated from the telehealth service during the service evaluation study are significantly lower than 82.6%; the rate of red alerts observed in the pragmatic trial.

6.2 Methods

6.2.1 Study design

The study is a service evaluation, which may be regarded as a cohort study in terms of telehealth home monitoring, including compliance to the telehealth service and red alerts. A cohort study is a specific type of an observational study where patients are followed up over time. Selected patients with long-term conditions (COPD, heart failure, and diabetes) and under the care of community nurses were offered telehealth service and followed up over a 24-month time period.

6.2.2 Setting

The study was conducted in Doncaster, a district in England, involving patients with long-term conditions who were under the care of community nurses (community matrons or heart failure nurse) and living in the community. A detailed description of Doncaster, as the study setting, was reported in Chapter 3, this contains population profile, geographical location and deprivation status.

6.2.3 Participants: eligibility criteria, selection and follow up

The main criteria for participants recruited onto the telehealth service were that they had long-term conditions and were under the case-load of community

nurses. Cases that made up community matron workload were selected based on patients who were considered to have intense health needs; often with multiple hospitalisations in the previous year and therefore regarded as most complex; they were also referred to as Level 3 long-term condition patients (Department of Health, 2006). Long-term condition cases that were considered to be under Level 1 and 2 were not part of community matron caseload, as they could be managed under disease specific protocol or by self-care. Cases on community matron workload were identified with the help of the English Department of Health risk prediction tool, which was referred to as "*Patients at Risk of Re-hospitalisation*" or PARR. The tool predicted the likelihood of a patient being admitted to hospital in subsequent 12 month period (Department of Health, 2006).

Recruitment into the study was undertaken by community nurses; who were either community matrons or heart failure specialist nurses. The community nurses had a number of patients under their care, with each nurse expected to manage up to 50 patients. The patients were considered to be in stable conditions. The community nurses had freedom to choose from among the patients on their caseload those patients whom they considered to be suitable for telehealth. These patients were then referred to the telehealth service under the coordination of a Telehealth Coordinator.

Consents from patients were obtained by community nurses before being offered the telehealth service. After obtaining consents from patients, the Telehealth Coordinator then installed telehealth device for the patients. Patients were free to withdraw from the service at any time of the telehealth service.

The author worked with the nurses and involved them in agreeing the new approach for selecting patients. This contrasted with the pragmatic trial, where nurses had no choice of which patients would get telehealth service. In this study, nurses were in control of selecting the appropriate patients for telehealth service, based on their own clinical assessment.

The recruitment of patients onto the telehealth service and their subsequent follow-up and analyses were on-going during the period from March 2010 to June 2012 for uptake of the telehealth service. A number of sub-analyses were undertaken over different shorter time-scales, but within the above broad time-frame. This was to investigate a number of outcome variables, for example compliance rate, acceptance of telehealth service, satisfaction with the service, etc.

6.2.4 Variables

The case definition was based on patients diagnosed with long-term conditions considered as requiring intensive use of health care (Level 3) see above; and patients had to be under the care of a community matron or specialist heart failure nurse. Referral to telehealth service was only received from community matron or heart failure nursing teams. The selected participants were offered the telehealth service (see description in Chapter 3).

- (1) The primary outcome measure for embeddedness of telehealth was the proportions of users accepting telehealth service over the whole study period. This was compared with an acceptance rate of 67.9% (640/942) in the previous systematic review (Gorst et al., 2014).

The secondary outcomes were:

- (2) Generalised linear modelling for binomial family of acceptance rate of telehealth service by month.
- (3) Compliance rate with telehealth service: percentage of readings received versus expected; and rate of readings received per day and per week
- (4) Proportion of red alerts generated from the telehealth service.

6.2.5 Data sources / measurement

The measures of embeddedness were based on uptake of telehealth under natural healthcare condition. Acceptance of the telehealth service was defined as proportion of patients who were referred to telehealth service and who subsequently used the service.

Compliance rate during the study period was calculated as percentage of actual readings in relation to the expected readings; while rates of red alerts were calculated as a proportion of all alerts received. Two readings were expected per day, one in the morning and the other in the afternoon, taken at specified time suitable for patients and agreed with the community nurse. A three-month sample was taken in order to assess compliance by patients' characteristics, including sex, age groups, diagnoses, and current or ex-users of telehealth service.

The telehealth Integrated Care Platform (ICP) Triage Manager (Tunstall online database for monitoring patients' vital signs) was accessed using a secure username and password. A compliance report was obtained from the ICP Triage Manager, which detailed the compliance status for each patient to

telehealth home monitoring. The telehealth readings were manually extracted and transferred onto an excel spread sheet for further analysis. The following colour codes were used to interpret the readings on patients' online home telehealth monitoring record (Table 6.1).

Table 6.1: Severity legend of telehealth readings

Colour	Classification	Meaning
	Red	High risk answers or vital alerts (outside parameters set)
	Amber	Medium risk answers, no vital alerts
	Blue	Reading not submitted when expected (patient non-compliance)
	Grey	Lost contact (no response from patient's equipment)
	Yellow	Incomplete data (reading submitted with missing data)
	Green	Low risk answers, no vital alerts (vitals within limits, questions with no or low risk)

A monthly trend of all active cases on telehealth between April 2010 and June 2012 was produced from Tunstall online database of patients' records of telehealth users.

6.2.6 Study size

The findings from Gorst et al. (2014) on proportion of patients accepting a telehealth service was used as comparison of proportion accepting the telehealth service in the observational study. The power of the study to detect embeddedness of the telehealth service was calculated using Stata version 11.1 Software.

The report from Gorst et al. (2014) can be summarised, as would be done with meta-analysis, as an uptake by 640 of 942 patients, giving a rate of 0.679. For the service evaluation, it was anticipated that 147 patients would be offered telehealth during the study period. To provide a guide to the power that would arise from a test of proportions, the following calculation was undertaken. Using the following Stata command: *sampsi 0.679 0.810, n1(942) n2(147)*; where:

Test Ho: $p_1 = p_2$, where p_1 is the proportion in population 1;
and p_2 is the proportion in population 2;

Assumptions: $\alpha = 0.0500$ (two-sided); $p_1 = 0.6790$; $p_2 = 0.8100$;
sample size $n_1 = 942$; $n_2 = 147$; $n_2/n_1 = 0.16$;

This determined the power of the study to be 0.9065 (or 90.7%). Therefore, a difference in uptake of +/-13% can be detected with a power of at least 90%.

6.2.7 Quantitative variables: statistical analyses

Statistical analyses were performed using Z-test for proportions (as outlined in the sample size calculation above) or equivalently a chi-squared test and Generalised Linear Modelling Binomial Regression, using Stata version 11.

Chi-square test was performed using Chi-square Calculator (Stangroom, 2015) to detect difference in proportion of existing users of the telehealth service in the systematic review by Gorst et al (2014) and the current observational study.

Monthly numbers of existing users of telehealth was presented graphically.

Summary statistics were produced in a tabular format for compliance rates and rates of red alerts to telehealth service. Test of two proportions and Chi-squared test were undertaken to assess difference in acceptance of the telehealth service. The monthly uptake data and the compliance data were generated from Tunstall online database for telehealth; the Integrated Care Platform (ICP). This was analysed using an Excel spread sheet to calculate summary statistics, such as compliance per person per week. A structured satisfaction questionnaire was analysed, which represented a sample of existing users of telehealth service during the period April 2012 and June 2012.

6.3 Results

6.3.1 Participants at each stage of the study

There were 204 paper referrals made to the telehealth service during the period from March 2010 to August 2011, from 147 patients. Some patients were referred more than once to the service. Referrals were linked with patients on telehealth service using their NHS number. One hundred and nineteen patients (81.0%) that were referred to the telehealth service were able to use the service, while 28 (19.0%) patients referred for the service did not use it.

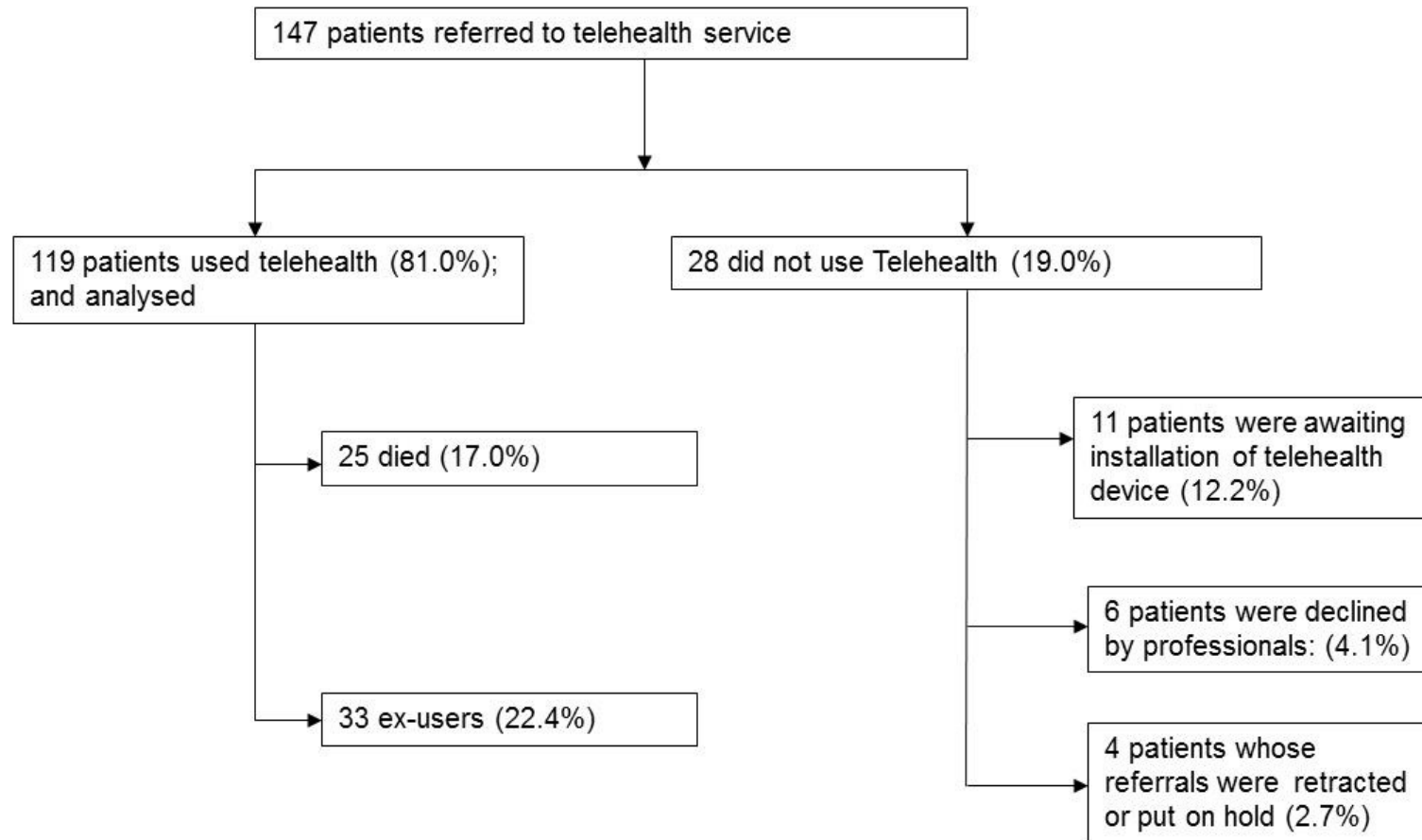
The reasons for not using the telehealth for the 28 patients who were referred to the service included: 11 (12.2%) patients were awaiting installation of the telehealth device; 6 (4.1%) patients were declined telehealth by professionals because they were deemed unsuitable for telehealth service; and 4 (2.7%) patients had their referral withdrawn by referring health professional.

All 119 patients who used the service were followed up and analysed. They included 33 (22.4%) ex-users of telehealth service. There were also 25 deaths (17.0%) during the study period.

6.3.2 Flow chart

Figure 6.2 shows referral of patients to the telehealth service, and those who subsequently used the service, were followed up. It also shows patients who were referred but did not use telehealth service.

Figure 6.2: Flow chart showing referral to telehealth service: March 2010 to August 2011



6.3.3 Descriptive data: study participants

There were a total of 119 users of telehealth during the study period, from March 2010 to August 2011. An analysis of users of the telehealth service revealed that the majority of them (49%) were patients who were issued with devices for congestive heart failure (CHF). A total of 41% of patients were issued telehealth devices for patients with COPD; 9% of patients were given devices, which were referred to as Chronic Disease Management (CDM), for patients with both COPD and heart failure; and 1% of patients received device for those with diabetes. The 9% of patients who received telehealth devices designed for CDM was given to patients with COPD and heart failure, based on the clinical judgement of the community nurses at the time. The 9% of patients did not represent all patients in the study with multiple comorbidities. Most of the patients with heart failures and COPD were likely to have multiple conditions even though they were not explicitly identified.

The sex profile was 58% males and 42% female, while the age distribution varied with majority patients concentrated in the age group of 70-79 years old (Table 6.2), with average age being 70.6 years old.

Table 6.2: Age and sex profile of patients on telehealth service

Age groups (years)	SEX				All persons	
	Male		Female			
	n	%	n	%	n	%
Less than 50	4	3.4	3	2.5	7	5.9
50-69	6	5.0	7	5.9	13	10.9
60-69	20	16.8	11	9.2	31	26.1
70-79	22	18.5	14	11.8	36	30.3
80-89	15	12.6	14	11.8	29	24.4
90 and over	2	1.7	1	0.8	3	2.5
All ages	69	58.0	50	42.0	119	100.0

6.3.4 Descriptive data: follow-up time

Embedding of telehealth was analysed based on active users of telehealth service per month between April 2010 and June 2012, see Figure 6.3. The compliance to telehealth home monitoring was analysed over 17 months during the period from April 2010 and 31 August 2011 based on readings received, expected number of readings, and alerts generated.

A sub analysis of compliance by sex, age groups, diagnoses, and discharge from telehealth service or active users was performed for a cohort of patients over a 3-month follow-up period between 1 July 2010 and 30 September 2010. This analysis was to gain an in-depth understanding of compliance to telehealth service by various patients' characteristics.

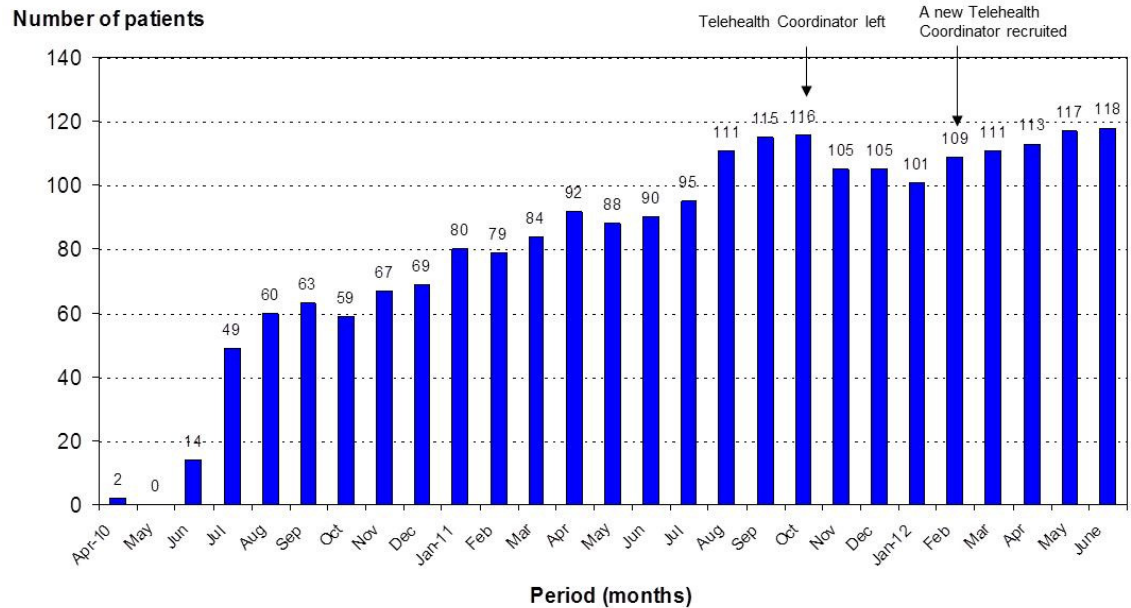
6.3.5 Outcome data on embeddedness of telehealth service

6.3.5.1 Uptake of telehealth service

It was found that uptake of the telehealth service increased steadily over time between April 2010 and June 2012 (Figures 6.3). Evidence of the importance of the role played by staff in recruitment and implementation of the telehealth service is illustrated by uptake of telehealth when the Telehealth Coordinator was in post from February 2010, until when she left the job in October 2011. After this period, recruitment of patients into the service not only stopped, but started to decline when there was no dedicated Telehealth Coordinator in post. Tunstall was contracted to monitor the existing patients during the period following the departure of Telehealth Coordinator from October 2011 and February 2012. However, it did not recruit new patients during this time. A new

Telehealth Coordinator was recruited in February 2012, after which, uptake of telehealth began to rise again (Figure 6.3).

Figure 6.3: Existing number of patients on telehealth in Doncaster per month April 2010 to 26 June 2012



Statistical tests

Compared to telehealth service acceptance rate of 67.9% (95% CI: 64.9%, 70.9%) found in the systematic review by Gorst et al. (2014), the findings on acceptance rate in the whole observational study period was statistically higher at 81.0% (95% CI: 74.7%, 87.3%); $p = 0.001$ (Table 6.3). The Chi-square statistic (10.1934) also showed statistically significant difference in acceptance rates between Gorst et al. (2014) and the current study, ($p = 0.001$) (Table 6.4). The Chi-squared test is almost equivalent to the z-test for proportions and both tests are presented here to enable comparison with the approaches taken by other authors. Either test could have been selected.

Table 6.3: Two-sample test of proportion of users accepting telehealth service

Variables	Mean	Std. Err.	z	P> z	[95% Conf. Interval]
x	.679	.0152111			.6491867 .7088133
y	.81	.0323564			.7465826 .8734174
diff	-.131	.0357536			-.2010757 -.0609243
	under Ho:	.0407658	-3.21	0.001	

Note: Where x is the number of observations in Gorst et al (2014) = 942; y is the number of observation in current work = 147. Stata command used in the analysis was: *prtesti 942 0.679 147 0.810*

Table 6.4: Chi-squared test: refusal and acceptance of telehealth between Gorst et al. (2014) and the observational study

	Gorst et al. (2014)	Observational Study	Totals
Refused telehealth	302 (285.45) [0.96]	28 (44.55) [6.15]	330
Accepted telehealth	640 (656.55) [0.42]	119 (102.45) [2.67]	759
<i>Totals</i>	942	147	1089 (Total)

Chi-square statistics = 10.1934; p=0.001409

Sub analyses of telehealth service uptake: statistical tests

A sub-analysis of the uptake of the telehealth service, based on those accepting referral to the service, indicated that acceptance rate of the telehealth service over time remained high. The average acceptance rate of the telehealth service for the first five months was 91.1% (ranging from 66.7% to 100.0%). While the average uptake of telehealth service for the three months towards the end of the service was 90.0% (range 83.3% to 100.00%). The uptake rate by months for the sample period for undertaking binomial regression analysis is shown in Table 6.5.

Table 6.5: Acceptance rate of telehealth over time

Month	No. Referred	No. Accepted	Percentage accepted
01/04/2010	20	16	80.0
01/05/2010	3	2	66.7
01/06/2010	6	6	100.0
01/07/2010	14	14	100.0
01/08/2010	13	13	100.0
01/03/2012	6	6	100.0
01/04/2012	8	7	87.5
01/05/2012	6	5	83.3

A binomial regression analysis showed that there was no statistically significant difference in uptake of telehealth service over time ($p = 0.864$; OR= 1.000 per month 95% CI: 0.998, 1.003), (Table 6.6).

Table 6.6: Acceptance of telehealth service among those referred to the service: binomial regression analysis

Accepted	Odds Ratio	EIM* Std. Err.	z	P> z	[95% Conf. Interval]
Month	1.000235	.0013688	0.17	0.864	.9975557 1.002921
_cons	.1255659	3.191612	-0.08	0.935	2.91e-23 5.43e+20

*EIM = Expected Information Matrix

Stata command: *binreg Accepted Month, or n(Referred)*

6.3.5.2 Compliance with telehealth service

During the period covered in the analysis of telehealth compliance (1 April 2010 to 31 August 2011), a total of 28,873 telehealth readings were received from telehealth monitoring system (ICP Triage Manager, Doncaster). The compliance rate of telehealth home monitoring was 87.6% (95% CI: 87.2, 88.0). This

represented 25,258 actual readings received from both vital signs and individually tailored questions from the telehealth home monitoring service. A third of the total readings (32.4%; n=9,341) were classified as low risk (green); while 43.9% (n=12,687) were considered as high risk, generating red alerts on the telehealth home monitoring system (Table 6.7).

The mean number of readings per person was 166, and the mean compliance was 84 readings. The corresponding mean readings for red alerts was 73 per person; and that for low risk (green) was 54 (Table 6.7).

Therefore, the main finding from the telehealth monitoring was that it generated 12,687 readings, which was an equivalent of 43.9% of all the readings. This amount of red alerts required assessments and appropriate interventions by a nurse, and consequently they generated additional workload.

Table 6.7: Compliance to telehealth in Doncaster by alert categories
Between 1 April 2010 to 31 August 2011

Variables	Total		Mean per person
	n	% (95% CI)	n (95% CI)
Readings	28,873	100.0 (100.0, 100.0)	165.9 (145.6, 186.3)
Alerts	19,026	65.9 (65.3, 66.4)	109.3 (88.1, 130.6)
SEVERITY:			
High (Red alert)	12,687	43.9 (43.4, 44.5)	72.9 (60.9, 85.0)
Moderate (Amber)	28	0.1 (0.1, 0.1)	0.1 (0.00, 0.04)
Low (Green)	9,341	32.4 (31.8, 32.9)	53.7 (44.7, 62.7)
Missed	3,202	11.1 (10.7, 11.5)	18.4 (13.5, 23.3)
Compliance	25,258	87.6 (87.2, 88.0)	84.4 (82.3, 86.5)

Note: based on reading from verified number of 119 patients. Compliance = (High + Moderate + Low + Missed)/Readings x 100). Missed reading = vital signs and questions reading received with some missing readings.

6.3.5.3 Compliance with telehealth service: 3-month audit

Compliance rate to telehealth service by age group was categorised in five age bands and the results are shown in Table 6.8. A more detailed analysis of compliance was carried out on a sample of data covering a three-month time period. The three-month compliance data (July 2010 to September 2010) revealed a compliance rate of 90.1% (95% CI: 89.2, 91.1) with telehealth home monitoring. There was variation in compliance rate by sex, age-group, diagnoses, and discharge status from telehealth monitoring. There was a slightly better compliance among females than males, and older patients aged 70 years old and over complied better than those below the age of 70 (Table 6.7).

Based on utilisation of telehealth consultations per person per week (c/p/w), the average consultation per week per person was 6.8 (95% CI: 6.2, 7.4) or the equivalent of at least one telehealth reading per person per day.

There were 3489 readings, which contained vital signs or responses to questions. Of these, 2669 readings (68.8%) were considered as alerts. The main finding of the compliance was that sixty-two per cent (62.1%, n=1658) of all the alerts were rated as severe (red alerts).

Table 6.8: Patients compliance to telehealth service by sex, age-groups and diagnoses

Telehealth home monitoring in Doncaster: 1 July 2010 to 30 September 2010

Variables	Actual Readings (Vital signs and questions)		Missed Reading		Total Readings		Compliance
	n	%	n	%	n	%	% (95% CI)
Total	3498	90.1	383	9.9	3881	100.0	90.1 (89.2, 91.1)
Sex:							
Male	1996	88.8	251	11.2	2247	100.0	88.8 (87.5, 90.1)
Female	1502	91.9	132	8.1	1634	100.0	91.9 (90.5, 93.2)
Age-groups:							
<50	307	84.8	55	15.2	362	100.0	84.8 (80.7, 88.3)
50-59	242	79.9	61	20.1	303	100.0	79.9 (74.9, 84.2)
60-69	1128	90.8	114	9.2	1242	100.0	90.8 (89.1, 92.4)
70-79	1095	92.5	89	7.5	1184	100.0	92.5 (90.8, 93.9)
80+	726	91.9	64	8.1	790	100.0	91.9 (89.8, 93.7)
Diagnoses:							
CDM*	235	84.8	42	15.2	277	100.0	84.8 (80.1, 88.8)
CHF**	1661	86.5	260	13.5	1921	100.0	86.9 (84.9, 88.0)
COPD***	1602	95.2	81	4.8	1683	100.0	95.2 (94.1, 96.2)
Discharged from telehealth:							
No	2980	90.9	299	9.1	3279	100.0	90.8 (89.8, 91.8)
Yes	518	86.0	84	14.0	602	100.0	86.0 (83.0, 88.7)

Note: CDM*=Chronic Disease Management Telehealth units or multiple co-morbidity; CHF** = Patients with congestive heart failure machine; COPD*** = Patients with chronic obstructive pulmonary disease telehealth units.

6.3.5.4 *Levels of satisfaction and experience with telehealth service*

A self-completion satisfaction survey, on a sample of 52 (44.8%) active users of the telehealth service during a three-month period between April to June 2012, yielded a completion rate of 69.2% (n=36). There was a 100% satisfaction rate with the telehealth service among those surveyed. The different perspectives of patients on various aspects of the telehealth service are presented in Table 6.9, which suggest favourable experiences with telehealth service.

Table 6.9: Experience of patients in relation to telehealth service

Variables	Strongly agree	Agree	No opinion	Disagree	Strongly Disagree
	n (%)	n (%)	n (%)	n (%)	n (%)
I received an explanation of how to use the monitor, in terms I could understand.	23 (63.9)	13 (36.1)	-	-	-
The monitoring system is easy to use.	25 (69.4)	11 (30.6)	-	-	-
The monitoring system is/was useful in assisting me to manage my health.	24 (66.7)	9 (25.0)	3 (8.3)	-	-
I felt more involved in my care by participating in the telemonitoring programme.	24 (66.7)	11 (30.6)	1 (2.8)	-	-
I believe daily monitoring assisted the clinicians in understanding changes in my condition.	25 (69.4)	11 (30.6)	-	-	-
Home monitoring provided me with a sense of security and peace of mind.	27 (75.0)	7 (19.4)	2 (5.6)	-	-
I would recommend the use of daily home monitoring to my family and friends.	29 (80.6)	3 (8.3)	4 (11.1)	-	-

Note: Total (n) = 36 respondents

6.4 Discussion

6.4.1 Summary of key results with reference to study objectives

The main objective of the study was to determine embeddedness of the telehealth service in routine practice based on uptake of the service. The null hypotheses stated that the uptake rate of the telehealth service would be 67.9%, similar to that observed in the systematic review by Gorst et al. (2014). The findings of the current study showed that the uptake of telehealth was in fact significantly higher in the observational study, at 81.0% (95% CI: 74.7%, 87.3%); $p = 0.001$.

Acceptance of telehealth remained high from the beginning through towards the end of the assessment period. The null hypothesis was rejected in favour of the alternative hypothesis, that is, the evidence supports embeddedness of telehealth service in routine healthcare practice. There was however high rates of red alerts, and extra workload created in dealing with them. Compliance rate to telehealth home monitoring was 87.6%, and satisfaction with telehealth service was 100.0%. Acceptance of the telehealth service following referral remained high at around 90.0%, and there was no statistically significant difference over time, based on binomial regression modelling; ($p = 0.864$; 95% CI: 0.998, 1.00).

6.4.2 Limitations of the study

The main limitation of the study was that of selection bias by community matrons, as the eligibility criteria for the study was left to their clinical

judgements. As a result, it remained uncertain as to which group of patients were most suitable for telehealth service, since recruitment was undertaken based on the subjective views of clinicians. This was the compromise that was accepted in view of the challenges faced during the conduct of the pragmatic trial in order to observe uptake of telehealth service in routine practice.

There were also challenges of reconciling information sent to the telehealth service, such as referrals, to ensure that they were related to individual patients, rather than duplicate referrals of the same patients. Linkages were made using NHS number to ensure that duplicate referrals were identified.

The high rates of red alerts represented a major limitation to implementation of telehealth service. This could be due to technical issues related accuracy of vital sign readings or how staff set the alert parameters.

6.4.3 Interpretation of findings

The findings suggest that telehealth service was starting to embed in routine healthcare practice. The study shows a sustained increase in telehealth uptake over more than a year. The acceptance rate for the early months of implementation of the telehealth service was very high and, as such, it was difficult to improve on that. Patients appeared to accept the telehealth service and they were satisfied with it. Since the increase was sustained over a year, then the telehealth service in Doncaster could be described as having met the criteria for success advocated by Heeks (1999); where the major goals of stakeholders were met (Heeks et al., 1999).

Unfortunately, embeddedness was undermined by high rates of red alerts, which increased workload of staff. If a telehealth service is to embed in routine practice in the future, mechanisms to reduce the level of red alerts will need to be addressed in order make it more attractive for healthcare practitioners.

Telehealth service was more acceptable to patients in this study because of a number of factors, including improved features of the telehealth technology, which generated fewer red alerts compared to the pragmatic trial and the fact that community nurses had more control in recruiting patients. A fuller understanding of why and how new technologies fail or succeed to embed in routine practice is further explored in Chapters 7 and 8, using the NPT framework.

The uptake of telehealth service in the study was higher compared with some of the telehealth projects in England (Joseph et al., 2011), and in systematic review undertaken to assess acceptance and refusal of telehealth service (Gorst et al., 2014). The current study has produced a compliance rate for telehealth; evidence on compliance rate is limited in the published literature. Contrary to expectation, older people over 60 years of age appeared to comply better than those aged 50 years old and below. This suggests that older people, once trained, can engage effectively with new technology in health.

Between the pragmatic trial and observational study, there were significant changes in the physical structure and operation of telehealth technology, as shown in Table 6.10 below. At least five software changes were observed within a period of five years, which averaged at one software change per year.

Table 6.10: Key changes of versions of telehealth software/machines over time

Software version	Key operational features
RCT: Genesis (2007)	a) Patients' data could be accessible from only one base where computer was installed in a health centre by means of user name and password. b) Output could be produced in PDF and printed off or saved. It was not compatibility with excel spread sheet. c) Lots of wires connecting the peripherals d) No wireless machines; people without phone lines were excluded. e) Dedicated British Telecom phone line to operate the base unit.
Observational study: Lifestream – Honeywell HomMed (2009)	a) Patients' data could be accessed from multiple sites, but the computers from where access could be gained need installation of specific software. b) Output documents included PDF, which could be printed or saved. Output was compatible with excel spread sheet. c) Fewer wires; d) Options for wireless machine; patients without phone line could be given one.
Tunstall CSO (Clinical Systems Organiser)/ Telehealth (June 2010)	a) Patients' data could be accessed from multiple sites, without the need for installing special software on them; all what was required was user name and password. b) Output document include PDF, which could be printed and saved. c) Compatibility of outputs with excel spread sheet.
Tunstall icp (Integrated Care Platform), 2011	d) Fewer wires to be connected to electric sockets; blue tooth technology, which allowed for peripherals vital signs records to be transmitted to base machine without the need for physical connection by wires. e) Options of wireless machine for patients without phone line. f) Ownership of company also changed from Honeywell to a separate entity.
Mymedic (Tunstall, 2013)	a) Tailored vital signs and questions; large colour display; blue tooth; and secure N3 data storage.
Docobo Care Portal (Docobo, 2015) – <i>a new provider of telehealth service in Doncaster</i>	a) Can measure a range of vital signs, and ability to select tailored questions, camera for wound care. Mobile units that can be taken around the house, central docking station, all wireless. Patients can access own data.

6.4.4 Generalisability of the study results

The study shows that it is possible to implement and embed telehealth service in routine healthcare practice.

Overall, the telehealth service was acceptable to users, and they were satisfied with it. Older people (aged 60 and over), had been shown to comply very well with telehealth home monitoring once shown how to use it.

The study presents original contributions to knowledge on telehealth and its implementation in a routine healthcare setting. Specifically, the study contributes to understanding of embeddedness of telehealth in routine healthcare practice.

6.4.5 Conclusions

The telehealth service appeared to be embedding in routine healthcare practice in an observational study context. The service had high acceptance rate over time and patients were satisfied with it. The high uptake rate however was undermined by high rates of red alerts, which was lower than that found in the pragmatic trial. The compliance rate to telehealth monitoring was higher than that found in the pragmatic trial.

6.4.6 Funding

Funding for rolling out telehealth widely in Doncaster came from Doncaster Primary Care Trust (PCT), the responsible commissioner for health service in the area at the time of this study. The original study (pragmatic trial) was funded through Neighbourhood Renewal Fund and administered by Doncaster

Metropolitan Borough Council, as part of assistive technology grant by the Government in England (described in Chapter 3). The PCT commissioned telehealth service to be rolled out widely in Doncaster for patients with long-term conditions. It did not influence the evaluation design, analyses, outcomes and publication of the study findings.

Chapter 7: Interviews with Stakeholders on Why and How New Technologies Fail or Succeed to Embed in Routine Health Services: A Qualitative Study

7.1 Introduction

This chapter addresses the research question related to why telehealth, as an example of new technology, embedded or not in routine healthcare practice.

The reason for the focus on embedding was to understand why uptake of telehealth failed to embed in the trial, while it appeared to have embedded in the observational study. Understanding the reasons for this will help to increase future uptake of new technologies being introduced in routine health services.

The ultimate purpose of this knowledge is to improve health and to save lives of people suffering from long-term conditions.

The original protocol of the pragmatic randomised controlled trial (RCT) included conducting a qualitative study in order to determine the views of patients, and staff who were involved in telehealth service. Since the RCT was stopped, the qualitative study was not carried out. When the observational study was designed, conducting a qualitative study parallel to it was planned.

This chapter presents the views of stakeholders in relation to telehealth implementation. It uses a qualitative evaluation approach. The chapter contributes towards understanding of why and how telehealth service performs in routine healthcare practice. The objectives of the chapter are (1) to identify and describe a theoretical framework to help with interpretations of findings of

the study; (2) to determine how telehealth performed in routine practice, from qualitative perspective; and (3) to investigate factors that influenced the uptake of telehealth service in the observational study.

This chapter will contribute to answering the research questions stated in Chapter 1. The specific research sub-questions that are relevant include the following:

1. **Technology:** Are there factors associated with the new technology used in the randomised controlled trial (RCT) versus the ones used in the observational study that made a difference in uptake of the new technology?
2. **Patient group:** Are there factors related to the patient group recruited for the RCT as opposed to the observational study that made the difference in uptake of new technology?
3. **Staff:** Are there factors associated with staff involved in the RCT, as opposed to the observational study that made a difference in uptake of new technology?
4. **Evaluation:** Are there factors associated with RCT methodology approach, as opposed to observational study that made a difference in uptake of new technology?

This study is reported in line with recommended standard for qualitative study: *consolidated criteria for reporting qualitative studies (COREQ): 32 items checklist* (Tong et al., 2007).

The remainder of this chapter is structured as follows:

- A brief overview of Normalisation Process Theory (NPT), the main theoretical framework used in the thesis.
- Methods: a description of qualitative research methods used in this study; staff involved and reflexivity, study design (tools, data collection, and participants), and analyses.
- Results: four themes were identified that explained why and how telehealth performed in the observational study. The four themes covered factors related to (1) service design, (2) the technology, (3) staff and (4) patients and carers. The findings from the study showed that there was a mixed picture regarding performance of telehealth in routine practice, with both positive and negative views expressed by staff and patients. The benefits of telehealth appeared to outweigh its negatives as reported by patients and staff. The evidence also suggests that telehealth was starting to embed in routine practice but was not yet fully embedded.

A full discussion of the findings from this chapter is presented in Chapter 8.

7.2 Normalisation Process Theory

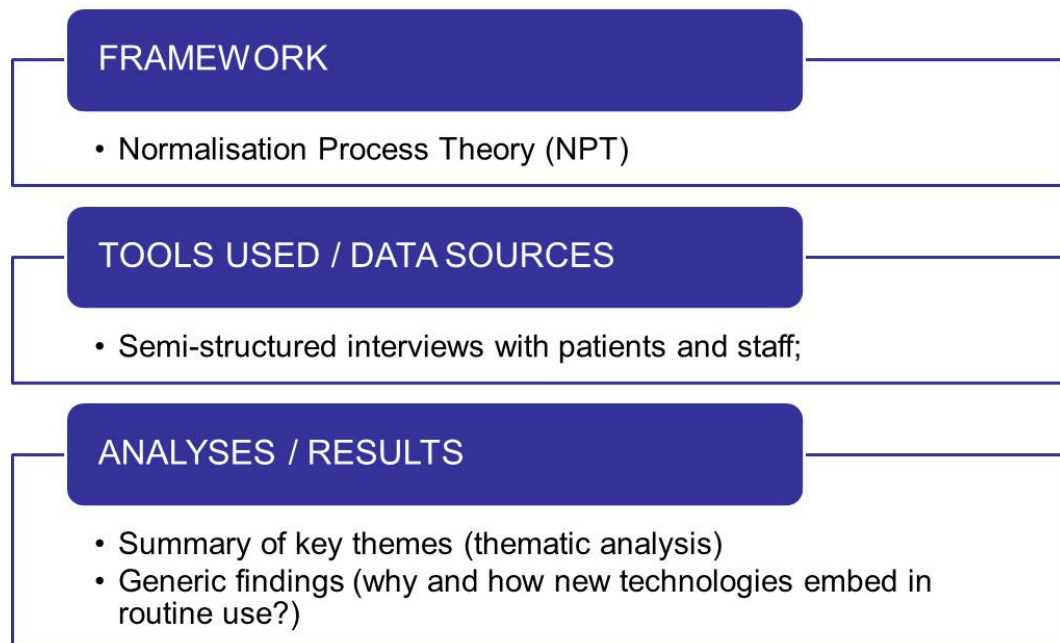
The theoretical framework used in this study is Normalisation Process Theory (NPT). It has been described in detail in Chapter 2. In brief, NPT helps to explain why and how new technology embeds in routine use through: (1) accommodation of new practice into social and organisation structures; (2) four stages of implementation: understanding the usefulness of a practice, decision to take part, collective actions, and collective efforts in evaluating the practice

as worthwhile; and (3) continuous investment of efforts of people involved in the implementation of a practice (May and Finch, 2009).

7.3 Qualitative case study methods

The methods used in this qualitative evaluation of the study are represented in Figure 7.1 below. The choice of method used for the qualitative evaluation was a pragmatic one, guided by NPT, and utilising interview questions relevant to the evaluation of telehealth service.

Figure 7.1: Summary of research methodology used



The research received favourable ethical approvals, and the details of ethical opinions are shown in Annex 2.

7.3.1 Qualitative research methods

Integrating quantitative and qualitative research methods in complex interventions had been recognised as best practice in understanding

implementation of complex interventions (Campbell et al., 2000). Further evidence of the importance of embedding qualitative study in the evaluation of telehealth is described in the literature review (Chapter 4).

There are several approaches to qualitative research (Creswell, 2007, Willig, 2008, Glaser and Strauss, 1967). Five main approaches to qualitative research had been described in the literature, which were described as follows: narrative research; phenomenology; grounded theory; ethnography; and case study (Creswell, 2007). According to Creswell (2007), a narrative research was best suited for understanding detail stories of a single individual or a small number of individuals; phenomenology research enabled understanding of several individuals' shared experiences of a phenomenon; grounded theory was helpful for generation of theory to explain a phenomenon, where there was no or incomplete theoretical basis; ethnographic studies was appropriate in describing how cultural groups operated and to explore their cultural behaviours; and case study research was used where there was clear identified cases with boundaries and an in-depth understanding of cases or where their comparison was needed (Creswell, 2007).

This study employed case study research methods, in enabling an in-depth understanding of telehealth implementation in a routine health care setting.

7.3.2 Staff involved in research and reflexivity?

The author interviewed the Telehealth Coordinator, and facilitated a group discussion involving stakeholders' event held on 29th March 2011 and analysed the results. The author is male, and he undertook qualitative evaluation as part

of his degree of Master of Public Health (MPH), which he held and he received appropriate training in research methods. At the time of the study, the author was employed with Doncaster Primary Care Trust (PCT) as a Consultant and Assistant Director of Public Health.

The service contract between the PCT and the provider organisation required that the provider would collect patient satisfaction feedback on regular basis. This was part of standard quality assurance requirements included in a range of services commissioned by the PCT, and telehealth service was one of them. The telehealth contract was written by the author and a Commissioning Manager for Long-term Condition, and it was approved by Programme Director for Long-term Condition at Doncaster PCT.

On behalf of the provider, the Telehealth Coordinator interviewed staff and patients on the experience related to telehealth service. This also enabled the process of collecting feedback from patients and staff to be seen as part of embedded routine delivery of health service, rather than as a separate initiative. The role played by the Telehealth Coordinator in interviewing both patients and some frontline staff, was in line with the service contract. The Telehealth Coordinator was a female, and she had experience of undertaking similar interviews, and possessed a bachelor degree. The Telehealth Coordinator had established some relationship with the patients and staff in that she installed telehealth machine in the homes of the patients, and she also trained the staff and helped them with any on-going problems at the time related to telehealth in use by patients. The author provided the Telehealth Coordinator with interview schedules (questions containing the guide) for interviewing patients and staff

(Annex 3), as well as a tape recorder for recording the interviews, as part of collecting patients' feedback. She undertook the interviews with community matrons, heart failure nurse, administrative staff, and healthcare assistants and recorded them. She transcribed the interviews and gave them to the author for analyses.

There was potential area of bias in the role of Telehealth Coordinator as being involved in implementing telehealth service as well as interviewing stakeholders. This bias was minimised by the fact that the Telehealth Coordinator had no direct healthcare responsibility for the patients, but this role rested with the community nurses; and the role that the Telehealth Coordinator played with the community nurses was that of coordination of the service. Most community matron involved in telehealth service would have known the Telehealth Coordinator. However, her involvement with patients was minimum and it related to installation and trouble-shooting if there was any problem with the telehealth equipment. Hence, many patients would not have known the Telehealth Coordinator as well as the nursing staff did.

At the start of the roll out of telehealth service, some of the patients were introduced to telehealth as part of the pragmatic trial, however, when the trial was formally stopped, the community nurses introduced telehealth to anyone of their patients that they considered to be appropriate, including those who were previously part of the trial.

The author approved the change in methodology from RCT design to service evaluation. In the service evaluation, the community nurses did not need to have patients whom they considered suitable for telehealth service to be

randomised into intervention and control groups. The author led the evaluation of the telehealth service, including the analyses of the results, and engaging with the local delivery and strategic groups on telehealth service. The author was the public health lead for respiratory disease, and COPD was part of this. He was responsible for delivery of health improvement strategy for people with respiratory diseases in Doncaster on behalf of the PCT.

7.3.3 Study design: tools, data collection and participants

The study adopts qualitative research approach, using case study research method, which allows for triangulation of data from both qualitative and quantitative sources and an in-depth understanding of the phenomena (Creswell, 2007). A further description of case study research method is outline in Chapter 8).

Interview schedules (semi-structured questionnaires) were developed and used to guide interviews with selected patients and staff (Annex 3.1 questionnaire for patients; and Annex 3.2 questionnaire for staff). The questions were formulated taking into account evidence from the literature review and further described in Chapters 4 (Robson, 2002, May et al., 2007, May, 2006). The interviews with staff and patients were carried out by the Telehealth Coordinator; tape recorded, transcribed and handed to the author for analyses. Three one-to-one (repeat) interviews, over an 18-months' period, were conducted by the author with Telehealth Coordinator that was tape-recorded and transcribed. The interview duration lasted between 40 minutes to 1 hour, and the transcripts were shared between the author and Telehealth Coordinator to confirm their accuracy.

Information from the author's reflective log was used. The reflective log contained key issues encountered and information which was considered to be important in the implementation of telehealth service in both the trial and observational study.

7.3.3.1 *How participants were selected*

The purpose of selection of participants was to cover a range of informants; hence a convenience sampling method was used. Participants for the interviews were selected to include views of (1) patients, (2) community nurses and healthcare staff, and (3) group meeting, consisting of multi-disciplinary and multi-agency staff.

(1) Patients

The selection was designed to include sample of patients who had used telehealth service and had chronic obstructive pulmonary disease (COPD), and heart disease. These were the two main patient groups represented in the telehealth project. These groups of patients were specified by the author in the service contract. The community nurses identified the patients, while the Telehealth Coordinator carried out the interview with patients. Interviews with patients were conducted in patients' own homes. The interviews were conducted face-to-face, and prior arrangements were made by telephone and / or face-to-face. There were no other participants present besides the participants and interviewer. The interviews were conducted between June 2010 and October 2011.

(2) *Community nurses and healthcare staff*

Community nursing staff selected for the interview included community matrons (nurses), healthcare assistants, administrative staff and heart failure specialist nurses. There was only one heart failure team in Doncaster and the Team leader was interviewed by Telehealth Coordinator. On the other hand, there were several community matrons teams in Doncaster, and two of the teams were selected for interview with the respective community matrons. The Telehealth Coordinator interviewed the community nurses, as per commissioning service level agreement, using interview schedule developed by the author. Interviews with staff were conducted at work and over the period from June 2010 and October 2011.

(3) *Multi-stakeholders' group meeting*

The views of stakeholders at a specially convened event on telehealth on 29th March 2011 were obtained using group discussion facilitated by the author who carried out the interview. The author also analysed all the results of the interviews.

7.2.3.2 *Analyses*

Analyses of qualitative (interview) data were carried out manually, identifying key themes and patterns emerging from interviews, as recommended by a number of authors (Boyatzis, 1998, Robson, 2002, Braun and Clarke, 2006). The author coded the data for the analysis. The key steps recommended by Boyatzis (1998) were followed, which consisted of reducing the data, identifying themes within sub-samples, comparing themes across sub-samples, and

creating codes. Guidance for creating a good code was used, as outlined by Boyatzis (1998), where each code was assigned a label, and it was defined, giving a description of what it meant. Examples of the codes were given, by identifying the most relevant quotations by individuals interviewed; and exclusion and inclusion criteria of items were used.

Analyses were conducted by drawing on key themes. The author was guided by data in the thematic analysis; hence the method was considered to be a bottom up approach (Boyatzis, 1998). The four research questions posed at the beginning of this chapter were referred to in the analyses of the qualitative interviews.

7.4 Results

The results sections are structured covering qualitative interview with staffs and patients, exploring why and how telehealth performed the way it did, as part of the observational study.

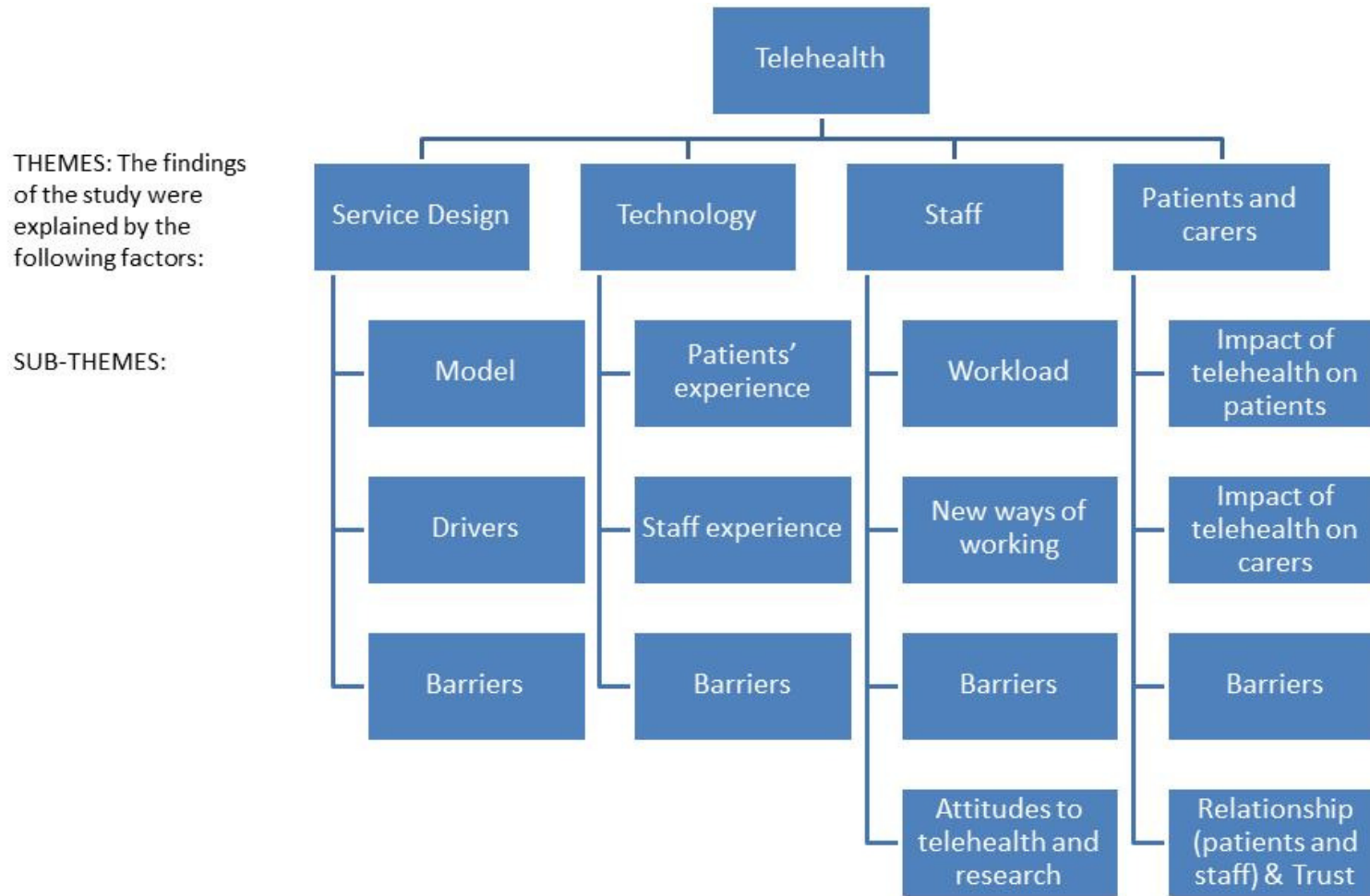
The views of 49 participants were obtained in the course of the evaluation; of which 29 were on one-to-one or small team basis; and 20 participants were part of a time-out session with key players at an event for telehealth and telecare. The individual or small team feedback involved 29 participants (16 patients and 13 staff). This included 13 in-depth interviews that were tape recorded and transcribed (6 with staff and 7 with patients) and 16 satisfaction questionnaires (7 staff; and 9 patients).

7.4.1 Qualitative interviews with patients and staff

The results reported in this chapter relate to observational study (also reported in Chapter 6) in Doncaster, using semi-structured qualitative interviews with patients and staff.

A thematic analysis revealed four main themes on how and why telehealth performed in Doncaster. These themes were categorised as follows; indicating that the findings of the study were explained by factors related to (1) service design (2) technology; (3) staff; and (4) patients and carers (Figure 7.2). The quotes provided are representative of the themes.

Figure 7.2: Explanation of why and how telehealth performed



7.4.2 Theme 1: Service design: The findings of the study were explained by how the service was designed

Successful model of telehealth service delivery

The local model of telehealth delivery was described as being successful during the observational study period. Key characteristics of this success included the following: staggered service, expanded bit by bit, team by team; removing strict eligibility criteria; having a coordinator; and flexibility of the service to adapt to changes. This is illustrated by the quote below:

“They [Tunstall] think that having a coordinator has been essential to the success of the project in Doncaster as a whole. They also think that the way in which we have done it, sort of bit by bit, a team at a time, has helped us to be able to cope with any problems; adapt to the way we do things and build it to a stage where we are now. It has gradually got bigger and there is no reason that it is not going to continue to do that. And basically, what has been said to me is that as supposed to somewhere buying; investing in 2000 kits, and planning this big major roll out, actually it’s far more sensible to do things in a much staggered way of doing it. And it’s proved successful that we have done it and so they approached other organisations with that model” Staff 4; Telehealth Coordinator, 7/10/2011

Recognising the drivers of telehealth for relevant stakeholders

This sub-theme was scored when individuals specified the drivers for adoption of telehealth. To qualify for coding this theme, individuals mentioned any of the following: competition among health service providers; recognising the drivers (and threats) to professional practice of clinicians; preventing hospital admissions; achieving financial savings from hospital

activities; and reducing admissions into residential care homes. The following examples further showed the drivers for health professional in relation to their practice:

“I think the way you overcome that cultural barrier is you get them to do one consultation. If we are talking about telemedicine you need to get them to do one consultation. And they walked out from that and they’ve all said: ‘I get what you are saying; I can see where it will work in my specialty; it will work in that area, it won’t work for those patients but will work over there.’ And then they say one of two things; they either say, ‘I am happy to do this whenever you want me to or I’ll never do another one.’ And I’ll say, ‘why would you not do another one?’ When you get under the skin, because it is a threat, and it is a threat to their independent practice.” Staff 6, Consultant Physician, 29/03/2011

Another example of driver for telehealth implementation related to competition among health service providers:

“And then there is the argument, if you don’t do this, another hospital is going to do it to you. And that hospital maybe the Mayo Clinic or it might be the Hammersmith, or might be UCL [University College London]. You know, you have got to really stand your corner against those guys because they bring very heavy weight clout to commissioning. So this is coming; join us or the bus is over there.” Staff 6, Consultant Physician, 29/03/2011

Service design barriers

This sub-theme was coded if individuals identified negative factors that were related to service design. To qualify for coding this category, individuals must have mentioned any of the following factors: lack of integration of telehealth into existing health system (e.g. IT, and care pathways); logistical

problems (coordinating sites, office, and storage); randomised controlled trial service design as a barrier; purchasing telehealth machine from suppliers (rather than renting them), as local experience showed that a lot of telehealth machines were not used when purchased by the organisation. This sub-theme is illustrated by the following quote below, about the need for embedding telehealth to be part of standard operating system of delivering healthcare service:

“I think it needs documenting somewhere on the SAF [Single Assessment Framework – information system] when we see a new patient, but also maybe on the community matron admission analysis forms that we fill in because it is making you think of it twice and you are having to justify why or why not. The problem with that though is that it is TPP [computer software system used in primary care] and it takes ages to change a form. It has got to go through all sorts of governance.” Staff 3, Community Matron, 21/12/2010

7.4.3 Theme 2: Technology: The findings of the study were explained by the use of a particular technology (telehealth)

Patients' satisfaction with telehealth

In this sub-theme, individuals described telehealth in the following ways: smashing, fantastic, amazing, happy with telehealth, a good thing, good idea, honoured using it, good feedback, and patients being on board with it. This is illustrated by the following quotes:

“I thought it was a good idea. Yes, I did. I didn't understand it.... I mean technology, I don't understand anyway, but I think it's been a really fantastic thing.” Patient 3, COPD, 12/11/2011

"I thought it was smashing. It put everybody's mind at rest here, and it went through to the doctors [care team] and they got in touch with me if anything was wrong." Patient 2, COPD, 25/11/2010

Staff satisfaction with telehealth

This category was scored when healthcare staff indicated satisfaction with telehealth; or if they expressed readiness to recommend telehealth to other healthcare professional colleagues or patients; or if they identified the benefits of telehealth to themselves. This is shown by the examples below:

"I have started saying to people [colleagues], now that it is just a trial for a month and we'll see how it goes, so we can take it out if needs be. I'm feeling ok with it at the moment." Staff 3, Community Matron, 21/12/2010

"So you know that if they are not looking good on screen, it may pre-empt a visit there and then. You think that their oxygen level don't look great, so maybe I should go out. So, it does have a benefit that way with us." Staff 3, Community Matron, 21/12/2010

Technological barriers

Under this sub-theme, individuals mentioned any of the following points: breakdown of telehealth machine; difficulties of differentiating between true and false red alerts generated by telehealth; and installation issues (e.g. lack of backup of telehealth during installation, including wireless ones, where there were problems with telephone lines). The example below illustrates this point:

"The extent of the problem is quite evident in that we have had at least three patients that have had the equipment (telehealth) removed

for the specific reason that the case manager does not believe that the readings from the blood pressure [machine] is accurate. It was constantly causing red alert because, obviously the nurses feel that they have to put limits, which were within guidelines, which they have been advised; the NICE Guidelines, etc. And the nurse believes that those red alerts are not necessary, and therefore believes that the equipment is causing work that is not necessary.” Staff 4, Telehealth Coordinator, 9/11/2011

7.4.4 Theme 3: Staff: The findings of the study were explained by how the new technology (telehealth) service was implemented

Telehealth increased workload of staff

This sub-theme was scored if individual mentioned that telehealth increased the workload of staff. To qualify for this code, individuals must have acknowledged increased workload in their responses; this included visits to patients and/or increase telephone contacts to support patients in their own homes. This is shown by the example below from a community nurse:

“In some ways, I would say that it [telehealth] does increase workload, but not tremendously. Having said that, I probably haven’t got that many patients on it. You do have more telephone contact with patients, which is fine if you are saving [hospital] admissions. I think that’s the point. You are having more contact but you are nipping things in the bud. I can change medication and advise patients over the phone, I can advise them to increase antibiotics or whatever. So though there are more consultations, they are generally telephone consultations and not visits. I think for the patients that I have on it, it is appropriate and it is saving admissions.” Staff 3, Community Matron, 21/12/2010

Participants talked about telehealth as introducing new ways of working

This sub-theme was coded if individuals identified telehealth as introducing a new way of working. Any of the following points mentioned qualified to be coded: references made to new roles for healthcare assistants or administrative support staff in monitoring telehealth readings; and enhancing their career development; the role of community nurses identified as making referral of patients onto telehealth and responding to red alerts; the role of Telehealth Coordinator in overall coordination of the service; telehealth was seen as enhancing team working among professional teams that was made up of community nurses and administrative support staff.

The above position is best illustrated by the example below in relation to investigating problems identified with patients:

“I think it’s different and maybe changes some things that you would do slightly. You might see a patient more often because actually you have picked something really appropriate up and you have investigated it deeper and you have highlighted a new problem. I think it’s a different way of working really and we are still getting to grips with that and in terms of long term monitoring for some of our patients, we are looking at how we might use it further.” Staff 2, Heart Failure Specialist Nurse, 11/11/2010

Another example shows the importance of having a coordinator in order to coordinate the service and to maintain standard:

“I think that having at least a person to coordinate the service is essential. I think the idea that it can be maintained without somebody with an overview is a very unlikely scenario to be honest. I think as with a lot of things, unless it has got somebody constantly keeping

things in check, things crumble you know, and what will also happen is this person will start doing things different to this person, and before you know it, you haven't got a standard, and it is not functioning as a proper service should." Staff 4, Telehealth Coordinator, 7/10/2011

Staff barriers and enabling factors, including staff attitudes to telehealth

Barriers to uptake of telehealth by staff were identified as described below.

These were identified from the interviews with staff and from observations, and meetings attended by the author:

1. Fear among clinicians for a number reasons, including the effects of telehealth on patients, potential increase in staff workload, and threat to professional independent practice;
2. Training for telehealth was not made mandatory, giving rise in some occasions to poor attendance at telehealth training sessions set up for staff;
3. Lack of clinical network on telehealth to discuss clinical aspects of telehealth e.g. setting the right alert parameters;
4. Lack of staff capacity; and
5. Lack of acceptance of telehealth by some health professional colleagues. Timeline was recognised to be associated with acceptance of telehealth by professionals (as time went by, resistance by staff gradually reduced to telehealth as it got embedded into routine service delivery).

The following example of resistance of professional colleagues illustrates this sub-theme:

“The biggest difficulty is colleagues’ acceptance, and there is timeline to it. You struggle and struggle and struggle and suddenly it seems to be the norm. Today, our consultants have all got telemedicine in their job plans and they are all completely cool with doing it apart from two orthopaedic surgeons who have refused. We have not gone against them. We’ve said, that’s fine, your colleagues can do them.” Staff 6, Consultant Physician, 29/03/2011

Another example related to making training on telehealth mandatory to staff who might be involved in telehealth service provision:

“...We got to January [2011] and I was getting no response to my invitation, and in hindsight, there has been a lot going on over the last few months, a lot of transferring issues [transfer of staff employment contract from one organisation to another]; a lot of issues with mandatory training – obviously telehealth is not mandatory”
“....so I would hope that in the future they would attempt to make the training mandatory, that would mean there would be no way we would have an empty training session.....” Staff 4, Telehealth Coordinator, 08/04/2011

Attitude of staff towards telehealth

Staff attitude towards implementation of telehealth was an important factor that explained why patients’ were offered telehealth or not by their case manager. Any of the following evidence was coded: positive attitude of staff towards trying telehealth on patients, and not being held back by pre-conceived prejudice; selection of patients; and overcoming fear of unknown potential effects of telehealth on both the patients and its effects on staff workload.

Examples of quotes that illustrate the above theme are shown below:

“And I think sometimes, and this may be why we are not getting a lot of people on it, that there is a fear of putting people on because you are not sure how they are going to respond to it and how it is going to work for them really.” Staff 4, Telehealth Coordinator, 9/11/2010

“If you think somebody might not be suitable, you are probably more likely not to try it because you know it’s going to be hard work and very intensive. They are going to be anxious and you are going to be ringing and visiting and all the rest, and that kind of puts you off a bit.” Staff 3, Community Matron, 9/11/2010

A prevailing view (assumption) among respiratory specialist nurses in Doncaster at the time was that patients who were considered to be “end of life” (palliative care) patients, such as patients with severe chronic obstructive pulmonary disease (COPD), were not considered suitable for telehealth. The respiratory specialist nurses had not been involved in telehealth at the time. This view was not held by one community matron, who looked after respiratory patients as well, including those with severe COPD, and she found that not all “end of life” patients were unsuitable for telehealth, but some could benefit from it. This view is illustrated by the quote below:

“So, sometimes I think with the community matrons, a lot of our patients possibly are coming towards end of life. But for some, it may be appropriate because although they are coming to the end of life, they are still bobbling in and out of hospital. It may be that you can avoid those types of situations. But I think patient selection is a biggy [big issue] really.” Staff 3, Community Matron, 9/11/2010

7.4.5 Theme 4: Patients and carers: The findings of the study were explained by the experiences of patients and carers

Positive impacts of telehealth on patient

Impacts of telehealth on patients are described as positives and negatives. Positive experiences are first described in this sub-theme; while negative impacts are described separately under sub-theme entitled as patients' barrier (negative experience).

This sub-theme was coded if individuals indicated positive impacts of telehealth on patients. Anyone of the following descriptions below applied for inclusion into this sub-theme: a description that patients felt more confident, supported, and in control of their conditions, patients felt reassured, their minds were put at rest, anxiety relieved and they were more independent; patients described a feeling of being monitored; not suffering in silence, or not being neglected by health professionals, a description of the care received as being similar to that of being in a hospital; individuals described some of the impacts of telehealth as improved health (felt better), reduction in visits to the doctors (GPs), reduction in number of visits by community nurses to the patients at home; prioritising home visit to patients; face-to-face visits to patients in their own homes were still regarded by community nurses as being important; impacts of telehealth were also described as saving hospital admissions; changing medication; enabling easy decision-making on patients' care; and telehealth was described as having embedded and its uptake was steadily increasing.

Example of this is shown by the quote below from staff in relation to patients feeling in control of their condition:

"I think that they [patients] feel more supported. I think it [telehealth] gives them a lot of control. They feel a bit more in control of what's happening because a lot of it is educating them as well. A fella I have put on it recently keeps asking me 'what should my Sats [SpO2] be? What's normal?' So he is learning about it and you can see that he is interested and he wants to learn about it so it is giving him a bit of autonomy and control I suppose. I think the patients get more care, more contact and I am not visiting those patients any less than I was before because of the telehealth but I am contacting them more."

Staff 3, Community Matron, 9/11/2010

Two further examples from patients' perspective of the impact of telehealth on their confidence are illustrated by the quotes below:

"You know that you are using it and people are watching you all the time. It gives you that bit of confidence if you know what I mean. You know you are not being neglected because there is always somebody at the other end keeping a check on you." Patient 4, COPD, 26/11/2010.

"Very high [impact of telehealth]. It has made me feel better and more confident and everything. Because I was scared a lot you know; I was. Sometimes, I had really bad days and that [telehealth] has put my mind at rest." Patient 2, COPD, 25/11/2010

Patient barriers

This category was coded if individuals identified any of the following negative factors related to patient's experience of telehealth: discrepancies between telehealth readings and case manager's own (manual) readings for

blood pressure; alert parameters, as recommended by NICE, was considered to be a barrier; lack of consensus on selecting the right patients for telehealth; and some possible unknown factors in patients that was the cause of inaccurate vital signs reading (see examples below).

Issues related to accuracy of telehealth device are shown by the quote below:

“I need to have someone [a clinician at Tunstall] to tell me what is happening because technically it’s [machine] fine, the nurse [in Doncaster] is saying it’s not and we need to know what the reason is. Not only that, we need to pre-empt it for when we are installing it because actually it is a waste of time to install it for certain people....”
Staff 4, Telehealth Coordinator, 8/04/2011

Issues to do with the right vital signs parameters are illustrated by the following quote:

“And the other thing is if the red alert is coming up every day, then I would say to them they need to start reviewing whether that is a normal parameter for that patient. If the patient says they are fine, but for a number of weeks, every day they have been on red alert, then the parameters are obviously not right. And so what I advise them is that they set parameters based on what’s helpful to them and not what they think should be guidelines. That’s a sensible way of using the equipment.” Staff 4, Telehealth Coordinator, 7/10/2011

Impacts of telehealth on carers

This sub-theme was coded if references were made about the impacts of telehealth on carers. The following references qualified for inclusion:

reassurance of carers, and happiness with telehealth by carers. This is illustrated in the example below:

“A big impact. Like I said, my husband mind is at rest. He doesn’t worry half as much about me. He sees my temperature is alright, my blood pressure..... He sees my Sats [SpO2] aren’t bad. Sometimes, they are 90, but sometimes, like today, they are 94. They might be 89 tomorrow, it depends you know.” Patient 2, COPD, 25/11/2010

Relationship between patients and healthcare staff

In scoring this sub-theme, individuals described the relationship between patients and staff. Patients used the following form of words to describe such a relationship with healthcare professionals: marvellous, lovely ladies, nurses were smashing, wonderful, great, and same as face-face visit. Nurses on the other hand, described their relationship with patients as enhanced, anxieties of patients were alleviated, and they felt supported. This is captured in the following examples:

“Well, they have rung me to make sure I am ok; if everything is going a bit ‘upsy-daisy’ you know. But they are smashing women; the nurses.” Patient 2, COPD, 25/11/2010

“Oh! Great. Great yeah.” [In response to relationship with staff];
Patient 4, Heart Failure, 26/11/2010

There was trust by patients in their community nurses that explained why patients enrolled onto telehealth, even though they were not quite sure about it at the beginning:

“Yes, I recall her just saying about this telehealth, which I didn’t really know what she was talking about. She asked if I was willing to

participate and I just said yes, that's fine. We'll give it a whirl." Patient 3, COPD Patient, 12/11/2010

A discussion of the findings from this qualitative study is found in Chapter 8.

7.5 Conclusions

The performance of telehealth was explained by a combination of factors related to service design, technology, staff, and patients and carers. There was mixed evidence regarding performance of telehealth in routine practice, with positive views from staff and patients, but there were also a number of challenges identified that needed to be overcome. The benefits of telehealth, from the interviews, appeared to be greater than its negatives. The evidence suggests that telehealth was starting to embed in routine practice but was not yet fully embedded.

7.6 Summary

This chapter investigated how and why telehealth performed in routine health care setting. It also investigated factors associated with the uptake of telehealth in observational study and how telehealth performed in routine healthcare practice. The methods used were semi-structured interviews guided by Normalisation Process Theory (NPT). The study uncovered four main themes that explained why and how telehealth performed in routine healthcare practice; factors related to: (1) service design; (2) telehealth device; (3) staff; and (4) patients and carers. The findings suggest that telehealth was embedding in routine healthcare use.

Chapter 8: Synthesis

8.1 Introduction

This thesis aims to investigate why new technologies fail or succeed to embed in routine healthcare practice. Chapter 1 outlined the research aims and objectives. The theoretical framework underpinning the research, normalisation process theory (NPT), was described in Chapter 2. This was followed by background information relevant to the study, which described the study setting, the health status of the local population, and a description of telehealth (Chapter 3). A literature review on effectiveness and cost-effectiveness of telehealth was presented in Chapter 4, along with literature on factors influencing successful implementation of new technologies and why trials failed to recruit to their intended targets. The effectiveness of telehealth was assessed using a pragmatic randomised controlled trial (RCT or referred to here as pragmatic trial) and it was reported in Chapter 5, while Chapter 6 (referred to here as service evaluation) assessed the uptake of telehealth using quantitative outcome measures to determine embeddedness of telehealth service. A qualitative study examining why new technologies embedded or not was explored in Chapter 7 (qualitative study), where factors related to staff, technology, service design, and patients' groups were found to be possible explanations. The current chapter synthesizes all the evidence from the thesis to answer the research question posed in Chapter 1, in line with Yin's (2009) case study research method (Yin, 2009). NPT presented earlier in Chapter 2 is used as the theoretical

framework in the synthesis of the findings, using the propositions stipulated in the theory.

This chapter is structured as follows:

1. Each of the five research sub-questions are addressed in order to understand why new technologies embed or not in routine practice. The findings from all the chapters thus far were synthesised.
2. The way forward to help new technologies embed in routine practice is discussed.
3. Recommendations on practice, policy, and research are made in order to promote new technologies embed in routine healthcare practice.

8.2 Synthesis of why new technologies fail or succeed to embed or not in routine healthcare practice

In the sub-sections below, evidence is drawn from previous chapters of the thesis, using Yin's case study research methods to address each of the five research sub-questions outline in Chapter 1. NPT was used in order to make sense of what happened in relation to the findings.

8.2.1 Setting

The following research question was posed in relation to setting: *“Is there something about Doncaster that made it more difficult to operate a randomised controlled trial (RCT) versus a service evaluation?”*

Using Yin's case study research approach (Yin, 2009), the evidence to address this question was derived from the following sources: (1) research experience of Doncaster in relation to other districts in England (Chapter 3); (2) experience of uptake of telehealth service in Doncaster during the pragmatic trial (Chapter 5), (3) the service evaluation (Chapters 6) and the qualitative study (Chapter 7).

Factors related to recruitment into research studies and uptake of telehealth service in Doncaster

Evidence from Chapter 3 showed that recruitments into observational and interventional studies in Doncaster were comparable to other districts in South Yorkshire. The same chapter showed that recruitments into national portfolio studies were higher in Doncaster than the average for primary care trust organisations in England.

Experience of implementation of telehealth service from the published literature (Chapter 4) showed that it was possible to implement telehealth in various settings from around the world. From the literature review reported in Chapter 4, no evidence was found relating to setting as being a barrier to successful implementation of telehealth. On the other hand, comparison of uptake rates of telehealth service in Doncaster was higher than in some districts in England (Joseph et al., 2011).

In Chapters 5 and 6, comparison of uptake of telehealth service during the pragmatic trial versus the service evaluation showed that within Doncaster, it was possible to increase the uptake of the service. If uptake rates of telehealth service could be low and later increase in the same setting, then

setting can be eliminated as the possible reason for the performance observed in both the pragmatic trial and the service evaluation.

There was no evidence that Doncaster, as a setting, was the reason why the uptake of telehealth service was low in the pragmatic trial and higher in service evaluation. Therefore, the hypothesis that Doncaster was significantly different in its experience of uptake of telehealth service compared to other districts in England was rejected.

8.2.2 Technology

The research question posed was: *“Are there factors associated with the new technology used in the RCT versus the ones used in the service evaluation that made a difference in uptake of the new technology?”* The following evidence was used to answer the research question:

- (1) Changes in relation to telehealth device: physical and software (Chapters 3, 5 and 6);
- (2) Compliance rate and level of red alerts (Chapters 5 and 6);
- (3) Uptake of telehealth and withdrawal of cases from its usage (Chapters 5 and 6);
- (4) Views of patients and staff from the qualitative study (Chapter 7), and NPT to make sense of the findings (Chapter 2).

Factors related to physical features of telehealth technology

The physical structure of telehealth machines used during the trial and service evaluation had changed over time (Chapters 5-7). Changes were observed in base units of telehealth machines, and there were fewer wires in

the newer versions of the machines than the older ones (Chapter 3: Figures 3.15a and 3.15b). However, features of the telehealth devices for measuring blood oxygen saturation (SpO₂) and blood pressure cuff remained the same. As shown in Chapter 6, between 2007 and 2013 there had been 5 versions of telehealth technologies that were released by the same company, Tunstall. This meant that on average, a new version of telehealth technology was released into the market per year. Features of these new technologies also differed. There were operational differences in transmission of data and access to information for nurses who monitored the readings from telehealth monitoring system. The software used in the pragmatic trial was different from that used in the service evaluation. Software used in the latter study enabled easy remote access via internet by safe and secure username and password.

Senior managers within Tunstall acknowledged that in 2009, there were some technical changes in telehealth between 2007 and 2009. They advised Doncaster PCT at the time that if it was considering rolling out telehealth service in Doncaster, it was appropriate for the organisation to wait and use the newer version of telehealth technology, which they considered to be more user-friendly, for both patients and staff. The new version of the technology was about to be released at the time. In the contract with Tunstall during the service evaluation, the PCT therefore, replaced the older machines with the newer ones for existing and new patients who were on telehealth in Doncaster at the time. This act acknowledged the significant changes in the technology and the fact that it was better to use a newer version of the technology for the population of Doncaster.

Telehealth Co-ordinator and community nurses in Doncaster reported that there were a lot of changes in the machine between those used during the trial and service evaluation; the more recent machines were smaller and neater, and represented an improved version (Chapter 7). The evidence of the difference in the performance of telehealth during the trial and service evaluation can be observed in the rates of red alerts that were reported in Chapters 5 and 6.

Factors related to symptom questions in the machines

Some questions chosen from a bank of questions on the telehealth machine for COPD patients during the pragmatic trial had some inherent limitations in the way how they were framed, as a result it was inevitable that unnecessary red alerts were generated. For example, questions such as the one below meant that patients would return similar answers in the same week even though their daily situation might have changed for that week:

“Did you have an unexpected visit to your doctor this week?”

During the service evaluation, such questions were changed or omitted altogether for some groups of patients at the discretion of community nurse.

Factors related to remote access to telehealth readings of patients by staff

The pragmatic trial had records of patients accessed only from a central location, while in the service evaluation, patient records were accessed from multiple sites where community nursing teams were located using the internet. This made it more acceptable and accessible for staff.

Factors related to technical accuracy and red alerts

In the pragmatic trial and the service evaluation, the red alerts were serious challenge to the implementation of telehealth service, as some patients were withdrawn from the service due to high levels of red alerts. In addition, the red alerts also created workload for staff, which was regarded as unnecessary by some of the staff. Some of the red alerts were attributed to lack of training and experience (practical guidance) in setting realistic alert parameters. In an attempt to follow NICE clinical guidance 12 on the management of COPD in adults in primary and secondary care (NICE, 2004), this appeared to cause confusions, anxiety and uncertainty for the inexperienced staff that were new to telehealth service. Tunstall constructed a decision-tree (pathway) for use during the period of the pragmatic trial, which included specific reference to NICE guidance CG 12. Although the evidence reported in the qualitative study showed that staff workload did increase, staff also indicated that they needed to know some of the information so that they could prioritise their workload and see appropriate patients at the right time; hence telehealth helped in introducing a new way of working.

Interviews with Telehealth Coordinator showed that telehealth performance suggested that the uptake of the service was increasing steadily and it was embedding (Chapter 7). This pattern was supported by evidence from the service evaluation on embeddedness of telehealth (Chapter 6). Problems were uncovered and resolved, where possible in the course of the implementation of telehealth service. However, there remained some unanswered questions for further research, policy makers and

manufacturers, for example, “*why does telehealth machine appear to work for some patients and not others?*” Such question arose from observation made during the course of the implementation of service evaluation where vital sign readings from telehealth machines for some patients appeared to be consistently different from those obtained using traditional tools such as sphygmomanometer (blood pressure measure). The differences observed by the clinicians resulted in less trust in telehealth machines, and they trusted their own tools more. Without independent assessment of the accuracy of these machines, it was difficult to know whether the telehealth vital sign measurements were inaccurate or the problem rested with clinicians’ traditional tools that they routinely use in their practice.

NPT highlighted the importance of understanding the meaning of a new practice by staff in order for them to embed it in their routine practice. The theory also stipulated that implementation of new practice had to fit in the social contexts and organisational structures in order for it to embed.

Proposition 1.1 of NPT (Chapter 2, Table 2.1) stated that: “*Embedding is dependent on work that defines and organizes a practice as a cognitive and behavioural ensemble*” (May and Finch, 2009). At the beginning of the implementation of telehealth service during the trial, fewer people, especially among healthcare staff, saw the meaning and uses of the new technology. Some staff even proposed that the available funds for telehealth be used to employ more nurses. At the time of introduction of telehealth service in Doncaster, as part of the pragmatic trial, there was limited evidence on effectiveness and cost-effectiveness of telehealth from the literature. The current evidence of literature review presented in Chapter 4 had been

updated after the studies were undertaken. As the new technology was being rolled-out in the service evaluation, the understanding of telehealth technology in the delivery of healthcare was better among healthcare professionals, especially among community nurses. However, not all healthcare professionals had a common understanding of the usefulness of telehealth service. Appreciating the usefulness of telehealth is what constitutes proposition 1.1 of NPT. It is the first step for a new practice to be taken up by practitioners.

Proposition 1.2 of NPT asserted that: "*Embedding work is shaped by factors that promote or inhibit actors' apprehension of a practice as meaningful*" (May and Finch, 2009). Factors related to differences in technologies that might have contributed to the performance of telehealth are described above. These factors included the physical features of telehealth technology, symptom questions used, remote access to patients' data by staff, technical accuracy and the issue of red alerts.

Proposition 1.3 of NPT stated that: "*The production and reproduction of coherence in a practice requires that actors collectively invest meaning in it*" (May and Finch, 2009). At the time of implementation of telehealth during the service evaluation, lessons were learned from new evidence in the field of telehealth. The new evidence came from the experience of implementing the pragmatic trial. In addition, some lessons were drawn from key challenges encountered in the implementation of telehealth as reported in the literature in Chapter 4. The key factors for successful implementation of telehealth service were used to inform the implementation of the service evaluation (Joseph et al., 2011). In the service evaluation, there was a broad

understanding among the various stakeholders that there was a place for telehealth in professional practice by community nurses, as described in Chapter 7. Hence, there was a much better collective investment in meaning of telehealth service in the service evaluation, than it was in the trial. The qualitative study showed that a stakeholders' workshop was held to try to get a shared understanding of the value of telehealth service that had been implemented. The stakeholders' workshop aimed to establish how the knowledge and experience gained could inform future roll-out of telehealth service. This was consistent with proposition 1.3 of NPT stated above. The usefulness and place of telehealth was affirmed by professionals in Doncaster, and the organisations involved, from both commissioners and providers of health and social care services.

From NPT perspective, there was organisational commitment to implementation of telehealth service in Doncaster when it was first introduced. However, initially during the pragmatic trial, telehealth service did not appear to fit in with the prevailing social norm and practices of community healthcare staff. During the service evaluation, there was a much better understanding of the usefulness of telehealth service, and the service appeared to be more acceptable to community healthcare professionals.

In summary, it had been found that there were changes in the physical characteristics of the telehealth device, and the network it was linked to. Similarly, changes were observed in the rates of red alerts, and uptake rate of telehealth service between the pragmatic trial and the service evaluation. The changes might have reflected in the technical accuracy or how staff became more experienced in interpreting the readings from telehealth

service. Experience from the qualitative study also confirmed that the technology had changed over time, as noticed by staff involved in the implementation process. All these resulted in a better uptake of telehealth service in the service evaluation study. Therefore, it was not possible to reject the hypothesis that *“there were factors associated with the new technology used in the RCT versus the ones used in the service evaluation that made a difference in uptake of the new technology”*.

8.2.3 Patients’ group

This section tackles the following research question: *“Are there factors related to patients’ group recruited for the RCT as opposed to the service evaluation that made the difference in uptake of the new technology?”*

The following evidence was considered in order to answer the above research question:

- (1) The primary types of diseases of patients who used telehealth service in both the pragmatic trial and the service evaluation;
- (2) The evidence from the literature, including Chapter 4;
- (3) Uptake rates of telehealth service in both the pragmatic trial and the service evaluation.

Factors related to types of disease of patients involved in telehealth service

Patients in the pragmatic trial and the service evaluation study on telehealth implementation were different in that the pragmatic trial focused on COPD patients. While in the service evaluation, there were patients with various

types of diseases that used telehealth service, including those with COPD, heart failure, and diabetes.

Evidence presented in Chapter 4 from the published literature indicates that there were a number of studies that reported on various long-term conditions, including heart disease, diabetes, stroke, and COPD. One of the largest telehealth programmes in the United States of America, the Veteran Health Administration (VHA), had also various groups of patients with different long-term conditions, including heart failure, hypertension, COPD, diabetes, and mental illness (Darkins et al., 2008). While in the UK, the Whole System Demonstrator (WSD) telehealth project had patients with COPD, heart failure and diabetes on telehealth (Steventon et al., 2012). Based on evidence from the literature, it can be argued that the uptake of home telehealth monitoring was possible by various patients groups.

Factors related to uptake rate of telehealth from the pragmatic trial and the service evaluation

The findings from the pragmatic trial and the service evaluation showed that it was possible for patients with COPD to be recruited in the studies.

Although recruitment into the pragmatic trial was limited (Chapter 5), it increased during the service evaluation (Chapter 6).

There was limited evidence to accept that the uptake of telehealth service in both studies was explained by differences in types of diseases of patients.

Therefore, the hypothesis that “*there were factors related to the patients’ group recruited for the RCT as opposed to the service evaluation that made the difference in uptake of new technology*” was rejected.

8.2.4 Staff

The research question addressed in relation to staff was: “*Are there factors associated with staff involved in the RCT, as opposed to the service evaluation that made a difference in uptake of the new technology?*” The objective here was to determine whether the implementation of telehealth was better managed in the service evaluation than in the trial. Evidence was drawn from the thesis (the pragmatic trial, service evaluation and the qualitative study) by examining the following factors:

- 1) Capacity of staff and team involved in the management of telehealth
- 2) Project management,
- 3) Staff resistance, and
- 4) Training for staff.

Factors related to capacity of staff and team involved

When the pragmatic trial was being planned, there was a concern expressed by some members of the Respiratory Working Group (RWG) in Doncaster around lack of capacity among the respiratory nurse specialist team, as a member of the team had left for a job as a community matron. It was feared that the introduction of telehealth service would deprive staff capacity from existing service. Subsequently, the telehealth service was conducted with the district nursing team, who had COPD patients on their case workload, in the East side of Doncaster, with the support of clinical nurse manager. The telehealth service involved only one district nursing team located physically in one health centre where the telehealth monitoring base unit was hosted. Two district nurses were tasked with the responsibilities of recruiting patients

into the telehealth service and monitoring them. They visited the site on daily basis to check patients' readings on one computer installed in an office at the health centre. The telehealth office was in a different location from the usual health centre where the two district nurses usually worked from. This made it operationally difficult, as they struggled to find time to travel from their usual base to the telehealth office to view patients' readings that were transmitted online (detail description can be found in Chapter 5). This contrasted with the service evaluation (Chapters 6) where several teams of community matrons, based in different health centres across Doncaster had access to their patients' record online by means of special user names and passwords from computers within the health centres where they worked from. The teams comprised of healthcare assistants, as well as administrative support staff who checked the telehealth readings and they let the community matrons know when to follow up further cases with red alerts. The implementation of telehealth during the pragmatic trial lacked dedicated administrative support.

In the service evaluation, it was planned that the system was going to operate as part of an integrated community care pathway (ICCP). An ICCP was defined as one where patient care was provided by a team of multi-disciplinary staff within the right time-frame in order to achieve the best outcomes for the patient with a specific condition (Middleton et al., 2001). The ICCP in Doncaster was led by a steering group in the PCT to oversee the implementation of community matrons programme in Doncaster and telehealth service was seen as an integral part of the process for these healthcare workers.

In the pragmatic trial, there were only two district nurses responsible for the implementation of telehealth service and they did not have protected time for telehealth work. Doncaster PCT had made financial provision for employing two full time nurses to support the delivery of the telehealth service.

Although, two district nurses were identified, arrangement was not made by their manager for them to deliver telehealth service on full time basis. The two nurses were required by their managers to continue to discharge their district nursing duties as well as that of telehealth service. As a result, the delivery of telehealth service did not happen as envisaged and there was limited staff capacity for the service. There was also a high turnout of staff observed during the pragmatic trial, which suggested a lack of satisfaction among the staff with the service.

Although further efforts were made to increase the recruitment of participants in the pragmatic trial, it did not yield expected results. It was agreed that a Tunstall Nurse Consultant would undertake recruitment into the pragmatic trial, as part of contract arrangement with Tunstall, this did not happen. The reason given by the Tunstall nurse was that she was not an employee of NHS Doncaster and therefore she was not legally protected to go and meet patients in their homes for recruitment unless she was accompanied by another PCT employer. There was no administrative support available for the telehealth project to accompany the Tunstall nurse to visit patients for recruitments at home (Chapter 5).

The service evaluation benefited from a full-time dedicated Telehealth Coordinator in terms of uptake of telehealth, in addition to several community matrons and their teams across Doncaster who were supported

by administrative staff, including healthcare assistants. This improved the efficiency of the delivery of telehealth service; with the healthcare assistants taking the initial reading and flagging up any issues such as red alerts with community matrons or heart failure specialist nurses, as described in Chapters 6 and 7.

Factors related to project management

During the service evaluation, a project implementation plan was agreed by a steering group, the Telehealth Delivery Group. Lessons learned during the trial were built into the plan during the service evaluation period. Most importantly, there was a full-time Telehealth Coordinator in place, community matrons were on board, along with other activities agreed by the delivery group. Two GP champions were also enlisted. In the pragmatic trial, there was a protocol in place to guide the delivery of telehealth service, however, implementation was hampered by the end of employment contract of the Project Manager who subsequently left and there was neither a replacement to the post nor any dedicated project manager. Other healthcare professionals who were previously involved in the implementation of telehealth were busy with other work duties; telehealth was not in their main job. The pragmatic trial had only one GP champion on board, as part of a steering group. These were a number of critical factors identified in failed trials (Chapter 4) that were not addressed in the pragmatic trial.

Factors related to staff resistance

Before the start of the trial in 2006, there was some resistance even among some members of the professional groups in Doncaster, for example, the

Respiratory Working Group (RWG). Some members of the RWG expressed alternative views for using the money for telehealth for other purposes, for example, employing more nurses or purchasing other equipment, other than telehealth. They did not see the usefulness of telehealth at the time.

Although there was professional resistance during the trial, the situation was different in the service evaluation where the attitude of staff appeared to have softened with time in favour of telehealth. More staff began to accept that there was a role for telehealth service for certain groups of patients. The experience of nurses in the service evaluation showed that even some of the patients on community matron's workload who were regarded as end-of-life care, including those with respiratory diseases (severe COPD), were thought to benefit from telehealth service.

Earlier views of community matrons showed resistance to telehealth, as it was considered by them to be a potential risk to their job security if the service was to show effectiveness in reducing hospital admissions (Chapter 5 and Chapter 7). Their perception was that fewer community matron nurses would be needed if telehealth service were to prove successful, as fewer face-to-face visits would be needed. Some of those professionals who were still resistant to telehealth service were willing to accept that there was a place for telehealth for some patients. Telehealth service did not result in the loss of jobs of the community nurses after all. The acceptance of telehealth service also extended to secondary care where the local clinicians were keen to engage with telehealth activities and they wanted hospital business managers to be on board, as part of the local planning process.

Factors related to training

Training was better organised in the service evaluation than in the pragmatic trial. In the pragmatic trial, a total of six staff had been trained, which consisted of four district nurses, one Project Manager and the Chief Investigator of the pragmatic trial. While in the service evaluation, during the first 6 months of implementation, there was a total of 48 staff trained. The training, however, needed to have been continuous and increased. The scope of staff trained increased over time in the service evaluation, and the training was better organised and delivered initially by Tunstall staff and subsequently all the training in the service evaluation was delivered in-house by the Telehealth Coordinator (Chapters 6 and 7).

The training activities provided during the pragmatic trial and at the service evaluation were limited to how to operate the telehealth equipment, access patients' readings from online monitoring system (database), interpret them, and manage the information recorded such as entering information on patients' record regarding observation or intervention done. However, the training did not cover change management, and process re-designs. This would have improved the understanding of all those involved in the implementation to see the bigger challenges involved in embedding telehealth in routine practice. However, issues related to change management, and service re-design were considered by policy makers and managers at the PCT and the local authority.

Findings from the published literature showed that the implementation of telehealth service was related to staff input and workload, as shown by

examples of the VHA telehealth programme in the US where over 6000 staff were trained (Darkins et al., 2008); and examples of staff role in telehealth projects elsewhere in Scotland (Roberts et al., 2010) and in Italy (Vitacca et al., 2010). Although the service evaluation achieved a high level of staff trained in telehealth service, lessons from the VHA indicated that there needed to be a continuous programme of training of staff involved in telehealth service and a much higher number of staff needed to be trained. The level of training of staff in telehealth service during the service evaluation study was considered to be still limited in light of the work that needed to be done.

In Chapter 3, it was also shown how hospital trusts that had a dedicated staff nurse for managing recruitment of participants into portfolio research studies, did better than those where there was no dedicated research nurse. Having a dedicated staff had been recognised as one of the important factors for successful recruitments of participants into research studies, as shown from the literature review (Campbell et al., 2007). The pragmatic trial did not have dedicated staff, from nursing and managerial perspectives.

Normalisation process theory (NPT) stipulated that for practices to embed in routine practice, it was necessary that those responsible for implementation needed to fully understand the usefulness of a practice, be engaged in it (cognitive participation), and collectively take action in implementing the change (May and Finch, 2009). The extent to which the work on implementation of telehealth service related to the propositions 2.1-3.3 of NPT is synthesised below.

Proposition 2.1 of NPT stated that: *“embedding is dependent on work that defines and organises the actors implicated in a practice”*. The qualitative study showed that there was evidence in support of the fact that some health professionals (community nurses) were finding telehealth to be useful in their practice, however, this was not across the board, and there were some staff that needed to be convinced of the usefulness of telehealth. Staff involved in telehealth, found that telehealth was compatible with their work practice and it was introducing some new ways of working, as evidenced from the interviews. Community nurses and healthcare support staff were beginning to identify how telehealth could fit into their job roles and the wider potential for telehealth in enhancing their practice. This was consistent with NPT proposition 2.1 stated above.

NPT proposition 2.2 stipulated that: *“embedding work is shaped by factors that promote or inhibit actors’ participation”* (May and Finch, 2009). In the context of telehealth service in the qualitative study (Chapter 7), there were concerns also around workload of staff arising from telehealth, and lack of training for staff. Although there had been training provided, this was not given priority by the relevant staff as it was not considered to be mandatory by the organisation. There were some barriers that were identified and drivers to be recognised if progress for embedding telehealth was to be realised.

An important issue highlighted in the service evaluation was related to the attitude of staff. While healthcare staff needed to know the evidence of effectiveness of interventions to inform their actions, barriers such as staff resistance and negative assumptions posed a significant problem for

implementation of telehealth. As shown in the qualitative study, such resistance appeared to be overcome when staff tried to use telehealth in some of their patients. This approach seemed to be a reasonable way forward for clinical staff that are in doubt about the role of telehealth service in their clinical practice.

Unlike in the pragmatic trial where there was lack of protected work time for staff undertaking telehealth implementation, in the service evaluation there was agreement by senior managers at Assistant Director level of healthcare provider organisation to oversee the implementation of telehealth service. In the pragmatic trial, implementation was overseen by a clinical manager who did not have direct power to influence some of the changes required by front line nursing staff. Therefore, the above factors that shaped implementation of telehealth service were consistent with NPT proposition 2.2: *“Embedding work is shaped by factors that promote or inhibit actors’ participation”* (May and Finch, 2009).

Proposition 2.3 of NPT stated that: *“The production and reproduction of a practice requires that actors collectively invest commitment in it”* (May and Finch, 2009). Stakeholders on the Long-term Condition Steering Group in Doncaster accepted telehealth as the future means of delivery of healthcare for patients with long-term conditions and the group considered its implementation to be in the best interest of patients, thus legitimising the use of telehealth. There was also organisational commitment to the implementation of telehealth, in terms of financial resource investments. The level of commitments in telehealth was greater in the service evaluation than it was in the pragmatic trial. Without such financial investment in telehealth

service, the work on implementation would not have been realised. The investment of efforts was therefore consistent with above the proposition.

NPT propositions 3.1-3.3 related to collective actions by actors to implement a practice. Proposition 3.1 of NPT stipulated that: *“Embedding is dependent on work that defines and operationalizes a practice”* (May and Finch, 2009). The interaction between professionals and patients (interactional workability) in the pragmatic trial was poor, as evidenced by higher rate of red alerts and limited number of staff (2 nurses) to respond to the alerts. On the other hand, staff-patient relationship improved in the service evaluation (Chapter 7). Similarly, the relationship among community nursing teams also improved in the service evaluation compared with the situation during the observed in the pragmatic trial. For example, healthcare assistants played an important role in screening alerts for the nurses to look at (Chapter 7), thus improving the skills for the work that needed to be done in the service evaluation. While in the pragmatic trial, the community nurses did both the administrative job of reading the alerts and responding to the technical issues (malfunctions of the machines), and their role extended to performing clinical duties of interpreting the alerts, thus displaying poor skill-set workability. All these added to the workload of the community nurses, and coupled with time constrain, they made the job more difficult to undertake for the limited nurse capacity available at the time. The key challenges encountered in implementing telehealth in healthcare settings as reported in service evaluation (Chapter 7), were consistent with propositions 3.1 of NPT.

Propositions 3.2 of NPT stated that *“Embedding work is shaped by factors that promote or inhibit actors’ enacting it.”* (May and Finch, 2009). These

factors in relation to implementation of telehealth service are described above, and they included capacity of staff, project management, staff resistance, and training.

Proposition 3.3 of NPT: *“The production and reproduction of a practice requires that actors collectively invest efforts in it”* (May and Finch, 2009).

This proposition was demonstrated by implementation of both the pragmatic trial and the service evaluation. As implementation of telehealth progressed in both the pragmatic trial and the service evaluation, there was a realisation of the role of telehealth service in the delivery of healthcare, and the collective investment of efforts made by various players: the Telesolution Delivery Group, Telesolution Programme Board, the community nurses and other staff involved in the implementation of telehealth. This collective investment of efforts by health professionals in the implementation of telehealth service was consistent with proposition 3.3 of NPT.

In summary, the implementation of telehealth in the service evaluation was better managed than it was in the pragmatic trial. There was dedicated staff and team to manage telehealth service in the service evaluation, whereas the pragmatic trial lacked both dedicated coordinator and team. Lessons learned from the pragmatic trial were used to improve implementation of telehealth service in the service evaluation. The way staff capacity was used to manage telehealth service helped to explain the reason for better uptake of telehealth in the service evaluation compared to the pragmatic trial. The implementation of telehealth was better managed in the service evaluation than in the trial, based on a number of factors considered, which included levels of team organisation, staff capacity, project management, professional

resistance, and training. Therefore it was not possible to reject the hypothesis that *“there were factors associated with staff involved in the RCT, as opposed to the service evaluation that made a difference in uptake of new technology”*.

8.2.5 Evaluation

The research question to address the evaluation design of the service was: *“Are there factors associated with the methodological approach used within a randomised controlled trial (RCT), as opposed to service evaluation that made a difference in uptake of the new technology?”* It was hypothesised that the methodological approach used within the RCT hindered the uptake of telehealth service, while service evaluation method enhanced the uptake of telehealth service.

The evidence was drawn from the pragmatic trial, the service evaluation, and the literature review (Chapter 4) to answer the research questions.

Factors examined related to methodological approach were: (1) the inclusion criteria; (2) the randomisation process, and (3) sources of data for recruiting participants.

The key features of an RCT were that patients with similar baseline characteristics (e.g. disease characteristics, age, sex, etc.) were selected and they were randomly allocated into an intervention group and a control group, as described in Chapter 3. This approach was considered to minimise bias in assessing the effects of an intervention. The RCT operated on strict participant inclusion and exclusion criteria.

The following factors were identified, as possible explanations for the difference in uptake of telehealth service in the pragmatic trial and the service evaluation:

Factors related to sources of data for recruiting participants

The pragmatic trial encountered difficulty in identifying eligible cases based on the inclusion criteria from hospital admission records as most of the cases were not easily reached or some had already died after they were last discharged from hospital. While the service evaluation participants were recruited from among community matron caseload, which had live patients.

Factors related to randomisation process

The random allocation of eligible participants into the pragmatic trial was not under the control of community nurses, but a third party. Community nurses were uneasy with having to randomise their patients, when they had identified them initially as being eligible for telehealth service, but were subsequently allocated to the control arm of the trial. They preferred patients whom they identified for the telehealth service to be allocated telehealth machines. On this basis, the nurses considered the randomisation process of the trial as being unfair (Chapter 7). On the other hand, the service evaluation enabled the community matrons to offer telehealth service to the patients whom they considered to be appropriate, and they were in control of the process. Another possible reason for the difficulty in recruiting participants onto telehealth service under RCT design by healthcare staff might be related to the fact that RCT was outside the comfort zone of most frontline healthcare practitioners.

A Cochrane systematic review of strategies to improve recruitment to RCTs found that open design of trial, where participants knew in which arm of the trial they would be, was significantly associated with higher uptake of participants into trials (RR 1.22; 95% CI: 1.09, 1.36) (Treweek et al., 2011). However, the pragmatic trial was not an open design, but one where participants did not know before-hand which of the two arms of the trial they would be allocated to.

Factors related to inclusion criteria

The strict eligibility criteria for the pragmatic trial, was viewed as a barrier by community nurses. The community nurses welcomed the fact that the strict eligibility criteria were removed for the service evaluation. The only eligibility requirement left in the service evaluation was for patients with long-term conditions being on the case-load of community matron or heart failure nurses. The nurses were much comfortable with these changes (Chapters 6 and 7).

Evidence from the published literature on how telehealth service was implemented indicated a flexible system of provision of home telehealth monitoring had better uptake, like that observed at the Veteran Health Administration (VHA) system in the United States based on observational study (Darkins et al., 2008). It had been shown that where an RCT was inflexible in its inclusion criteria, there was an associated high drop-out rate and lower uptake rate of the service (Shea et al., 2009).

NPT enables researchers to understand how practices get understood and assessed (reflexive monitoring); these were captured in propositions 4.1-4.3

(May and Finch, 2009). The authors of NPT described how embedding was dependent on work that defined and operationalized every day practice (proposition 4.1); factors that shaped or inhibit appraisal (proposition 4.2); and the need for actors to collectively invest in understanding of a practice (proposition 4.3).

In the pragmatic trial, the methodology that was used made it difficult to enrol participants into the telehealth service. As a result, some community matron staff showed reluctant to put forward the names of their patients to be randomised for fear of unknown effects of telehealth service. A system of appraisal of the work on telehealth was established in both the pragmatic trial and service evaluation. However, in the pragmatic trial, this was limited to a steering group with a few members of stakeholders, which did not include patients' representatives. While in the service evaluation, there was a wider representation of stakeholders, including patients and staff from both the local authority and the health service sector. The steering group assessed how telehealth service was being implemented, with updates received at its regular meetings, often held on monthly basis or bi-monthly. This was consistent with proposition 4.1 of NPT: *“Embedding is dependent on work that defines and organizes the everyday understanding of a practice.”*

Proposition 4.2 of NPT stated: *“Embedding work is shaped by factors that promote or inhibit appraisal”* (May and Finch, 2009). The specific factors that promoted or inhibited the uptake of telehealth service under pragmatic trial and service evaluation have been described above, consisting of difference

in inclusion criteria, randomisation process, and sources of data for recruiting participants.

Proposition 4.3 stated that *“The production and reproduction of a practice requires that actors collectively invest in its understanding”* (May and Finch, 2009). The steering groups in both the pragmatic trial and the service evaluation provided a forum to appraise the development of telehealth implementation and institute appropriate remedial actions, where appropriate. In the service evaluation, there were additional layers of committees, such as Telesolution Programme Board with membership from both the PCT and the local authority, and senior management team in the PCT with decision-making power of allocating resources to programme areas. The experiences on appraising local practices in the implementation of telehealth were captured in both studies.

Therefore, it was not possible to reject the hypothesis that *“there were factors associated with randomised controlled trial (RCT) methodology approach, as opposed to service evaluation that made a difference in uptake of new technology”*.

8.2.6 Strengths and limitations of the research

The strengths and limitations of the pragmatic trial and the service evaluation had been discussed in the respective chapters (Chapters 5 and 6). The strengths of the qualitative study (Chapter 7) was that it covered a range of stakeholders (staff, and patients with COPD and heart failure), and a number of methods and data sources were used. The use of Telehealth Coordinator in undertaking interviews with patients and staff could be

considered as strength on the one hand, and a limitation on the other. The strength of using the Telehealth Coordinator in undertaking the interviews was that the role was consistent with routine delivery of telehealth service expected, as per service contract for the provider to obtain patients satisfaction feedback on their experience of using telehealth service. The potential limitation of the use of Telehealth Coordinator in undertaking the interview was that certain important observations of interviewees during the interview process might not have been captured. Such clues were considered to be an important part of undertaking qualitative interviews (Boyatzis, 1998).

Another strength of the qualitative study was that it had been reported according to accepted standard, consolidated criteria for reporting qualitative studies (COREQ) (Tong et al., 2007). Further strength of the qualitative study was also that the views on telehealth service were from patients who used telehealth service, which reflected a true assessment of what the service in use was. This contrasted with the Whole System Demonstrator (WSD) qualitative study that explored barriers to participation and adoption of telehealth among patients who declined to participate or withdrew from the study before actually taking part in the telehealth service (Sanders et al., 2012). The authors of the WSD project found that potential participants for the pragmatic trial had initial fears about telehealth service. Some of them thought that they needed some technical competencies in order to operate telehealth equipment effectively. The qualitative study in Doncaster had shown that some users held negative views about telehealth prior to using it, and some even did not possess any prior technical knowledge of using

technology, yet after using it, they liked it. These experiences were similar for staff; those initially sceptical about telehealth became comfortable with using it after they tried it.

Taken together, the pragmatic trial, service evaluation, and the qualitative study provided a rounded evaluation of telehealth service using mixed methods advocated by researchers in the field of complex interventions (Campbell et al., 2000, Ekeland et al., 2012). The qualitative study confirmed that the difference between telehealth care and standard care was due to increased contacts (interactions) between patients and healthcare staff, and the associated care needed as a result of those contacts.

Despite the limitation of having too many propositions ($n = 12$), some of which appeared to be overlapping, NPT was found to be a useful theoretical framework in this work to organise and explain the findings of the studies. NPT was able to provide explanations as to why and how telehealth failed to embed in practice in the pragmatic trial, while it appeared to have succeeded in the service evaluation. The differences in the technologies used, factors related to staff, and evaluation methodologies appeared to have explained why and how telehealth performed in the pragmatic trial and the service evaluation.

8.3.7 Overall conclusions

This chapter used a range of evidence drawn from previous chapters of the thesis to address five research questions on why new technologies failed or succeeded to embed in routine healthcare practice. This approach was consistent with that advocated by Yin for case study research (Yin, 2009).

The better uptake of telehealth service in the service evaluation, in comparison with the pragmatic trial, were likely to be explained by a combination of factors including differences in approach to evaluation of the service, changes in the technologies, and better use of staff capacity in the management of telehealth service in the service evaluation. Geographical setting, such as Doncaster, was not considered to be the reason for failure or success of new technologies embedding in routine practice. Both studies had patient group with similar disease (COPD) but their uptake of the service were better in the service evaluation than in the trial; thus showing that difference in patients' groups could not explain the uptake of telehealth service.

Therefore, on the basis of the evidence presented, the following hypotheses could not be rejected as possible reasons why new technology embeds or not in routine practice:

1. There were factors associated with the new technology used in the RCT versus the ones used in the service evaluation that made a difference in uptake of the new technology.
2. There were factors associated with staff involved in the RCT, as opposed to the service evaluation that made a difference in uptake of new technology.
3. There were factors associated with randomised controlled trial (RCT) methodology approach, as opposed to service evaluation that made a difference in uptake of the new technology.

There was insufficient evidence to accept the following hypotheses:

4. Doncaster was significantly different in its experience of uptake of telehealth innovation compared to other districts in England.
5. There were factors related to the patients' group recruited for the RCT as opposed to the service evaluation that made the difference in uptake of the new technology.

8.3 What needs to be done to help new technologies embed in routine healthcare practice?

This section discusses what needs to be done to help new technologies embed in routine healthcare practice. From the evidence synthesised in Section 8.2, there were three possible explanations as to why new technologies fail or succeed to embed in routine healthcare practice. They related to factors associated with staff, technology and evaluation methodology used. This section focuses on these three areas in exploring what could be done to enable new technologies to embed in routine practice.

8.3.1 Staff

From the conclusions of this research, factors related to staff could not be excluded as possible reason as to why new technologies embed or not in routine healthcare practice. The pragmatic trial and the service evaluation showed the important role played by staff in ensuring proper management of implementation of new technologies. A range of measures related to staff can enable new technologies succeed in routine practice. One of these is training. Incorporating on-going programme of training and education is

essential if new technologies are to embed into routine use in order to ensure basic standard of service delivery.

Staff in the field also identified the need for having a professional network in place to discuss emerging challenges related to implementation of new technologies. It is also important to acknowledge that staff are people and therefore, there is need to consider human psychology as part of implementation of new technologies. Staff need to contextualise what a new technology means for them and their interaction with patients, as described in NPT (May and Finch, 2009). Thus there needs to be proper consultation upfront to ensure that staff understand the technology and the problem that it is intending to address. They also need to understand any evaluation strategies.

Organisations need to set the right culture where new technological innovation thrives. Failure in implementation of new technologies should be taken as an opportunity to learn from and develop on it, as highlighted by expert in the field of innovation (Lundin, 2009).

There is still a mismatch between the intent and the reality of encouraging research and innovation in terms of giving protected time to staff in the health service who might be interested in undertaking relevant research on new technologies. For research to be translated into operational role of staff, it needs to be reflected in protected time of staff.

8.3.2 Technology

8.3.2.1 Assessing effectiveness and cost-effectiveness of new technology

In 1977, body scanners were introduced into the British National Health Service (NHS) with the funding from the Government (Stocking and Morrison, 1978). However, the authors did express concerns around the cost-effectiveness of the body scanners, which were sold at a cost of £250,000 (British Pound) per machine at the time; and a total of 11 machines were bought in Britain. More than 30 years on (2015) after the introduction of the body scanners, the technology can be said to have normalised (embedded) into routine health service delivery; they can be found in major hospitals in the UK.

The lessons that can be drawn from the body scanners case study are that more attention is needed in considering factors relevant for acquisition and sustainability of new technologies. These factors include consideration for current evidence of effectiveness and cost-effectiveness; as well as future costs (likely to reduce); diagnostic and technical accuracy; competing technologies; and the influence of policy makers (Stocking and Morrison, 1978). For telehealth technology, this means that there are challenges that remain to be overcome related to its effectiveness and cost-effectiveness, and to improve its reliability and validity so as to gain the confidence of staff and users. Evidence from the literature (Chapter 4) shows that for some diseases, telehealth appeared to be effective, although evidence for long-term conditions generally remains limited. For specific disease areas where

telehealth had been shown to be effective, the costs of the technology remain one of the obstacles in the implementation of telehealth in routine healthcare practice. Current level of costs of the new technology, are still too expensive to make the technology cost-effective, where evidence of effectiveness had been demonstrated (Chapter 4). The advances in new technologies, along with increased range of products in the market may drive down future costs, and thus make the service more cost-effective. It is likely that once these challenges are addressed, along with other factors, there will be more confidence in telehealth services, and the technology will normalise in the health service in decades to come. However, a continual assessment of the new technologies is required, along with the opportunity costs of investing in them against other competing health priorities (Stocking and Morrison, 1978).

As the work by other authors showed (Arthur, 2009, Keen et al., 2012, Feldman and Orlikowski, 2011), it is more than just cost that will determine the adoption of new technologies. There will be the need for flexibility of adoption of new technologies to new use that fits with organisational goals. The designers of new technologies will also need to actively engage healthcare stakeholder from the early stage of development of the new technological services and right through to their implementation stages and evaluation. Synthesised evidence from the literature on implementation of new technologies related to factors that determine their embedding (see Chapter 4), needs to be considered and taken on board if future technologies are to embed in routine use.

8.3.2.2 Evaluation of interventions involving new technologies

There is a broad consensus in the literature that evaluation is an important part of development of new technologies in order to assess their effectiveness and cost-effectiveness (Stocking and Morrison, 1978, Ekeland et al., 2012). However, there is uncertainty on what approach of evaluation was ideal for use: summative assessment versus formative assessment (Ekeland et al., 2012). In summative assessment (also referred to as positive paradigm), Ekeland et al. (2012) described how the assessors maintained objectivity, and were value free and there was assumed causal link, as typically found in RCTs. While in formative assessment, they acknowledged that objectivity was difficult to achieve, there were multiple causal links, all entities were continuously changing and shaping each other and the inquiry was value based. Ekeland and colleagues (2012) recommended both of these approaches in evaluation of new technologies, which seemed to be a reasonable way forward. This research has also demonstrated the value of using these two forms of evaluation.

Measuring health outcomes has not always been straight forward as shown throughout the thesis. While commonly recognised health outcomes such as hospital admissions and mortality are considered to be the key health outcomes, there are a number of outcome measures that are rarely included in the evaluation of new technologies. These include outcomes related to quality of life, assurance and confidence, work efficiency, change in medication, keeping in touch with friends and relatives, being in control of managing health conditions, and living independently, among others (Morrison and Barnett, 2009). A report by the International Union for Health

Promotion and Education recognised these types of outcome measures as health promotion outcomes (intervention impact measures), or intermediate health outcomes (modifiable determinants of health) or health and social outcomes (ECSC-EC-EAEC, 2000), (Table 8.1).

Table 8.1: An outcome model for health promotion outcomes

Health & Social Outcomes	Social outcomes: measures include quality of life, functional independence, and equity.		
	Health outcomes: measures include reduced morbidity, disability, and avoidable mortality.		
Intermediate Health Outcomes (<i>modifiable determinants of health</i>)	Healthy lifestyles Measures include tobacco use, food choices, physical activity, alcohol and illicit drug use.	Effective health services Measures include provision of preventive services, access to and appropriateness of health services.	Healthy environments Measures include safe physical environment, supportive economic and social conditions, good food supply, restricted access to tobacco, and alcohol.
Health Promotion Outcomes (<i>intervention impact measures</i>)	Health literacy Measures include health-related knowledge, attitudes, motivation, behavioural intentions, personal skills, and self-efficacy.	Social action and Influence: measures include community participation, community empowerment, social norms, and public opinion.	Healthy public policy and organisational practice: measures include: policy statements, legislation, regulation, resource allocation, and organisational practices.
Health Promotion Actions	Education: Examples include patient education, school education, broadcast media and print media communication.	Social mobilisation: Examples include: community development, group facilitation, and technical advice.	Advocacy: Examples include: lobbying, political organisation and activism, and overcoming bureaucratic inertia.

Source: (ECSC-EC-EAEC, 2000), page 6.

RCT has been used to assess efficacy and effectiveness of new drugs or interventions. The distinction between efficacy and effectiveness is that:

“Efficacy refers to whether a drug demonstrates a health benefit over a placebo or other intervention when tested in an ideal situation, such as a tightly controlled clinical trial. Effectiveness describes how the drug works in a real-world situation.” (Thaul, 2012), page 4.

In practice, undertaking trial of efficacy and effectiveness both would involve patients using telehealth machines and health professionals monitoring the readings generated from the machines and responding accordingly.

However, the differences in conducting trials of efficacy and effectiveness of telehealth are outlined below.

To conduct an efficacy of telehealth trial, tighter inclusion criteria would be required, along with dedicated staff. This was not realistic for Doncaster PCT, and indeed similar NHS organisations in England at the time, given the limited resource constrains. It was also not realistic to do efficacy trial on telehealth in Doncaster PCT because the prevailing culture in the organisation was not really fully established as an institution for doing research, even though it valued it. This can be seen from the evidence in Chapter 3, where most of the research activities in PCTs at the time involved observational study or service evaluation, and few interventional studies that assessed efficacy of interventions. Hence, it is really difficult to undertake a trial of efficacy of telehealth in routine NHS practice.

On the other hand, a test of effectiveness should be undertaken once efficacy had been established. In this work, efficacy trial of telehealth was mainly derived from evidence in the published literature (Chapter 4). In practice, many pilots of telehealth were taking place in England at the time

of introduction of telehealth in Doncaster, and it was considered appropriate to undertake a pragmatic trial of effectiveness of telehealth. Ideally, conducting a trial of effectiveness of telehealth should have flexible inclusion criteria. It requires the involvement of staff, who normally work in the organisation. This might involve dedicated staff if that is how the intervention is envisaged, but they will not be research staff delivering the intervention.

Therefore, efficacy is measured in as controlled environment as possible to maximum likelihood of identifying a benefit if it exists, whereas effectiveness is assessed in real life settings.

Regarding embeddedness of a new practice in routine practice, a service evaluation, with a robust mix method of evaluation, seems to be the right approach to use for evaluation of new technologies. The RCT concept is still regarded as unacceptable by some front-line staff, both in health and social care organisations (Hendy et al., 2012). Staff felt opposed to RCT, as it allocated users whom staff regarded as suitable for new technologies into a control group where they ended up not receiving the anticipated technology (intervention). The underlying premise among these staff was that such new technology was beneficial to users, and by allocating them to a control group, the users were denied the potential health benefit from the technology. Hence the position that staff adopted was not at equipoise.

The findings from the pragmatic trial concluded that telehealth was neither effective nor cost-effective. Study outcomes such as these could be the subject of publication bias due to the negative results on effectiveness and

cost-effectiveness. The knowledge gained from the pragmatic trial had been vital in informing the uptake of new technologies in subsequent service evaluation. The reporting of negative results from research studies needs to be viewed in a similar way as those with positive results by journal editors.

8.3.2.3 *Integration into mainstream healthcare use*

If new technologies, such as telehealth, are to be accepted and normalised into routine use, their features and use needs to be generally accepted to users and it must be integrated into social use. The social use of new technologies means that such technologies are widely accepted and used in social networks or activities. For example, some modern mobile phones and watches have features that can also measure vital signs of users. Such features need to be less obtrusive and be able to integrate with other technological devices in social use. There are emerging devices in the market with features that are less intrusive, although it may be sometime before they become widely available. For this to happen, designers need to work closely with those who are going to use the new technologies of the future in co-designing them.

Users should have the option of owning the data generated from the new technologies, and they should be in control of the data and be able to determine who they can share it with. Current experience shows that patients did not have access to their own data.

The technical accuracy and performance of new technologies need to be assured if they are to gain acceptance among professionals and users. Evidence in this thesis showed that on some occasions, the diagnostic

accuracies of new technologies were called into questions resulting into loss of confidence in the technologies and subsequently, health professionals abandoning their use in preference for old technologies that they were familiar with.

8.3.2.4 *Practical and ethical issues raised by new technologies*

The introduction of new technologies raises some practical and ethical issues, as identified by other researchers (Stocking and Morrison, 1978) and further presented in Chapter 4. In the pragmatic trial, it was found to be one of the reasons why health professionals were resistant to implement new technology because they considered RCT approach to be unfair. It can be seen that the health professionals were not at equipoise. Equipoise had been defined as a position where “there is genuine uncertainty in the expert medical community over whether a treatment will be beneficial” (Freedman, 1987). From ethical point of view, it is unfair to withhold treatment where there is evidence that one form of treatment is better than the other. In the pragmatic trial that is reported in Chapter 5, the treatment was telehealth service (the intervention), while the control group received standard care. Healthcare professional appeared to believe that telehealth service was beneficial for their patients. This position was influenced by the Government (England) position, which supported the use of telehealth and saw it also as being beneficial for self-management of individuals (Chapter 3). Given the findings of the pragmatic trial, patients would not have been disadvantaged and indeed some may have been better off to be randomised to the control group (standard care) if it meant that they weren't being frightened by red alerts given that there was no improvement in hospital admission rates or

death rates. However, there remained uncertainty in confidence that can be placed on the conclusions of the pragmatic trial, in view of the limitations discussed in Chapter 5. The position of health professionals was confirmed by findings from the qualitative study (Chapter 7), where patients appeared to be reassured by being on telehealth service, despite the levels of red alerts experienced.

Current evidence around effectiveness and cost-effectiveness of new technologies presents a practical and ethical issue to practitioners and policy makers on whether to recommend new technologies to users widely before establishing their effectiveness and cost-effectiveness. It seems there is a gap between the current evidence of effectiveness and cost-effectiveness and policies about some new technologies and/or variations in interpretation of current evidence. Current evidence does not support the wider roll out of new technologies on cost-effectiveness ground. For example, the Department of Health in England seemed to advocate telehealth service before the evidence on cost-effectiveness was available, and had planned to roll out telehealth to 3 million users within five years (3MillionLives, 2012).

The other practical issues in both the trial and service evaluation were to do with how red alerts were addressed, and if there were issues uncovered, whether they led to the appropriate course of actions. There had not been adequate exploration of actions related to the red alerts by community nurses. In future, audit of the actions based on response to patients' telehealth readings should be an integral process of the new technological services on how patients are managed. From ethical point of view (Shickle and Chadwick, 1994), it may be unethical to generate unnecessary anxiety

among patients and staff from inappropriate alerts. The harm caused has to be outweighed by the benefits for the patients and/or significant public health benefits. This is consistent with the Declaration of Helsinki on the principles of undertaking ethical medical research involving human subjects (World Medical Association, 2013).

8.3.3 Service Design

8.3.3.1 Integrated whole-system service model

A better service model is required that (1) has a sound procurement process, and (2) integrates with various elements in the health and social care system.

Procurement process

The existing procurement process used in both the pragmatic trial and the service evaluation, and those used elsewhere in England, for example in North Yorkshire (Evanstad, 2013), had some major limitations. In this type of service model, commissioners purchased the technological devices and pay for them regardless of whether they ended up using them or not. If these devices were not used, the organisation responsible for the purchase had to take responsibility for the storage of the devices, in addition to the inefficiency of not using equipment that had been purchased. These devices, as time progressed, also became obsolete, as newer versions were developed and released into the market. Experience showed that the turnover of new technologies occurred rapidly; with changes in new technologies coming into market every one to two years (Chapter 6). Experience of

introduction of whole body scanner in the UK in the 1970s also encountered similar problem of running costs, repairs, and storage among others, which were not included in the initial costs of the technology (Stocking and Morrison, 1978). To overcome these limitations, future service models need to address these challenges in the procurement processes such that commissioners of health services are clear about the initial and maintenance costs of new technologies into the future. It would be preferable for commissioners to pay for the actual machines used, regardless of the number of devices agreed in contracts. Commissioners should also have the option of terminating the service without any penalty or heavy losses incurred, including financial expenditures. This may entail commissioners renting the devices with the options to upgrade them, at supplier's expense, when newer ones become available in the market. This needs to be built into contractual agreements.

The Veteran Health Administration (VHA) model offers a particularly helpful model where a range of telehealth products were available for a care coordinator to choose from to suit the needs of individual users (Darkins et al., 2008). Although the telehealth technology used in the pragmatic trial and service evaluation had got 'add-on' peripherals, essentially the package of the technology was standard. In the future, front line staff should be able to determine what additional devices or peripherals of new technologies that they need for their patients. These peripherals should be compatible with each of the existing system if they are from different suppliers.

Current model of telehealth service is driven by technology industries that are trying to find a market for the new technologies, rather than finding the

technologies to address identified health problems. A similar issues had also been highlighted by other researchers in relation to whole body scanners (Stocking and Morrison, 1978). The starting point for any commissioning of service must begin with an assessment of population health needs in order to ensure that the limited resource is targeted where more benefits can be gained in terms of population health outcomes. This process needs to be followed by systematic review of the literature to identify possible cost-effective interventions. This will allow providers and/or commissioners to consider the options available in order to invest their limited resources. It is important to note that the Department of Health in England had a strong influence on healthcare providers as it directed priorities for health services in the country. However, the directives might not always be based on cost-effectiveness evidence (3MillionLives, 2012). Therefore, future demand for new technology should be driven by health needs of the population.

Integrated service

Integration of new technologies with services provided by health (NHS) and social care (local authority) had been a desired ambition of the government in England when it funded the Whole System Demonstrator (WSD) telehealth RCT project, however, this goal was not achieved (Hendy et al., 2012). The authors of the WSD pragmatic trial attributed the reasons for the failure of integration of telehealth to the following factors: different cultures between health and social care organisations, the problem with RCT itself as the study design, and lack of joined funding. It was likely that the technology did not help staff in those organisations to do their job better; hence they did not adopt it. This would be consistent with normalisation process theory

(NPT) which stipulated that people enacting a new innovation need to see meaning in it and how it could enhance their work (May and Finch, 2009). A better integration of new technologies among different organisations could be achieved if such an integration was supported by a common goal that addresses identified needs, pooled funding system, joint team that are working together, co-located and under joint leadership arrangements. Assessment of users and their subsequent monitoring also needs to be undertaken jointly, along with associated training of staff.

Most of service designs for telehealth in England had been 'in-working-hours' service (provided between 09:00 to 17:00 hours; Mondays to Fridays), as described in Chapter 3, and in the evidence from the literature (Chapter 4). There remained gaps in providing the service to patients 'out-of-hours' (in the evenings between 17:00 hours to 9:00 hours and over the weekends) when patients were likely to be left exposed, anxious and vulnerable and the option available for them would be to turn up to accident and emergency departments of the local hospitals, if their conditions deteriorated. This gap represented more than three-quarters of the time per week that were not covered by telehealth service. This is a scenario, commissioners and health service providers would want to avoid in the future and therefore it needs to be addressed.

Therefore, the future provision of new technology service needs to be integrated into the whole health and social care system and cover both 'in-working-hours' and 'out-of-hours': i.e. 24-hours per day and 7 days per week across primary and secondary care interface, and embracing public health agenda of prevention. Integration should also be aimed at health and social

services, especially in certain common areas such as intermediate care. Operating systems, such as ICT (Information and Communication Technology) in organisations should incorporate mechanisms for information collection and sharing related to the new technologies. The service model should be an integrated model, as described in the literature review (Bartoli et al., 2009) where a committee will be responsible for the design of the services, including guidelines development, selection of patients, and related human resource planning (Chapter 4).

8.3.3.2 Outcome measures

The financial benefit from new technologies such as telehealth is difficult to quantify. There are some outcome measures that are hard to cost e.g. reassurance, quality of life, and independence for users. A system for quantifying and costing new technological service (e.g. tariff payment) would be helpful as financial incentive for providers and this could be used for evaluation. In the UK, the National Institute for Health and Care Excellence (NICE) uses cost per QALY (quality adjusted life years), yet it does not cover all aspects of outcome measures that were expressed by users from the qualitative interviews (Chapter 7).

A model for assessing effectiveness of health promotion intervention proposed appropriate levels of outcomes (ECSC-EC-EAEC, 2000) (Table 8.1). Patient-reported outcomes measures (PROMs) are being recognised in current health service delivery in the NHS in England, and in the wider literature (Frost et al., 2007).

Based on the health promotion model of assessing health promotion interventions, the most appropriate outcomes measure for new technologies needed to include (1) health promotion outcomes (intervention impact measures related to health literacy), (2) intermediate health outcomes (modifiable determinants of health related to effective health services; and (3) health and social outcomes (ECSC-EC-EAEC, 2000). The latter category might be less specific to one particular intervention. In addition, some of the health and social outcomes might take a long time to realise; well after an intervention had taken place.

Patient-related outcomes included information about patients' symptoms, health-related quality of life (physical and social functions), treatment adherence, and satisfaction with treatment (Frost et al., 2007). Frost and colleagues (2007) identified that PROMs were particularly helpful to influence decisions when interventions showed similar outcomes to usual care or where the interventions provided only small clinical benefit.

Lessons from the service evaluation showed that when choosing suitable quality of life questionnaires, it was important to involve front line staff in the choice of the questionnaire. One of the key characteristics for the choice of questionnaires was their simplicity (often one page) and they were easy to analyse (by adding up the score manually) and staff could establish the outcome of the assessment. Short instruments that are easy to analyse may not be valid. Therefore, it is important to use validated instrument or to do a formal validation process if the instrument is being developed from scratch (Frost et al., 2007). The instruments used to measure quality of life in this research were validated ones (EQ5D, Generalised Anxiety Disorder 7-

dimensions or GAD-7, Minnesota Living with Heart Failure or MLHF), and they could be used and easily analysed by community nurses while they were with patients.

Overall, this was found to have worked well in the service evaluation. This approach enables the quality of life questionnaires to embed in routine use, unlike those with several pages to complete such as SF-36 and St George's Respiratory Questionnaire. Therefore, practitioners should promote the use of simpler questionnaires that are easy to analyse and interpret by frontline practitioners that can enable them to make management plan for users and provide on-going monitoring.

8.3.3.3 *Data source for selecting users of new technologies*

The use of hospital admission data proved to be an unreliable source of data for selecting patients for telehealth service due to limitations already discussed in Chapters 5. The limitations included: patients might be dead by the time the selection was being considered; not contactable; or simply the information was out of date to inform meaningful actions. As a result, future suitable alternative source of information for selecting users of new technologies should be derived from live source of data used by service providers. Such source of data could be staff existing workload, or information at the point of discharge from services or when patients are still in hospitals where they are considered for new technological service; and not after they are discharged from the services.

8.3.4 What could be done differently if starting the RCT again?

If an RCT were to be carried out once again, a number of key lessons learned would be used to do the trial differently. For example, this will include careful consideration of factors influencing successful recruitment into pragmatic trial described in Chapter 5, key challenges in developing and implementing telehealth projects, and lessons from failed trial could be taken on board, as described in Chapter 4.

An early engagement with relevant clinical staff and organisation will be held to secure engagement with the pragmatic trial and to discuss the trial objectives, and its conduct. The trial protocol will be developed with clear research questions, objectives, hypothesis, outcome measures, and methods of analysis (pre-specified outcomes – *a priori* analysis). A team will be assembled to develop, and implement and evaluate the trial. The trial will be registered with the Trial Register of Promoting Health Interventions (TRoPHI).

Depending on funding, the choice of individual pragmatic RCT versus cluster RCT will be made, with the latter requiring more funding. A cluster pragmatic trial would be a preferred option. Cluster trial would allow participants to know whether or not they are in the intervention or control group, as evidence shows open design trial improved recruitment into trials (Trewick et al., 2011). If individual pragmatic trial is undertaken, however, consideration will be given to how participants are recruited. This could be at the point of discharge from hospital to avoid using hospital admissions as the basis for identifying patients. Alternatively, the choice could be using

community matron caseload as the source of selecting patients. The advantage of these sources of information is that they have live patients at the point of selection.

Dedicated staff for the implementation of the project will be agreed and secured. There will be implementation plan and a business model for the pragmatic trial delivery, as outlined in Chapter 5 (Campbell et al., 2007). The intervention will need to be well understood and the associated components, how the model of delivery fits with existing health and social care system.

Other processes that had been done before, which required to be carried out in a similar way will be conducted accordingly, such as ensuring the study is compliant with the ethical requirements and the necessary approvals are obtained.

8.3.5 Areas for future research

Future research in new technology in health needs to investigate the most appropriate health outcomes that need to be adopted that are valid and that reflect the intervention of the new technologies. Current outcomes, such as hospital admissions and mortality rates tend to be less sensitive outcome measures for new technological interventions. The reasons for this include the fact that these outcomes maybe attributed to multiple causes that are unrelated to, or have little association with, the interventions of interest such as new technologies. Therefore, in addition to the above outcomes, other more sensitive health outcomes measures need to be examined as well. Such outcomes may encompass: blood pressure, level of oxygen saturations, blood glucose, or weight, some of which had been reported in

Chapter 4. For quality of life, the health outcomes may need to include those identified by users in this thesis (Chapter 7) and other literature such as keeping in touch with social network (friends and families), being in control of one's condition, and enabling patients to live independently (Morrison and Barnett, 2009).

By suggesting that mortality and hospital admissions are less sensitive outcome measures of new technologies, this may potentially pose some risk of being seen as “moving the goalpost” for outcome measures in evaluation of interventions. Such risks could be justified if the suggestions made were seen as efforts to provide excuses for ineffective interventions that have failed to demonstrate their worth. In addition, such criticism could be labelled if the proponents and evaluators attempt to find outcome measures or intermediate outcome measures that are easy to measure. There is also the risk that by suggesting new and sensitive outcome measures, the existing outcome measures might be considered to be inappropriate ones. On the other hand, the notion that hospital admissions and mortality outcomes maybe considered to be less sensitive outcome measure can be viewed objectively. Firstly, new evidence gained from the work in this thesis demonstrate that there are other outcome measures, from patients' perspective that have not been well reflected in a range of outcome measures observed in the published literature. Examples from the field of health promotion, supports the view that outcome measures such as mortality are not meaningful when evaluating interventions whose appropriate impacts are intermediate health outcomes such as those likely to impact on healthy lifestyle, effective use of health service and health

literacy (State of Victoria, 2003, ECSC-EC-EAEC, 2000). Table 8.1 presents the evidence of health promotion effectiveness and the appropriate outcome measures. The intermediate outcomes enable patients to gain knowledge and skills to access health services, and make informed decision to improve their health (State of Victoria, 2003). Systematic reviews on new technology targeting lifestyle such as smoking supported the use of intermediate health outcomes (Sheikh et al., 2011).

New technology such as telehealth can be viewed as a tool for educating patients and providing them with empowerment. Hence the appropriate outcomes are those related to health literacy, which can lead to modification of determinants of health (ECSC-EC-EAEC, 2000).

Secondly, for patients' groups targeted for intervention, as in the pragmatic trial and the service evaluation, their average age was around 70 years old, suggesting that they were likely to have multiple co-morbidity, not all of the conditions would be amendable to intervention using new technology. Therefore, to attribute mortality outcomes among this group of patients, to the effects of new technologies may not be very sensitive outcome measures.

Thirdly, by highlighting the case of sensitivity of hospital admissions and mortality as compared to intermediate outcomes for evaluating impacts of new technologies, new areas for research exploration are being suggested for further validation. This may lead to more realistic assessments of outcomes when effectiveness of new technologies is being made. Ideally, (1) health and social care outcomes on the one hand; (2) intermediate health

outcomes; and (3) health promotion outcomes; all of these need to be assessed in determining effectiveness and cost-effectiveness of new technologies.

There is need to exercise caution in trying to establish a causal relationship between the effects of new technologies and mortality and hospital admissions outcomes. The assumption that such a relationship is causal is false when assessed against Bradford-Hill Criteria (Lucas and McMichael, 2005). The Bradford-Hill criteria were formulated for determining cause-effect relationship. For example, one of the criteria of Bradford-Hill relates to “specificity” in which exposure to a single agent must result in a particular outcome observed, if it is to be considered as a cause of the disease or outcome. As it was observed in the pragmatic trial (Chapter 5) and observational studies (Chapters 6 and 7), the mortality and hospital admission outcomes were also experienced among patients who received telehealth as well as those who did not. Therefore, this weakens any argument that there was a causal relationship between telehealth and health outcomes (e.g. mortality and hospital admissions). However, what both the trial and observational studies did was to lend argument to the strengths of the association between telehealth and the outcomes observed, rather than established a causal link. It leaves the possibilities open to the fact that the outcomes observed could be due to other factors.

There is currently an inverse care law in the distribution of disease burden in the population and the use of new technologies by age groups; the burden of the disease falls disproportionately among older people whereas the use of new technologies is limited among them. More use of new technologies

among older people needs to be encouraged in order to help in managing the burden of long-term conditions that are predominant among older people. For younger people, new technologies that encompass health elements need to be incorporated, such as those that promote healthy lifestyles. While for the older population, there is evidence of increasing use of new technologies among this population (AgeUK, 2011), which needs to be encouraged. Current new technologies tend to be targeted at older people, due to high prevalence of morbidity and high usage of health services in this group of the population, although this may make sense from cost-effectiveness point of view, the strategy is less likely to achieve epidemiological health impact at population scale (Stocking and Morrison, 1978). Therefore a preventive strategy is required for new technologies to be sustainable and to achieve epidemiological impact where a wider target population will benefit from them.

8.4 Recommendations

For new technology to embed in routine healthcare practice, the following are recommended:

8.4.1 Implications for practice

1. When introducing a new technology in routine practice, it is important for policy makers to regard the new technology service as being a whole system service, which includes the technological device, staff and other associated services, rather than the “black box” only. Implementation of new technology is a complex intervention; focusing

on the device alone would undermine it being embedded in routine health service delivery.

2. New technological devices that are to be introduced for use in routine healthcare service need to be simple and easy to use for patients and staff.
3. Where possible, new technology should be tailored to the needs of the individual patients; and frontline healthcare professionals should be empowered to choose the appropriate technologies for the patients.
4. Before initiating the use of new technologies among new users, a period of initial assessment is required in order to agree threshold cut-offs as to what constitutes normal and what requires urgent or non-urgent follow-up for each an individual patients.
5. There should be continuous process of education and training for staff who are involved in the implementation of new technological services. This should include promoting regular network events for professional to share experiences related to the implementation of the services. Such training needs to be made mandatory requirements for the relevant staff involved in the service delivery.
6. Education of users of new technologies needs to be embedded as part of a continuous process of implementation of the service in order to ensure that they fully understand the purpose of the service.
7. There need to be a dedicated project coordinator and a project team to manage the implementation of new technology service in healthcare delivery.

8.4.2 Implications for policy

8. When designing a policy for implementation of a new technology service, it needs to adopt a whole system delivery model, which covers patients' pathway of care, for example, ensuring integration between primary and secondary health services.
9. There is a need to ensure that new technologies are used to address identified health needs of the population.
10. Effectiveness in practice as oppose to efficacy of new technology should be established in pilot sites to identify implementation issues, before the technology is recommended for widespread roll out.
11. Policy-makers need to ensure that introduction of new technological services do not inadvertently exacerbate health inequalities. Some people may be disadvantaged in being able to access the new technology if there needs to be a landline telephone (some old people do not have landline telephone, while some young people do not have telephone landlines any more as they use their mobiles instead), computer access, or own a smartphone capable of running an app.

8.4.3 Implications for research

12. Research is needed in determining technical and diagnostic accuracy of new technology devices that are introduced in routine healthcare practice. This should continue to be monitored in the course of implementation, not only when the technologies are released for wider use.

13. More research is needed in determining the effectiveness (as opposed to efficacy) and cost-effectiveness of new technology in healthcare under routine healthcare conditions and in different disease areas and levels of disease severity. If a technology is tested on one category of patient, disease type or severity, it should not be assumed that it would also be effective or cost-effective in another.
14. Research is needed in expanding appropriate health outcomes for assessing effectiveness and cost-effectiveness of new technologies that include intermediate health outcomes, health and social care outcomes and patient reported outcome measures (PROMS).
15. Future research should assess which of the following sources are more reliable for helping to recruit participants into research studies:
(1) historical routine data or “non-live data” sources (e.g. hospital admissions data); and (2) “live data” sources such as existing caseloads of health professionals.

Chapter 9: Reflections

9.1 Introduction

This final chapter of the thesis offers reflections on the following areas: the extent to which the research questions have been answered and the author's own learning; the influence of the author's public health background as well as his role as Consultant and Assistant Director of Public Health at Doncaster Primary Care Trust (PCT) in the conduct of the research; potential areas of conflicts; and the contributions of the PhD work to knowledge.

9.2 The reflections

9.2.1 The extent to which the research questions have been answered and author's learning

Reflections on the final research questions

The final primary research question of this thesis was: *Why does a new technology embed or not in a routine health service?* There were five hypotheses that were developed (Chapter 1) to try to address the above research question.

On the basis of the evidence available in the thesis, it was not possible to reject the stipulated hypotheses related to technology, staff and evaluation methodologies used. On the other hand, the evidence available could not allow the hypotheses related to setting and patients' group to be accepted.

The answers to the research questions also formed important learning for the author on factors related to why new technologies fail or succeed in routine practice.

The thesis has presented complex and technical sets of information in various chapters. It was a challenge to synthesize the information from the various chapters into Chapter 8, in order to address the research questions. Case study research method was found to be a very useful methodological approach to pull all the information together in order to confirm or reject prior hypotheses (Yin, 2009).

Earlier on in the PhD research, a number of possible choices of appropriate theoretical frameworks were considered; some of them were not included in Chapter 2. Some of those that were not included in Chapter 2 included diffusion of innovation theory (Greenhalgh et al., 2004), and the DEPOSE (Design, Equipment, Procedures, Operators, Supplies and materials, and Environment) model which was related to investigation of systems failures of high risk technologies such as nuclear plants (Perrow, 1999). These two theories were discarded, as they were not considered to offer adequate explanation to the challenges posed in this thesis related to new technologies as used in routine healthcare. Of all the theories considered (Chapter 3), Normalisation Process Theory (NPT) was found to be the most appropriate and helpful one. It was useful in providing the explanation as to why new technologies fail or succeed to embed in routine practice. All the theories considered had some useful aspects in them that were relevant to this research and had some influence on the thinking of the author.

Reflections on the original research question

The original research question of the PhD was: *What effects will telehealth monitoring have on people with COPD, the care they receive and resources required to maintain that care?* The attempt to address this research question was subsequently abandoned, as the pragmatic randomised controlled trial (RCT) that was envisaged to answer the research question was prematurely stopped.

It was not feasible to address the original research questions with certainty given the limited resources using the pragmatic trial that had been reported in Chapter 5. As discussed in Chapter 8, more staff would have been needed, and the research would have to be designed differently as a cluster pragmatic trial.

Some of the main learning points from undertaking the pragmatic trial included the following:

- It was realised that undertaking an RCT in routine health service was not easy, especially involving the evaluation of new technology, which had been acknowledged as a complex intervention (Campbell et al., 2000). With the resources available, the trial was too ambitious. There were several original objectives, each of which could have formed a separate study.
- There were lessons drawn from what did not work so well in the pragmatic trial, details of which were reported in Chapter 5 and

synthesised in Chapter 8. This learning was used to improve subsequent service design (Chapter 6 and 7), and to change the course of the PhD research, which focused on why new technologies failed or succeeded to embed in routine practice.

By undertaking a systematic review of effectiveness and cost-effectiveness of telehealth service (Chapter 4), the original research question of the research was also addressed. In this sense, doing the systematic review was helpful in answering the original research question. However, a service evaluation would have been necessary, after effectiveness and cost-effectiveness of telehealth service had been established. There are two forms of service evaluation that could be undertaken: (1) to test effectiveness of telehealth service in the “real world setting” such as in pilots sites before wider roll outs; and (2) to audit performance of service against standards of care. In the course of the implementation, lessons could be learned regarding practical application in routine healthcare setting. The service evaluation conducted in Doncaster was not the best approach for assessing effectiveness or cost-effectiveness of telehealth service because of its limitation related to high degree of bias, as per hierarchy of evidence (SIGN, 2011). The sources of biases include the fact that service evaluation does not usually have control group to compare the findings obtained, and the findings could be subject to regression to the mean.

At the time the pragmatic trial was being planned, the evidence base from the literature was limited regarding effectiveness and cost-effectiveness of telehealth. If the author had undertaken a systematic review instead of conducting a pragmatic trial at the time, there were likely to have been

limited findings from the literature to support informed local decisions. More published papers on telehealth became available later on after the pragmatic trial was conducted (Chapter 4). A service evaluation would have still been necessary in order to provide assurance of the quality of service gained.

From the literature review, the author learned more about effectiveness and cost-effectiveness of telehealth service, factors related to successful implementation of telehealth and how to improve uptake of participants in RCTs.

There was a push from the Department of Health in England to implement telehealth service, for the National Health Service (NHS); and telecare, for the local authorities at the time of the pragmatic trial. This push was backed up by financial grant from central government to promote assistive technologies. Hence, the influence of the Department of Health in England was too great to ignore by local health and social care organisations. Similar influences still remain, at the time of completion of this thesis, in driving the implementation of new technologies in health and social care in the form of 3Million Lives (3MillionLives, 2012) and its successor programme, the Technology Enabled Care Services (NHS England, 2015). The Government's five year plan (2015/16 to 2020/21) for England's "*Five year Forward View*" also highlighted the role of new technologies in health service delivery: "*We will invest in new options for our workforce, and raise our game on health technology – radically improving patients' experience of interacting with the NHS*" (NHS England, 2014).

Was doing an RCT in Doncaster the right thing to do? At the time, it was probably thought to be the right thing to do an RCT when there was limited evidence of effectiveness of telehealth at the time. However, the infrastructure for undertaking such a trial was not in place in a routine NHS setting at the time. To do the RCT properly, it would have required more dedicated staff and financial resources than it was available at the time. The involvement of local hospital and academic partners would have improved the buy-in to the trial, and increased its likelihood to succeed in recruiting participants.

The choice of doing the RCT was taken before the author chose the topic on telehealth for a PhD research. A number of other potential topics could have been chosen. The final choice of topic was made after discussions with one of the PhD supervisors at the University of Leeds prior to registration for PhD study. Therefore, the PhD did not influence the decision of doing the pragmatic trial. The author, however, maintained an interest in implementation of new technology and in doing a PhD.

9.2.2 The influence of public health training in undertaking the research

As a Consultant and Assistant Director of Public Health with Doncaster Primary Care Trust (PCT) at the time of conducting the pragmatic trial, the author's public health training and values associated with public health practice had some influence in the ways how the research was conducted. The areas of influence for reflections were: (1) evidence base and its influence on practice, including exploration of whether doing the literature

review earlier by the author could have influenced actions; (2) the challenges of stakeholders being at equipoise during the evaluation of the telehealth service; and (3) the importance of population health, and regards to reducing health inequalities.

The evidence base and the potential to influence commissioning of service

One of the key strengths of public health is its focus on evidence base to inform interventions, and the expertise needed to appraise such evidence. RCTs are regarded as the gold standard in assessing evidence of effectiveness of an intervention where none existed. Systematic reviews that were reviewed at the time were of poor quality and were unable to answer the question of effectiveness and cost-effectiveness of telehealth service. The challenges of assessing effectiveness and cost-effectiveness of telehealth service are discussed in Chapter 4, and they included varying definitions of interventions used. At the time, given the small scale of telehealth technologies available, it was considered that the best way forward was to conduct a pragmatic RCT. Assessing effectiveness through observational study was thought to be more likely to yield biased results, as observed in pilot projects in England at the time.

There are circumstances in which conducting an RCT might not be an appropriate thing to do. Examples, of these circumstances are:

1. Where a service has been accepted as part of routine service delivery, it may not be possible to undertake an RCT. RCTs should be undertaken at the stage of equipoise, before the routine introduction of an intervention into practice to test its effectiveness

and cost-effectiveness. The problem that is faced in practice is that if the technology is already in use, then people may not be in equipoise and it becomes very difficult to stop it, and offer a placebo or standard care instead.

2. In some situation, such as certain aspects of surgery, it had been observed that conducting RCT might be difficult, instead practitioners should follow guidelines recommended by professional bodies and adhere to ethical norms (Das, 2011).

Evidence from the literature reviews could have influenced how telehealth was implemented in Doncaster. It could have informed a better implementation process. The procurement model, for example, might have been done differently, whereby the commissioners could have considered renting the equipment rather than purchasing them. There would have been a better service integration with mainstream health services, and the RCT study design could have been different, such as a pragmatic cluster trial.

Equipoise

The concept of equipoise related to a state of indifference in assigning research participants to one group rather than another in an RCT (Joffe and Miller, 2012). This concept was developed into what is currently referred to as clinical equipoise (Freedman, 1987, Joffe and Miller, 2012). In order to achieve clinical equipoise, it had been argued that the responsibility of ethics of the trial should rest with community of physicians rather than individual physician-investigator (Joffe and Miller, 2012). The following statement captures the essence of clinical equipoise:

“...So long as “there exists (or, in the case of a novel therapy, there may soon exist) an honest, professional disagreement among expert clinicians about the preferred treatment,” investigators may initiate a trial and, more importantly, individual physicians may participate in it or refer their patients to it even when doing so is contrary to their own treatment preferences.” (Joffe and Miller, 2012)

Clinical equipoise in trials is important in generating knowledge that is generalisable to benefit future patients or population (Joffe and Miller, 2012). Therefore, it is ethically acceptable to randomise patients to intervention arm of trial rather than the control group (placebo, standard practice, or an alternative mode of care) if there is genuine uncertainty among the medical profession regarding the benefit of the intervention under investigation.

There are, however, problems with clinical equipoise. For example, in the field of maternal-foetal surgery (MFS), Rodrigues and Van Den Berg (2014) argued that the concept of clinical equipoise was unsuitable. The reasons for their argument included: (1) misconception about clinical research and research subjects. In clinical equipoise, Rodrigues and Van Den Berg (2014) further argued that it incorrectly assumed that researchers had the duty to provide the best care for the patients; and that research participants were incorrectly assumed to have rights to interventions that was considered to be beneficial as standard care; (2) lack of clarity in determining who the research subjects were (mother or foetus); and (3) difficulties in determining who should be in equipoise where it was a multidisciplinary team.

Meanwhile, Joffe and Miller (2012) identified the problems of clinical equipoise as that of imposing ethics of medical care on the design and conduct of research; the challenge of defining clinical equipoise as there is limited professional consensus coupled with lack of data to measure degree of clinical equipoise; and reliance on biased opinion of clinicians that were never validated.

Research shows that an ethical committee would consider a trial to be unethical if the level of equipoise was beyond 80% i.e. 80% members were in favour of an intervention versus 20% in favour of an alternative treatment (Rahul and Barry, 2013). Note that in an ideal equipoise state between intervention and control arm of a trial, the level of indifference should be equal (50% versus 50%) in both arms of the trial. Ideally, equipoise should be assessed based on objective evidence as to whether treatment A is better than treatment B. This can be difficult where more than one outcome is used in the assessment, and the weight put on each of them.

The main issue with undertaking research in service delivery and policy oriented organisation, such as Doncaster Primary Care Trust, was that no one was at equipoise. This experience is not unusual in the real world, where various stakeholders may hold different views regarding the benefit of new technologies. These stakeholders include, among others, the manufacturers of new technologies, local healthcare organisations, academic institutions involved in research, patients or users, voluntary organisations, charities, professional bodies, arm-length government agencies, etc. Some of these stakeholders are advocates for new technologies while others are sceptics. In light of the various views held by

stakeholders, the question that arises is whether or not all stakeholders should be at equipoise in the course of the research. It is probably impossible for all stakeholders to be at equipoise. The innovators, for example, develop an idea that they consider are beneficial to society, before such an innovation undergoes field trials and evaluation. Manufacturers of new technologies, on the other hand, have primary interest of selling the new technologies, and the interest of benefit for users is secondary to them. However, those involved in evaluating new technologies should randomly allocate participants into a trial with objectivity when conducting an RCT to assess effectiveness of an intervention.

There are stakeholders whose primary interest is that of patients or users. Such stakeholders are likely not to be at equipoise when a new intervention is being introduced in routine care. This is because they have to be convinced that a new technology is beneficial for their users before they can advocate for its introduction in routine use. Of course, there are some people who also assume that new treatments are better. This group includes health policy-makers, commissioners, service providers, clinicians, and patients or users of the technologies. However, it is important that evaluators / researchers maintain skepticism about effectiveness of new technologies in order to ensure an objective and independent assessment of any claimed benefits are adequately assessed. Such evaluation findings need to be peer-reviewed and published.

The Department of Health in England and healthcare organisations seemed to be enthusiastic despite the lack of conclusive research with regards to introduction of new technologies in routine healthcare practice. Patients or

users are the ultimate target population for these new technologies. Depending on the information that is available to them and their level of health literacy to understand and critically appraise the information in order to make informed decision, they can decide for themselves whether or not new technologies are beneficial. If they are convinced of the benefits of new technologies, it has been shown that some patients or their carers were willing to buy some of the new technologies for their own use. On the other hand, users can also decide to abandon new technologies if they deemed them to be of no benefit or indeed harmful to themselves. It is important that such information about benefits or harms comes from independent and trustworthy source. This is important because each stakeholder is likely to be biased in favour of their position, regarding communicating information about the benefits and/or harms of new technologies. Independent arm-length bodies such as the National Institute for Health and Care Excellence (NICE) in England, is an example of an independent source of advice. However, NICE guidance is frequently contested and it has to operate within its terms of reference.

Evaluators / researchers should maintain an equipoise position. However, it can be difficult to maintain an equipoise position in the assessment of new technologies. They should, however, need to ensure that they do not have conflicts of interest that undermine an objective assessment to be carried out.

In Doncaster, at the time of implementation of the pragmatic trial, everyone came from a position that there was potential benefit for the new technology. This stance was built on limited evidence. The evidence base, at the time,

was also more in favour of implementation of telehealth service, and they were derived from poor quality studies or from different contexts to the situation in Doncaster.

Population health and reducing health inequalities

The challenges of long-term conditions were described in Chapter 3. A key part of public health practice is the concern with reducing health inequalities among the population of an area. New technologies could inadvertently, widen health inequalities between deprived and affluent sections of the population in an area. The author was cognizant of the fact that patients who had no landline telephone lines were excluded from the pragmatic trial and the likely impact this might have on widening health inequalities. As a result, in the observational study, provision was made in ensuring that patients without landline telephones were offered wireless telehealth technologies. Intervention, such as this, could contribute to widening health inequalities. However, there was no evidence to substantiate this claim. Data on impact of health inequalities may need to be built into future design for evaluating new technologies.

9.2.3 Author's role in Doncaster in influencing things

The author was the lead professional responsible for commissioning of services for respiratory diseases in Doncaster at the time of conducting the research. He was employed with Doncaster Primary Care Trust. The author chaired Doncaster Respiratory Working Group, a multi-disciplinary and multi-agency group in Doncaster bringing together hospital staff (respiratory physicians, nurses, physiotherapist, and others), primary care staff (GPs,

community nurses, and managers), and PCT staff. The author chaired the meeting in which the pragmatic trial idea was conceived and subsequently developed. He worked with other members to make the case for the initial fund for the pragmatic trial. In addition, he made the case for additional fund to increase the size of the pragmatic trial (Chapter 5). The author was the research lead for the PCT, and a board member at South Yorkshire Comprehensive Local Research Network (SYCLRN, 2010).

9.2.4 Potential areas of conflicts

This section explores areas of potential conflicts in (1) the conduct of the research and performing the analysis of findings; and (2) securing additional resources for the research, and how the author maintained integrity during the process.

The conduct of the research and performing the analysis of findings

In the course of the research (both the trial and service evaluation study), the author was the lead professional staff in Doncaster Primary Care Trust on respiratory diseases. He was responsible for the implementation of telehealth service for managing patients with COPD, and later this expanded to include patients with heart failure and diabetes. Being the lead for health policy in a topic area was different from being a pure researcher. As a health policy-maker, there was a value-based position that was more in favour of telehealth service being effective because of the message emanating from the Department of Health, as discussed above under equipoise. On the other hand, taking the position of a researcher was different and it involved being more objective in determining effectiveness of telehealth. It was

difficult to separate the two positions; as a policy-maker and a researcher. Ekeland (2012) recognised two type of evaluation methodologies; one was a formative assessment or naturalistic paradigm, where realities were considered to be multiple, constructed and holistic, and objectivity was partly possible (Ekeland et al., 2012). In the second type of evaluation methodology (positivist paradigm or summative assessment), the researcher would assume a neutral positions, and objectivity; and the researcher was value-free (Ekeland et al., 2012). Both of this methodological approaches were recommended in research (Ekeland et al., 2012). The author attempted to balance the two methodological approaches. During the course of the research, the author had maintained objectivity, as far as possible, for example, the final hypothesis of the trial was phrased such that it stated “telehealth made no difference”, rather than “telehealth was effective” at the beginning. It was impossible to be completely objective, as a policy-maker as well as a researcher; hence the line of assessment was more of a formative one.

The conflicts in adopting a formative assessment or naturalistic paradigm in evaluation of intervention was that authors might look for results they like, including post-hoc analyses (analysis undertaken that were not pre-specific before the study begun). This conflict has been considered and addressed in Chapter 5. It was not clear before the trial commenced what additional statistical analyses could be used. With additional training in statistical methods, it was realised that it was possible to use certain statistical methods to carry out the analyses.

The author maintained integrity by acknowledging limitations of the research. With regards to statistical analyses, the author maintained integrity by seeking expert statistical advice from his PhD supervisor.

Justification of the author's role in securing further funding for telehealth

The author's role in securing further funding during the pragmatic trial was justified for technical reasons to strengthen the power of study so that the findings of the pragmatic trial could be more generalisable. The funding for the roll-out of telehealth, as part of the service evaluation study, was the decision of the organisation to embed telehealth service within integrated community care pathway. The author's role was to evaluate the service.

The original sample size of the trial was based on the minimum number of participants calculated in order to identify a true difference in readmission rates between intervention and control group patients, if such a difference existed. At the time, the minimum number of participants was just enough based on the resource requirements at the time. However, more funding became available in the organisation (Doncaster Primary Care Trust), to support "innovation". The author made the case for more funding to support the expansion of telehealth project, which could also strengthen the power of the trial. The application for additional funding for telehealth service met the requirements for the innovation fund and was subsequently funded. The increased funding could have allowed more participants to be recruited into the trial, thus strengthening the findings of the study and making it more generalisable. However, due to the challenges reported in Chapter 5, the trial had to be stopped prematurely.

The author maintained integrity in relation to seeking for funding. The assessment of funding application for telehealth service was made by an independent group. The author accounted to the PCT for the fund obtained for the telehealth service.

9.3 Statement of contributions to knowledge

This thesis contributes to knowledge in the following areas: (1) understanding of why new technologies fail or succeed to embed in routine health services; (2) effectiveness and cost-effectiveness of telehealth service; and (3) embeddedness of new technology in routine practice. Both abstract and particular knowledge contributions in each of the above three areas are outlined below.

9.3.1 Why new technologies fail or succeed to embed in routine health services

The thesis has demonstrated the utility of normalisation process theory (NPT) in helping to explain why new technologies embed or not in routine practice. The specific propositions and how they related to the work of the thesis are described in the relevant parts of this section.

(a) Technology

The thesis contributes to our understanding of factors associated with the technology that determine the uptake of new technologies in practice. This knowledge was gained from the conduct of the pragmatic trial, service

evaluation, and systematic review literature on implementation of telehealth service.

The thesis also contributes to specific aspects of propositions of NPT and our understanding of embedding of new technologies in routine practice. Proposition 1.1 of NPT stated that: *“Embedding is dependent on work that defines and organizes a practice as a cognitive and behavioural ensemble”* (May and Finch, 2009). Telehealth service appeared to be better accepted by staff in the context of routine implementation examined in the service evaluation as opposed to implementation within a trial context.

The second proposition (1.2) related to factors that promoted or hindered actors' apprehension of a practice as meaningful. The factors related to the technology that promoted or hindered actors' apprehension of a practice as meaningful included the following:

- Physical features of the telehealth technology;
- Symptom questions in the machines;
- Remote access to telehealth readings of patients' health information by staff; and
- Technical accuracy, red alerts and associated workload of staff.

The thesis adds to our understanding of proposition 1.3, which states that: *“The production and reproduction of coherence in a practice requires that actors collectively invest meaning in it”* (May and Finch, 2009). The collective investments of meanings in telehealth service was demonstrated through work involving the implementation of the pragmatic trial, systematic review of evidence on implementation of new technology, and the service

evaluation. There appeared to be a better collective investment in meaning by staff in the context of implementation of telehealth service examined in the service evaluation as opposed to implementation within a trial context.

(b) Staff

The thesis contributes to our understanding of staff factors associated with uptake of new technologies. After examining a number of factors associated with staff in the context of a pragmatic trial and service evaluation, it was not possible to reject the stipulated hypothesis: *“there were factors associated with staff involved in the RCT, as opposed to the service evaluation that made a difference in uptake of new technology”*. Proposition 2.1 of NPT stated that: *“embedding is dependent on work that defines and organises the actors implicated in a practice”*. The thesis adds to our understanding how staff involved in the implementation of telehealth service found the service compatible with their work practice and it also helped to introduce some new ways of working.

The thesis contributes to our understanding of factors that promote or inhibit actors' participation (NPT proposition 2.2). These factors included:

- Capacity of staff and team involved in the management of telehealth service;
- Project management;
- Staff resistance; and
- Training.

The thesis advances knowledge in relation to Proposition 2.3 of NPT, which stated that: *“The production and reproduction of a practice requires that actors collectively invest commitment in it”* (May and Finch, 2009). There was evidence of stakeholders’ engagement and organisational investments to realise the outcomes related to telehealth service.

The thesis contributes to understanding of work that defined and operationalizes a practice of embedding of telehealth (NPT proposition 3.1). Interactions between healthcare professionals and patients appeared to have improved in the context of routine implementation examined in the service evaluation as opposed to implementation within a trial context.

(c) Evaluation

The thesis contributes to knowledge about factors associated with randomised controlled trial (RCT) methodology approach, as opposed to service evaluation in relation to uptake of new technology. On the basis of the evidence available, it was not possible to reject the stipulated hypothesis that: *“there were factors associated with randomised controlled trial (RCT) methodology approach, as opposed to service evaluation that made a difference in uptake of new technology”*. Proposition 4.2 of NPT stated that *“Embedding work is shaped by factors that promote or inhibit appraisal”* (May and Finch, 2009). This thesis contributes to our understanding of factors that promote or inhibit appraisal work to embed new technologies, and they include:

- Sources of data for recruiting participants;
- Randomisation process; and

- Inclusion criteria

The work of the thesis contributes to knowledge on embedding and how it helped to define and operationalize everyday practice (proposition 4.1 of NPT), through the work of the steering group. Through the same group, there was a collective investment in understanding of the work on telehealth service, which is consistent with NPT proposition 4.3.

(d) Setting

The thesis adds to our understanding of the relationship between geographical setting and embedding of new technologies in routine health service. There was no evidence to support the view that new technologies cannot be implemented in particular setting. This knowledge has been derived specifically from uptake rate of telehealth service in Doncaster, where no significant difference was observed in comparison with other districts in England. In the same setting, it was shown that uptake of telehealth service was lower during a pragmatic trial than in a service evaluation study.

(e) Patient group

The thesis contributes to our understanding of uptake of new technologies in various studies in relation to factors associated with patients' group. It was found that there was limited evidence to accept the proposition that the uptake of telehealth service in the pragmatic trial, and the service evaluation was explained by differences in types of diseases of patients.

9.3.2 Effectiveness and cost-effectiveness of telehealth service

The thesis contributes to our understanding of effectiveness and cost-effectiveness of telehealth service, from the literature review and conduct of the pragmatic trial.

The evidence from the systematic reviews showed that there was limited evidence of effectiveness of telehealth services for patients with long-term conditions. However, for some specific disease areas such as COPD, heart failure, severe asthma and diabetes, there was evidence of modest effectiveness in reducing hospital admissions and mortality. Patients seemed to be generally satisfied with telehealth services. Evidence of cost-effectiveness of telehealth was mixed, and the impact on quality of life was limited from systematic reviews. While evidence from the pragmatic trial showed that telehealth service had no effects on hospital admission rates, mortality rates, and it was not cost-effective. The findings from systematic reviews were updated, and therefore they were more recent than those obtained from the pragmatic trial reported in Chapter 5.

9.3.2 Embeddedness of new technologies in routine practice

The thesis contributes to knowledge on assessing embeddedness of telehealth service in routine healthcare practice. Acceptance rate of telehealth service by patients was used as a marker of embeddedness. The rate of acceptance in the observational study was compared with that obtained from systematic reviews. It was found that the acceptance rate of telehealth service during the observational study was significantly better

[81.0% (95% CI: 74.7, 87.3%); $p = 0.001$] compared to that reported in systematic review [67.9% (95% CI: 64.9, 70.9%)] (Gorst et al., 2014).

There appeared to be high compliance rates by patients to telehealth service in the context of routine implementation examined in the service evaluation as well as within a trial context. The levels of red alerts from telehealth service appeared to have reduced in the service evaluation context as opposed to a trial. Satisfaction of patients with telehealth service in the context of routine implementation examined in the service evaluation appeared to be high.

ANNEXES

- Annex 1: Literature review
 - Annex 1.1 Literature search strategy on Ovid Medline
 - Annex 1.2 An example of appraised systematic review articles on COPD
- Annex 2: Ethical approvals and considerations
 - Annex 2.1 South Humber Research Ethics Committee Approval
 - Annex 2.2 NREC Advice on service evaluation of Telehealth
 - Annex 2.3 The University of Leeds REC approval
- Annex 3: Questionnaires used with patients and staff
 - Annex 3.1 Interviews with patients
 - Annex 3.2 Interview with staff

Annex 1.1: Literature search strategy on Ovid Medline

Table A1.1: Search history of Ovid Medline: 1996-2012

S/No.	Searches	Results
1	telehealth.mp. or exp Telemedicine/	12159
2	exp Relative Biological Effectiveness/ or exp Comparative Effectiveness Research/ or effectiveness.mp.	145463
3	cost.mp. or exp "Costs and Cost Analysis"/	190762
4	chronic disease.mp. or exp Chronic Disease/	108777
5	2 or 3	307464
6	1 and 5	2174
7	2 and 6	695
8	healthcare.mp. or "Delivery of Health Care"/	92128
9	7 and 8	115
10	limit 9 to humans	104
11	Limit 10 to review articles	25

Table A1.2: Updated literature search history on effectiveness and cost effectiveness of telehealth for patients with LTCs from systematic reviews (Web of Science database)

Set	Results	Search History
# 7	Approximately 30	#6 AND #5 <i>Timespan=All years</i> <i>Search language=Auto</i>
# 6	Approximately 4,860,458	TOPIC: (review*) OR TOPIC: (systematic review*) <i>Timespan=All years</i> <i>Search language=Auto</i>
# 5	Approximately 138	#4 AND #3 <i>Timespan=2012-2015</i> <i>Search language=Auto</i>
# 4	Approximately 428	#2 AND #1 <i>Timespan=2012-2015</i> <i>Search language=Auto</i>
# 3	Approximately 483,879	TOPIC: (chronic disease*) OR TOPIC: (long term condition) OR TOPIC: (long term illness) OR TOPIC: (long-term condition) OR TOPIC: (long-term illness) <i>Timespan=2012-2015</i> <i>Search language=Auto</i>
# 2	Approximately 1,102,211	TITLE: (effect*) OR TITLE: (cost*) OR TITLE: (cost-effectiveness) OR TITLE: (effective*) <i>Timespan=2012-2015</i> <i>Search language=Auto</i>
# 1	2,542	TITLE: (telehealth) OR TITLE: (telemedicine) OR TITLE: (telecare) OR TOPIC: (telemonitoring) <i>Timespan=2012-2015</i> <i>Search language=Auto</i>

Search conducted on 11 July 2015, Web of Science. All databases in Web of Science were searched: Web of Science core collection; BIOSIS Previews; BIOSIS citation index; Data citation index; KCI – Korean Journal Database; Medline; and SciELO (Scientific Electronic Library Online) citation index.

Table A1.3: Literature search history of review articles on trials that fail to recruit participants to their targets (Web of Science database)

Set	Results	Search History
# 7	1	#6 AND #5 <i>Timespan=All years</i> <i>Search language=Auto</i>
# 6	Approximately 1,076,234	TITLE: (systematic review*) OR TITLE: (review*) <i>Timespan=All years</i> <i>Search language=Auto</i>
# 5	22	#4 AND #3 <i>Timespan=All years</i> <i>Search language=Auto</i>
# 4	Approximately 12,285	#2 AND #1 <i>Timespan=All years</i> <i>Search language=Auto</i>
# 3	Approximately 107,232	TITLE: (recruitment*) OR TITLE: (participant*) <i>Timespan=All years</i> <i>Search language=Auto</i>
# 2	Approximately 678,545	TITLE: (fail*) <i>Timespan=All years</i> <i>Search language=Auto</i>
# 1	Approximately 754,103	TITLE: (trial*) OR TITLE: (RCT) OR TITLE: (randomised controlled trial) <i>Timespan=All years</i> <i>Search language=Auto</i>

Annex 1.2: An example of appraised systematic review articles on COPD

Systematic review article: (McLean et al., 2011)

Key of Score: 2 = Yes; 1 = somewhat; 0 = No or can't tell

QUESTIONS	SCORE	COMMENTS
REVIEW FOCUS		
1. Did the review address a clearly focussed issue?	2	COPD patients were studied. Primary outcomes: total exacerbation; Quality of life (QoL), emergency department visits; hospitalisation, and deaths. Secondary outcomes: FEV1, FVC, patient satisfaction, study withdrawal, costs, and cost-effectiveness.
2. Did the review assess a clearly focussed technology?	1	Intervention (telehealth) used varied, not only telehealth, or poorly described.
3. Did the authors look for the appropriate sort of papers?	2	10 RCTs were included. Review question was the focus.
VALIDITY OF REVIEW RESULTS		
4. Do you think the important, relevant studies were included?	2	A comprehensive search strategy and process was demonstrated
5. Did the review's authors do enough to assess the quality of the included studies?	2	Appropriate consideration appeared to have been given to assess the quality of the studies included, including risk of bias, measure of treatment effect, unit of analysis, and heterogeneity, among others.
6. Were the studies accurately described?	1	Some descriptions of the technologies were described, but not adequately. There were no reports of compliance with the technologies.
7. Are the results of	1	Meta-analysis did not present study

individual studies reported in a clear and meaningful way or just listed with no real flow?		outcomes by type of technologies used.
8. If the results of included have been combined, was it reasonable to do so? (overall result presented from more than one study or meta-analysis)	1	Meta-analyses were performed. However, the outcomes were not stratified by technologies used.
9. Did the review demonstrate awareness of its own limitations?	2	Limitations of the studies were discussed, and future research gaps were suggested by the authors.
RESULTS		
10. Does the review present an overall result?	2	Yes, overall results were presented related to study questions. The authors' conclusions were precautionary in favour of telehealth.
11. How precise are the results?	2	Odds ratios and 95% CI were presented.
APPLICABILITY		
12. Implications for policy makers and or those considering implementing such technologies? Appropriate based on findings?	2	The authors were cautious against widespread adoption of the technology without further evidence from larger RCTs.
13. Are the results generalisable beyond the confines of the setting in which the work was originally conducted?	0	It hard to generalise the findings of the review, given the various telehealth technologies used, and different settings of the studies.
14. Were all important outcomes considered?	1	Some outcomes around workflows, practitioners' performance and negative outcomes were not reported.
15. Are you able to assess the benefit versus harm and costs?	1	To some extent. Not all costs associated with the technologies were accounted e.g. cost of staff time, patients and carers' time, among others.
CASP Total Score	22/30 (73%)	

Annex 2: Ethical approvals and considerations

Annex 2.1: Research Ethics Approvals (reference number 06/Q1105/64)



South Humber Local Research Ethics Committee

Room FC27
Coniston House
Trust Headquarters
Willerby Hill Business Park
Willerby
HULL
HU10 6NS

Telephone: 01482 389157
Facsimile: 01482 303916

07 February 2007

Victor Joseph
Senior Practitioner in Public Health
Doncaster PCT
Directorate of Public Health
Doncaster PCT, White Rose House,
Ten Pound Walk, Doncaster
DN4 5DJ

Dear Mr Joseph

Full title of study: Effects of Telehealth on COPD Patients in the Community
(TELECCOM) Study
REC reference number: 06/Q1105/64

Thank you for your letter of 6 February 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by the Dr Herber (Chair) South Humber REC.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application	Version 5.2	08 January 2007
Investigator CV	Version 1	08 January 2007
Protocol	Version 2	05 February 2007

Covering Letter	Version 1	26 December 2006
Summary/Synopsis	Version 1	05 April 2004
Letter from Sponsor	Version 1	05 January 2007
Peer Review	Version 1	08 January 2007
Questionnaire: End of Study Questionnaire for Primary Healthcare Staff	Version 1	08 January 2007
Questionnaire: End of Study Questionnaire for Patient	Version 1	08 January 2007
Questionnaire: End of Study Questionnaire for Carers	Version 1	08 January 2007
Questionnaire: St George's Respiratory Questionnaire (SGRQ)	Version 1	08 January 2007
Letter of invitation to participant	Version 1	08 January 2007
GP/Consultant Information Sheets	Version 1	08 January 2007
Participant Information Sheet	Version 2	05 February 2007
Participant Consent Form	Version 1	08 January 2007
Flow Chart	Version 2	05 February 2007
Letter from Neighbourhood Renewal Fund 2006-2008	Version 1	16 May 2006

Research governance approval

You should arrange for the R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research governance approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1105/64

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Dr K. Waltham

**Dr Stefan Herber
Chair**

Email: karen.waltham@humber.nhs.uk

Enclosures:

Standard approval conditions [SL-AC1 for CTIMPs, SL-AC2 for other studies]

06/Q1105/64

Page 3

Copy to:

Doncaster Primary Care Trust
White Rose House
Ten Pound Walk
Doncaster
DN4 5DJ
[R&D Department for NHS care organisation at lead site]



Please ask for: Nicola McMaster
(Research & Development Officer)
Telephone: 01302 320111 Ext. 4001
Fax: 01302 365234
Email: Nicola.McMaster@doncasterpct.nhs.uk
Our Ref: NM/DPCT54

White Rose House
Ten Pound Walk
Doncaster
DN4 5DJ

Tel: 01302 320111
Fax: 01302 365234
Safe Haven Fax: (01302) 343127

Victor Joseph
Directorate of Public Health
Doncaster PCT
White Rose House
Ten Pound Walk
Doncaster & South Humber NHS Trust
DN4 5DJ

www.doncasterpct.nhs.uk

26 March 2007

Title of project: Effects of Telehealth on COPD Patients in the Community (TELECCOM) Study

Dear Victor,

Doncaster Primary Care Trust have reviewed your above project for Organisational approval. This means that it meets the requirements for Research Governance, but if the protocol should change you would have to re-submit your new proposal. May we remind you that you are obliged to adhere to the Research Governance Framework for Health and Social Care (2005) and if it is found that this is not the case then your research will be terminated pending an enquiry. Your research may be subject to auditing proceedings; and I would appreciate it if you would send copies of interim and final reports to me at the above address.

May I take this opportunity to wish you well with your project. If you have any concerns please do not hesitate to contact me (Nicola McMaster, Research & Development Officer), on the number above.

Yours sincerely

Nicola McMaster, Research & Development Officer
Doncaster & Bassetlaw Primary Care Trust

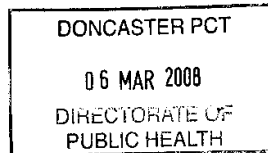
.....
Kath Allen (Head of Clinical Governance, Doncaster Primary Care Trust)
Doncaster Primary Care Trust RM&G Lead



National Research Ethics Service
South Humber Local Research Ethics Committee

Room FC27
 Coniston House
 Trust Headquarters
 Willerby Hill Business Park
 Willerby
 HULL
 HU10 6NS

Tel: 01482 389157
 Fax: 01482 303916



05 March 2008

Victor Joseph
 Senior Practitioner in Public Health
 Directorate of Public Health
 Doncaster PCT, White Rose House,
 Ten Pound Walk, Doncaster
 DN4 5DJ

Dear Mr Joseph

Study title: Effects of Telehealth on COPD Patients in the Community
 (TELECCOM) Study
REC reference: 06/Q1105/64
Amendment number: Version 3.1
Amendment date: 04 March 2008

The above amendment was reviewed by the Chair and Vice Chair of South Humber REC.

Ethical opinion

Dr Herber - Chair
 Mrs W Witter - Vice Chair

Reviewed the Substantial Amendment

The members of the Sub- Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Annual Progress Report	Version 3.2	04 March 2008
Notice of Substantial Amendment (non-CTIMPs)	Version 3.1	04 March 2008
Covering Letter	Version 1	04 March 2008

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

**Annex 2.2: NREC Advice on Service Evaluation of Telehealth
(Case Study 2)**

From: NRES Queries Line [mailto:queries@nres.npsa.nhs.uk]
Sent: 11 June 2010 14:43
To: Joseph, Victor - Doncaster PCT
Subject: RE: Service Evaluation clarification

Your query was reviewed by our Queries Line Advisers.

Our leaflet "Defining Research", which explains how we differentiate research from other activities, is published at:

<http://www.nres.npsa.nhs.uk/rec-community/guidance/#researchoraudit>

Based on the information you provided, our advice is that the project is not considered to be research according to this guidance. Therefore it does not require ethical review by a NHS Research Ethics Committee.

I'd deem this an evaluation.

If you are undertaking the project within the NHS, you should check with the relevant NHS care organisation(s) what other review arrangements or sources of advice apply to projects of this type. Guidance may be available from the clinical governance office.

Although ethical review by a NHS REC is not necessary in this case, all types of study involving human participants should be conducted in accordance with basic ethical principles such as informed consent and respect for the confidentiality of participants. When processing identifiable data there are also legal requirements under the Data Protection Act 2000. When undertaking an audit or service/therapy evaluation, the investigator and his/her team are responsible for considering the ethics of their project with advice from within their organisation. University projects may require approval by the university ethics committee.

This response should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that ethical approval is not required under NHS research governance arrangements.

However, if you, your sponsor/funder or any NHS organisation feel that the project should be managed as research and/or that ethical review by a NHS REC is essential, please write setting out your reasons and we will be pleased to consider further.

Where NHS organisations have clarified that a project is not to be managed as research, the Research Governance Framework states that it should not be presented as research within the NHS.

If you have received advice on the same or a similar matter from a different source (for example directly from a Research Ethics Committee (REC) or from an NHS R&D department), it would be helpful if you could share the initial query and response received if then seeking additional advice through the NRES Queries service.

However, if you have been asked to follow a particular course of action by a REC as part of a provisional or conditional opinion, then the REC requirements are mandatory to the opinion, unless specifically revised by that REC. Should you wish to query the REC requirements, this should either be through contacting the REC direct or, alternatively, the relevant local operational manager.

Regards


Queries Line
National Research Ethics Service
National Patient Safety Agency
4-8 Maple Street
London
W1T 5HD

The NRES Queries Line is an email based service that provides advice from NRES senior management including operations managers based in our regional offices throughout England. Providing your query in an email helps us to quickly direct your enquiry to the most appropriate member of our team who can provide you with accurate written response. It also enables us to monitor the quality and timeliness of the advice given by NRES to ensure we can give you the best service possible, as well as use queries to continue to improve and to develop our processes.

Website: www.nres.npsa.nhs.uk
Email: queries@nres.npsa.nhs.uk

Ref: 04/02

Streamline your research application process with IRAS (Integrated Research Application System). To view IRAS and for further information visit: www.myresearchproject.org.uk

 Help save paper - do you need to print this email?

From: Joseph, Victor - Doncaster PCT
[mailto:Victor.Joseph@doncasterpct.nhs.uk]
Sent: 11 June 2010 09:15
To: NRES Queries Line
Cc: vuni.joseph@tinyworld.co.uk
Subject: Service Evaluation clarification

Dear Sir / Madam,

Can you confirm if I need ethical application for a service development of Telehealth roll out in Doncaster? Community matrons will be using Telehealth to aid in their case management. We would like to evaluate the service using before-and-after related to hospital admissions avoidance and get feedback from staff and patients, consistent with the practice the PCT would use for any other service it commissions.

I would be grateful if you can confirm that I do not need ethical approval to carry out the evaluation?

Thanks.

**Victor Joseph, Dip Med, MPH, Dip Epid(FPH), FFPH, FRIPH.
Consultant in Public Health and
Assistant Director of Public Health**

Directorate of Public Health
NHS Doncaster
GE House, Ten Pound Walk, Doncaster, DN4 5HW
Direct Tel: 01302 566124

Kirstie Jones (Secretary): 01302 566029

Mobile: 077 6644 3769
Email: **Victor.joseph@doncasterpct.nhs.uk**
Safe Haven Fax: 01302 556321

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Annex 2.3: The University of Leeds Research Ethics Committee Approval

Faculty of Medicine and Health
Research Office

Room 10.110, Level 10
Worsley Building
Clarendon Way
Leeds LS2 9NL

T (General Enquiries) +44 (0) 113 343 4361
F +44 (0) 113 343 4373



UNIVERSITY OF LEEDS

Mr Victor Joseph
Consultant in Public Health &
Assistant Director of Public Health
Directorate of Public Health
NHS Doncaster
GE House, Ten Pound Walk
DONCASTER DN4 5HW

09 August 2010

Dear Victor

Re ref no: HSLTLM/09/042

Title: Factors influencing whether or not new innovations are adopted in routine healthcare settings: case studies on the introduction of home Telehealth

I am pleased to inform you that the above research application has been reviewed by the Leeds Institute of Health Sciences, Leeds Institute of Genetics, Health and Therapeutics and Leeds Institute of Molecular Medicine (LIHS/LIGHT/LIMM) joint ethics committee. Following receipt and review of evidence of NHS approval being in place, I can confirm a favourable ethical opinion on the basis described in the documentation at submitted at date of this letter.

Please notify the committee if you intend to make any amendments to the original research as submitted at date of this approval. This includes recruitment methodology and all changes must be ethically approved prior to implementation. Please contact the Faculty Research Ethics and Governance Administrator for further information (r.e.desouza@leeds.ac.uk)

I wish you every success with the project.

Yours sincerely

Laura Stroud

**Professor Alastair Hay/Mrs Laura Stroud
Chairs, LIHS/LIGHT REC**

Annex 3: Questionnaires used for Interviews with patients and staff

Annex 3.1: Questionnaires for interview with patient

<p>Note: Introduction of self to Interviewee</p> <ol style="list-style-type: none"> 1. Explain purpose and nature of the study 2. Give assurance that respondent will remain anonymous in any written report and responses given will be treated in strictest confidence. 3. Some of the questions may be difficult to understand; there is no right or wrong answer. 4. Feel free to interrupt, ask for clarification of the interview, and criticize a line of questioning. 5. Interviewer will tell respondent something about himself/herself e.g. area of work. 6. Interviewer is to ask permission to tape-record the interview, explain why he/she wishes to do this.

Your feedback helps us to continuously improve the home care services we provide. Thank you for taking the time to complete this survey and for participating in our Monitoring Programme.

Listed in the box below are a number of questions about your recent telehealth experience. Please answer each question by marking the box that best indicates your opinion.

	Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
I received an explanation of how to use the monitor, in terms I could understand.	€	€	€	€	€
The Telehealth monitor is easy to use.	€	€	€	€	€
The peripherals are easy to use	€	€	€	€	€
The Telehealth monitor is/was useful in assisting me to manage my health.	€	€	€	€	€
I felt more involved in my care by participating in the Telemonitoring Programme.	€	€	€	€	€
I believe daily monitoring assisted the clinicians in understanding changes in my condition.	€	€	€	€	€

Home monitoring provided me with a sense of security and peace of mind.	€	€	€	€	€
I am happy to continue using Telehealth, or would use the Telehealth Monitoring System in the future.	€	€	€	€	€
I would recommend the use of daily home monitoring to my family and friends.	€	€	€	€	€

Unstructured Interview Questions

1. Tell me about: the first time the nurse mentioned to you Telehealth machine:
 - a. What did you think?
 - b. What were you told?
 - c. Your Community Matron or Nurse recommended you to use the Telehealth equipment, how did you feel being chosen to use Telehealth machine?
2. What is your experience of using Telehealth so far?
3. How do you describe the relationship with your community Matron after having been on Telehealth?
4. What impact, if any, has Telehealth has on your self-confidence and independence?
5. Overall, how would you describe the impact of being on Telehealth for you?
6. How would you describe the impact on your family members (or carer) of having been on Telehealth?
7. How could we improve the service?

THANK YOU

Annex 3.2: Questions for interviews with staff

Unstructured Interview Schedule with Staff

Note: Introduction of self to Interviewee

1. Explain purpose and nature of the study
2. Give assurance that respondent will remain anonymous in any written report and responses given will be treated in strictest confidence.
3. Some of the questions may be difficult to understand; there is no right or wrong answer.
4. Feel free to interrupt, ask for clarification of the interview, criticize a line of questioning.
5. Interviewer will tell respondent something about himself/herself e.g. area of work.
6. Interviewer is to ask permission to tape-record the interview, explain why he/she wishes to do this.

Unstructured Interview Questions

1. Tell me about: the first time you were involved in Telehealth in Doncaster:
 - a. What did you think?
 - b. How did you feel about Randomised Controlled Trial? (if involved in it)
 - c. How did you feel about service evaluation of the Telehealth Monitoring? (if involved in it)
2. What is your experience of monitoring patients on Telehealth so far?
3. How do you describe the relationship with your patients after having been involved with Telehealth?
4. What impact, if any, has Telehealth has on your workload?

5. Overall, how would you describe the impact on patients' care resulting from Telehealth?

6. How would you describe the impact on your staff of having been on Telehealth?

7. How could we improve Telehealth service in Doncaster?

THANK YOU

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