FACTORS AFFECTING THE IMPLEMENTATION OF A NATIONAL DIGITAL HEALTH & WELLBEING SERVICE AT SCALE

PhD THESIS

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Published Book Chapters

1. **Agbakoba, R.**, McGee-Lennon, M., Bouamrane, M., Watson, N., and Mair, F. (2015) Implementing a national Scottish digital health & wellbeing service at scale: a qualitative study of stakeholders' views. In: Sarkar, I.N., Georgiou, A. and Mazzoncini de Azevedo Marques, P. (eds.) MEDINFO 2015: eHealth-enabled Health. Series: Studies in health technology and informatics, 216. IOS Press, pp. 487-491. ISBN 9781614995630 (doi:10.3233/978-1-61499-564-7-487)
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4. **Agbakoba R**, McGee-Lennon, M., Bouamrane, M., Watson, N., Mair FS. (2014) Delivering Innovative e-Health Services at Scale: Implementers Views on Achieving 'Buy-In'. *BCS Health Informatics Scotland (HIS) Conference*, Glasgow, United Kingdom, 2nd – 4th September.
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Invited Speaker

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Academic Blogs – Online Contributor to Award Winning Blog, Jean Thompson Memorial Prize, 2015

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Academic and Personal Development Opportunities

2016 – Social Convener for Internal GPPC PhD Social Gatherings Promoting Knowledge Exchange
2015 – Organising Committee for Institute of Health & Well-being Student Conference (IHAWC)
2014 – Chartered Management Institute (CMI) Qualified (Project Management and Leadership Course)
2014 – Recipient of Training and Awards Committee (TAAC) Scholarship for NAPCRG, University of Glasgow
2013 – Competitive Bursary, Scottish Informatics & Computer Science Alliance (SICSA), St Andrews University
2013 – Conference Bursary Holder, Scottish School of Primary Care Conference (SSPC), Inverness, Scotland

International Peer-Reviewer

2017 – British Medical Journal UK – ScholarOne Manuscripts
2016 – International Journal for Health Policy and Technology – ELSEVIER Publishing
2015 – International Conference Workshop for Computer Human Interaction (CHI), Seoul, Korea.
2014 – International Journal for the Health Informatics – SAGE Publishing

Graduate Teaching Opportunities

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Fr Felix Adiele – Spiritual Director, St Michaels Roman Catholic Church, Dumbarton, Scotland.
Fr Philip and Fr Stephen – Spiritual Directors, University of Glasgow, Catholic Chaplaincy, Scotland
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Our Lady of Miracles Parish – Canarise, Brooklyn, New York (*Special mention published in newsletter*, Nov *2014*)
Our Lady of Perpetual Help, Our Lady Undoer of Knots, Almighty God, Alpha and Omega! All Glory & Praise!

DEDICATION: TO MY GRANDPARENTS

Akunnia Ogonabo Gregory Henry Igweze Egbunike (1916 – 2005)

Omekaenyi Dimfulumnanya Dolly Ekwunife Egbunike (1926 – 1972)

SPECIAL MENTION

The higher you build your barriers, The taller I become
The further you take my rights away, The faster I will run
You can deny me, you can decide, To turn your face away
No matter cause there's, Something inside so strong
I know that I will make it!
– Labi Siffre –

There is a well-known African Proverb which states that 'it takes a village to raise a child'. Words seems to fail me at this point in time, they don't seem adequate enough to fully express my sentiments and sincere gratitude towards the people that have played different but significant roles during this journey however I would like to take this opportunity to give particular thanks and praise to them:

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THANK YOU GOD FOR NEVER FAILING ME! "*Do not be anxious about anything, but in every situation, by prayer and petition, with thanksgiving, present your requests to God. And the peace of God, which transcends all understanding, will guard your hearts and your minds in Christ Jesus*". Philippians 4:6-9.

AUTHORS DECLARATION

I declare that this thesis has been composed by myself and that the work has not be submitted for any other degree or professional qualification. I confirm that the work submitted is my own, except where work which has formed part of jointly-authored publications has been included. My contribution and those of the other authors to this work have been explicitly indicated. I confirm that appropriate credit has been given within this thesis where reference has been made to the work of others.

Ruth Ngozika Ifunanya Obianuju Egbunike – Agbakoba

ABBREVIATIONS

ANT	Actor Network Theory
CASP	Critical Appraisal Skills Programme
CET	Community Engagement Team
CHW	Community Health Worker
CM	Community Managers
CRS	Care Records Service
COPD	Chronic Obstructive Pulmonary Disease
DALLAS	Delivering Assisted Living Lifestyles
DOI	Diffusion of Innovation Theory
eHealth	Electronic Health
EHR	Electronic Health Record
ERS	Exercise Referral Scheme
GP	General Practitioner
HIE	Health Information Exchange
ICT	Information Communication Technology
LiU	Living It Up
LMIC	Low Middle Income Countries
LTC	Long Term Condition
MOU	Memorandum of Understanding
NIHR	National Institute for Health Research
NHS	National Health Service
NPfIT	National Programme for Information Technology
NPS	National Patient Summary
NPT	Normalisation Process Theory
PHR	Personal Health Record
PID	Project Initiation Document
PPP	Public Private Partnership
PM	Project Manager
RAFT	Réseau en Afrique Francophone pour la Télémédecine
RCT	Randomized Control Trial
SCR	Summary Care Record
SHS	Shared Health Summary
SSA	Single Shared Assessment
SST	Strong Structuation Theory
TPB	Theory of Planned Behaviour
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation
WSD	Whole Systems Demonstrator

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CHAPTER ONE INTRODUCTION

1.1 Background: Digital Health and Population Ageing

The global challenges facing healthcare systems in the 21st century have been well documented within the scientific literature. These challenges include ageing populations with complex health and social care needs, rising hospital admissions, limited healthcare resources, unsustainable care models, economic pressures and insufficient capacity (both in terms of workforce and finances). Ageing for instance is a result of longer life expectancy and declining fertility rates, where the proportion of people aged 60+ in almost every country is growing faster than any other age-group worldwide [1]. According to the *National Institute on Ageing* and the *United Nations Statistics on World Population Ageing*, the global share of older people aged 65+ will for the first time in history outnumber children aged 0-4 by 2020 [2]. Many developed nations are due to celebrate this milestone of longevity; although how best to deal with the impact of this unprecedented change in demographics remains uncertain.

The global phenomenon of ageing presents a large number of difficulties as older people are more likely to suffer from chronic non-communicable diseases (NCDs), often coping with two or more NCDs, which is known as multimorbidity [3]. This has been linked to rising hospital admissions which are evidenced in recent trends across the western world [4]. According to the *World Health Organization* (WHO) NCDs account for 38 million deaths each year with cardiovascular diseases representing 46% of all NCD related deaths; more than respiratory diseases, diabetes and cancer combined. In some cases, older people who are hospitalized for NCD related reasons often have no place to go upon discharge due to insufficient capacity within the health and social care systems. This presents a problem known as '*Bed Blocking*' which means that new patients are prevented from being admitted despite requiring immediate treatment and care. In the same vein, studies have shown that when a patient is prematurely discharged from hospital they may be readmitted to hospital within a month [5]. Therefore, there is a need to re-evaluate service provision and consider new models of care now more than ever.

Limited resources and economic pressures create insurmountable obstacles with unfavourable consequences for the current service models. For instance, the National Health Service (NHS) is facing severe financial pressures with hospitals across the country struggling to remain within budget [6]. There are demands to create savings in order to deliver and maintain standards of care and to better serve patient needs and a 'seven-day' NHS service has been proposed. [7] This proposal in particular received backlash from the British Medical Association (BMA) as doctors already feel overstretched given that many already work evenings and weekends. Each day £110 million is spent on the day-to-day operational running of the NHS, and the number of hospitals accumulating debt has risen to an unprecedented level. In 2012, the United Kingdom (UK) government was compelled to place one hospital trust in

administration as it had accumulated a £65 million deficit. This led to the closure of some services as well as the hospital trust being dissolved [8].

In the UK, *Health and Wellbeing* services operate under four separate NHS bodies (there are devolved versions for Scotland, England, Wales and Northern Ireland) where they are provided when needed and free of charge at point of care. Poorly coordinated services means that people are in danger of falling between the gaps of health and social care [9]. The UK government has now set out to integrate health and social care by 2018 in order to provide the best continuity of care for patients designed to meet their needs and be a sustainable service fit for the future [10]. Despite the many challenges, there are many benefits to be gained from encouraging active and healthy ageing in a move towards promoting self-care to empower people to play an active part in the decisions affecting their own health and wellbeing. Advances in digital technologies provide us with capabilities that were not thought possible just a decade ago. Technology has become so streamlined in some sectors that it is effectively part and parcel of the fabric of our daily lives. For instance, mobile 'smart' phones are now being used to check everything from current affairs, to when the next train is coming, to download flight details or to even manage bank accounts. However when it comes to our health and wellbeing the same 'progress' has not been made.

Digital Health can be defined as "the use of modern information and communication technologies (ICT) to meet the needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers" [11]. We have now entered into an age where even daily communication is by digital means. So what does this mean for healthcare? Well, now is the time to seize the opportunities promised by digital health. Reported benefits include improved quality of care, improved access to healthcare services, improved operational efficiencies, productivity, cost-savings and return on investment [12]. As health services are being overwhelmed by demand there is a need to move towards preventive care and promoting preventative measures to improve quality of life whilst easing the strain on health and social care services [13] and digital health may have a role to play in this area. The UK is well positioned to become a global leader in digital health if some of the challenges that will be examined in this thesis can be addressed.

1.2 Statement of the Problem: Importance of Implementation Research

Implementing change within any healthcare system takes time and there are numerous examples of failed government-funded digital health projects which set out to revolutionize the way healthcare is provided but failed. A catalogue of errors have been described ranging from a lack of investment in planning and implementation strategies, lack of support for evaluation, poor recognition of organisational cultures and social systems, limited focus on the digital maturity of organizations to effect change, the readiness of staff to accept change and the ability of consumers to engage in new practices [14]. The difficulties experienced when implementing digital health are increasingly recognized and the research area underpinning this problem is known as *'Implementation Science'* (IS).

Implementation Science is concerned with "the scientific study of the processes used in the implementation of initiatives /programs as well as the contextual factors that affect these processes" [15].

This thesis focuses on a) identifying what factors contribute to the success or failure of implementation in the digital health sphere, b) to understand how, if at all, barriers can be circumnavigated; and c) to examine what lessons can be learned when implementing digital health at scale and on a national level. The global market for digital health was worth £23 billion in 2014 and is expected to almost double to £43 billion by 2018 [16]. It is a lucrative and expanding market and the use of technology as an 'enabler' in healthcare shows promise. However, a key barrier impeding previous efforts has been the 'translational gap' between digital health interventions that we know have the potential to optimize health and wellbeing and what actually gets implemented into daily practice [17]. Existing literature indicates that the phase of making an intervention routine and part of normal everyday practice is where implementations commonly fail [18]. This thesis aims to address this knowledge gap and to aid understanding of what needs to be put in place to help bridge this gap.

1.3 UK and Scottish Policy Context

UK policy makers have made a concerted effort to be at the forefront of health innovation. Government publications now aim to emphasize that care services should take a person-centered approach in order to meet the holistic needs of citizens. In October 2014, NHS England published its '*Five Year Forward View*' report. This document provided an insight into the future direction of the NHS over the next five years, with particular reference to tackling four main problem areas [10]. These are to: 1) address the root causes of ill health, 2) to give patients more choice and control of their own care; 3) to make changes in order to accommodate an ageing population; and 4) to improve investments in workforce, technology and innovation. The review allocates several sections to digital health as an agent of change to help to transform service provision with a very important commitment made to closing the £30 billion financial deficit by 2020/2021 [19].

In Scotland, 60% of all deaths are attributable to having a NCD and they account for 80% of all general practice consultations [1, 3, 4]. This has major implications for primary care and there have been strategic investments made to try to incorporate the use of technology in health and social care with the idea being that new technologies will play a key role in contributing to the re-design of existing services. Scotland's digital health strategy is set within the context of national legislations to ensure that digital health remains at the top of the agenda. Key publications include *Building a Health Service fit for the Future* (Kerr Report, 2005), *Delivering for Health* (Scottish Government, 2005), *Better Health, Better Care: Action plan* (Scottish Government, 2010), NHS Scotland – eHealth Strategy 2014-2022 (Scottish Government, 2008), *Seizing the opportunity: Scottish Telecare strategy 2008-2010* (Scottish Government, 2008), *Digital Health and Social care Strategy 2017 – 2012*, *Personalisation Agenda* (Changing Lives, Scottish Government, 2009) and the *Quality Strategy 2020 Vision* (Scottish Government, 2010). All of these make it clear that digital health is seen as having a key role to play in health services in Scotland.

The Scottish government set out an objective to become a 'world class digital nation by 2020' with efforts focused on developing innovative approaches which meet the needs of service users as a priority [20]. The Christie Commission which advises on public services in Scotland advocates an asset-based, grass-root level community approach towards developing sustainable services [21]. Emphasis has also been placed on championing close working partnerships and moving away from the service-centered model in order to create value in healthcare. "*What distinguishes these positive approaches is that they are grounded in people's lives, and the lives of communities (of place and of interest). Typically, people, communities and services work together to decide priorities and how to achieve their delivery while the focus is on fitting services to people, not people to services. They also maximize all the resources and assets available, and the process itself builds the capacity of all those involved*" [21]. Scotland is an ideal nation to spring-board national efforts as it has a unique environment to develop and test out new digital health innovations given its ability to test scalability across diverse environments.

1.4 Shaping the Future of Health and Wellbeing

The Scottish approach to shaping the future of health and wellbeing is to tackle some of the challenges inherent in providing care to people living in remote and rural locations, as well as making efforts to resolve the root causes of NCDs such as physical inactivity, the harmful effects of alcohol and poor lifestyles (such as an unhealthy diet). People will be encouraged to take part in designing public services in order to improve health and wellbeing. A key goal will be to ensure that people disadvantaged by health inequalities are primary beneficiaries of digitally enabled care. This holistic approach unites various sectors and stakeholders in the development and procurement of digital products to work across boundaries in order to develop collaborative solutions with the potential to provide added value.

The concept of *personalisation* and *self-management* has been strongly promoted across the UK and within Scotland and digital health is seen as having real potential to underpin this agenda [22]. The 'dallas' programme is an example of a new and cutting-edge UK-wide endeavour which aimed to develop the building blocks to integrate health and social care, as well as empower citizens to take ownership of their health and wellbeing, by employing digital health technologies on a national scale. The programme involved four "communities" across Scotland and England. One community was located completely in Scotland and was known as 'Living It Up' (LIU). This thesis seeks to study the LiU journey from initial inception through to implementation as part of routine health and social care services in Scotland in order to improve understanding of barriers and facilitators to deployment of digital health services at scale and make a unique contribution to the field of implementation science.

1.5 Research Aims and Objectives

The aim of this thesis is to *understand the barriers and facilitators affecting the implementation of digital health innovation on a national scale*. This will be done by studying the LiU project in Scotland, the nation's first digital

health, wellbeing and self-management platform delivered at scale across the country. Special attention will be paid to exploring the impact of this innovation on the 'work' of implementers involved in the project. In order to meet this overall aim the following objectives have been set:

- **Conduct** a 'Structured Literature Review' to examine the existing literature regarding the implementation of national digital health projects in practice and to identify the factors affecting large-scale endeavours.
- **Explore** the attitudes and experiences of 'implementers' as key stakeholders involved in the national deployment of LiU over time.
- **Identify** and explain the underpinning factors which promote or inhibit successful normalization (implementation, embedding, and integration) of the LiU digital health programme.
- **Produce** a set of recommendations and lessons learned to inform future large-scale implementations, national digital health policies and practice.

1.6 Research Design and Methods

An interpretive philosophical approach has been adopted in this study in order to understand the dynamics involved in the implementation of the LiU digital health innovation into routine practice. Particular focus is on the 'change processes' and 'structural problems' involved in the 'normalization' of the LiU programme; and the findings will be evaluated in order to ascertain 1) how social actors assess the impact of new ways of thinking and working and 2) the impact, if any, on existing organizational practices. The focus here is primarily on the dynamic processes which lead to innovations to become integrated, embedded and sustained.

This interpretive stance enables the researcher to study this social phenomena in its natural environment. In addition, this approach is commonly used by researchers who interact with people and therefore provides an opportunity for the researcher to understand their world and the 'meaning they give to it from their point of view' [23]. Case study design has been chosen as the method of research because of its potential to provide a 'rich picture' of the 'influencers' towards large-scale implementation and the response of the implementers to those influencers [24]. Data will be collected and triangulated using the following research techniques: a) semi-structured interviews with key stakeholders involved in the deployment of LiU, b) observation of the design process and development journey of LiU over time and c) collection and analysis of project documentation with permission.

1.7 Original Contribution Sought

Implementation research within healthcare is considered to be a relatively young field and therefore there is the potential to unearth some novel and fascinating findings in this area. There have been a plethora of pilots and demonstrations of digital health which have taken place however these trials have generally not met robust evaluation standards [18], furthermore services have often not shown benefit neither have they managed to be

integrated into routine care [18]. A great deal of the digital health research domain involves smaller studies however it has proven difficult to aggregate these findings to produce a generalisable message as the outcomes are so varied. The rare opportunity to have an insider's view of Scotland's first national digital health deployment is unique. This study aims to add knowledge by capturing the complex and multi-faceted nature of implementation at scale.

In addition, obtaining evidence about the sustainability of the LiU intervention will provide valuable new learning and inform future efforts to promote uptake and utilization of digital health in practice. This contribution is supported by the use of the Normalisation Process Theory (NPT) as the underpinning theoretical framework for the study. It has an important applied relevance to the implementation of complex interventions by providing 'reasoning' behind the 'work' of implementation as a factor to facilitate the understanding of why some processes lead to a practice to become normalized while others do not [17]. A service evaluation of this kind is required to shed light on the problems arising when an initiative is rolled-out or scaled-up in the real world.

1.8 PhD Thesis Structure

Chapter One: Introduction. This section sets the scene and provides some background that outlines why this work is timely and important and the potential contribution of the work to the digital health research field. It provides a brief account of the drivers for change including the political, economic and social challenges facing health care systems. The potential for digital health innovations to shape the future of health and wellbeing is discussed, and the research aims and objectives described.

Chapter Two: Structured Literature Review. This chapter examines the existing literature regarding national digital health implementations. The objectives are three-fold: 1) to identify what the published literature documents as the barriers and facilitators towards the implementation of digital health innovations in practice; 2) to elicit any lessons that have been learned; and 3) to highlight any outstanding research gaps.

Chapter Three: Methodology. In this chapter the philosophical, theoretical and methodological underpinnings of this research are explored and justifications made for the chosen research strategy. A general introduction of the qualitative research approach is discussed followed by the appropriateness of the methods as well as a justification for the selection of Normalization Process Theory (NPT) as the underpinning theoretical framework. Data collection and data analysis methods are explained as well as the objective role of the researcher in undertaking this study. This section closes with a detailed discussion about evaluation strategies: validity, reliability and generalizability of the findings.

Chapter Four: Results. Context Chapter. LiU as a digital health innovation is described as well as the context in which the research is being conducted. The researcher provides a holistic account of LiU from pre-implementation through the implementation journey and describes the programme's development, key elements and evolution. This

chapter is central to the thesis as it provides a unique insight in to the complexities of a novel and ground-breaking innovation in the real world. The ensuing chapters five and six then describe the 'journey of implementation' and the process from start point (baseline) to endpoint i.e. how implementers circumnavigated obstacles and challenges to move from point A to point B.

Chapter Five: RESULTS: Planning and Engagement Work '*Thinking about Doing*'. This chapter examines how key stakeholders and organizations involved in the implementation process make sense of and understand a new digital health innovation. The work required to enable participation and engagement with the LiU programme is also explored. Findings from this chapter (barriers and facilitators) are thematically grounded and mapped onto NPT as an analytical framework which is used to aid interpretation of the data .

Chapter Six: RESULTS: Enacting and Appraisal Work '*Doing the Doing*'. This chapter examines the practicalities and the work that key stakeholders and organisations do in order to ensure that LiU is operational in practice. In addition, informal and formal appraisal of LiU once in use is assessed and explored to understand the advantages, disadvantages, barriers and facilitators to large-scale implementation. This reflective piece is equally thematically grounded and mapped onto NPT to aid comprehension of the effects of a new digital health innovation at scale.

Chapter Seven: Discussion and Conclusion. The results presented in chapters two, four, five and six are synthesized and the findings are compared to existing knowledge about large-scale digital health implementations. An explanation of the LiU journey in terms of what did or did not work, what was difficult or helpful is presented to aid understanding of the key learning points and messages from this study. Strengths and limitations as well as personal reflections are described. The final aspect of this chapter provides a set of key recommendations and '*Critical Success Factors*' intended for policy makers, researchers and future implementers involved in future national large-scale digital health endeavors.

CHAPTER TWO
LITERATURE REVIEW

2.1 Introduction

The objective of this chapter is to provide an overview of the current state of knowledge on implementation issues in relation to large scale digital health innovations in practice. A 'Scoping Review' was conducted as it was considered to be the most suitable approach in meeting this objective. This approach has been used by the 'Health Foundation' previously and has been demonstrated to be a highly methodical and comprehensive strategy used to understand the scope of an emerging domain [25]. Colquhoun et al define a scoping review to be "*a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined area or field by systematically searching, selecting and synthesizing existing knowledge*" [26].

The need to 'scope' the emerging and diverse evidence base of digital health implementations at scale is the main factor supporting the use of the Scoping Review approach. This study was guided by the principles of the Arksey and O'Malley framework; a widely cited and robust approach used to conduct scoping reviews [25]. This framework provided guidance in the planning and execution of the study using the following steps: 1) Classifying the Research Question, 2) Identifying the Search Strategy, 3) Study Selection: Inclusion & Exclusion Criteria, 4) Charting the Data and 5) Collating, Summarizing and Reporting Findings. The Scoping Review process requires analytical reinterpretation of the results and therefore the final section of this study maps the results onto the Normalisation Process Theory, the chosen conceptual framework supporting this thesis. It places emphasis on interpreting the findings through this lens as a means to understand the 'work' of implementation and the factors that facilitate or impede embedding new ways of working [18].

2.2 STEP 1: Classifying the Research Question

This study aimed to answer three key questions: 1) What does the published literature tell us about the barriers and facilitators to the implementation of national large-scale digital health projects in practice? 2) What were the lessons learned? and 3) What, if any, are the main research gaps?

2.2 STEP 2: Search Strategy – Identification of Sources

This review involved conducting a comprehensive search of published studies in the last 10 years from the year 2000 – 2015 up until 25th July 2015. In order to capture both breadth and depth in terms of coverage I used a combination of search techniques such as MeSH headings, Boolean operators (AND/OR) and truncation (*

symbol used to broaden a search) within my approach. The following section outlines the identification of sources, search terms (and string), study selection: inclusion and exclusion criteria, and the final set of papers eligible to be included for data synthesis. As a preliminary exercise I consulted a specialist University of Glasgow subject librarian Ms Susan Ashworth on the 9th March 2015 to help me identify relevant sources and this proved to be a useful starting point. Prior to this initial meeting, I was provided with an initial set of key articles by my supervisory team to use as a quality indicator of the 'search' to see if they would appear in the final set of results.

A combination of electronic bibliographic databases: MEDLINE & WEB OF SCIENCE © (WEB OF KNOWLEDGE) and EMBASE © were used. Additional records were identified through 'Snowballing' and reading the reference list of articles of interest. The search strategy is based on the following three concepts: **e-Health**, **implementation** and **scale**. The search strategy includes a general free-text term for e-Health and eHealth. The term 'Digital Health' was not used as the MeSH headings for both e-Health and eHealth broadly covers the synonyms which encompass the use of Information and Communications Technologies in Healthcare. This includes but is not limited to: Mobile Health, Telehealth, Telemedicine, Digital Health and Health Informatics.

There are no thesaurus terms for implementation, therefore this concept was searched for by looking for the exact terms used in a systematic review of reviews by Mair et al (2012) on e-health interventions in healthcare settings [5]. Therefore, I added the following synonyms: Implement*, Routin*, Normali*, Integrat*, Facilitat*, Barrier*, Adopt*, Deploy*, Challenge*, Factor*, Driver*, Oppor*, Readiness and Evaluation. The use of the * function enabled me to retrieve variants of words containing the same root of a word, in addition it proved useful in capturing plural and singular forms of a word within the search. Thesaurus terms referring to scalability were: Large-scale; National; Nationwide; State-wide; Wide-reaching; countrywide and scale.

The three main concepts were combined using the AND function and terms within the individual groups of concepts were combined using the OR function. Searches were conducted from 23rd March 2015 and the literature was revisited to check for any updates. I ran searches within each electronic database and then combined the output of EMBASE (N=265) with WEB OF SCIENCE (N=503) and additional electronic records (N=33) using Endnote Web™ which enabled me to sift through citations easily. The search yielded 801 records and there were six duplicates that emerged between the databases. Once removed, 795 record citations remained. I reviewed citations in the first instance by creating three sorting piles: *Exclude, Undecided* and *Include*. The undecided pile was reviewed by Prof Frances Mair on 18th May 2015 and 1st June 2015 at 'weekly catch-up' sessions. The records were assessed on the basis of whether the abstract or citation met the inclusion criteria. Records that did not meet the criteria were immediately excluded. However in discussions if it was not clear or a decision could not be reached then the full paper was obtained. The selection criteria outlined below applied to all 795 references [see Figure 2.1 – Identification of Relevant Publications].

2.3 STEP 3: Inclusion and Exclusion Criteria for considering studies for review

The importance of clearly conveying what scalability refers to within the review was discussed with the wider supervisory team and a key distinction was made and agreed amongst advisors. In terms of assessing papers to be included, scalability specifically refers to national implementations, regional implementations (e.g. an NHS board or equivalent level), multi-institutional (e.g. implemented across several healthcare settings) and deployments at consumer level for mass market wide-scale reach.

Inclusion Criteria

1. The focus of the review is to capture qualitative studies that describe a specific deployment and their experiences of the barriers and facilitators to the implementation process in practice.
2. Study types include those that provide descriptions of method including a) qualitative systematic reviews where a transparent methodological criteria has been used to systematically assess papers, b) narrative reviews which summarises different primary studies into a holistic interpretation underpinned by models and theories of adoption and sociotechnical aspects of implementation and c) qualitative meta-synthesis or meta-ethnographies where the literature has been identified by means of a structured search and the outcome has an objective to elaborate or extend existing theory.
3. Published papers which relate to a large-scale implementation study with varying aims and objectives.
4. If a paper draws on a mixed-method approach, at least half of the findings should be qualitative in nature in order to be considered. In addition the findings should be practical and tangible in terms of barriers, facilitators and lessons learned and supported by primary data.

Exclusion Criteria

1. Protocol studies where the authors describe the methods for a study but no data analysis is provided. The focus of the review is to capture what has actually happened; therefore studies that do not meet this objective are automatically excluded.
2. Furthermore studies which are commentaries, editorial discussions or wholly focused on outcomes rather than implementation process in practice 'real life-setting' (i.e. specific factors which promote of inhibit the implementation process) will also be excluded.
3. Studies that review the barriers and facilitators to eHealth in general or the advantages and disadvantages of eHealth in general will be excluded. Reasons: This study is focused on capturing a rich implementation qualitative experience and not general themes. Although I will draw upon such articles for discussion purposes within the wider thesis, but not as part of this scoping review. For instance, studies which provide rich learning experiences as a descriptive piece but have no clearly defined methods or a lack of original data to support the study's propositions.
4. Studies that have been carried out as small pilots or small-scale demonstrator projects that are limited to a single site, healthcare setting or small geographical area. In addition, studies which are secondary analyses that present either cumulative outcomes or integrative outcomes from various research programmes and studies which bring together small-scale pilots as a means to present as a large 'case'.

Summary – Location, Screening and Selection of Relevant Publications

Review Questions: What does the published literature tell us about:
1) The barriers and facilitators to the implementation of national large-scale digital health projects in practice? 2) What were the lessons learned?
3) What, if any are the main research gaps?

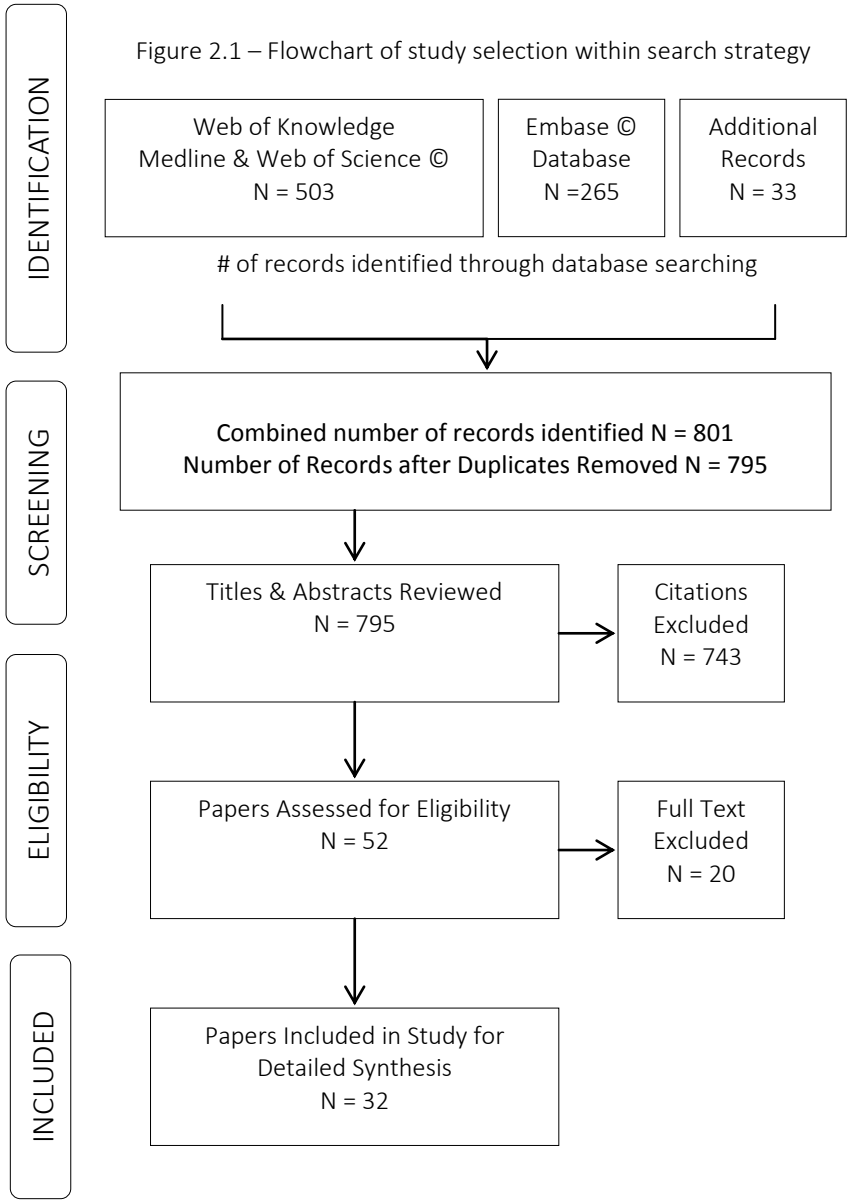
Limitations:
No Grey Literature (Published Only)
Dates from 2000-2015 (Date Restrictions)
Qualitative studies (Publication Type)
Language English (Language Restriction)

Search Strategy Tips: Use of Truncation* and Boolean Operators
Inclusion Criteria: Published studies only
Exclusion Criteria: Small-Scale Studies
Abstract identified them as potentially relevant but lacked applicability in the main text, Studies focused on outcomes rather than implementation processes

Check for Completeness: Mesh Headings in Ovid
Check for Suitable Keywords: Key Papers WHO & NIHR
Search Strategy (after meeting with Ms Susan Ashworth – Librarian)

Search String:
TOPIC: (E-health or ehealth) *AND* **TOPIC:**(Implement* or Routin* or Normali* or Integrat* or Facilitat* or Barrier* or Adopt* or Deploy* or Readiness or Evaluation or Challenge* or Factor* or Driver* or Oppor*) *AND* **TOPIC:**(Large-scale or National or Nationwide or State-wide or Wide-reaching or countrywide or scale)**Refined by: Databases:** (WOS OR MEDLINE) AND **LANGUAGES:** (ENGLISH) AND **DOCUMENT TYPES:** (ARTICLE)
Timespan: 2000-2015.
Search language=Auto

Figure 2.1 – Flowchart of study selection within search strategy



5. Usability, user satisfaction, acceptability, feasibility (i.e. to test the practicality of a proposed large-scale deployment or method) and comparison studies. Reasons: These study designs are not suitable given the aims of the review. If a paper did not provide a descriptive account about the barriers and facilitators, the challenges faced or lessons learned through an implementation process it was excluded on that basis.

2.4 STEP 4: Charting Data

Fifty Two citations were deemed relevant and the full-text articles were downloaded using 'Mendeley Web Importer' and Google Scholar. Twenty articles were excluded with reasons directly related to the exclusion criteria above. A table was created to extract and categorise data from eligible studies in terms of the following: Author(s) including year of publication and study location, intervention type, objective of study, study setting (i.e. primary, secondary or tertiary care), methodology (and theoretical framework where stated), key barriers, facilitators and learning points. To aid understanding the interventions identified in this study are categorised as follows: *Telehealth and Telecare Solutions* [N=2], *Telemedicine and Video-Conferencing Solutions* [N=6], *Care Pathways* [N=2], *Multi-Intervention Projects* [N=6], *Electronic Health Records* [N = 10], *Mobile Health Interventions* [N=2] and *Health Information Exchange* [N = 4]. [Table 1 – Summary of the Charting Process].

2.5 STEP 5: Collating, Summarizing and Reporting Findings

The findings from this scoping review are presented in two ways. The first section includes a descriptive numerical summary of the nature and distribution of studies included in the review. This preliminary part of the analysis sheds light on the dominant areas of interest as well as unveiling where the main research gaps exist. The second section presents a thematic analysis of the factors affecting the implementation of digital health at scale. Further interpretation of the findings is provided by mapping them onto the Normalization Process Theory (NPT), the theoretical framework used to underpin analysis and conceptualisation throughout this thesis. NPT can be described as a useful tool and 'lens' with which to make sense of the 'work' that underpins implementation. The framework has been widely used for this purpose and the justification and rationale for using NPT in this thesis are detailed in chapter three [27]. Using this approach helped to identify barriers, facilitators and lessons learned with regard to large-scale digital health implementations. In addition it provides a foundation to compare and contrast the findings from this thesis with that of the wider literature and evidence from the qualitative study of the national deployment of the Living It Up (LiU) digital health programme described in Chapters 4-6.

2.5.1 – Descriptive Information

This review yielded a mix of studies with papers emanating from various countries including: United Kingdom (56% N=18; England –14 and Scotland – 4), North America (13% N=4; United States of America – 3 and Canada – 1), Scandinavia (6% N=2; Norway –1 and Sweden – 1) and Australia (6%, N=2) with the remaining articles relating to large-scale projects in Brazil and Low and Middle Income Countries (LMIC): Rwanda, Sub-Saharan Africa & Latin America, Kosovo, Cape Verde and Botswana (19%, N = 6). In some cases more than one study

related to the same project such as the UK National Programme for Information Technology (NPfIT) where 28% of studies (9 papers) stem from the same intervention. The methods employed in research papers were mainly of a qualitative nature (81%, 26/32 papers) with a limited number employing mixed methods (19%, 6/32 papers). Most papers were published relatively recently with the majority of publications between 2010 – 2015 (91%, 29 papers) with two publications in 2005 and one each in 2007 and 2009. There were no publications between 2000 – 2004 and in the years 2006 and 2008. This skewed distribution is in line with the advances in information technology and communications.

Several studies reflected on the range of models used to implement a large-scale project such as the Initiate, Build, Operate and Transfer (IBOT) strategy used in the Cape Verde telemedicine project, the gold-standard Randomised Control Trial (RCT) used in the UK Whole Systems Demonstrator (WSD) project and the Plan–Do–Study–Act cycle used in the Australian Shared Health Summaries (SHS) project. Equally several studies indicated whether the project was a 'Success' or a 'Failure' which was due to a number of interrelated factors on micro, meso and macro system-wide levels. The next section describes the findings from the thematic analysis that was undertaken.

2.5.2 – Thematic Analysis

A considerable amount of time was taken to familiarize myself with the key findings within the literature in order to establish a robust thematic framework. Through a process of reading and rereading key issues were identified that enabled development of a coding system stemming from the identification of recurring patterns or themes. Through this iterative process the data was then indexed into themes and subthemes. Positive and negative factors impacting on the implementation process were identified through this process of thematically analysing the data extracted from the reviewed articles. Five 5 key themes were identified as crucial factors impacting the large-scale deployment of digital health innovations. These categories were: organisational factors, human and social factors, political factors, economic factors and technical factors. It is important to note that due to the complexity and nature of the health and social care domain, some factors are interrelated and therefore cut across one or more category. In addition to the above themes the notion of context and scale of endeavours were key issues that many authors cited as being important and under-estimated . The following section discusses each thematic category in more detail based on the findings of this structured scoping review and then shows how the themes mapped onto the constructs of NPT. A thematic analysis was undertaken in the first instance to allow themes to emerge from the data without use of any framework that might constrain analysis in the first instance. It also served to help illustrate to what extent the themes identified fitted with the chosen conceptual framework for this thesis.

2.5.2.1 Organisational Factors

The literature shows that the healthcare industry has inherent complexities in the way that it operates compared to other industries which influence implementation of digital health initiatives. There are internal and external influencers as well as complex hierarchical structures within and between organisations. This is due to

the fact that it is comprised of different organisations of varying sizes, with different organisational cultures and backgrounds, located in different geographical areas, with different systems in place and at different starting points. The employees that work within these organisations have a combination of skills working in a variety of roles across the field at different levels. Furthermore, work processes are usually aligned to an organisational culture; put simply a way of doing the same task can differ from organisation to organisation. Infrastructure and organisational resources which encompass financial budgets, man-power and time again vary as well as the strategic vision for future direction [28, 34, 53].

A thorough examination of the organisational factors impacting large-scale eHealth interventions is necessary as findings from other industries are not readily transferable and have limited applicability. The literature shows that the following factors need to be considered at both hospital and individual department speciality levels: organisational readiness, planning, leadership and management, education and training, roles and responsibilities, start-up resources: man-power, time and finances, users' expectations and organisational cultures. These will be discussed each in-turn in the following section.

2.5.2.1.1 Organisational Readiness and Planning: Ready, Set, Go?

The term organisational readiness in the context of large-scale digital health implementations relates to the ability to prepare and plan for the forthcoming changes that a new intervention is likely to cause [28, 38]. This includes ensuring that staff are engaged, that there are adequate resources in place to support the implementation and any potential barriers are highlighted pre-implementation [28,30,32,46,56]. In cases where this has been overlooked many large-scale implementations failed at the first hurdle [46]. There is a real issue regarding the digital maturity of healthcare organisations in being able to maximise the full potential of transformative technologies to support service innovation. In the case of the UK National Programme for Information Technology (NPfIT) and the US Veterans Affairs Virtual Lifetime EHR, preliminary risk assessments and readiness surveys were undertaken to ensure that a) any organisation involved in a wide-scale deployment met the criteria expected of partner organisations and b) to ascertain the likelihood of adoption of the intervention in terms of appealing to patients or consumers [46, 56]. For example, Greenhalgh and colleagues set out to understand the factors affecting adoption, non-adoption and abandonment of the personal electronic health record as part of the NPfIT [46]. This national endeavour was centrally-led by the UK government although due to poor execution and assumptions within government strategy documents about consumers; the risk assessment failed to highlight significant barriers which led to low adoption rates [46]. Successful implementation of national digital health innovations depends on seamless utilisation and adoption, therefore an assessment of the current state of affairs is necessary in addition to a comprehensive plan addressing organisational gaps affecting readiness [56].

2.5.2.1.2 Start-up Education and Training

Digital readiness refers to helping individuals to acquire the skills to use technologies, build trust and the capacity for them to uptake a a digital health innovation. It is of primary importance to ensure that some form

of training (either in-house or external provider) is undertaken pre-implementation and this is sustained with on-going support to facilitate adoption and user acceptance [30, 31, 33, 35, 36, 40, 43, 44, 49, 50, 52, 54, 55]. In the organisational context lack of training and education to staff proved to be the basis of a series of subsequent setbacks [43]. Training is required in order to help staff become familiar with a new intervention [44] it also serves an important purpose of helping all staff to be on 'the same page' in terms of gaining the basic skills to navigate a system. In many cases such as NPfIT staff had low-level IT skills [50] coupled with a lack of understanding regarding the main aims of the national programme. In fact in some organisations across the UK, upskilling and IT literacy in general took a back seat "there are many other priorities other than IT at this hospital…we serve a local community" [40]. This could be due to the fact that even up to today digital health plays a limited formal role within higher education curriculums for medical, nursing and allied health students.

Even more important, the time frame in which training is provided and a new intervention introduced should be within a suitably short period. Again a clear example of inadequate responsiveness towards encouraging user acceptance within the NPfIT, was the large gap between when training was provided and the actual implementation. Staff reported that they had in fact forgotten what they had learnt [52]. Additionally, not all the training that was provided within sessions was applicable to all staff in terms of job role, experience and organisational level. Therefore great attention should be paid to tailoring training to meet the needs of users. Where a concentrated effort was made to adequately train staff a number of enablers emerged such as improvements to work-practices, professional development as staff gained increased confidence as they interact with the system, increased knowledge and eHealth awareness [35, 36, 48].

In terms of telemedicine solutions knowledge sharing opportunities began to increase on the back of careful preparation pre-implementation, the creation of an established training programme and continuous support for users [31, 33]. The Réseau en Afrique Francophone pour la Télémédecine (RAFT) project set out to create a telemedicine network across 17 Low and Middle Income Countries (LMIC) with operations established in North, West and Central African countries, as well as in Madagascar, Chad, the Democratic Republic of Congo and Guinea. This project was centrally-led and coordinated by a team of medical experts, policy makers and a range of stakeholders based in Geneva University Hospitals (HUG) in collaboration with the World Health Organisation (WHO).

One of the main aims of the network is 'tele-education' in webcasting interactive courses, sharing of expertise and best practices between member countries. The project established a pool of experts across continents where learning can take place especially between remote-rural areas in countries with limited specialised doctors and health professionals [4]. A virtual electronic library was also made available to lead professionals of member countries which enabled them to continue their professional development. In turn this created a network of externalities as lead professionals became known as 'knowledge multipliers' in transferring the knowledge they have gained to their home country. In cases where on-the-job training is provided this has equally proven to be of great value to nursing professionals and radiologists where they are able to see how an expert in a developed country has examined a scan and the thinking behind their decision making process (given

the medical notes), therefore continuous education is needed to foster longevity of a system well after its introduction [35].

2.5.2.1.3 Leadership and Management: Planning, Vision & Implementation Approach

The literature reflects greatly on the importance of skilled leadership and clear management structures as crucial success factors [34, 35, 36, 42, 43, 48, 49, 50, 51, 53, 55, 56, 57, 59]. It should be a top priority for any given national digital health project to have this in place from the outset. Leadership and management includes having a clear strategy, defined and agreed aims and objectives, milestones (or deliverables) [34, 42, 43, 48, 59], defined roles and responsibilities [33, 34, 38, 43, 55], a contingency plan given acknowledgement of any project risks: strategic or operational, ensuring that there is adequate funds set aside to sustain employment of key personnel, and a sustainability plan [34, 35]. Management needs to be flexible and open to receiving feedback in terms of future direction and ensuring that staff play an active role in the implementation process.

In studies where there was little attention paid to leadership and management (in some cases unintentional), this led to a lack of understanding across the board. In the case of the NPfIT and the implementation of the National Care Records Service (CRS) multiple translations of the overall vision occurred where there was a different understanding of the concept of the programme as a whole [53]. Additionally, little effort was made to align perspectives between stakeholders, thus poor communication channels exacerbated misunderstandings. In large-scale projects this is likely to occur because of the skill-mix of professionals involved in a deployment [24]. This was a key finding from the Single Shared Assessment program in Scotland [32] as different professions have different views on what is important to them and their work. It is therefore important for leaders to develop clear lines of communication to enhance working relations [37, 43, 48, 53].

Great attention should equally be paid to roles and responsibilities and ensuring that there is a formal lead appointed with dedicated time to a project and ensuring that staff know what is expected of them in terms of their obligations and duties [38]. There is also a need to balance responsibilities between key stakeholders, consider support measures for staff in new roles and staff stability in relation to sustainability of national projects [43]. Failing to delegate and identify who is responsible for what can lead to disarray. In the first scale-up project of a mobile telemedicine solution in Botswana 'Kgonafalo' a Memorandum of Understanding (MOU) which detailed roles and responsibilities between the Botswana government, Ministry of Health (MoH) and stakeholder organisations was signed and this facilitated public-private partnerships (PPP) and overall sustainability of the project for the next 3 years [35].

There are various styles and approaches which can be used to facilitate strong leadership and management. In terms of rolling-out digital health services on a national level various approaches have been debated within the literature. The majority of the evidence base consists of projects that were 'top-down' centrally led by a government within a given country but it is clear that this approach in itself can be a barrier to implementation. National implementations are dynamic in nature and usually require room for negotiation of contracts, room for scope and room for iterative appraisal due to the sheer scale of the endeavour [43, 53]. An imposed agenda

without consultation can have several ramifications as a one-size-fits-all approach neglects the need of users and side-lines their involvement in the decision making process [40, 54]. Gradual dis-engagement, low adoption rates and loss of credibility of a new intervention are documented consequences of poor leadership and management [39, 40].

A clear example of where the top-down approach has worked well relates to the US Veterans Affairs Virtual Lifetime EHR programme, where the project was overseen by central leadership and there were local implementation teams based in each of the 12 communities involved in the study across the nation. The most important factor explaining why it worked so well was the clear lines of communication between the Veterans Affairs and partner organisations. VA community coordinators (who helped with trouble shooting and general enquiries) were appointed to act as local liaison officers in order to align and maintain the goals of the programme. Similarly, the eCollaborative Shared Health Summaries (SHS) deployment in Australia demonstrated that clear communication channels was a central component of good leadership and management. Collaborative Program Managers (CPM) were provided to each participating regional primary healthcare organisation where they assisted with management and technical issues. Although the project did not meet their target in terms of their aims and objectives, it shed light on the challenge and value of being ground breaking and the first project of its kind [47].

In many cases throughout the last 15 years, national health technology projects represent the first attempt at digital innovation for many countries and persuading people that it is 'worthwhile' has been an uphill struggle [47, 57]. Ironically, the UK hosting a National Health Service where there is a common 'foundation' in terms of the principles of the service found difficulties in applying this standardised top-down approach. This is probably because while there is a National Health Service, individual primary and secondary care facilities function autonomously. Hendy and colleagues reported that there was poor communication from NPfIT headquarters to local sites and participants felt that there was no clear direction [41]. The learning point here is about the importance of creating good relationships between organisations and developing a strong commitment to leadership and management in order to facilitate lasting change [43, 55].

A collaborative 'bottom-up' user needs approach is now being widely advocated to ensure that all stakeholders are engaged and on-board at grass-roots level as this is where the bulk of the 'work' is required [36, 38, 45]. Motivation and ownership are key aspects which can be fostered by using a participatory approach [50, 57]. What is not well documented and evidenced within the literature is the degree to which this approach is successful and whether user needs are translated seamlessly in line with strategic goals. Meeting user expectations is hugely important and where this has been underestimated in projects it has been considered a high risk factor in contingency plan documents. The momentum of an implementation can be affected with staff eventually losing confidence in an intervention. The combination of unrealistic expectations about the capabilities of an intervention, unrealistic deployment timescales, mismatch in general expectations and poor leadership can contribute to complete failure [42, 46, 50, 53]. The Single Shared Assessment program in Scotland is a clear example of how staff began to question 'why bother' with the implementation as a whole

[59]. Robertson and colleagues made a suggestion of combining aspects of both top down and bottom up approaches to form a 'middle-out' approach; a recommendation from the implementation of electronic health records (EHR) as part of NPfIT. The authors go on to state that the middle-out approach succeeds in a) "combining government direction with increased local autonomy" which may be the key towards seamless implementation at scale; and b) strong visionary leadership can help to overcome a lack of 'trust between trusts' and create a model of local co-operation [50].

2.5.2.1.4 Start-up Resources: Man-power, time and finances

Several studies explained that start-up resources which include having adequate man-power, finances and realistic timescales for deployment are essential [30, 33, 35, 41, 42, 47, 52, 53]. Investment at the very beginning with backing from senior management and funders is also important to secure a robust approach towards successful implementation. The 'Kgonafalo' mobile telemedicine solution in Botswana is the first country in Africa ever to invest in a nationwide mHealth scale-up. In a naturally limited setting in terms of resources special attention must be paid to economical use of resources. This study demonstrated the value of telemedicine with the opportunity to use mobile phones as tools to improve access to specialised healthcare services [35]. In projects where there was a lack of resources such as NPfIT where there was not enough actual computers in some hospital departments and limited finances to sustain the project this increased tensions between all stakeholders [41]. It is therefore important as part of the planning stages to set aside adequate start-up resources.

2.5.2.1.5 Organisational Cultures: Communication and Relationships

The importance of acknowledging organisational cultures and the development of good relations between organisations is a key success factor within large-scale implementations. Cultural differences between health and social care coupled with inherent challenges associated with crossing professional boundaries need to be considered [35, 41, 43, 40, 45, 50, 52, 53, 57, 59]. Sociocultural considerations are important as attention to such issues facilitates the co-operation of front line staff which in-turn can help to overcome barriers to implementation [41]. Implementing across more than one site is challenging due to cultural factors such as differences in ways of working, public service bureaucracy and professional hierarchical structures[41, 43, 45], but even more challenging is the implementation of multi-faceted interventions. The existing literature is packed with studies and evaluations that are single-faceted in nature such the EHR, mHealth or Health Information Exchange (HIE). It is evident, that policy makers usually focus on a single intervention, and rarely does a national project venture to attempt to become a 'jack of all trades' in solving global challenges.

Ling and colleagues evaluated the English Integrated Care programme and made brief comparisons in relation to sites with single-faceted interventions versus multi-faceted interventions; the authors went on to state that single-faceted interventions made more progress within the same time frame. However the authors stated that challenges for multi-faceted interventions were due to increased complexity of the 'work' required within the implementation and having to re-negotiate professional boundaries to bring together previous silo organisations [45]. The literature shows that the introduction of a new intervention can make professional

hierarchies more visible, which can negatively impact the progress of a deployment, such as the nurse participants within the NPfIT who felt that their professional autonomy was undermined at times. They reported that in some instances with the introduction of the EHR it was clear that some nurses (with special training) had the 'authority' to order x-rays and some had to ask doctors to order [45]. Resistance towards this change and change in general has been widely discussed within the literature; factors such as anxiety and poor IT skills are the leading contributory causes [52].

Implementation drivers which can overcome some of the issues faced within the cultural aspect lies in the value of good existing relationships (between organisations and individuals) which helps to facilitate communication (the creation of a common language) and progress [37, 45]. Conversely poor relationships can lead to low levels of engagement of staff [43]. Having these drivers in place creates an opportunity for organisational learning and reflective practice [53]. Feldman et al of the *Medical Evidence Gathering and Analysis through Health IT* study (MEGAHIT) which set out to exchange standardised patient health information across a Nationwide Health Information Network (NwHIN) evaluated the first organisations (US Department of Social Security Administration and MedVirginia) to share live data. They stressed that although participants faced communication challenges, they strived to use a variety of methods to communicate with stakeholder partners by all means [57]. Fostering close collaborations is a significant catalyst in aligning organisational perspectives and a basis for consideration of organisational cultures.

2.5.2.2 Human and Social Factors

This dimension relates to the social factors surrounding the implementation of a large-scale intervention and the human factors concerning the actual users that engage with the intervention. This includes the need to actively engage clinicians, patients and stakeholders as proactive participants of the implementation process [28, 29, 31, 32, 34, 39, 41, 43, 46, 47, 48, 49, 51, 53, 54], exploring the value of clinical champions [28, 34, 36, 37, 38, 39, 41, 43, 50, 56], impact on working practices [28, 30, 31, 32, 36, 42, 45, 46, 53] and impact on patient outcomes [8, 21, 13, 17 19, 22, 26, 27, 28]. The following section will discuss these factors each in turn and reflect on how these impact wide-scale deployments.

2.5.2.2.1 Patient & Consumer Engagement

Inadequate attention to engaging patients as active consumers of healthcare is considered a deal breaker in the provision of digital health services at scale. If this is neglected this can lead to poor uptake and adherence to interventions. This was evidenced by patients involved in the world's largest roll-out of telehealth and telecare: the Whole Systems Demonstrator (WSD) trial in the UK. Low adoption rates have been documented to be the result of non-meaningful user-engagement [39], incorrect assumptions made about the contribution and role of patients as 'passive' and unnecessary obstacles which makes the engagement process cumbersome for patients [46]. For instance low uptake within the '*Health Space*' Personal Electronic Health Record (PEHR) programme (an aspect of the NPfIT NHS CRS) stemmed from not knowing much about it and an unnecessarily 'trying'

registration process. So once, patients came to know about the new system, in order for them to 'participate' they were required to bring in three forms of identification to their general practice (one must be photographic: driving license or passport) and proof of address to create a user account. As a result of this process being overwhelmingly cumbersome to begin with many users did not bother using the system. The initiation process itself was off-putting and sustaining engagement was also a problem as one patient described the whole process as the 'sleeping gym membership'; the notion of registering and using the system once and then losing interest completely. Across the board, patients were not keen on engaging and this was the largest contributory factor to the complete failure of the program. Therefore, greater attention must be paid to creating awareness as the first and most crucial part of the participatory process [49].

Creating awareness is key for all users of a new eHealth service. Lenhbom and collaborators explored the opinions of Swedish consumers and health professionals on shared regional EHRs and the National Patient Summary (NPS) which was actively being deployed. Perhaps not so shockingly, most consumers were not aware about the NPS at all, whilst health professionals were much better informed about the national progress [49]. Getting people on board and creating support for eHealth awareness amongst patients and the community is a lesson that has been learnt across a number of national digital health implementations.

How to best go about creating awareness can take a variety of forms; several studies demonstrated that implementers maximised their opportunities in engaging patients and stakeholders. The introduction of the nationwide telemedicine programme for Kosovo (TPK) provided introductory seminars as an engagement tool to wet the appetite of stakeholders and professionals which proved successful [34]. Similarly, the development of a regional mHealth application in London, England: the Imperial Antimicrobial Prescribing Application (IAPP) deployed across 5 NHS trusts to assist doctors and clinical pharmacists at point of care was strategically planned to launch in the first week of August to coincide with the new intake of qualified doctors entering the NHS [54]. This maximised uptake and the diffusion of the application among junior doctors. Additionally in Australia, patients were invited to attend and freely participate in workshops concerning the Shared Health Summary (SHS) and this provided enthusiasm for the project [47]; and GP practices participating in the roll-out of the PCEHR developed targeted mail-outs to their patients with the aim of creating awareness and recruiting many patients to PCEHR but there was slight concerns about traction and retention [49]. In any case, it is clear that two important facets of consumer engagement are required; the first being 'opportunity' (point of engagement) to identify occasions to encourage potential users to buy-in and the second 'timing' [39].

Several studies reflected on the benefits of getting consumers of large-scale digital health services on-board and involved early on. These include conveying the value of the intervention to others, voluntarily acting as informal champions in helping to recruit other participants and bridging the cultural gaps within the engagement process between stakeholders in a single healthcare journey [47, 48]. Cresswell and colleagues examined approaches and experiences of user engagement to the implementation of the EHR within NPfIT. Their findings indicate that local engagement efforts can be negatively influenced by a lack of user involvement in procurement decisions and this resulted in notable disengagement. Efforts to re-engage participants who lost interest (using clinical

champions) was then a mitigation strategy used to prevent further alienation of users, although emphasis is placed on the initial point opportunity for engagement [39].

2.5.2.2.2 Impact on Working Practices & Routines

Integrating and implementing large complex systems into routine practice requires a great deal of effort. This is because the introduction of a new system can impact and change the way people work (existing work practices) and this can have several 'knock-on' effects [30, 31, 32, 36, 42, 45, 50, 52, 53]. Negative impacts include increased workload, impact on existing roles and responsibilities, impact on quality of care provided (i.e. within a consultation: patient – clinician encounter), disempowerment, undermined professional autonomy (and erosion of professional identity) and frustration [36, 42, 43, 45, 50, 53]. The degree to which these impacts affect individuals or groups of individuals is dependent on factors such as organisational level and work stream. The Norwegian Centre for Telemedicine (NST) initiated the The Display Window (TDW) telemedicine solution to ease the communication and collaboration between general practitioners (GPs) and specialist hospitals. The authors argued that the innovation project became 'normalised' (embedded and fully integrated) into clinical workflows but not into the management work. Although it could be argued that for a system to become fully integrated they should go hand in hand. A planned re-structuring of workflows pre-implementation can help to facilitate the transition process; or else 'workarounds' are likely to emerge in a bid to overcome usability issues [32, 45, 53]. Operational factors inherent within this domain are the socio-technical interactions which should be accounted for in the planning stages. In a study conducted by Ser et al that investigated the reasons for non-compliance of staff in using the EHR as part of NPfIT; they noted that participants felt that the system did not integrate well with existing work practices [52]. Furthermore participants explained that "whoever designed it made assumptions about how our work is organised…doesn't really fit". In cases like this, the literature illustrates that it is usually senior staff in clinical settings that end up delegating tasks to administrative or junior staff to carry out and ironically system designers usually did not account for this user group being the primary users [53].

In many instances the time factor is required to take its natural course. A great deal of learning emerged from the NPfIT and over time users in some hospitals became more familiar with the system which helped to develop their confidence. However it must be stressed that users had to invest a significant amount of time and resources to fit the technology to meet their everyday work practices [38, 45]. Most importantly, users changed their work processes; and a benefit of incorporating electronic transmission has been faster and enhanced workflows [53]. Pearce et al argue that in order for users to see any benefit from changing work practices there needs to be realisation in terms of identifying a meaningful use of digital health primarily as this can promote readiness and adoption resulting in improved societal and economic outcomes [49]. Again, the need for continuous evaluation and collaborative working is required in the planning stages to promote cohesion and increase the likelihood of a smooth implementation process [59].

2.5.2.2.3 Clinical Champions

The value of clinical champions (doctors, nurses, allied health professionals) in particular in facilitating the adoption of digital health systems has been a reoccurring and critical success factor documented by several authors [28, 29, 33, 34, 36, 37, 38, 39, 40, 41, 45, 50, 51, 53, 56, 58, 59]. There are many examples within the literature of poor or inadequate clinician engagement. These include: GPs in the Whole Systems Demonstrator (WSD) not being made aware of the programme in its early stages and clinicians' restricted involvement in the procurement process in NPfIT (contractual arrangements and program deliverables). This can lead to low morale, reluctance to endorse an intervention, low adoption rates and gradual disengagement [29, 39, 40, 41, 51, 53, 58] In such an instance, like in the English Integrated Care Pilot program, clinicians felt that they did not have adequate time to prepare themselves and that the system was forced upon them.

Clinicians can be a powerful barrier to digital health implementation and thus should be an integral part of the implementation process as they can be an important factor determining the success or failure of an implementation. A clinical champion (a key individual) is advantageous because in their capacity they are able to provide credibility for the intervention to their peers acting as a key enabler [43]. In the case of NPfIT which was divided into 5 implementation 'regional monopolies', there was little done to "*win the hearts and minds of health professionals*" and in turn this was a contributory factor towards its complete failure. It is clear that merely introducing technology without the use of local and/or clinical champions is effectively useless as it may require clinical end-users to spend more time with technology than with actual patients which in reality is unlikely to happen [33, 45].

Genuine consultation for both patients and clinicians pre-implementation is warranted. In reference to work carried out by Charani and colleagues with the IAPP mHealth app, they used four methods to create awareness and get clinicians on-board. The authors firstly marketed the app during lectures for junior doctors on pharmacy modules; secondly emails were sent to newly recruited doctors within each trust; information was also posted onto the intranet homepage and a viral hard copy of a trust newsletter was made accessible [47, 54]. Examples of benefits of clinical champions within the literature have been described in relation to increased willingness to endure protracted procurement processes despite delays and challenges, continuity of care and bridging the cultural gap between professional boundaries [50, 56].

2.5.2.2.4 Impact on Patient Outcomes

This structured scoping review has highlighted that the potential of digital health in some cases is yet to come to fruition. An unintended consequence of poor implementation is negative impacts on patient outcomes [39, 40, 46, 49, 53, 54]. Issues such as patient safety – the unknown risks of introducing an intervention plays a vital role in deciding whether or not to proceed with wide-scale deployment [40]. Innovations that make use of mobile devices within clinical environments for example introduce the risk of infection at the bedside for patients as stated by Charani and colleagues [54]. In terms of patients or consumers of healthcare, differing levels of health literacy can lead to health inequalities and therefore there is a need to a) invest in upskilling end-users to use

interventions and b) involve users in the design process to create a collaborative and ubiquitous solution with limited training required [46]. A lack of skills in particular has contributed to users not being digitally confident and feeling unable to adequately engage in self-care [29]. Several studies did however report that digital health has helped to improve healthcare provision and make it more efficient in some cases. Benefits such as improved continuity of care, improved patient autonomy, reduced waiting times for patients, cost savings in travel to and from healthcare facilities, reduced over-prescribing and rapid medical attention are factors that underpin the push towards large-scale digital health and wellbeing solutions [35, 44, 48, 46, 55].

2.5.2.3 Political Factors

Changes in the political landscape of government-led deployments have several implications for the longevity of a given intervention. The existing literature has made it clear that there is a need to develop further digital health policies to foster digital health strategies in promoting adoption [51]; a need to align digital health policy with local needs and national health strategies [31, 40, 50, 51] and a need to secure government backing [28]. Political factors belong to the wider-external environment which has a direct impact on large-scale implementations. It is important for these factors to be scoped and included in preliminary plans for nationwide deployments. In the context of the Canadian endeavour to implement a national system and interoperable EHR across the country (provinces and territories) there was an absence of adequate digital health policy to align with the $1.6 billion investment into technology for the project as a whole [51]. This misalignment prevented progress by impeding efforts to harmonise provincial policy and the priorities of the healthcare system to guide the deployment.

Likewise, in relation to the NPfIT, there were constant changing milestones and changes to NHS policy [53]. There had been a significant policy shift since the launch of the project and early policy documents failed to feature the needs of end-users [40]. Additionally, the systems in place could not respond quickly enough to changing national and local NHS priorities; at a time of austerity with significant budget cut-backs arising, this meant that the objective of having an electronic record for every NHS patient was not achieved under the programme [40]. Fontaine and colleagues evaluated the EHR and the exchange of healthcare information in Minnesota primary care settings. They noted that some practices involved in the study performed better than others, and those that faced financial challenges in particular and lagged behind in meeting implementation milestones viewed federal legislation as negative. Participants went on to state that it felt like the "l*egislation is breathing down your neck*" [58].

The literature illustrates that top-down policy initiatives alongside national implementations have been relatively unsuccessful and over ambitious [40, 51, 58]. In some cases a focus on the national performance took precedence and overlooked local needs and clouded local priorities (i.e. regional versus local interoperability). Errors such as failing to establish a sound business case for using technology, failure to support local innovations and limited will-power to bring adequate resources to match implementation objectives are leading causes of project failures [51, 58].

National projects are closely tracked by the public sector [34, 39, 40, 50] and media coverage is a given. However, negative coverage can threaten an entire nationwide implementation [40, 50, 58] and especially when approaching election periods as was the case for the NPfIT where some respondents were in favour of political statements supporting dismantling the programme or drastic changes to internal organisational structures. This was due to uncertainties about the future of the programme coupled with the negative political outputs.

2.5.2.4 Economic Factors

Economic considerations are important when implementing digital health systems. This section discusses the costs associated with national implementations; considerations for appropriate funding periods [28, 50], on-going maintenance and sustainability [30, 31, 33, 36, 43, 54, 55], the value of financial incentives [40, 49, 54, 58] and funding models [41, 42]. In the case of the WSD project, time-limited funding meant that staff were specifically employed for the duration of the study (RCT) and this affected local spending plans because it meant that they had little opportunity to stay in post. This had implications, the first was that an inability to retain staff meant there was a human resource deficit for the programme once the trial concluded which then had a negative impact on the sustainability of the project. Policy makers and stakeholders involved in real-time, complex national implementations tend to favour funding periods of 5 years or less to allow for efficiencies to take effect. Limited funding periods provides less time for the benefits of a given project to be demonstrated and these premature findings are at times, the basis for future decision making regarding digital health initiatives.

In terms of on-going maintenance and sustainability of digital health innovations; acknowledgment of preliminary economic risks within project plans can help to account for unforeseen circumstances. Without this acknowledgement additional short-term expenses can affect the long-term viability of an intervention. This was the case for the IAPP mHealth application that cost £5000 to create but ongoing maintenance fees cost £400-800 per update. Updates would be required if there were changes of modifications to guidelines, the user would also be required to update to the latest version. Several studies have re-iterated the need to consider start-up fees, cost of integrating new systems and ongoing licensing fees when implementing at scale [31]. The above is even more significant as there is now a push towards integrating health and social care services. Financial budgets that were previously either for health or social care would in this instance become 'pooled' and spending plans would need to be reviewed [54]. Therefore there is a need to include consideration of the longer term financial stability of digital health projects within government plans [31].

In reference to clinical practice, financial incentives have been discussed within the literature as important 'motivators' for individual users and healthcare organisations to adopt and implement systems [40, 49, 54, 58]. Special attention is made to providing clinical incentives to adopt information systems to improve clinical practice [40]. Examples of where incentives have been introduced and worked effectively have been for 'participating' in a study and local improvement changes [47, 58]. The underpinning financial models however, should align with the operational context of a project. For instance, within NPfIT stakeholders received

payments retrospectively and these were often delayed which impacted local provider finances [53]. It is clear that further research is needed to determine whether incentives are necessary and if they are to identify models that would be well suited in supporting different types of deployments.

2.5.2.5 Technical Factors

Factors under the technical dimension relate to interoperability and standardisation issues [28, 33, 36, 39, 43, 44, 45, 47, 51, 51, 53, 56, 58, 59], infrastructure [31, 33, 34, 38, 54, 55, 58, 59], user satisfaction and usability (i.e the design of the eHealth intervention itself: an influencing factor on success or failure of an implementation) [32, 41, 44, 45, 46, 48, 51, 53, 53, 54, 56] and privacy and security [43, 46, 48, 50, 53, 54, 56, 57].The following section will discuss these factors each in turn and its impact on wide-scale national deployments.

2.5.2.5.1 Interoperability and Standardisation Issues

The need for systems which are compatible and able to 'speak' to one another in a standardised way is considered to be the 'holy grail' of implementation science. Efficient communication allows professionals to share information and best practices maximising the benefit for patients and users all round. Data sharing benefits include fostering multi-disciplinary team working [53], easier access to better structured information, and improved patient safety [48]. On this basis the Canadian endeavour documented by Rozenblum and colleagues started from creating a single architecture for the country based on linking local systems with regional provincial registries in order to create a 'longitudinal' EHR. National standards were established which enabled participants within the study to have a comprehensive national approach to standards for health information technology and this set the foundation for interoperability and established a framework for collaboration across provinces, territories and jurisdictions [51]. Although this approach was deemed valuable there were concerns from participants that a heavy focus on national interoperability would not support local innovation. Participants' feedback included the need to focus on regional interoperability to enable successful adoption and speed the process of implementation as a whole. Furthermore, participants explained that a local approach was needed to gain value for money and this would provide a degree of flexibility. There have been many examples within the literature where a lack of standards and 'common language' affected interoperability and the implementation process as a whole. The difficulty with large-complex interventions is usually due to the fact that different systems are being used by different partner organisations and the attempt to interface with them creates even more challenges [44, 58]. Ling et al note that this may not be due to the technology itself but as a result of 'poor implementation' [43].

Many centrally-led digital health innovations set out with the aim of becoming fully interoperable and integrated into the context in which it is being applied however there seems to be a recurring trade-off between standardisation and localisation. For instance, in the national deployment of the EMR in Scotland, Bouamrane and colleagues noted that due to the fact that the government advocated for an electronic National Health Service, the need to customise software to fit local needs versus the wider program proved problematic. This

was exacerbated by the fact that some existing legacy systems were still in place and users were required to operate between the new and the old system. In comparison in the case of NPfIT, there were some regions where 'off-the-shelf' applications were being offered as an interim solution, whilst waiting for a replacement of the legacy systems [42]. Studies which primarily focused on HIE within the literature were able to demonstrate success factors that led to a fully interoperable system. This includes the use of legal agreements such as the Data User Reciprocal Service Agreement (DURSA) used in the US Veterans Affairs Virtual Lifetime EHR programme which provided a framework for safe and secure data transmission and promoted trust between participants [56]. Caution needs to be taken when dealing with interoperability and standardisation issues; and facets such as flexibility and adaptability are key facilitators in dealing with integration and migration issues.

2.5.2.5.2 Usability and User Satisfaction

Usability problems can be significant barriers to the successful implementation of digital health systems. A system which is not user-friendly and difficult to use is often rejected by users [36, 41, 44, 45, 46, 48, 52, 53, 54, 56]. Conversely, a system which is perceived to be intuitive, easy to navigate and easy to learn is likely to be adopted more readily than the former [32, 51, 56]. Technical performance (functionality) and usability challenges impede on both the hardware and software aspects of an intervention. Several studies reported that issues such as having to make "too many clicks" to complete a task or action, slow performance or unavailable data, information and alert overload and limited customisability at user level were considered to be major turn-offs for users [44, 45, 48, 56]. Even more so, system failures and crashes encouraged users to become more reluctant to use a new system; in fact users are more likely to revert back to previous ways of working [44, 52] in such situations. Further barriers cited within the literature include negative impacts on quality of care (i.e. interference in remote consultations) [32], and not being fit for purpose [44]. In some cases participants reconfigured their work practices to overcome usability issues inherent in a system [53].

Greenhalgh et al make reference to the 'design-reality' gap which was made evident during deployment of 'Health Space' PCEHR within the context of the NPfIT [46]. This is usually one reference point for why e-government projects succeed or fail. It sheds light on the translational journey and the amount of change required between the current standpoint of service provision to what government projects see as the future of digital healthcare provision. This 'change' requirement is built into a project's design as assumptions and therefore the success or failure of a project is dependent on the gap between the current reality of how healthcare services are currently delivered and the degree of change required by the digital health innovation project. Hence, the larger the gap the greater the risk of failure and the smaller the gap the greater the likelihood of success. The authors of this study set out to identify mismatches between the design features of the PCEHR (including the assumptions made about it by participants) and the lived reality of patients self-managing a long term condition such as diabetes.

The majority of patients found the PCEHR to be of limited value which was an important reason for abandonment. Poor ease of use was reported by users but the main concern was the disparity between the anticipated design of what Health Space would look like and do (patients expectations) and the reality which led

to dis-engagement of the system. The authors stated that “None entered any health data on to it and none intended to continue using it in its present form”. This underlines the importance of incorporating participatory and user-centred design principles into large-scale deployments to help improve the chances of adoption in reference to future projects [46].

2.5.2.5.3 Infrastructure: Internal and External Factors

There needs to be adequate infrastructure in place as the underpinning basis of any given digital health venture. In particular with reference to scalability a well-accounted for and robust infrastructure can help to overcome physical barriers to implementation. An example which demonstrates the importance of infrastructure in this review relates to the design and implementation of a mobile SMS-based system to track pregnancy and maternal child outcomes in Rwanda [55]. This study was conducted in the Musanze district which serves a population of 347,692 in the northern province of Rwanda. The project was set up to enable effective communication between *Community Health Workers* (CHW) who were trained volunteers within the community (working on the front line) and the wider healthcare system. This was the first large-scale mHealth project to go beyond pilot phase in Rwanda. The Ministry of Health (MoH) provided the central, strategic direction, whilst each district is equivalent to health boards which are responsible for providing care to all within their catchment area down to sector, cell and village.

The components of the robust infrastructure included the use of human resources: CHW who were instrumental in addressing geographical barriers in particular that could negatively impact access to care. More importantly, the government had a strong commitment to innovation and provided mobile phones to every CHW in the country and covered the cost of SMS messages within the frame of the project. Rwanda in general has ‘good’ mobile phone coverage and the only issue encountered by CHW was the lack of electricity to charge phones; and so the MoH encouraged CHWs as part of technical maintenance to charge phones at the nearest charging points in their closest health facility. Ultimately this project helped to reduce delays on communication associated with maternal and new-born related deaths in Rwanda.

Broadband, connectivity and internet capabilities need to be considered when implementing at scale due to differences in geographies’ and funds available to overcome these challenges [58, 59]. In remote-rural settings in particular where there are limited capabilities, a contingency or fall-back strategy should be in place to enable the project to continue to run given the limitations. Dedicated fibre-optic cables are now being actively used to support communication and fast data transmissions [33]. Fontaine and colleagues advocated for the need for fibre optic capabilities in rural settings in America and therefore the premise of adequate infrastructure cuts just as deep in more developed countries as well as under-developed countries [58].

2.5.2.5.4 Privacy and Security Issues

Concerns about privacy, confidentiality and security were voiced among patients, health professionals and a variety of stakeholders [43, 46, 48, 50, 53, 54, 56, 57]. Privacy issues in relation to EHR centred on unauthorised access to patient records and role-based security mechanisms. In relation to the shared EHRs and the National

Patient Summary (NPS) in Sweden, healthcare professionals are required to gain verbal consent from patients every time they set out to access a patient's record [48]. Surprisingly patients within the study were not aware that clinicians must obtain verbal consent from them before they are able to access their clinical information. Conversely, health professionals were aware but stressed the need to access a patient record in the patients best interest at times, and called for changes to be made to this 'impractical process'. Additionally, tiered access was deemed 'cumbersome' as it was the consensus that clinicians should have access to 'relevant information on a need to know basis' [48].

In Sweden health professionals are at risk of being struck off for misconduct if the appropriate guidelines and procedures are not followed in line with national legislation. Consumers suggested that 'general consent' should be established to prevent health professionals having to obtain consent at each encounter. Access to patient records (National Patient Summary) over the internet in this study was also addressed and thought to be 'unsafe' by both healthcare professionals and consumers. Although a level of transparency was discussed in order for patients to know and understand what had been written about them. In relation to the US Veterans Affairs Virtual Lifetime EHR program, over a third of veterans had concerns about privacy and security however it was felt that the overall benefits of the programme far outweighed the risks. 90% of VA providers trusted the privacy and security protections of the Virtual Lifetime EHR (VLEHR), although 81% veterans felt their data should only be exchanged with signed authorisation; "every one person has his own choice", "the VA should not have the authority to do it [make security decision] for us". Byrne and colleagues argued that this project as a whole helped to address important technical and scalability issues by improving the trust and confidence in the value and accuracy of Health Information Exchange (data sharing) amongst users.

Some studies revealed instances where security was compromised due to the fact it was thought of as laborious. In the case of the NPfIT, to avoid lengthy log-in processes in one hospital, identification cards were often left in the system to enable all users to access the system freely. This finding in the context of a large-programme was not exactly shocking but echoes the importance of further training for all stakeholders to understand the importance of patient confidentiality, data integrity and security of healthcare information across all organisational levels and professional boundaries.

2.6 Discussion and Conclusion

This scoping study set out to examine the current state of knowledge on implementation issues of national digital health innovations at scale. The results of the study demonstrate that 5 key factors are worthy of consideration (organisational factors, human and social factors, political factors, economic factors and technical factors) when embarking on large-scale deployments. Some of the evidence within the literature has been previously documented and echoed from pilot studies however many of these sub-factors are unique to scale and others magnified due to sheer scale. In the next section, the NPT framework is applied as a theoretical lens to help explain the social processes and actions that frame the 'work' of implementation [15]. Developed by Prof Carl May and colleagues, NPT has been widely cited as a robust explanatory framework that captures the 'change processes' involved when implementing, embedding and integrating digital health in practice. NPT

makes reference to four distinct generative mechanisms namely Coherence, Cognitive Participation, Collective Action and Reflexive Monitoring (Figure 2.2 below). Each NPT construct consists of four sub-domains which highlight the necessary social actions involved in achieving sustainability and integration into routine practice. These sub domains are discussed in further detail in chapter three (theory and methods). Figure 2.3 provides a visual of the analytical process in how themes identified in this review map onto NPT. In the case where a theme did not map onto the framework this is explored in further detail.

May C, Finch T. Implementation, embedding, and integration: an outline of normalization process theory. Sociology 2009;43:535-54

2.6.1 NPT: Coherence Domain ('Making Sense' of digital health initiatives)

The Coherence domain relates to how people individually and collectively develop a shared understanding and 'make sense' of new ways of thinking and working. The components of this domain are 1) Differentiation which specifically refers to whether people have a clear understanding of how a new intervention and set of practices differ from existing practices. 2) Communal Specification focuses on how individuals develop a shared sense of understanding in relation to the aims, objectives and projected benefits of a new intervention. 3) Individual Specification looks at how people come to know and understand their individual roles and responsibilities and how that fits into the context of the wider intervention. 4) Internalization looks at whether individuals understand the importance of the intervention and the underlying future value.

The findings from this scoping review highlighted that organisational factors satt within this domain but were also covered within the cognitive participation and collective action domains as described in the next section. For example, the literature demonstrated that due consideration should be given to undertaking preliminary digital maturity and readiness assessments to ensure individuals understand the value of the proposed implementation (*Readiness Sub-Factor, Internalisation*). Implementation barriers include the lack of a clear set of project aims and objectives stated from the offset (*Leadership & Management Sub-Factor, Communal Specification*) and a lack of understanding of initial roles and responsibilities (*Leadership & Management Sub-Factor, Individual Specification*). It is equally important as part of the planning stages to set aside adequate start-up resources and if this is overlooked this could hinder progress significantly.

2.6.2 NPT: Cognitive Participation Domain (Engagement)

The second domain Cognitive Participation relates to the relational work of 'engagement' and how to ensure participants 'buy-in' and can help sustain an intervention. The introduction of a different set of practices due to

a new intervention may require individuals to re-organise themselves in order to collectively contribute to the new ways of working. The components of this domain are 1) Initiation which places emphasis on the key individuals engaged and participating in implementation and whether they are willing to drive it forward. 2) Enrolment which looks at whether participants actively participate and 'buy-in' (are recruited) to the new intervention. 3) Legitimation, a very important component which looks at whether participants believe it is right for them to be involved, and equally if they feel that they can make a valid contribution. 4) Activation, which specifically focuses on whether people sustain their involvement in the new intervention or simply eventually withdraw.

The findings from this scoping review highlighted that organisational, economic, political, human and social factors also sit within this domain. For example, the literature demonstrated that suitable investment in education and training facilitates engagement and helps drive implementation forward (*Organisation Factor, Initiation*). Similarly, the use of clinical and community champions play a key positive role to encourage buy-in (*Human and Social Factor, Engagemen*t). Financial incentives also appeared to be an implementation facilitator if used tactfully and for the benefit of all stakeholders (Economic Factor, engagement). It became evident that poor communication channels and relationships between stakeholders are significant barriers to progress which could lead to withdrawal in some circumstances (*Organisation Factor., Activation*) Political factors equally need to considered as the impact of media coverage for example could be beneficial or high risk as demonstrated in the literature.

2.6.3 NPT: Collective Action Domain (Operationalising Work)

The Collective Action domain makes reference to the work of putting the intervention into practice (operationalising) put simply what needs to be done to ensure that the intervention works in reality. The components of this domain are 1) Interactional Workability which seeks to identify if the intervention and the new set of practices make peoples' work easier and how they operationalize it. 2) Relational Integration refers to the intellectual work that people do to develop accountability and build confidence in the intervention. The notion of developing and maintaining trust is also a point of focus. 3) Skill-set Workability looks at what the necessary skills are to actively operationalize the intervention; whether additional training is required or the intervention changes roles and responsibilities. Specific emphasis is placed on the allocation of work which underpins the division of labour. 4) Contextual Integration seeks to identify the resources needed to manage a new set of practices due to the introduction of a new intervention.

The findings from this scoping review highlighted that organisational, economic, political, and technical factors also have aspects which sit within this domain. For example, the literature was saturated with examples of the impact of inadequate attention given to technical aspects of large-scale implementations. These included a lack of consideration for infrastructure, interoperability and standards (*Contextual Integration*); insufficient time spent on enriching the user experience in relation to usability and user satisfaction (*Interactional Workability*), and the need to consider privacy and security issues (*Relational Integration*). Additional findings from this study

illustrate that significant investment should be made to up-skill and ensure stakeholders have the necessary skills to carry an implementation forward. Organisational factors such as impact on working practices, roles and responsibilities proved to be key factors to be considered (*Skill-set Workability*). Finally, factors which promote sustainability include the need for sufficient manpower, time, finances and resources as well as political support for digital health initiatives.

2.6.4 NPT: Reflexive Monitoring Domain (Appraisal work)

The final domain Reflexive Monitoring provides an opportunity for reflective practice. It centres on the work of appraising an intervention and assessing the effect of a new set of practices individually and collectively as a group. The components of this domain are 1) Systematization which refers to the measures of success and how participants determine the effectiveness (benefits and limitations) of the intervention. 2) Communal Appraisal looks at how people collectively judge and evaluate the intervention. 3) Individual Appraisal focuses on how individuals evaluate the effects of a new set of practices on them and their work environment. Particular focus is on the on the new relationship that they develop with a new intervention. 4) Reconfiguration the final component seeks to identify whether participants attempt to create a 'work around' as a means to refer back to their previous set of practices or how they modify new practices to suit their needs.

The findings from this scoping review highlighted that organisational, economic, political and technical factors also feature within this domain. For example, the literature reflects on the need to create a compromise in identifying the most appropriate implementation strategy for large scale deployment. A robust evaluation plan needs to capture and assess project performance as well as include exploitation and future sustainability opportunities (System*atization*). Several studies highlighted the need to assess a) how users interact and judge an innovation and b) the effects on their existing work practices (Communal Appraisal). It is important to note that the more complex an innovation (multi vs. single intervention focused), the greater the difficulty to capture and realise benefits. Many of the findings overlap between NPT domains and this is representative of the dynamics involved in large-scale digital health implementations.

Two external themes outside of NPT which merit further consideration are 'Scale' and' Context [15]. The notion of context has been an obvious and transparent factor impacting the implementation of many at-scale digital health projects. Notable barriers were cited in several studies where the local context was undermined [28, 29, 31, 35, 36, 37, 45, 50]. Several studies re-iterated the need to account for local organisational needs and the need to consider interdependencies [37]. Equally, the literature highlighted a large number of facilitators advocating the need for large-scale programmes to be mindful of the setting and circumstances inherent in complex deployments [38, 49, 50, 55]. These include incorporating flexibility and adaptably for national strategic approaches to provide variation and greater local choice in support of local activities [50]. In regards to the Australian PCEHR study, local support was more valued and likely to produce change than the use of a central approach [49]. This finding validates the shift towards encouraging 'ownership' and the roll-out was mainly supported through face-to-face locally contextualised support processes. Bediang and colleagues suggest that

the key in terms of sustainability, from their experience of evaluating ten years of telemedicine in LMIC is to integrate local context, stakeholders, technology and adopt a suitable a funding model to provide added value [31].

2.6.5 Strengths and Limitations

A strength of this scoping review has been the systematic approach to the search and selection of papers for review. In addition, the use of a thematic approach rather than a framework approach to data analysis allowed themes to emerge from the data, avoiding the risk of shoe horning data to fit any particular coding framework. In addition, the use of NPT as a conceptual lens with which to consider the themes identified provided a basis for learning and critical reflection. The use of this framework also helped to readily highlight the barriers, facilitators and lessons learned. A limitation of this study is the absence of any formal quality appraisal of the literature. However, it is important to note that it is not the aim of a scoping review to conduct an assessment of the weight of the evidence, rather, the aim of the scoping review is to shed light on this emerging domain. The restriction of the search to ENGLISH only papers may also have resulted in papers from some countries being missed and could also have been viewed as a limitation, although recent publications suggest this may not be a major issue [60] and this review did identify publications relating to work in low and middle income countries.. Equally grey literature was not sought which could also be considered a limitation.

2.7 Conclusions & Key Evidence Gaps

Valuable lessons have been learnt from the implementation of large-scale projects in practice and gaps in the literature have emerged such as a) the limited use of participatory bottom-up approaches and user-centred design principles for digital health innovations, b) the limited number of multi-intervention innovations and c) scalability factors. It is important to consider the interrelatedness of these dimensions and the use of a theoretical model has the potential to help to shed light and make sense of these factors.

The UK Medical Research Council strongly suggests that large-scale, complex interventions should have a sound theoretical basis in order to provide grounds for exploration before they are scaled up and implemented in practice. Several studies were underpinned by a theoretical framework or model which were used to interpret their findings; such as the use of Actor Network Theory (ANT) to understand the implementation and adoption of Electronic Health Records (EHR) in the NPfIT, the Normalisation Process Theory (NPT) to examine the sociotechnical factors affecting adoption of Electronic Medical Record (EMR) systems in Scotland and Critical Realism used to understand the impact of introducing Personally Controlled Electronic Health Records (PCEHR) in Australia. The ensuing chapter will explore these theoretical methods in greater detail in order to identify the most suitable framework to underpin the work involved in this thesis in the context of a National Scottish Digital Health & Wellbeing Service – Living It Up (LiU). The next chapter will proceed to outline and discuss the methodology and methods used to support this thesis.

FIGURE 2.3 – MAPPING TO THE NORMALISATION PROCESS THEORY

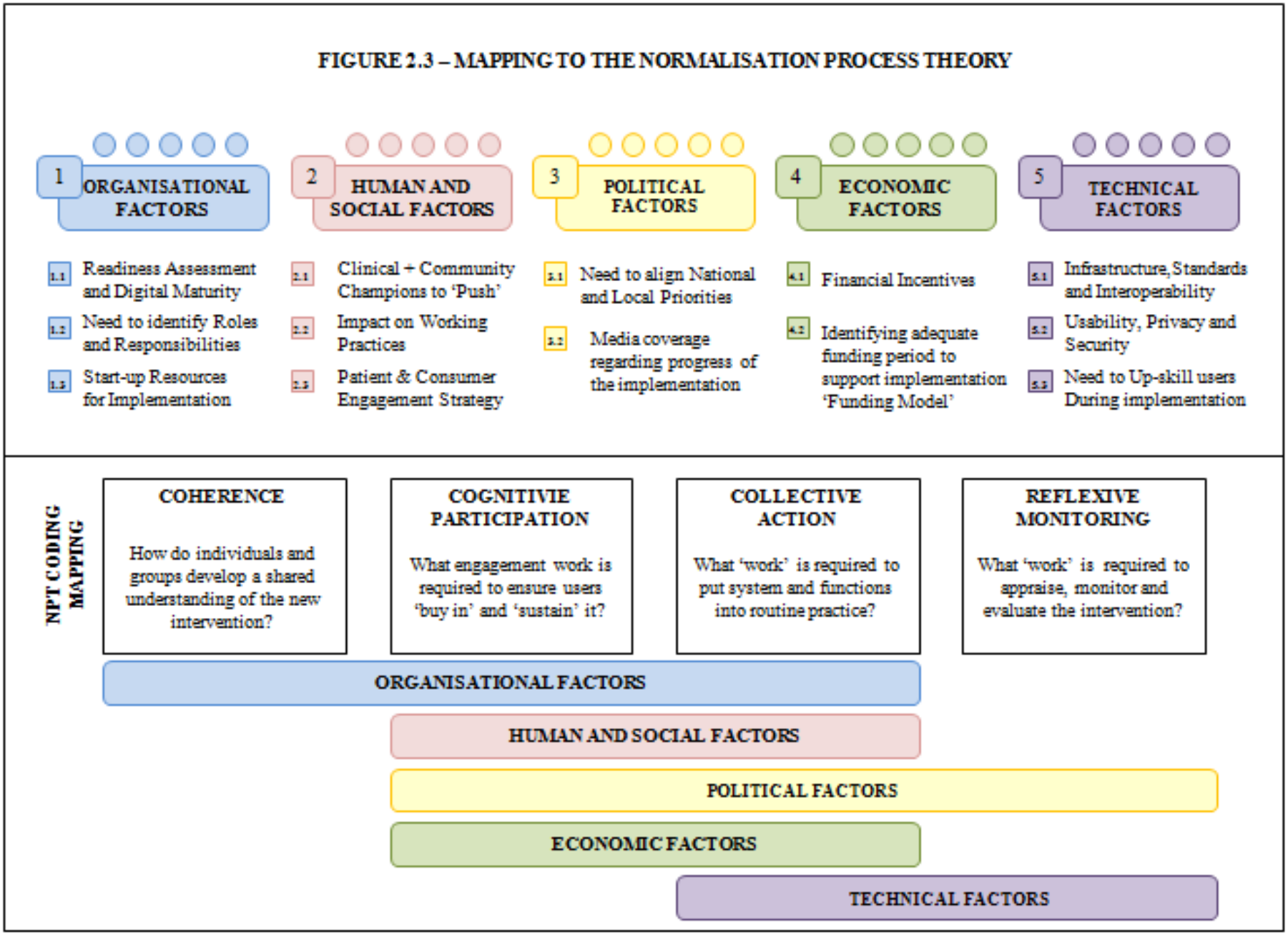


TABLE 2A Authors	Objective	Setting	Design & Theory	Key Barriers	Key Promoters	Learning Points + Other Comments
[Intervention] – Telehealth & Telecare Solutions						
Hendy J, Chrysanthaki T, Barlow J et al. 2012; UK [28]	To investigate the organisational factors affecting implementation of re-designed services for people with LTC	Multisite three primary care settings in England: Cornwall, Kent and London	**WSD** project. RCT – each site was a case study. Participant observation and interviews during implementation	- patient recruitment - telehealth bias - no data sharing system or model - organisation readiness - local needs - funding period	Successful + building relationships + improved communication + GP champions + engaging staff + trust, awareness	Use of RCT hindered the deployment Need for flexibility for intervention to organically evolve
Sanders C, Rogers A, Bowen R et al. 2012; UK [29]	To explore the barriers to participation and adoption of TH + TC from those who declined to take part in **WSD**	Pooled from primary care settings in England: Cornwall, Kent and London	N = 22 interviews and observations Recruited from 4 streams: COPD, HF, Diabetes, Social care)	- technical skills, language barrier, not digitally confident, uncertain use of technology, disrupt services, staff restricted time to explain devices, - tech undermine independence, tech threat personal control of self-care, reminder ill, laziness, hypochondriac - prefer existing services and hcp relationships they know well - not all GPs aware of WSD		Poor uptake of and adherence to interventions for complex chronic conditions due to heavy burden on patients. Need to account for organisational context
[Intervention] – Telemedicine Solutions & Video Conferencing						
Andreassen, HK, Kjekshus LE, Tjora. 2015; Norway [30]	To identify aspects of **TDW**: original and spin-off projects that could demonstrate the slow diffusion of ICT in healthcare	Introduced tech to ease interaction between GPs and specialist hospitals. Multi-intervention	Case Study Mapping of Norwegian telemedicine services Document analysis and interviews 3 specialties	- resources and funding delegated to implementation and organisation but not 'operating' in practice	Management failure but… + Normalised in clinical work not management workflows + flexible handling of resources + training + professional engagement + align policy and practice	Failed local innovation projects can contribute to system correction: addressing how services can be handled in new ways.
Bediang G, Perrin C, Ruiz de Castaneda. 2014; Geneva LMICs [31]	To provide an overview of **RAFT** for LMICs, key challenges and lessons learnt form 10 year project and outlook towards	17 countries in Sub-Saharan Africa and Latin America. Urban and rural areas. 60 active sites connecting central +	Literature review, document analysis and informal discussions with key collaborators of RAFT regarding remote education +	- financial sustainability and incorporating into government plans -Digital divide as it mainly targets individuals not institutions	+ RAFT relies on network of motivated individuals + workshops strengthen inter-personal links + builds capacity of hcp + training 'knowledge	Challenge aligning ehealth activities with local needs + national health strategies in each country > RAFT able to support new partnerships (top-down and bottom-up). Need to integrate '***local context***', stakeholders, technology with added-

	sustainability	rural hospitals with specialist expertise, VC connect	clinical activities to support clinicians	- Scaling-up - socio-political aspects	multipliers' transferable to home country + recognition* + data infrastructure	value + sustainable funding model
Dos Santos AF, dos Santos SF, de Melo B et al. 2011; Brazil [32]	To describe and analyse the process of implementing telehealth into primary care units in the city of Belo Horizonte, Brazil	Belo Horizonte Tech. implemented in 148 basic primary care units. Main activities include: Education via videoconferencing + Assistance via teleconsultations in primary care units with each unit a team of 1 doctor, 1 nurse, 2 nurse aux. and 6 community health nurses.	i) Literature review – To identify primary care units with telehealth incorporated into service model ii) Document analysis – To describe the process of implementing telehealth [internal documents] iii) Incorporated findings from wider evaluation	Communication - users may feel not leading actor in process- Organisational - quality of consultations and ability to speed diagnosis Technology - connectivity speed Other (Cultural) - Lack of training - Knowledge transfer to/from specialist	Communication + professionals attribute greater value to job Organisational + sense of virtual belonging Technology + fast incorporation of technology into units Other + professionals admitting need second opinion + Some patients prefer conventional appointments	Results – 3 streams: a) relationship between telehealth + setup of primary care units. b) characteristics that focus on assistance + educational training in Belo Horizonte and c) positive /negative aspects of the process. Main Lessons: disruption to workflows + restructuring of work practices though the project enabled the strengthening of ties between academic environment + hcp as the study involved 1/5 professionals of higher education, providing educational video content.
Latifi R, Dasho E, Merrell R et al. 2014; Cabo Verde [33]	To present preliminary results from the implementation of an Integrated Telemedicine and e-health Program (ITeHP-CV) for Cabo Verde.	10 fully functional telemedicine centres in all nine inhabited islands of the Republic of Cabo Verde, Africa	A Prospective Cohort study Used the International Virtual e-Hospital Foundation strategic approach known as "Initiate-build-operate-transfer" over 26 month period. (Nov 2011-Dec 2013). NB. Data collected for study not clear!	NB: need for physician training and fostering local champions is essential in promoting use and adoption of teleconsultations. Merely installing telemedicine equipment without it is effectively useless. -Government of Slovenia funding bulk of project and therefore complete ownership by Cabo Verde not transferred until project is complete	+ Balance of responsibilities between key stakeholders + Government backing (MoH) + Use of IBOT ensure interoperability, infrastructure and ownership +Tele-education trailed telemedicine consultations due to (careful preparation of clinical programs, continuous support and tech training). +overcame internet capabilities using dedicated fibre optic cables supported by the internet provider	Results: 5 main implementation outcomes: a) capacity building, b) network development + deployment of equipment c) clinical telemedicine, d) continuing medical education and e)electronic virtual library. Project laid foundation for sustainability: good organisation, use of IBOT, continuous training, infrastructure, policy dialogue with Ministry of Health, development of close partnerships with key players, adequate funding + negotiation [13 ***positive measures***]. NB. Long-term results are not yet known yet.
Latifi R, Merrell R, Doarn C et al.	To introduce telemedicine and e-	Kosovo. Created a Telemedicine	Use of a 4 part strategy to implement, assess + ensure adoption of TPK	Transfer: In case the government support is not supportive i.e MoH	Initiate: + Seminars wetted appetite of professionals and stakeholders (engage tool)	IBOT stages: Introductory Seminar, 1. assess healthcare needs of country, 2. Develop curriculum for tele-program 3.

2009; Balkans (Kosovo) [34]	learning in Kosovo using the Initiate-Build-Operate-Transfer Strategy to support health infrastructure **IBOT**	Programme for Kosovo (TPK) as an International Virtual e-Hospital (IVeH).	using (IBOT). "Initiate-build-operate-transfer". TPK developed in 3 phases. 1) Telemedicine Centre of Kosovo (TCK) set up with state of the art facilities. 2) Six regional telemedicine + ehealth education centres constructed + linked to TCK and 3) link to remote centres (RTC) in villages providing family medicine services.	not fully on-board would need to adjust strategy to generate additional revenue to support the program. - Establishing telemedicine programs in developing countries is complex and time intensive NB. No primary data included but paper presents just a description of the 'successful' program –	+ Internal Funds provided by Balkans Gov. as seminar showed evidence that proved program worthwhile to invest. **Building**: + Set up adequate infrastructure + Special attention paid to human capacity building: getting staff to run program independently (tech, managerial, e-library staff) + Leadership roles + clear division of obligations and duties **Operate**: + Keeping program high profile via research publications + collaborations with universities around the world – year-round eTeaching + Champions	Establish nationwide network and 4. Integrate program into host nation, when fully mature transfer ownership to MoH maintain sustainability. NB. End program belongs to the institution and the country that has made the investment. Lessons Learned (tables 4-6 of paper): In order to ensure sustainability – preparation needs to be made clear at beginning so that specific objectives and goals are clearly defined, funds allocated to sustain employment of key personnel. In this case they will become employees of MoH or entity based on country's arrangements. Table: 4) Requirements for a successful program 5) Do's and 6) the Don'ts for implementing telemedicine in dev. countries
Ndlovu K, Quinn R, Park, E et al. 2014; Botswana [35]	Botswana UPenn Partnership (BUP) a collaborative to use mobile phones as tools to improve access to specialised health care services. **Kgonafalo** – ehealth solution.	Botswana	Pilots – 4 medical specialities and the outcomes formed the evidence in support of scale-up **Kgonafalo** project ***[descriptive paper]*** *Scale-up scheduled late 2014*	- Sociotechnical challenges in pilots - malfunctioning phones - accidental damage to phones - alignment between IT and Health providers	+ Lessons learned include need for support at senior management level, solid sustainability plans and public/private partnerships. +MOU between gov. and private telecommunication firms, award of tender to local IT firm and MOU MoH. + close working relationships among stakeholders fostered communication + Reduced waiting times for patients and £ saving in travel + Improved patient outcomes with quick medical attention received	Botswana the 1st in Africa to invest in a nationwide mobile telemedicine scale-up project. NB. Resources (context) are naturally limited: human + technical. Few specialised doctors therefore barrier to patient access, poor IT infrastructure. Hope lies in use of wireless telecommunication services + mhealth – consumer demand for mobiles Continuing professional development for nurses at MoH will enable them to gin more knowledge as they interact with system

[Intervention] – Care Pathways						
Bouamrane M-M, Mair F S. 2014; UK [36]	Describes the complex sociotechnical factors that have influenced adoption of the new 'Electronic preoperative integrated care pathway' (**eForm**) which allows hospitals to access comprehensive patient medical history via a clinical portal on the health board intranet to assist the assessment process before a patient goes into surgery.	National Health Service (NHS) in Greater Glasgow and Clyde, largest health board in Scotland and one of largest in UK Estimated patient population: 1,210,254 in 2011.	RATS checklist used to describe qualitative research methods. (Relevance, Appropriateness, Transparency, Soundness) NPT used as theoretical framework to identify key success and hindering factors and to interpret the results. Stakeholder interviews: N=6 face to face semi-structured interviews (sample), N=1 focus group and N=2 workshops with key stakeholders involved in the PCIP and EPR programmes.	- When a record is simply not accessible or either being used by a different member of staff, in a different location in the hospital or at a different hospital or other health board. - occasional system breakdowns and slow at times as well as the notion that it takes longer to complete the electronic version than paper (IT literacy issue) - impact on consultation and patient-clinician encounter	+ At a local health board level the PCIP (Planned Care Improvement led to the rationalisation of the surgical assessment clinics and standardisation of the pre-op process. + At a national level the wider eHealth programme selected portal technology as an iterative solution towards virtual electronic patient records. + Nurses play a key role in gathering all the info required for pre-op assessment every day therefore having a central accessible repository enabled effective info sharing, patient case management + continuity of care (Champion) +consultant led the development of common guidelines + streamlining the organisation processes helped towards the smooth running and management of the pre-op workflow for both hcp and patients	The adoption of eForm into routine working practices can be attributed to: 1) a policy context, promoting the rationalisation of surgical pathways – a coherent pathway, 2) readily available financial and organisational resources to support service redesign and use of IT in operationalising the standardisation of the pre-op process, 3) sustained engagement with stakeholders throughout all phases of the eForm development, 4) the use of pragmatic IT as a solution and 5) a context-related implementation in consideration. The establishment of a generic template means that the same guidelines are being used across this health board. + Use of a bottom up approach ensured that everyone was engaged as that is where the bulk of the information is coming from (Paper £ to store, transport) Changes to work practice more efficient, in-house training was provided (CoAc) Change requirements and requests can be communicated back to the EOR eForm team on an 'as needed basis' to be incorporated into future versions (ReMo)
Dent M, Dylan T. 2014; UK [37]	The study reports on the experiences of 2 NHS hospitals implementing and using IT to support integrated care pathways	England: Walsall (N=24) [Urban] + Northants (N=20) [Rural] and their networks (acute, social care,	Longitudinal study i) Mapping six care pathways. 4 in study ii) Interviewing IT + HCPs Total **N=44** iii) Obs. Meetings +	-Org issues IN + OUT for all players to talk using 'common language' -info not crossing boundaries easily + reliably – lack system integration [diff systems	+ Some players based similar or same geography or room thus able to manually achieve system integration + sharing of info across boundaries [social workers, OTs] + face-to-face communication	Implementing eICPs is not easy [due to interdependencies, diff. cultures + strategies of informatics department - context] Lessons: suggest use of 'hybrid' role for hcps i.e. nurses as clinical change facilitators (champions) + 'patient surveillance' for complex cases with

		private care homes)	Doc. Analysis	for diff org. players]	+ Adaptive + work arounds	multiple conditions whilst crossing org. boundaries - logics
[Intervention] - Mutli-Intervention Projects						
Bower D, Barry N, Reid M et al. 2005; Scotland UK [38]	This paper examines 4 'national projects' which were priorities of the Scottish Telemedicine Action Forum (STAF) as national priorities to be routine services. The authors identify key issues that emerged as critical factors in carrying projects successfully through to implementation	Project 1 – Multisite VC network linking 15 minor injury units to a main A+E centre Project 4 – A multisite software audit tool to support the care of cleft lip palate patients from birth NB. Projects 2 + 4 were single-site and therefore excluded from literature review	Analysis of reports, discussions and reflections recorded at regular on-site progress meetings within individual project groups over a 2-year period. Interviews with people involved at different levels of the innovation	Project 1 - Technical issues with equipment although regular feedback between stakeholders helped to resolve issues where limited resources. Project 4 - Technical supplier issues: limited IT capabilities i.e. NHS proprietary network, NHS.net - Importance of evaluation was overlooked	+ Involvement of local IT (hospital based) in implementation Project 1 + Org issues: new patterns of developed and knowledge sharing opportunities between stakeholders Project 4 + Collaborative approach used to design and develop the project + Formal project lead with dedicated time to the project helped to engage with staff in various sites and ensure know their roles and responsibilities	The study illustrates importance of clinical champions as there were difficulties experienced in embedding services as routine within organisations Project 4 deemed successful as project lead able to persuade individuals to effect necessary changes into practice. Relationships with external IT providers deemed significant to the overall as in many instances applications have to be adapted to fit the professional routines of staff
Cresswell K, Morrison Z, Crowe S et al. 2011; UK [39]	Poor UE highlighted as a key factor in failed EHR projects. This study examines approaches + experiences of UE to implementation within national program large-scale shared EHR(**NPfIT**)	Purposive sample of N=4 hospitals (each a case study site) implementing early versions of EHR software (iSOFT Lorenzo) via National CRS under the NHS Connecting for health agency	Longitudinal, qualitative case-study. Data: N=123 interviews with users and managers + N=15 stakeholder interviews + N=43 hrs of non-PO, documents meetings + system use	-'Meaningful' UE not achieved -hospital staff not consulted in sys. choice at initial POE > 'sell' - limited customisation of software (not mature enough functions) affected interoperability - clinicians disengage	+ UE developed to local level, but top-down national approach did not foster close working relationships + Local champions asset to UE but hierarchy within HCP teams barrier to progress. UE focused on clinical staff with limited consideration for management + admin staff.	Political pressure to implement system Early system not in final form therefore benefits not readily available to users (limited feedback for tech. issues) Overtime hospital management began to lose credibility among users of system Start > vision POE lack of involvement in decisions, usability > disengage. Re-engagement (champs) helped to extent

Currie W. 2012; UK [40]	This study provides insights on the impact of the introduction of gov. policy to modernise NHS using ICT and impact of introducing IT into hospitals (Four sub-projects of NPfIT: e-Prescriptions, PACS, Care Records and Choose + Book'	N = 10 NHS hospitals in three NPfIT regions of England [NHS CRS] Summary + Detailed	Literature review, N= 140 Interviews and documentary analysis of secondary sources Exploratory longitudinal study from 2001 – 2011 (10 years)	- From outset the top-down policy used to introduce a large-scale IT programme across NHS was ***ambitious*** + ***risky***: several lengthy delays: IT procurement, management issues increased contract costs (£) - ***Politically driven*** agenda posed a major challenge there was a lack of clinical engagement as many clinician knew little about NPfIT policy – some had not even heard of the programme - Attempts to introduce a ***one-size fits*** all to achieve standardisation led to issues evidently impeding culture, size and variation of different NHS organisations - issues surrounding clinical incentives to adopt information systems to improve clinical practice - England divided into 5 regions: ***regional monopolies***, as large firms won multi-billion pound contracts to undertake IT work in 1 or more region which did little to 'win the hearts and minds' of health professionals - '***Coercive isomorphism***' where external and internal pressures are placed on one org. by another.	*Other negative factors*: IT literacy in some sites took a back seat "there are many other priorities than IT at this hospital…we serve the local community". Patient safety: unknown risks about introducing EHRs, clinicians do not want professional autonomy compromised because of 'fashionable idea about patient choice'. Negative media coverage described as a 'computer failure' There has been a significant policy shift since the launch of the project early policy documents failed to feature HCP and patients (NAO 2008) and cut-backs at time of austerity meant that the objective of having an electronic record for every NHS patient not achieved under programme (NAO 2011).
Hendy J, Reeves B, Fulop N et al. 2005; UK [41]	This study describes the context of implementing the NPfIT in England, the barriers and opportunities to implementation in particular NHS Care Records Service	N=4 acute NHS trusts in England	Case study sites. In-depth interviews with N=23 senior managers, clinicians, chief execs, directors of IT, nursing + medical directors Round 1 Interviews (Sept-Dec 2004)	- Implementation process – suboptimal - System functionality issues + ***legacy system*** issues - Long wait + timescales and ***deliverables*** not met. Timescales should be realistic! -Implementing across more than 1 site is challenging, ways due to difference in ways of working, organisational cultures, can increase tensions if not enough flexibility to account for context - ***Poor communication*** from NPfIT HQ to local sites, no clear direction / clarity felt by many participants -***Clinician engagement*** was poor, low morale and therefore they were reluctant to go on and 'sell' the systems to front line staff -Local ***funding*** sources + existing deficit, central funding does not cover all	In terms or nationally led, top-down implementations, persuading people it will be 'worthwhile' is as great a challenge as technical barriers Sociocultural considerations need to be considered in context of IT implementations – need to gain co-operation of front line staff important to overcome some barriers Better 2-way communication is essential Genuine consultation using reps of users would be beneficial > likely lead to sense of 'ownership' + embrace change even when going gets tough.
Hendy J, Fulop N,	This study describes the	N=4 acute NHS	Case study sites. In-	- Implementation costs associated with IT + staff are ready for IT modernisation + support	-3 issues still apparent (finances, communication + timescale delays)

Reeves B et al. 2007; UK [42]	context of implementing the **NPfIT** in England, the barriers and opportunities to implementation in particular NHS Care Records Service [Update]	trusts in England	depth interviews with N=25 senior managers, clinicians, chief execs, directors of IT, nursing + medical directors Round 2 Interviews (Jan-Apr 2006)	modernisation still high + > £ market supplier outside of the program -£ deficit also acted as a distraction – PM could not prioritise plans due to uncertainties - disempowerment + frustration [limited involvement in process] -delays in system change over presents risk to patient safety	goals of programme but hesitation from staff of PMs capability and the need for products to 'work' soon enough + 'turn-around teams' put in place to resolve £ issues + stay on track [performance] + interim solutions enable trust to move forward but not achieve promised wide scale connectivity + there is a lack of integration between these temporary solutions	-5 new issues (mainly barriers to deployment) - In 18 months between studies changes in personnel 11/23 still in post [years] Off the shelf application being offered in the interim whilst waiting for replacement of legacy system + new PAS > but £ savings need to be made! Main concerns: whether NPfIT deliver the products and whether deliver in reasonable timeframe Monopoly of IT contracts by suppliers within the programme
Ling T, Brereton L, Conklin A et al. 2012; UK [43]	To review the barriers and facilitators to integrated care in England. A UK wide large-scale pilot for integrated care.	16 health and social care sites across England. NB. Interventions varied from site to site but mostly catered to multi-morbid patients	Mixed-method case study. N=213 in-depth interviews and questionnaire provided. Study informed by Kaplan (2010) and the Normalisation Process Theory (May et al., 2009).	- Org, issues: participants had to modify existing systems and work practices as 'new teams' were created due to integrating care. Participants no longer working in silo org. and therefore had to ***re-negotiate professional boundaries***. - NHS Public service ***bureaucracy*** slows down the implementation process in getting things done. - ***IT issues***: different systems being used by different partner organisations which caused difficulties in sharing data. Cause was not necessarily the IT but due to 'poor implementation' - ***Privacy + security*** concerns in sharing data some professionals didn't want others seeing their notes - ***Clinician involvement***: some staff felt had no time to prepare and therefore felt it was forced upon them. GPs were the strongest barrier if not engaged but a GP champion in an instance provided 'credibility' for the pilots as able to engage their peers. Another barrier is increase in workload and having to adopt new responsibilities with the system which they felt eroded their professional identity. - ***Resources***: Training required given additional responsibilities otherwise staff felt unprepared - ***Finance***: Budgets were previously either for health or		Sites with single-faceted interventions made more progress than sites with multi-faceted interventions. This was due to the increased complexity of the work required in the implementation as well as in some instances the significance of working with partners across primary, secondary and tertiary care takes longer. Important factors to consider: a) The importance of the relationships between various stakeholders and leaders of organisations involved in the project b) Scale of planned activities c) Governance and financial arrangements d) Support for staff in new roles e) Organisational and staff stability ***Other facilitators***: Having an agreed shared vision and value helps to promote

				social care but now integrated in project and 'pooled' exacerbates plans on spending as £ could be tied up in other organisation existing plans + ***Good existing relationships*** between org. and individuals help to facilitate communication and progress (conversely poor relationships led to low engagement of staff)		participation of stakeholders. + A strong commitment, direction and leadership from senior management facilitates lasting change + Co-location of stakeholders helps to promote cohesion. Project seen as platform to help reduce £ spending.
[Intervention] – Electronic Health Records						
Bouamrane M-M, Mair F S. 2013; UK [44]	Two-fold: a) Examine the sociotechnical factors affecting adoption of EMR (Electronic Medical Record) systems within primary care practices in NHS Scotland and b) understand GPs views of their system and the surgical pathway	GP practices across 9/14 territorial health boards across Scotland.	N=25 in-depth semi-structured interviews with primary care doctors. Authors made use of quantifying the qualitative feedback Underpinning theory: Normalisation Process Theory (NPT)	- functionality, navigation + usability too many clicks - system failures as the system was down at times or crashed - info. + alert overload - need for additional training to increase familiarity - interoperability issues having to flick between this and other systems - Some participants felt the system interfered with consultation	+ system facilitates shared care + improved patient safety with decision support + improved access to patient information when needed + user friendly + improved continuity of care although there was an initial hurdle + system provides added value such as key word based searches within patient records for history of an item within consultation history	Some participants felt that some things were easier to do in the old system. Additional training required and user-centred improvements needed in using IT as this can help promote increased understanding and familiarity of the new EMR system for doctors. *Readiness
Cresswell K, Worth A, Sheikh A. 2012; UK [45]	To explore the implementation process of the UK national EHR deployment at micro-level (local) and macro-level (national) taking into account 'context' and environmental factors. 'Lorenzo Software'	England. Sample across a range of healthcare settings (3 sites)	Qualitative + longitudinal: reviewed documents, carried out observations (38.5hrs) and interviews with stakeholders with those using the system in their everyday working. N=66 Participants	- Limited customisability at user level - not suited to local needs so seen as not fit for purpose initially and therefore increases workload for user - Gov. wants n electronic NHS and to be fully interoperable but 'trade off' between interoperability and	Coping strategies: + The system was introduced in phases as more functionality developed therefore the electronic system and existing paper-based system was operating in parallel. + Users developed 'work arounds' although participants noted that the system helped to improve	Additional negatives: Introduction of EHR made professional hierarchies more visible – i.e common language Autonomy undermined for some other nurses 'not qualified' to do so. The system also reduced the amount of time health professionals spent with patients as time spent on the computer; and quality of consultation less engaging. Left clinical staff frustrated.

			Informed by Actor-Network Theory (ANT) used to look at how a centrally procured EHR played a role in shaping social relationships & professional practice socio-technical factors) within organisations.	usability therefore impact on local work processes. -Introduction of EHR system changed the way people worked = 'knock on effects' impacted on roles and responsibilities. More emphasis on admin tasks for clinical staff so seen as a 'distraction' from clinical responsibilities	communication over long distances.	Learning Points: Overtime users became more familiar with the system which developed their confidence. But users had invested significant time and resources to adopt system to fit into everyday practices. Users had to change their work processes to fit the technology (new system) into their daily working. Introducing a new system requires a participatory approach and flexibility as not one size fits all. Overtime paper lost it's significance and used as a back-up.
Greenhalgh T, Hinder S, Stramer K et al. 2010; UK [46]	To examine the policy making process and the implementation of 'Health Space' an internet accessible Personal Electronic Health Record (PEHR) an element of NPfIT 'Summary Care Record' (SCR service). Authors assessed the extent to which 'Health Space' had been adopted and used in the 3 years after its introduction in 2007. NB. 2 types of online accounts: basic and advanced	NHS organisations in England: 2 'early adopter hospitals'	Several benefits anticipated by policy makers. Two main objectives of study was to a) identify reasons for non-adoption/ abandoning Health Space and b) Lessons Learnt Mixed-method multi-level case study. N= 160 interviews and ethnographic observations (approx. 3,000 pages) N=56 participants (patients and carers) to gain a 'Rich Pict12 re' Measure: creation of accounts	- Functionality and capability of google-style personal health record aligned poorly with expectations of users - Analysis of gov. policy documents' made no mention of patient expectations, motivation for use, or current self-care process and made no plans to incorporate. - Design-reality gap - In government strategy documents, software developers and implementation leads highlighted as the main experts in deployment - Low uptake in creating	+ 'Communicator' function similar to SMS text messaging was a secure messaging system between a patient and clinician, seen as straightforward by a number of participants (N=15). + Improved continuity of care… 'Full personal GP to myself' + Improve patient autonomy but users also became more dependent on GP in making decisions. - Felt by some that this system 'means' may affect GPs as they are not paid to interact over Health Space' compared to primary care doctors in the USA for instance within Kaiser Permanente who are paid for any consultation/ interaction be it face-to-face, email,	Assumptions of benefits to personalise care, empower patients, improve data quality, health literacy and reduce costs not realised. Mismatch in expectations with data protection and flexibility to see GP. Readiness to adopt low, cultural context overlooked. Authors unable to speak with users of advanced accounts as there were hardly any due to low adoption rates – seen as similar to the 'gym=membership' concept of signing up but hardly return to make use of facilities. Study echo's that technology is not always the answer but a facilitator towards achieving a given goal. Health inequalities affected health literacy and self-management of long term conditions therefore need to invest

				user accounts. Patients had low interest + the registration process was deemed cumbersome and bureaucratic: Need to bring in ID, proof of address, passport-like photos to create account - Patients found it limited value, poor ease of use as not user friendly	telephone etc. which is an incentive to increase uptake.	in upskilling people as users were not wholly involved in the design process. Great hurdles to overcome. Patients were to be 'passive' recipients of 'Health Space' and not 'active' and therefore need to promote this shift. Risk assessment was undertaken prior to implementation however some issues were not highlighted pre-implementation.
Knight A, Szucs C, Dhillon M et al. 2014; Australia [47]	To evaluate the deployment of 'Shared Health Summaries' (SHS) in Australian primary care practices. NB. The aim of the programme of study is to enable 2,000 patients from participating GP practices and health service in eCollaborative have an SHS established on a PCEHR by 1st Aug 2012.	Australian primary care practices.	Informed by the plan/do/study/act cycle (PDSA) Mixed-methods N=54 practices participated in study, 929 patients and 650 shared summaries uploaded. N=2 face-to-face national workshops and three webinars. NB. Limited primary data in this study	- delays in the provision of the national solution and therefore a reduced number summaries uploaded 'knock-on-effect' - data quality measures possibly failed to capture any improvements that did occur - Challenge in the fact that this was a new and ground breaking study for Australia.	+ eCollaborative provided resources, good example was manpower: CPM (Collaborative Program Manager) provided to each participating regional primary health care organisation where they assisted with management and technical issues. + eCollaborative made use of social media (twitter) to enhance communication during workshop events monitored by a GP- this created a 'live feed' + Development of a central Wiki for dissemination of news, events + resources related to the project	Iterative development process and deployment; at meetings participants would share success and failure strategies and incorporate suggestions before next workshop. eCollaborative set-up change principles as guidance and the model serves as a means for effective engagement. *Other Facilitator*s: ***Financial incentives***: practices were paid to include patient input in their local improvement changes. Additionally, patients were able to freely participate in workshops which provided advice and enthusiasm for the project. Suggestion from the: use of patients (themselves) to recruit other patients to register for PCEHR i.e champions.
Lehnbom E, McLachlan A, Brien J. 2013; Sweden	To explore the opinions of Swedish consumers and healthcare professionals on shared EHRs and the	Primary healthcare settings in Sweden	Semi-structured interviews with 7 consumers and 13 healthcare	- Consumers were completely ***unaware*** of shared EHRs and the move towards NPS - Patients not aware	+ Regional EHRs facilitated a holistic patient approach, follow-ups and reduced inappropriate over-prescribing	***Other drawbacks***: A major drawback perceived by both HCP and consumers was that consumers who 'doctor-shop' would be less positive and forthcoming

[48]	National Patient Summary (NPS)		professionals Total participants N=24.	that clinicians must obtain verbal consent before accessing clinical info of a patient (some HCP accessed record without consent) - HCP state that ***consent process*** should be changed – 'impractical'. At times need to access patient record in their best interest – still risky as could be struck off for misconduct - ***Privacy and Security***: Access to record over the internet thought to be 'unsafe' by both HCP and consumers (conversely for transparency some to know what written about them + explained)	+ Consumers felt it was of great value contrary to HCP + Consumers suggested that HCP should obtain 'general consent' and therefore will not require consent each time +benefits of digitally using EHR outweigh risks against 'privacy' + Perceived benefits by consumers: time and cost savings, safer and more efficient care. + Benefits perceived by HCP: electronic means makes it easier to access information, better structured, improved patient safety with a comprehensive medical history.	about having a shared EHR and a NPS. Additionally, 'tiered access' deemed cumbersome: HCP should have access to relevant information on a need to know basis. - Usability: drawback with the software 'too many clicks', no search function which made it difficult to scan notes quickly. Need for strict security measures to ensure no misuse of information! Most consumers were not aware about the NPS national roll-out but HCPs were much better informed therefore underlines need to effectively engage consumers – and getting the exact people on board.
Pearce C, Bartlett J, Mcleod A et al. 2014; Australia [49]	To describe the process undertaken and the experiences of introducing the personally controlled EHR (PCEHR) in general practices across Melbourne, Australia. NB. Large-scale Australian wide roll-out and adoption.	N=74 general practices	Informed by a Critical realism largely used to understand complex interventions (context + mechanism = outcome). 'What works for whom' and in what circumstances. > 100 meetings held across the country. Survey: N=84 staff responses, N=74	- GP practices participated in targeted mail outs to their patients with aim of creating awareness and recruiting many patients to EHR but concerns about traction and retention. - GPs felt inadequate remuneration for time spent using PCEHR - ***Output***: issues of concerns include the level of awareness and	+ Rollout supported through face to face locally contextualised support processes. + Medicare local (ML) an organisation setup to support general practices was instrumental in facilitating adoption + engagement + ***Mechanism***: organisation leadership from ML + Participating practices reported increased knowledge, skills + awareness of eHealth and eHealth	***Context***: article highlighted the importance of local support and local context. Local support was more valued and likely to produce change than central approach. ML important for wider context in driving eHealth implementation Large-scale programs should take into account small-scale needs There needs to be a balance between incentives and support Education and training should be provided to support the implementation

			practices	support for ehealth amongst patients and the community which can affect engagement with PCEHR solution	readiness. + Factors that motivated practices to engage with implementation include: strong existing relationships with ML, access to financial incentives for participation, wanting to be an 'early adopter' practice and active role + leadership from a highly interested GP inside the practice (Champion, Clinician Advocacy) also enhances consumer awareness	Vendors of EHR must work together with end-users (GPs) to meet practice needs as GPs felt that the vendors developed a system which did not meet their needs. Potential of eHealth not seen as yet to improve efficiency of care practices or communication flows. Starts with creating eHealth awareness to assist in the realisation of the benefits of eHealth and the gains that can come from changing processes or work practices. So identifying meaningful use of eHealth, can promote readiness+ adoption which ends with realisation of improved societal + economic outcomes i.e normalised into everyday working use.
Robertson A, Cresswell K, Takian A et al. 2010; UK [50]	To describe + evaluate the implementation + adoption of EHR in secondary care in England. NB. In the context of the ongoing local + national rollout of the NHS Care Records Service (CRS). The NPfIT approach is a national standardised top-down implementation. This approach was chosen due to the history of the deployment of IT in NHS before the programme.	England. 5 NHS acute hospitals/mental health trusts	Wider evaluation incorporates mixed-method case but study reports on the qualitative part of the longitudinal, multi-site case study. Looking at the Socio-technical factors Purposive sample Semi-structured interviews, documents + observations triangulated data to gain insights and experiences of the deployment. N=114 interviews across sites with N=91 staff across the trusts. Interim data collection.	- Political + financial factors: perceived to threaten the nationwide implementation: perceived uncertainties about the program before UK general election, respondents referred to statements in favour of … - Consequences of long-term centrally negotiated contracts to deliver solution - convoluted (unnecessarily complex) communication channels between stakeholders -unrealistic deployment timescales - applications could not	+ Despite considerable delays and frustrations, support for EHR remains strong including from NHS clinicians. + trusts wanted systems tailored to their organisations and not standardised – to provide greater control and ownership. There is need for leadership to overcome lack of 'trust between trusts' to create a model of local co-operation + In 2004, at a time of NHS restructuring + organisational change, leaders allowed foundation trusts to be able to implement their own EHR independently outside of NPfIT – direction and benefits not known + In 2007, PM devolved	Progress is slower than originally envisioned. Mismatch in in expectations and reality, trade-off clinician engagement. Top-down standardised approach needed to evolve to provide more variation + greater local choice which hospital trusts want in order to support local activity. Authors recommend a 'middle-out' approach to implement hospital electronic health records, combining government direction with increased local autonomy + for record sharing in local health communities. Need for flexibility, local adaptability and a tailored approach more aligned to NHS organisational needs. NHS should drive an 'economies of scale' through bringing together existing capabilities within organisation into a bigger shared service

				quickly respond to changing national + local NHS priorities -negative media coverage - Issues with local service providers having to re-negotiate contracts led to delays with service, reason cited as under-developed. -delayed financial (£) payments only after deployment of applications to hospital trusts that impacts on local provider finances	responsibility for delivering the programme locally in strategic health authorities which enabled sites to have responsibility for own sub-contracts with system supplier.	*Other barriers include*: low level of IT skills, lack of resources, lack of understanding of main aim of NPfIT, some technical specifications written into long-term contracts, which don't keep pace with technical advances. NB. Premature deployments had negative consequences. Deployment schedules/timelines were typically driven. Increased workload implications for HCP who see people at home and don't have access to the system. Blame culture 'pointing the finger' between stakeholders such as technical vendors/suppliers and local providers.
Rozenblum R, Jang Y, Zimlichman E et al. 2011; Canadaa [51]	In 2001, Canada set out to implement a national system and interoperable EHR. NB. A government funded project (Canadian Health Infoway) using a model for interprovincial + territorial collaboration to enable a national framework. NB. $1.6 billion initiative of federal funding. NB. 10 provinces in Canada + 3 territories	Community-based setting	Case- study approach to assess the 10 year history of this Canadian eHealth plan and to identify ways to increase adoption of EHR in Canada, National reports and documents were reviewed by authors. N=29 key stakeholders interviews with leaders in a position of leadership representing national + provincial organisations responsible for establishing policy + strategic direction for health information	- Lack of eHealth policy to foster eHealth strategies for adoption of adequate NB. No harmony between provincial policy to guide deployment - inadequate attention to actual users 'clinicians' led to low adoption Participants said that the direction + priorities for the eHealth plan needed to be aligned with the clinical + business needs of clinicians + the healthcare system through greater engagement of policy	+ adequate funding provided by Health Infoway (main role of organisation was to provide the funding and not a policy-setting body or give direction) gated funding (£) related to performance which was an enabler of provincial buy-in and commitment + national standards established: participants benefits of having a comprehensive national approach to standards for health information technology – which set the foundation for interoperability in the future + establish a framework for collaboration across provinces + territories and jurisdictions	The Canadian Approach: a) Canada created a single architecture for the country based on linking local systems with regional provincial registries – this was the creation of a longitudinal EHR. This approach also encompassed gated funding in accordance with performance (lower risk) and linking standards to support interoperability + agreed pricing with vendors. To accelerate adoption participants identified 4 key requirements: 1) meaningful engagement with clinicians, 2) co-ordinated and stronger leadership + investment in EHR across country, regions, provinces and jurisdictions 3) a revised payment model that can balance incentives based on patient outcomes i.e. QOF and 4) a focus on technology that would improve the value of healthcare.

			technology. Study informed by grounded theory– same model used by Hendy et al UK colleagues.	makers - Failure to establish sound business case for using EHR - A focus on national rather than regional interoperability which does not support local innovation - Absence of eHealth policy to align with the investment in IT to the priorities of the healthcare system.	+ patient registries + digital imaging (PACS) provides benefits for patients time and cost savings + co-ordinated support via national organisations – viewed as an enabler to appeal for/ call on political support	National standards welcome but participants feedback include the need to focus on regional interoperability to enable successful adoption and speed the process of implementation > local approach needed to gain value for money 'need for flexibility) Authors highlighted that I the top down vs bottom up debate that a top down architecture may lead to the same outcomes as bottom up clinician needs first approach. Thought top-down considered too slow and expensive!
Ser G, Robertson A, Sheikh A. 2014; UK [52]	To identify reasons for non-compliance i.e. developing workarounds; aim to gain the views of mental health staff using a national hospital EHR (NPfIT) NB. A workaround relates to how people use IT in their daily work + how they alter their work practices to navigate around obstacles to achieve task set-out to do.	2 'Early Adopter' Mental health hospitals	Purposive sample, semi-structured interviews with hospital staff (N=33) a range of clinical, IT, managerial and other workforce.	***Operational factors***: barriers: a) EHR system did not integrate well worth existing work practices "whoever designed it made assumptions about how our work is organised…doesn't really fit", b) less times with patients as most spent on entering information in EHR therefore felt that quality of relationship in consultation suffers c) EHR system did not meet clinical needs in meeting legislative requirements for psychologists. ***Cultural factors***: resistance to change from paper to electronic, some staff lacked IT skills struggled- caused anxiety especially for older staff not accustomed to IT. ***Organisational factors***: lack of resources (not enough computers + training), some felt that hospital leaders (senior management) did not understand the views of clinicians and didn't do enough to communicate staff about what gov. healthcare modernisation was about. ***Technical factors***: EHR system crashed at times and therefore staff reluctant to use it but paper-based system used as a back-up		Where IT systems are at odds with effective work practices, employees result to workarounds and clinicians generally leave the administration to staff and tension increases between the social-technical factors interplay. NB. Serious lack of coherence experienced by many about the NPfIT in terms of how the programme will help to improve patient care and work efficiencies, not enough done to get people on board as there was a large gap between the training and the implementation with participants saying that they had "forgotten what learnt" – additionally not all training material was relevant to job role – mix. Need for caution for data sharing , privacy and security of psychiatric patients
Sheikh A, Cornford T, Barber N et al. 2011; UK	To evaluate the implementation and adoption of NHS detailed Care Record Service (CRS)	12 early adopter NHS acute hospitals and specialist care	Longitudinal qualitative case study. a) 43 semi structured interviews, b) observations of	- Unrealistic expectations about the capabilities of systems - More time needed to	+ Enhance availability of data and management tools readily available in real time + Data is easily searchable	Implementing a national care record service is a complex process and impacts staff on all levels. Different staff have different expectations and experiences.

[53]	in early adopter hospital in England.	settings studied over two and a half years	strategic meetings (590 hours and 334 sets of notes) c) documentary analysis (809 NHS documents and 58 regional and national documents).	build, configure and customise software - The "work" involved to ensure that systems support the provision of care and meet the needs of end users - Constant change of milestones, NHS policy and priorities - Repeated renegotiations of national contracts - Complex communication processes between different stakeholders - Implementation proved to be time consuming and challenging, with limited benefits for clinicians and no clear advantages for patients - Some staff reconfigured their work practices to overcome usability issues inherent in the system. - Security risks (work around): To avoid lengthy log in processes, ID cards were often left in the system for all users to work on.	and retrievable anytime and anywhere by multiple users + Sharing data easily, brought about benefits for multi-disciplinary team working + Electronic transmission encourages faster work flow + Opportunities or organisational learning and reflective practice were encouraged NB. The facilitators only materialised after a critical mass of users and data were achieved	There is a need for flexibility in deploying health information technologies at scale. The top down national imposed strategy of the CRS had several local consequences (5 key themes emerged). ***Theme 1***: Multiple translations of the vision of the NHS CRS, which led to different understandings of the concept of the program as a whole (Lack of coherence). Little efforts were made to align perspectives between stakeholders – poor communication channels. ***Theme 2***: Gradual disengagement from the program by early adopter hospitals, due to challenges faced with implementation and phasing the system into existing workflows. Hospital providers felt they had a lack of autonomy regarding their contractual arrangements and deliverables. ***Theme 3***: Standardisation vs Localisation **–** customisation of the software to fit localised needs vs the wider program of a standardised and interoperable record for some hospitals proved problematic. ***Theme 4***: Reflection and Organisational learning "Staff wanted to get the best out of the new system". ***Theme 5***: Changes in work practices not accounted for: In practice many of the administrative work was allocated to junior or allied staff and thus the role that clinicians were assumed to play in using the system was not realised in the early stages of implementation.
[Intervention] – Mobile Health Interventions [mHealth]						
Charani E,	To report on the development and	5 NHS teaching	Mixed-methods case-study. Pre+ post	- Some hospital sites had very poor WiFi	+ To overcome barrier of poor internet connectivity, the app	Building apps for patients and clinicians helps to bridge the cultural gap between

Kyratsis Y, Lawson W et al. 2012; UK [54]	adoption and implementation process of the Imperial Antimicrobial Prescribing Application (IAPP) at point of care.	hospitals in West London, England, UK.	questionnaire intervention provided. Live data and application uptake tracked for 1 year. Focus groups with doctors and clinical pharmacists. NB. The development process was mapped, risks and benefits highlighted to individuals and organisation. Pre-survey questions related to a) clinicians awareness + existing usage of antimicrobial policy, b) prevalence of smartphone use amongst clinicians and c) experience of using external clinical applications on smartphone.	connectivity and limited internet access - Risk: infection control: hand hygiene needs to be considered. - Security: the app stored staff personal information, therefore a secure URL was created where the app could be downloaded. - Finance: Expenses for developing the app (£5000) and ongoing maintenance for updates of £400 - £800 per update. Other costs included advertisements for the app (posters) - 20% of clinicians (12/60) noted that it may look unprofessional to use an app in front of a patient. The perception of using smartphone during work was of concern. -It is up to the user whether they update the app or not.	was designed to work offline once downloaded + 71% of clinicians stated that using the app helped to improve their antibiotic knowledge +371 doctors downloaded the app in the first month, by 12 months 100% of doctors had downloaded the app +The app was launched to coincide with the first week of August which is when the new intake of qualified doctors enter the NHS. This maximised the uptake and the diffusion of the app among junior doctors. + The app was free + To update the app is more cost effective than publishing and printing new guidelines to the same cohort + Creating awareness: Four channels to market the app 1.) During teaching sessions on pharmacy for junior doctors 2.) Emails sent to new doctors upon recruitment to the trust 3.) Information posted to the intranet homepage 4.) Trust newsletter. +Doctors attended training sessions for the app at post graduate centres	different stakeholder in one healthcare journey The app was able to reach a wide audience in comparison to past desktop and paper versions. The app helped clinicians and pharmacists to inform their practice and adhere to the latest policy There needs to be adequate IT infrastructure in place to ensure that mHealth can help in the delivery of decision support at the point of care Barriers affecting the organisation as a whole in addition to individual user barriers all need to be considered prior to implementation through risk assessment
Ngabo F, Nguimfack J,	Describes the design and implementation of mobile	Musanze district which serves a	Quantitative usage statistics	-Telephone maintenance: lack	+ project helped to reduce delays in healthcare provision	NB. The project was set up to enable effective communication between CHW

Nwaigwe F et al. 2012; Rwanda [55]	phone SMS-based system to track pregnancy and maternal child outcomes in ***limited resource settings(LRS)*** to reduce the 3 delays om communication associated with maternal + new-born deaths in Rwanda	population of 347,692 in the northern province of Rwanda.		of electricity to charge phones so encouraged to charge at points in the closest centre	+ There were clear roles and responsibilities for CHW + CHW were instrumental in addressing infrastructure + geographical barriers that can negatively impact access to care + Government had strong commitment to innovation in general, they provided phones to every CHW in the country. + MoH facilitated private & public centre partnerships which enabled the lowering of the costs of SMS text messages +Local based software expertise was used in the project + Reporting compliance was 100%, and the SMS error rate decreased from 54% to 8% in the first four months of the project. +Rwandan MoH invested and covered the cost of SMS messages within the framework of the project.	and rest of the healthcare system. The Ministry of Health (MoH) provides central, strategic direction. Districts are equivalent health boards which provide care to all down in their area down to sector, cell and village. They are the first line of service at village level and it is provided by CHW (volunteers from the community who receive training). Rwanda has good cell phone coverage! mHealth can contribute to better emergency obstetrics and neonatal care, but it requires a well organised community structure in LRS . Setbacks prior to the project go live were due to lack of education and sexual health programs available to prospective mothers. NB. This was the first large scale mHealth project to go beyond the pilot phase in Rwanada NB. The system is a tool for CHWs to register new pregnancies, monitor them up to delivery and post-partum.
[Intervention] – Health Information Exchange and Infrastructures / Interoperability						
Bryne C, Mercincavage L, Bouhaddou O et al. 2014; USA [56]	Authors describe the department of Veterans Affairs (VA) Virtual Lifetime EHR (VLEHR) in 12 communities designed to exchange health information with private sector organisations and	N = 12 sites, 4 sites (3-way: DoD, US Department of VA and Private Sector) and 8 (2-way: US Department of VA	Mixed method used to monitor and evaluate the status of VLEHR 1) Quantitative data on veteran participation and usage of VLEHR health exchange.	- 37% of veterans had concerns about privacy and security, however felt that the overall benefits of the program outweighed the risks - Barriers included slow	+ Physician interest in using HIE: They believed care provision improved using HIE. + VLEHR has advanced HIE interoperability standards and patient consent policies nationwide	NB. This project has helped to address important technical and policy issues scalability by improving the trust and confidence in the value and accuracy of HIE amongst users. The project was overseen by central

	the department of defence (DoD)	and Private Sector) communication)	2)Qualitative in-depth interviews with providers and veterans 3) Collection of wide range of documents from VLEHR stakeholder meetings	and sometimes unavailable data retrieval. As the amount of data increased so did the retrieval time. The technical performance of the system was impacted upon. - Access requirements between pilot sites and separate logins: providers were less inclined to sign into a second application because they found it frustrating to memorise an additional login credentials.	+ The veteran affairs coordinators managed local troubleshooting issues, and established training and support needs. They acted as liaisons between the department of veteran affairs and partner organisations + VLEHR made use of data user reciprocal service agreements (DURSA) - a framework for safe and secure HIE, which promoted trust between participants + Veteran acceptance was high with 90% interaction + 90% of VA providers trusted the privacy and security protections of VLEHR. Benefits included: comprehensive view of patient record, continuity of care, faster access to information and expedited work flows. + All sites were able to exchange data	leadership and there were local implementation team at each site 81% of veterans felt that their data should only be exchanged with signed authorisation. “everyone person has his own choice” , “VA should not have the authority to do it for us”. New partners are asked to take a preliminary readiness survey to check if they have adequate resource to support implementation
Feldman S, Horan T. 2011; USA [57]	This study describes the (request and receipt) process via the nationwide health implementation network (NwHIN) – a secure, interoperable, Health IT standards – based transport platform of patient information) between SSA (the US dept. of social security	Virginia, USA	Qualitative case study design. a) literature review, b) collection of documents and c) N=43 semi-structured interviews and focus groups with the study reporting findings in terms of technical, organisational and	***Technical factors***: facilitators included the transfer of live interoperable and standardised health information and time savings with average processing time savings of 30%. Barriers’ included the network not able to keep up with gateway update which affected data transfer ***Organisational factors***: Facilitators included: central leadership (visionary leadership) all organisations recognised it was a cutting edge project and wanted to be a part of it - therefore the motivation was there to push project forward + collaborate – enable some to take ownership and become empowered even when		NwHIN produces standardised documents suitable for data transmission and analysis via electronic applications. There is a need for end-to-end governance structures to enable ‘trusted’ data agreements between partners. Multi-partner collaboration can lead to technical success but achieving that success is dependent on a variety of factors as resented in the results section. NB. SSA is a key provider of disability

	administration) and MedVirgina HIA (MEGAHIT) for disability determination		governance dimensions in terms of the challenges, success and considerations moving forward.	organisers share a common vision their value propositions can differ. In this case there was strong commitment / motivation but a challenge from 1 of their providers regarding the value of belonging to the HIE NwHIN, other barrier was ROI. Communication was a barrier as there were multiple parties involved which was challenging but phone, email helped to foster close collaborations. ***Governance factors***: privacy and security in terms of the limitations In sharing information		benefits + major user of health data
Fontaine P, Zink T, Boyle R et al. 2010; USA [58]	To evaluate the electronic health record (EHR) and health information exchange (HIE) network participation by healthcare centres and practices in Minnesota, USA	Minnesota, USA. 9 healthcare practices - small, medium and large practices <20 Physicians, varying degrees of EHR and HIE involvement Settings: mixed, rural community and metropolitan	Mixed methods: Organisational questionnaires (for descriptive statistics) and interviews with key informants (purposive sample) 39 individuals participated	Key barriers: Lack of interoperability. Each had their own EHR and these were linked to respective hospital systems which were also different - Lack of standards and a common language between systems affected interoperability - Challenges associated with start-up fees, cost of integration and ongoing licensing fees - Limited political will power to bring approached resources to the project in order to reach - Lack of buy in from physicians for a shared HIE vision - Technical infrastructure differed greatly between the sites - External factor:	+ External facilitator / motivator included: federal mandates - by 2015 healthcare practices were required to have interoperable EHRs. + Payer incentives for e-prescribing, to get staff and providers comfortable in sharing data electronically + Internal motivators – Linkage across the HIE network created efficiencies in workflows, time and cost savings. Clinicians had timely access to records when requesting data from another centre. + Strong leadership and strategic planning, physician involvement were success factors during the early phase of the project	NB. Practices were compensated for their time and involvement in this project but - 8 out of 9 practices could not exchange clinical data! To achieve complete HIE, regional health organisations must provide consistent leadership and suggestions for financial incentives for community wide meaningful use of interoperable EHRs. There is a need for federal standards and fibre optic capabilities in rural settings.

				Practices that faced financial challenges and lagged behind viewed the federal legislation as negative ("legislation breathing down your neck") Top down.	
King G, O'Donnell C, Boddy D et al. 2012; UK [59]	To explore the way structural, professional and geographical barriers affected the e-health implementation of the Single Shared Assessment (SSA) in Scotland NB. The authors wanted to streamline the assessment process of care needs	Three locations, (3/14 health boards were purposively selected to participate). 1 rural, 1 urban and 1 large geographical area	Qualitative retrospective case study. 30 interviews with healthcare professionals across the 3 sites and 11 interviews with data sharing managers across the 14 health boards. Framework analysis was used to draw themes from the data	- ***Barriers included***: progress was limited, different organisations were using different systems which needed to interface with each other. ***Structural:*** The project did not make the impact it was expected to. Competing priorities for the different stakeholders involved, affected the delivery of the SSA. The momentum for implementing the project was lost "why bother?". Management were seen to not lead this change and drive the project forward. Technical challenges include the need for adequate infrastructure. Financial implications: This project took place during a time of austerity. ***Professional factors***: different professionals involved which affected the respective understandings and acceptance of the aims of SSA. Different professions have different views on what is important to their work. Facilitator – professional boundaries can be overcome through the use of virtual teams designed to improve communication and understanding of professional roles. ***Cultural factors***: Cultural differences between health and social care providers. Challenge associated with crossing professional boundaries and willingness to share information (what data to share and with whom). ***Geographical factors***: Facilitator: sharing of information was more successful in defined locations which helped to promote cohesion.	The aim of the SSA was to reduce repetition and improve data sharing of information for patients who see multiple professionals involved with supporting their care needs.

CHAPTER THREE
METHODS & METHODOLOGY

3.1 Introduction

This chapter provides a detailed account of the research methods employed throughout this study. It has been divided into three sections which explore separate but interlinked components of this research: 1) Theoretical, 2) Philosophical and 3) Practical underpinnings. Each will be considered in turn and the chosen research strategy discussed and justified. This chapter serves an important purpose as it provides a rationale for the chosen approaches, outlining why they were appropriate to meet the research aim and objectives outlined at the beginning of this thesis. The aim of this thesis is to *understand the barriers and facilitators affecting the implementation of digital health innovation on a national scale*. The research objectives are as follows:

- To Conduct a 'Structured Literature Review' to examine the existing literature regarding implementation of national digital health projects in practice and to identify the factors affecting large-scale endeavors.
- To Explore the attitudes and experiences of 'implementers' as key stakeholders involved in the national deployment of LiU over time.
- To Identify and understand the underpinning factors which promote or inhibit successful normalization (implementation, embedding, and integration) of the national LiU digital health deployment.
- To Produce a set of recommendations and lessons learned to inform future large-scale implementations, national digital health policies and practice.

Below, the theoretical, philosophical and methodological approaches utilised in this thesis are described in detail. Note. The term 'eHealth' was used for purpose of Literature Review. Going forward term 'Digital Health'.

- Section One, will describe and explain the chosen theoretical framework for the study; the Normalisation Process Theory (NPT) and provide a critique against existing theories, their strengths and limitations. This section aims to provide a clear rationale for the chosen theoretical framework and why it was selected in preference to alternative theoretical approaches.

- Section Two provides an overview of the philosophy adopted to conduct the research presented within this thesis. It argues the suitability of the interpretivist approach combined with a single explanatory case study. This section in particular helps to provide a means to make sense of stakeholder perspectives over time as well as the factors affecting implementation and the value placed on it.

- Section Three outlines the practical components of this study in meeting the research objectives. Ethical considerations and procedures will be discussed as well as the impact of the role of the researcher. A quality criterion is also applied to assess the proposed effectiveness of the methodological strategy adopted in fostering future digital health policy and practice.

3.2 Section One: Theoretical Underpinning of the Study

More than a decade has passed since Foy and colleagues stressed the importance of using theoretical frameworks to underpin implementation research in primary care. The authors explained that uneven uptake of

research findings into clinical practice has led to poor care provision, which continues to occur across health care settings, between different countries and different specialties [61, 62, 63]. In order to provide effective and efficient patient care, professionals and organisations need to be able to adopt best practices and research which has been proven to promote improved health outcomes. The main issue that we are now facing in the digital age is that many of the lessons which have been identified from previous efforts have not been taken on-board as is demonstrated by the growing literature describing digital health implementation failures. Questions still exist in terms of how we can maximise the benefits of digital technologies in healthcare whilst minimising the risks that they present – many of which are largely unknown [64]. In addition, recent research has highlighted that 'we do not yet know how to best design, implement and use health IT'. Therefore it is has been advocated by many including the *World Health Organisation* (WHO) that it is important to identify strategies that are more are likely to promote effective implementation of digital health interventions [65]. The use of theoretical frameworks can help identify key issues and moving from mere description to explanation which is vital to inform policy decisions to effect practical change.

3.2.1 Determining the underpinning Theoretical Framework for the Study

Implementation research has to tackle several issues in order to improve the transferability of its findings into reality. The use of a theoretical conceptual framework to assess professional and organisational behaviours as well as identifying what factors affect whether or not an intervention is a success is crucial towards understanding how we can mitigate the risk of failure [18]. The overarching aim of this study was to capture the implementation journey of the LiU digital health programme over time. Therefore from the outset, a process evaluation was undertaken in parallel with the implementation of the programme in order to identify the underlying mechanisms that positively or negatively influence its implementation. Most research within global health innovation focuses on outcomes which either measure their impact or explore their effects however this type of evaluation is not always enough [18]. Outcome evaluations do not always answer what we need to know which is how effects come about and how evidence gets translated into everyday practice.

There have been quite a few debates within the literature which reflect on how best to understand implementation processes and about the variety of theoretical tools that can be used to do this [15, 17]. There are various theories which have emerged as the field has progressed coming from disciplines such as *Psychology* (Theory of Planned Behaviour and Social Learning Theory); *Sociology* (Diffusion of Innovations Theory, Normalisation Process Theory, Structuration Theory, Critical Realism) and *Science and Technology Studies* (Actor-Network Theory). Determining the underpinning framework for this study required a broad synthesis of these existing theories with great attention paid to the potential contribution to knowledge, applicability and transferability.

3.2.2 Exploration of Theories used to Evaluate Implementation Science

In this section a brief summary of Structuration Theory, Actor Network Theory, Diffusion of Innovations Theory and Theory of Planned Behaviour are provided. These theories are closely aligned to exploring the transmission

and organization of innovations and the psychology underpinning these interactions. These theories also cut across disciplines and therefore this provides a rational basis to draw comparisons.

3.2.2.1 Strong Structuration Theory (SST)

Structuration theory was proposed by Anthony Giddens in the eighties, it takes the stance that human agents and structures exist independently of one another and therefore should be considered separately. The notion is that the creation of social systems is based on the analysis of both structure and agents as equal elements not giving primacy to either. Giddens argues that the two have a mutually recursive relationship and co-evolve [66]. Stones refined Giddens work by developing Strong Structuration Theory (SST) which is concerned with linking its foundation with empirical research. It considers the following; a) external structures (i.e. technology, infrastructures, and institutions), b) internal social structures (i.e. people's capabilities, attitudes and morals), c) active agency (why people or 'agents' act in a certain way) and d) outcomes how these structures (internal and external) change or stay the same as they are feedback into this recursive and dynamic process [67]. Furthermore, SST can be seen as having emerged to try and make Gidden's work more empirical, shifting from the relatively abstract approach to one that was more grounded.

3.2.2.2 Diffusion of Innovation Theory (DOI)

Diffusion of Innovations Theory (DOI) was developed by Everett Rogers in the early sixties making it one of the oldest social science theories. The concept explains how over time an idea, product or technology (the innovation) gains momentum and diffuses or 'spreads' through a social system [68]. It pays particular attention to the innovations' 'journey' by which the term *diffusion* is defined as the process of how an innovation is communicated through certain channels over time among participants within a social system [69]. This is to say that the adoption of a new technology or product is dependent on the effectiveness of the diffusion process; and therefore adoption rates can vary according to the participants involved and the 'culture' of the system. People who adopt an innovation earlier are reported to have different characteristics than those who adopt an innovation later. Therefore the premise of the theory implies that when promoting an innovation, consideration must be given to the target audience or population that make up the 'social system' as this can help to identify what helps or hinders adoption of an innovation.

Adopters can be categorised as follows: 1) Innovators: those eager to be the very first to adopt an innovation also known to be risk takers, 2) Early Adopters: tend to be community or opinion leaders that are known as 'trend setters' as they are open to new ideas especially when there is a need for change, 3) Early Majority: this is where the bulk of the population reside that need some level of convincing that the innovation is worthwhile, 4) Late Majority: usually the 'sceptics' who will only adopt the innovation after the early majority has done so; this is because it has been 'tried and tested' and 5) Laggards: literally those with the biggest resistance towards change and the last to get on board. The above categorisation follows the classic normal distribution i.e. bell shaped curve and therefore knowing how to appeal to each type of 'adopter' is crucial to ensuring that an innovation becomes self-sustaining in reaching critical mass.

3.2.2.3 Actor Network Theory (ANT)

Actor Network Theory was developed by *Science and Technology Studies* scholars Michel Callon, Bruno Latour and sociologist John Law in the early eighties. It seeks to understand humans and their interactions with technology. An 'actor' is defined as the source of an action and this could be human or non-human and like SST takes a socio-technical perspective. This means to say that technology for example which is non-human can have 'agency'. A network is comprised of actors and the link between people and technology can be explored through the 'position' in the network that people and things take and the subsequent result of being in a certain position also known as 'relational ontology'.

3.2.2.4 Theory of Planned Behaviour (TPB)

Theory of Planned Behaviour (TPB) was developed by Icek Ajzen and is a theory which is firmly grounded in the field of psychology. The theory examines the relationship between beliefs and behaviours. It proposes that human action is guided by three states which include the following: 1) ***Attitude***: belief which informs the intentions of a behaviour (includes belief about the likely consequences of a behaviour) 2) ***Subjective Norms***: beliefs about the standard expectation of others and 3) ***Perceived Behavioural Contr***ol: this relates to the belief held about the perceived factors that may impede or enable the enactment of a behaviour [70]. Ajzen's three states are important especially in relation to implementation as it can help to foster understanding of how the introduction of an innovation can change the behaviour of people. This 'predictive' element is a powerful characteristic of the model as it may be able to explain the relationship between behavioural intention and actual behaviour.

3.2.2.5 Normalisation Process Theory (NPT)

The Normalisation Process Theory is a sociological framework developed by Professor Carl May, Dr Tracy Finch and colleagues and has been widely cited as a robust tool to understand the *implementation*, *integration* and *embedding* of new technologies and services into routine everyday practice [18]. This is to say that it is able to unpack the 'process problems' concerned with the implementation of new ways of thinking, acting and organising within health and social care. In addition the theory pays attention to the 'structural problems regarding the integration of new practices or systems into existing professional and organisational settings. In order to understand the implementation and integration elements of this theoretical model close attention is focused on the 'dynamic processes' that lead to a digital health innovation to become 'normalised' and 'embedded' into daily working patterns or everyday life. It is able to aid interpretation and understanding of contextual, structural and process factors affecting implementation.

3.2.3 Critique of Theoretical Frameworks & Decision-Making

It is clear that robust theories can explain the individual differences and behaviours towards new practices or the introduction of a new technology (Theory of Planned Behaviour), how innovations can spread and become

adopted among social systems (Diffusion of Innovation Theory), the socio-technical factors that are at play when implementing a new technology (Structuration Theory) and the abstract interactions between people and technology (Actor-Network Theory). However, there are obvious gaps which NPT can help to address as discussed below.

Greenhalgh and colleagues used SST in part to underpin their research concerned with the UK National Programme for Information Technology (NPfIT). Their main objective was to understand and explain what happens at macro, meso and micro levels when the UK government tried to modernise the NHS using top-down centrally procured IT [46, 71]. This approach enabled an exploration of the socio-technical factors that are at play on an abstract level however this thesis is concerned with taking a social ***action*** approach to implementation and therefore for this reason it was not considered appropriate for this study. NPT is able to overcome this limitation by capturing how individuals or groups of people and organisations involved in these social systems 'work'. NPT offers an explanation of the work of implementation, the work of integration and the work of embedding a digital health innovation.

In a similar study, Greenhalgh and colleagues used DOI to explore the introduction of the centrally stored, shared Summary Care Record (SCR) within the context of the NPfIT to draw lessons about the implementation of this programme at scale [46]. In comparison to NPT, DOI is able to explain how an innovation diffuses and reasons why. Rogers states that there are four core elements that influence the 'spread' of an innovation or any idea namely: time, the innovation itself, the communication channels in place and the social system. Advantages of the approach include the successful applicability of the theory in many other disciplines such as public health, agriculture and marketing. Cranfield and colleagues explains what the clear advantage is: "it's 'actionability' is reflected in its widespread use and application, including in the area of implementation" [72].

Limitations of the approach include the fact that less attention is paid to the "different structural and social processes within the system that make up the innovation's journey, including professional pressures or processes where organisations take up new technologies as a result of economic drivers, legislation, regulatory frameworks or state policy" [72]. In addition, the theory captures the adoption of certain behaviours but not the cessation of behaviours. DOI also does not take into account the individual or collective resources required to adopt a new innovation or the social support required to accept new practices or behaviours as a result of the innovation [72]. For these reasons DOI was considered not appropriate for this study.

Cresswell and colleagues used ANT to investigate the impact of EHRs on healthcare professional work practices within the context of NPfIT [45]. The framework provided a useful lens through which to view the role of technology in shaping social processes. Although the authors did note that it should be used "pragmatically with an appreciation of its shortcomings". A criticism of ANT is that it has a 'flat ontology' meaning it is without 'depth' and *missing* other layers such as structure to substantiate the theory [73]. This limitation means it does not help to explain why or how a network takes the form that it does. Secondly the notion that humans and non-human actors have a comparable status can be seen as reducing human virtues [73]. Given the reasons above NPT appears to be a suitable alternative to ANT as it seeks to be explanatory and it also does not insist on

the agency of non-human actors and therefore this framework was considered more appropriate than ANT for this study.

In terms of health –related behaviours previous research highlighted that the TPB model assumes that behaviour is a result of a liner decision making process. It does not take into account that it can change over time, whereas NPT places particular emphasis on continuous evaluation and the need for a holistic and dynamic decision making process. Furthermore, it does not take into account environmental or economic factors that may influence a person's mind-set and consequently their action and behaviour. May and colleagues demonstrate that NPT is able to account for the 'social production' and organisation of the 'work' required by actors be it on an individual level and organisational level [15]. For the reasons discussed above TPB was considered not appropriate for the study.

3.2.4 How NPT Can Help Overcome Existing Theoretical Limitations

NPT is a theory of action because it specifically looks at ***what people do*** not just their views or attitudes towards a new intervention and also ***how*** they feel about new working practices or changes to existing practices that result from introducing a new intervention or innovation or technology [17]. Also, it is able to capture the expressed intentions of individuals or organisations concerning what they say they are ***going to do*** as a result of a new intervention [18]. May and colleagues' first theoretical proposition states that in order to "understand the embedding (implementation and integration" of a complex intervention we must look at what people actually do and how they work".

The second proposition makes clear that what is defined as the 'work' actually translates to the work required to implement i.e. what needs to be done or put into effect and this can be explained through four operational domains and high level constructs namely: Coherence, Cognitive Participation, Collective Action and Reflexive Monitoring. The first domain, Coherence refers to identifying and understanding how people and organisations make sense of the work required to implement and integrate a new complex intervention. What do people or organisations do to develop a shared understanding and how they do that. The second domain, Cognitive Participation looks at the work required to engage with a new intervention, so what needs to be done to enable people and organisations to interact with this new intervention . What are the enablers or constraints towards the engagement and participation process for individuals and organisations? The third domain, Collective Action explains what individuals and organisations need to do to enact the changes that they need to put in place to accommodate a new intervention or service innovation and also what needs to be done in practice to ensure that the new intervention is operational and functional as a part of everyday practice. The fourth and final domain, Reflexive Monitoring, evaluates the effects of a new intervention. It appraises the effects of a new set or practices affects people and others around them.

Each of the four domains is divided into further constructs (four for each domain) that provide a deeper level of understanding about the work of implementation. All together the NPT framework consists of sixteen constructs which define the 'work' involved when implementing a new set of practices. The final proposition

that the theory makes is that integration relates to the need for continual efforts of 'action' to be made to ensure that the new practices and the complex intervention as a whole is able to progress and flourish to the point that people and organisations do not realise the work that they are doing because it has become routine and therefore no longer complex, with the difficulties and challenges of the 'material practices' no longer overtly present, hence the term 'normalised' as it has become routine in its social context. NPT can be summarised as focusing on three core components which are: ***Actors or Human Agents*** (the individuals and organisations involved in the implementation process, ***Objects*** (the new sets of practices or processes as a result of a new intervention) and ***Context*** in which it is being applied: both internal and external organisational, structural or professional factors influencing the boundaries of implementation in the real world.

3.2.4.1 Benefits and Disadvantages of the Approach

The Normalisation Process Theory (NPT) is grounded in more than 100 empirical research studies including qualitative systematic reviews [74] [75]. It has been incorporated in studies featured in WHO Publications and work commissioned for the National Institute for Health Research (NIHR) [76]. McEvoy and colleagues explain that NPT "extends beyond the initial introduction of an innovation" by providing the reasoning behind how and why an innovation becomes normalised [15]. Specifically capturing what factors appear to be problematic or act as facilitators towards successful implementation. In their systematic review of studies using NPT to research implementation processes, they go onto state that NPT pays unique attention to the legitimacy of an innovation by seeking to understand interpersonal relationships within social networks as they interact with the innovation. The framework is able to describe how and explain why the adoption and implementation of digital health innovation occurs. Ultimately the framework is able to offer transparent and transferable explanations to support its propositions which have been revealed in numerous empirical research studies.

The main limitation of NPT is that it is a middle-range theory and still evolving, however it can be federated with other theories to help explain new phenomena. Research from Nielson and May provide examples of how NPT can be used as an evolving theory to enhance our understanding of the world around us [15,17,18, 77], However, there is an obvious gap which NPT addresses in capturing how individual people or groups of people (i.e. health professionals) and organisations involved in these social systems 'work'. NPT offers an explanation of the work of implementation, the work of integration and the work of embedding a digital health innovation.

A theory can be defined as a 'set of concepts and propositions that provides a structured way to view a phenomenon'. A concept is essentially an idea that becomes the building blocks of a theory. Theories can be characterised as grand, middle-range or micro. Grand theories are broad and provide a general framework for structuring ideas. Middle-Range theory addresses more defined phenomena in terms of how people may use objects and structures and their associated behaviours associated with this; which can usually suggest an intervention. Micro theories focus on individuals and small groups and their interactions within defined conditions.

NPT has been described by its developers as a middle range theory and therefore was suitable to use to examine the LiU implementation. This is because it provides appropriate concepts and ideas to examine the experience of implementers and their subjective behaviours during this deployment of digital health at scale within the constraints and contexts of the LiU programme. It is important to note that despite the positive reception of NPT, there are some limitations attributable to the theory as it remains relatively new and its strengths and limitations are still emerging. NPT does not cover all eventualities concerning digital health service implementation and therefore it is not a theory of everything; however the theory does successfully provide an accurate lens to assess the deployment of complex interventions within a health and social care setting. Furthermore it can be federated with other theories to help explain new phenomena

There were two main reasons for choosing this framework: a) it serves a valuable explanatory purpose beyond the capabilities of some of the existing frameworks; b) pragmatic reasons as one of my supervisors had specific expertise in relation to this particular theory. Furthermore, NPT can be used at different stages in the life cycle of a research project with specific beneficial value for qualitative or mixed-method research projects. It has been used in previous research to help formulate the initial research focus and questions, to inform the research strategy i.e. the practical work of designing interview guides, sampling, recruitment and data collection. The theory consists of a set of domains or 'codes' which can be used as 'a priori' themes just like a template to help guide or structure the analytical process (coding and data synthesis). Finally, the framework's explanatory power helps in the interpretation of findings which can help to provide robust conclusions and recommendations as well as inform tool development. For the reasons discussed throughout this section, NPT was considered to be the most suitable theoretical framework to underpin this study.

3.3 Section Two: Philosophical Component of the Study

The philosophical underpinnings of any given study must be firmly grounded from the outset and these comprise of a 'set of beliefs' also known as *Research Paradigms* . The scope of this section is not to provide a comprehensive overview of each research paradigm but rather to provide grounds to support and explain the reasons for adopting or rejecting a particular paradigm. The focus of this study implies that an interpretive philosophical approach should be used as a tool of exploration in order to understand the subjective meanings motivating the individual and collective actions of social actors [23] however this requires additional context as to why this approach suits best.

It is important for a researcher to outline their philosophical position from the very beginning as it influences the research strategy used to carry out the study. The term 'Research Strategy' can be referred to as a logical framework which guides a researcher from their initial set of research aims and objectives into the research approach to be used for investigation (Methodology), how this should be carried out (Methods) and what data is required to be collected (Raw Data). The following sections will detail the individual path taken in conducting this study and the rationale behind the decision making process.

3.3.1 Ontological & Epistemological Considerations

Research can be seen as a systematic investigation which can take one of three forms; qualitative, quantitative or mixed-methods. There has been an ongoing debate between the use of these approaches in terms of which one generates 'real' knowledge to a given discipline. Newman (1998) states that this has been largely based on the "differences in assumptions about what reality is and whether or not it is measurable" (Ontology). In addition this debate has been fuelled even further with opinions regarding the "best way we can understand what we 'know' (Epistemology) whether through objective or subjective methods [23]. The main differences between these approaches have been categorized by Bryman to be as follows: 1) qualitative research sets out to generate theory (induction) whilst quantitative research sets out to test theory (deduction). 2) The epistemological orientation for a quantitative study is based on a natural science model which is heavily invested in a quantifiable and 'observable social reality' [23], whilst a qualitative study is based on the 'interpretive understanding of social action in order to arrive at a causal explanation of its course and effects'.

The ontological standpoint of a quantitative study states that "social entities should be considered objective entities that have a reality external to social actors" [23]. This means that objective reality is sought through facts whilst a qualitative study works on the basis that reality is socially constructed and what we know to be knowledge or the 'truth' is subject to an individual's interpretation and their overall experiences which can take many forms yet still remains valid and accepted . In carrying out this research study, an initial assumption was made in viewing the participants as acquiring tacit knowledge which could be accessed and interpreted with the methodology outlined in this chapter. Bryman suggests that 'reality' exists in the minds of the individuals (i.e. people cannot be separated from their knowledge) and therefore by exploring their views, attitudes and experiences as 'implementers' an insight into their subjective realities can be gained [78].

3.3.2 Research Paradigm: Interpretivist & Qualitative Nature

Keeping in mind the study's goals, the research philosophy needed to be orientated towards the discovery, description and holistic understanding of the specifics and context of the LiU digital health programme as well as the processes and activities underpinning its' development over time. The interpretivist approach lends itself as a suitable line of inquiry to help achieve this because the approach helps to understand the meaning that participants place on their experience of implementing at scale. The interpretivist approach also helps researchers to work out how participants view their world by effectively putting the researcher into the respondents' shoes. Advantages of the approach include being able to capture in-depth 'meaning' and understandings of the reality of what people perceive to be true. The approach is not only useful in forming rich and thick descriptions but also helping to generate explanation. This is in-line with the use of NPT as an explanatory framework to assist in the interpretation of the primary qualitative data collected.

However, disadvantages of this approach include the fact that there is no 'single' external reality. There are many interpretations of reality and the 'truth' given that people have different perspectives of the same experience but the interpretations themselves embrace an element of the scientific knowledge which many qualitative researchers pursue. Additionally, the likelihood of researcher bias using this is higher due to the fact that personal values and views play a key role in the final outcome, and therefore findings that are generated

from qualitative studies are only generalizable given similar context. In this study I have ensured that all findings provide a transparent and true representation of the themes which have emerged by incorporating methods to reduce researcher bias such as setting up data 'Coding Clinics' which I will elaborate on in the 'Practical Component' section.

3.3.3 Research Approach: Use of Deductive and Inductive Research Approach

Given the significance of NPT being used as the theoretical lens underpinning this study, the application of both inductive and deductive analytical techniques was employed. The deductive element of the research approach included using the 16 constructs of NPT as 'a priori' codes. This approach was used to conduct preliminary analysis however as a researcher a limitation of using this method was that it can restrict thought processes. The impression of having to fit data within these categories presents additional pressure. Murray and colleagues state that NPT is 'not a theory of everything' and therefore caution should be taken to ensure that data which could fall outside of the coding framework is accounted for and attempting to 'please' the framework is not the intended use (i.e. shoe-horning data) [79]. The inductive element of the study involved reviewing the data presented and organically identifying emerging themes and sub-themes. The major themes identified in the scoping review were useful starting points. I then mapped these themes onto the NPT framework and in instances where the mapping process was not possible these would constitute data which 'fell outside' of the framework such as the 'Context' and 'Scalability' themes. This translational work was useful in highlighting potential areas to expand and build NPT.

3.3.4 Research Strategy: Single Explanatory Case Study

A case study is most commonly used as a basis to provide an in-depth examination of a research phenomenon; and as a primary means of learning [80, 81]. There are different approaches to case study research and in this section I will provide a brief comparison of the two most prominent approaches advocated by leading researchers Robert Yin and Robert Stake in order to illustrate the suitability of an explanatory case study in conducting this research [80,81]. It has been widely agreed by social scientists Mariano, Lincoln and Guba that a study must comply with the following key elements in order to be considered a case study a) it must have a context b) it must have boundaries which determine what is and what is not the case, c) there must be a sufficient amount of time within its scope for the researcher to become familiar with the case and finally d) it must be intense enough to enable the researcher to develop an understanding of the "intricacies and subtleties of the case itself".

Yin uses the following terms to describe the range of case studies and these can be descriptive, exploratory or explanatory. Furthermore they can take the form of being either single, holistic or multiple [80]. Yin also provides a clear account in favour of both a quantitative and qualitative approach to data collection within a case study [51] whereas Stake's approach is essentially qualitative in nature. Stake identifies three types of case studies, they are as follows: ***Intrinsic*** – this study is undertaken because the researcher would like to achieve a comprehensive understanding of a particular case, this corresponds to Yin's '*descriptive*' case study.

Instrumental – this type of study is conducted in an attempt to advance the researchers understanding of a wider phenomenon, thus the case itself is simply of "secondary interest and plays a supportive role in facilitating" and developing the researchers understanding [80]. It can also help to provide insight into the refinement of a theory albeit a middle-range theory such as NPT. This corresponds to Yin's '*exploratory*' and '*explanatory*' case studies which seek to generate theory and test theory respectively

3.3.5 Strengths vs. Limitations of Case Study Research

One of the main limitations of case study research is the impact of the researcher themselves on the 'case' . For instance a researcher that embarks on a study with 'pre-conceived ideas' of what the outcome is likely to be can result in negative impacts for the study. This is can lead to researcher bias, where the researcher could effectively distort information collected to fit or align with a particular theory or in the same vein ignore evidence that challenges their given theory. The strengths of the case study approach in this thesis plays a crucial role in providing a basis to explore a large-scale complex intervention through a variety of lenses (i.e. investigator triangulation), using a variety of data sources and methods (i.e. data and methodological triangulation) [81, 82]. Therefore the use of a single explanatory approach was deemed to be most suitable.

3.4 Section Three: Practical Component of the Study

This section outlines the practical materials and methods used to collect and synthesise data. An-in depth review of the data sources and techniques used to gather evidence are discussed. This section pays particular attention to the 'inner layers' of the Saunders 'Research Onion' framework: Choices, Time Horizons, Techniques and Procedures.

3.4.1 Sampling and Recruitment of Participants (Key Informants)

In order to gain a wide range of perspectives and obtain a comprehensive picture of the implementation journey, a purposive sampling strategy was considered a suitable approach to participant selection. Patton (2002) has identified that there are sixteen different types of purposive samples and more than one purposive sampling procedure which can be used within a given qualitative study [82]. In this study, *Maximum Variation Sampling* was used to generate a heterogeneous rich sample of a range of 'implementers' i.e. different people, working in different sectors, at different organisational levels, in different settings / geographical areas and at different time points. This enabled me to gain a unique insight into how LiU is seen and understood among this diverse population.

Particular attention was paid to identifying and selecting individuals or professionals that were knowledgeable and gathered 'experience' being a part of the LiU implementation process. The LiU consortium included representatives from local, national and international organisations from across six sectors: industry, health and social care, housing, education, voluntary and statutory. A select number of consumers or end-users (including champions) and clinicians were identified and included in the study by referral. The final number of participants involved in the study included 10 Consortium Stakeholders (representing a third of all consortium stakeholders),

5 Project Managers (plus one replacement) from each of the implementation sites across Scotland, 6 Consumers (End-Users), 2 Community Champions representing rural and urban areas, 2 Clinicians (1 Clinical Specialist Physiotherapist: working with COPD patients using telehealth and 1 Weight Management & Physical Activity Specialist), 1 Community Engagement Officer, 1 Strategic Lead and 1 Programme Manager (both Government Officials) totalling N=29 participants. Embedded in the use of this strategy is the ability to identify similarities and differences across and within these sub-groups in order to compare and contrast the holistic findings from the implementation of LiU .

Despite the wide use of purposive sampling there are numerous challenges that can emerge in 'identifying and applying the appropriate purposeful sample strategy' in addition at times it can be difficult to know and determine the sample at the beginning of a study. Palinkas and colleagues explain that an exercise of iterative re-sampling may be required because from the outset a 'purposive' sample implies that one knows the range of variation required and who the information –rich key informants are to be included [83]. The rationale in choosing this sample links back to the aims and objectives of this study, as the participants individually and collectively qualify as longitudinal 'implementers' of the LiU digital health programme.

3.4.2 Data Collection: Multi-Method Qualitative Study

A multi-method qualitative approach was used to collect and triangulate a range of data sources though 1) *Participant Observation*, 2) *Semi-structured Interviews* and 3) *Documentary Evidence* . Tachakkori and Teddlie (2003) define a multi-method study to be where "more than one data collection technique is used with associated analysis techniques" [84]. The following section details the use of each chosen method in turn with particular reference made to the significance of each method in addressing the study objectives.

3.4.2.1 Ethnography and Participant Observation (Shadowing)

Ethnography relates to the study of a phenomenon in its natural setting or in 'situ'. Reeves and colleagues define it as "the study of social interactions, behaviours, and perceptions that occur within groups, teams, organisations, and communities" [85]. Its origins stem from the field of sociology and anthropology and it seeks to generate and provide rich insights into people's views and actions through detailed observations, interviews and discussion. The most common approach used is participant observation which is where a researcher goes "into the field" to learn about the culture of the phenomena . DeWalt (2010) describes that the process of participant observation plays close attention to the "daily activities, and events of a group of people as a means of learning the explicit and tacit aspects of their culture" [86].

In the case of LiU, this is in the real world without any controls and therefore participant observation in this study involved two components: 1) observing monthly stakeholder meetings (N=30 stakeholder representatives as each organisation in attendance) and 2) collecting data from quarterly meetings held between stakeholders (key informants) and researchers which served a primary purpose of capturing the changing face and shape of the LiU programme over time . A total of N=16 participant observation sessions occurred over a period of 14 months (October 2012 – December 2013) which translated to approximately 62 hours of interaction. Table 3A

– provides a summary of each session. The purpose of the monthly stakeholder meetings (N=8) was to provide an opportunity for consortium members to come together and co-produce; more explicitly provide a 'space' to draw people together to work across their professional boundaries in the iterative development of LiU. The degree of co-production and co-design in this project spanned approximately two years.

Members of the general public usually those categorised as 'expert patients' were invited to come along to stakeholder meetings having experienced challenges in dealing with a long term conditionsin everyday life or being isolated or lacking opportunity to be able to air their concerns to those able to 'action' change. Their perspectives were deemed highly valuable to inform a service that consumers would be more likely to use. In addition to these meetings, I also attended pop-up events in locations such as shopping malls, churches, summer fetes, days-out and leisure centres which were used to create awareness of the project and to invite the people of Scotland to get involved and jump on the co-design band-wagon. Feedback from the ground work conducted by implementation staff was incorporated into stakeholder meetings and any decisions made shared with to members of the public. A real challenge for me, as the researcher in the "field, was to understand the different dynamics at play as the service was a 'blank canvas' without a concept and in true organic fashion 'implementers' wanted to build a service from the ground up to support the 'needs' of Scottish citizens. In terms of record keeping, it was difficult to understand what aspects of the stakeholder meetings were 'important' to make note of at the very beginning and therefore in the early sessions, simply listening and observing (shadowing) the group as a whole and speaking to individuals was important to help me grasp this complex project. Additionally, I was also considered an 'outsider' and therefore it was necessary to take time to build rapport and a sense of familiarity so that I could be seen as a part of 'the team' . This was important to increase the likelihood of information sharing and enhance the 'openness' of consortium members.

In the subsequent sessions, field notes were taken and in some instances a digital recording. It was not possible to record all sessions due to the fact that I was an active participant involved in some of the activities that were taking place. Opportunities to take part in activities was very much welcomed although I was mindful not to disrupt the natural flow of the meeting and this usually meant sitting at the back of a room or in a corner. However, when notes were taken they were handwritten with a record of the description of the setting, date and activity and a direct quotation or a summary of what was discussed. Gaining access to carry out observations was approved by the overall Programme Manager and therefore all that was required of me was to structure my time according to their schedule where possible, manage resources and organise transportation. Stakeholder meetings took place in a variety of diverse locations across Scotland such as Inverness, Lothian and Isle of Sky.

In regards to the quarterly meetings, an agenda was created for each meeting and a record of attendance. A total of eight quarterly meetings occurred between 2012 – 2014 lasting two hours each. This provided an opportunity for project leads and research leads to 'touch base' in terms of progress of the national implementation and make comparisons to similar innovations within the context of the UK evaluation of digital health technologies and services at the forefront of transformational changes. Permission to record the

meetings was agreed by the project leads at the beginning of each meeting and those recordings were listened back to with notes taken to help form a better understanding of LiU and the complexity of the factors at play.

A noted benefit of using participant observation over an extended period of time is the opportunity to make comparisons. I made note of progressive statements documented in official project papers about what participants, users and government believed the transformational changes were 'going to be' and what actually happened in the project life-cycle. DeWalt explains that this enables researchers to uncover discrepancies and conflicts between "conscious representations and behaviour" [86]. This dataset was subsequently analysed manually based on its contents and formed a rich picture of early implementation issues facing large-scale digital health innovations which underpinned the first output of this research for the Journal of Health Informatics [87].

The use of NPT in combination with ethnography compliments the interpretive line of inquiry within this case study. It is important to note that as my work drew heavily on ethnographic principles this helped to focus data collection on implementation processes versus outcome whilst maximising my ability to grasp the subjective behaviours of this multi-stakeholder environment over time. In addition as evidenced in the literature review, several national endeavours such as NPfIT and WSD used field observations and they were shown to be an important facet in corroborating all the evidence collected. Therefore the use of qualitative research methods, specifically participant observation within this study, is an extremely appropriate method to use to help address the research aims and objectives.

3.4.2.2 Documentary Evidence

In part, I was given the privilege and unique opportunity to gain access to confidential documents that may not have been made available externally or be in the public domain. . All documents related to the project were hosted by a privately held cloud-based software company known as 'Huddle' (www.huddle.com). This company enables users to securely store and share data files across organisational boundaries and firewalls. Key documents were provided to me by the Strategic Lead however accessing this system was not granted due to the sensitivity of the information held on the server and security measures. Although, documents that were provided to me such as the Project Initiation Document (PID), Service Specification Blueprints, Quarterly Reports and Lesson Learned were all highly confidential and I was entrusted to maintain suitable measures to safeguard them. Given the sheer scale and size of this project, I was the 'gate-keeper' of LiU documentation which was securely held on the University of Glasgow's SharePoint © Service (https://sharepoint.gla.ac.uk/...dallas).

This platform was developed by Microsoft and integrates a secure intranet with content and document management facilitates. A secure folder was created on 01/08/2012 17:17 PM, with additional sub-folders being created as further documentation was received up until May 2015. Documentation was usually provided via email or in person when attending events and carrying out observations. Data file types included audio (which was then transcribed verbatim), electronic and paper-based formats (such as presentation hand-outs).

TABLE 3A — PARTICIPANT OBSERVATION							
ID	Name of Observation	Date of Observation	Location	Duration	Record Format	No. Of Participants	No. of Pages
1	Impromptu Meetings	Month: OCT, Year: 2012	University of Glasgow	—	Field Notes	—	24
2			University of Glasgow	—	Field Notes	—	—
3			NHS 24, Cardonald Park	—	Both	—	—
4	Co-Design & User Engagement	Month: FEB, Year: 2013	Livingston	—	Both	7	1
5	Stakeholder Co-Production		Edinburgh	—	Field Notes	—	—
6			Falkirk	—	Field Notes	—	—
7			Falkirk	—	Field Notes	—	—
8	ALIP Showcase Launch	Month: MAR, Year: 2013	Liverpool Football Stadium	2 Hours	Digital	190	N/A
9	Scheduled Quarterly Meetings	Month: OCT, Year: 2012	University of Glasgow	2 Hours	Digital	5—7	—
10		Month: FEB, Year: 2013	University of Glasgow	2 Hours	Digital	5—7	—
11		Month: MAY, Year: 2013	University of Glasgow	2 Hours	Digital	5—7	—
12		Month: AUG, Year: 2013	University of Glasgow	2 Hours	Digital	5—7	—
13		Month: NOV, Year: 2013	University of Glasgow	2 Hours	Digital	5—7	—
14		Month: FEB. Year: 2014	University of Glasgow	2 Hours	Digital	5—7	—
15		Month: MAY, Year: 2014	University of Glasgow	2 Hours	Digital	5—7	—

16		Month: OCT, Year 2014	University of Glasgow	2 Hours	Digital	5—7	—
Sum	62 Hours						24
C O L L E C T I O N O F D O C U M E N T S							
ID	Document Type	No. of Items	Description	Confidential	Archived	No. of Pages	Total Pages
A	Quarterly Reports	11	Progress Reports	Y	Y	76	76
B	Project Initiation Document	1	Official Planning Document	Y	Y	47	123
C	Specifications & Blueprint	5	Service Specifications	Y	Y	111	234
D	Lessons Learned Summary	1	Barriers & Facilitators	Y	Y	5	239
E	Community Presentations	2	Community Engagement	Public Domain	Y	41	280
F	Contract LiU Seed Application	1	Grant Application Form	Y	Y	16	296
G	Evaluation Plan	1	LiU Evaluation Plans	Y	Y	23	319
H	Products and Servers	1	LiU Procurement Overview	Public Domain	Y	4	323
I	Quarterly Evaluation Updates	16	Progress on LiU Evaluation	Y	Y	71	394
J	LiU Case Studies	5	Personal Insight Studies	Public Domain	Y	5	399
K	Reach & Recruitment Reports	1	Numbers Reporting	Y	Y	4	403
Sum		45				403	403

All documents in this context were therefore primary sources with a total of N=45 documents selected to be included for the study. These have been classed as primary data sources because the documents were specifically created for the LiU programme and are therefore central to the purpose of my research.

Yin (2003, p 87) explains that "for cases studies, the most important use of documents is to augment evidence from other sources" [80]. These documents helped to develop an accurate chronology of the development of LiU, the milestones reached, and the issues that arose as the programme developed. More importantly due to its evolving nature the need to capture the complexities of the project and change processes was crucial in facilitating the explanatory nature of the case. The criteria for including documents within the study was based on whether the documents provided additional context in relation to the implementation strategy, the anticipated benefits according to the local and national priorities, documents which reflected on stakeholder group insights and whether they discussed lessons learned. Analysis of project documentation (to interpret primary sources) was carried out manually (highlighter and pen for notes) in relation to its contents.

3.4.2.3 Semi-Structured Interviews and Sit-In Focus Group

Bryman (2012) states that the 'interview' technique is the most employed method within qualitative research. Qualitative interviewing is commonly categorized in three ways either being structured, semi-structured or unstructured [78]. The choice of interview method is mainly dependent on the 'depth' of the response sought by the researcher and the suitability in meeting the research objectives. In this study the use of semi-structured interviews was chosen because it is a less structured approach which allows the participant to be more flexible with their response. A fully structured interview does not allow that degree of freedom and at the other end of the spectrum a completely unstructured interview would have lacked guidance in prompting issues that may otherwise have been missed. The experience gathered in travelling to various locations whilst observing was a key decisive factor in opting to carry out telephone interviews. Travelling to inverness alone for example took 3 ½ hours by train one-way from Glasgow, in total 7 hours of travelling compared to a 45-60 minute scheduled interview by phone. This approach was therefore deemed the most logical in creating cost savings, managing time and resources. In addition, a very important benefit which emerged from prolonged observation was the development of a rapport with organisational leads which meant that this trumped the absence of a face-to-face interview because the majority of relationships had already been established.

N =29 participants as stated in the sampling and recruitment section were interviewed in the study . A total of N = 30 interviews were carried out between January 2014 – March 2015 which enabled both a longitudinal (N=16 interviews) and cross-sectional (N=14 interviews) dataset to be obtained. In order to capture both breadth and depth the longitudinal dataset consisted of following up with the Project Managers (PM) from each of the implementation sites across Scotland and the Strategic Lead at six month intervals and three time-points (Baseline – Jan 2014, +6 Months – July 2014, +12 Months – January 2015). At the mid-point stage, one PM resigned and therefore the interview was omitted, likewise at the 12 month mark another PM had resigned with their interview omitted and a new PM introduced to help in carrying forward shared implementation responsibilities for two sites (Lothian and the Western Isles). Data collected as part of the cross-sectional

dataset took place between June – August 2014 which include N = 10 Consortium Stakeholders and N = 2 Community Champions. There were difficulties experienced in gaining access and permission to speak with health professionals and consumers who had been using the LiU digital platform.

Extensive efforts was required to overcome the problems encountered and it was not until March 2015 that contacts for 2 Clinicians (1 Clinical Specialist Physiotherapist: working with COPD patients using telehealth and 1 Weight Management & Physical Activity Specialist) were provided as an endeavour to help provide me with a well-rounded picture of stakeholder perspectives. It was believed that approaching health professionals directly (such as GPs) would hamper implementation progress due to the fact that this stakeholder group as service users could become confused or receive mixed-messages due to their demanding work schedules, limited time and because the PMs themselves had not yet approached GPs at the time I requested to speak with them in April 2014. In addition, recruiting consumers to an evolving co-designed concept proved challenging, however further gentle persistence and co-operation with the Strategic Lead paid off by May 2015, with the opportunity to speak with consumers who were taking part in an ad-hoc focus group regarding wireless activity trackers for older people at risk or suffering from a chronic condition within Falkirk (Forth Valley Community).

In addition, a new digital Exercise Referral Scheme (ERS) was also being piloted and this group represented the first cohort of LiU service users testing out the trackers, as they were approaching their 12 week review of the product. Permission to sit-in and record was granted by the Strategic Lead and participants involved in the focus group. In this capacity I was able to capture the views of participants, their experience of being involved in the pilot and their feedback on the product. The focus group lasted from approximately 10.00 – 14:00 PM with regular breaks and therefore after each break a new recording file would automatically be created. A total of N = 4 transcripts emerged from the data spanning the entire focus group and a single interview with a consumer. This data (focus group and consumer interview) was not 'counted' as part of the N=30 telephone interviews that I carried out personally but represents secondary focus group data. This data was transcribed and analysed manually according to its contents for use in providing insights for the readiness landscape for public digital health interventions.

In preparing to carry out the telephone interviews, topic guides were created with questions relating to each of the sub-constructs of NPT (See Appendix). The framework was beneficial in serving as a template for designing implementation process type questions. These questions were reviewed within doctoral supervisory meetings and refinements made where advised. Each interview was recorded (Olympus-650) and lasted approximately 60 minutes and began with stating the aim of the study which was to gather views about the national deployment from their organizational point of view and as a member of the consortium. Kvale (1996) proposed nine different types of questions that should be included in an interview. These ranged from introductory, follow-up, probing, specifying, direct, indirect, structuring and interpreting questions [88]. The topic guides included a range of Kvale's suggestions as well as a 'mop-up' question along the lines of "I understand I have led this interview, is there anything else that you would like to add that I have missed?." This was a useful to ensure that interviewees were given the opportunity to freely express themselves and to mention matters that were

not already discussed. If and when recording equipment failed, re-recording would commence although it would coincide with a new file, this happened on two occasions where the batteries died [88].

Follow-up telephones interviews with PMs set out to see if there had been any change over a period of time in their thinking and in their actions. Stakeholder perspectives also set out the capture the dynamic social interactions and change processes involved in collective decision making process and in circumnavigating any challenges that arose individually and collectively. Detailed analysis of this rich dataset alone underpinned an additional research output which was highly credited as award winning research at the 15th World Congress on Biomedical and Health Informatics, in association with IBM Research [89].

3.4.3 Data Saturation

The complete dataset consisting of both the longitudinal and cross-sectional files were analysed along the way, i.e. as and when they had been carried out, transcribed and ready for analysis. This iterative approach helped to identify time-specific implementation issues and re-occurring themes such as financial constraints, readiness issues, the challenge of developing a coherent strategic vision, developing inter-professional relationships over organisational boundaries and insufficient resources. It can be challenging within qualitative research to know when to determine that the amount of data collected is sufficient. However with reference to Pope and colleagues, at the point in which a broad range of perspectives were attained by May 2015, follow-up issues discussed (according to the topic guide) and no new substantive themes or findings emerged, I was confident that data saturation had been reached [90].

3.4.4 Research Governance – Data Recording, Storage and Training

I undertook a number of Research and Development training courses in line with Domain C (Research Governance and Organisation) of the Vitae Researchers Development Framework (RDF). The emphasis of the courses was to enable researchers to acquire the knowledge of the standards and professional requirements to carry out independent research. I undertook a course titled “Managing Research and Data Records” in the academic year of 2012/3 and “Research Governance Training” in the academic year of 2013/4. I also participated in a workshop titled “Research Integrity” in the academic year of 2014/5.

I was given the tools to be able to manage my project in creating a SITE file to be hosted on a secure research governance database within the department (J:\HW\GPPC\Research\ResearchGovernance\Database). This procedure ensures that all documentation related to the project is complete and easily accessible at any time for monitoring and audit purposes [LINK]. This includes documentation such as ethical approval, consent forms and training logs. Regular ‘spot checks’ would take place every three months to ensure that research students and staff remain compliant in the efforts to uphold research governance principles. Five research records would be chosen at random to be examined for content and completeness. If there are omissions within the file then the researcher is contacted by a member of the GPPC Research Governance Group and asked to add the relevant information within 2 weeks, if at all possible.

I maintained an exact copy in a paper-based format that was locked in a secure filing cabinet for back-up purposes. Audio files from the telephone interviews were immediately transferred to a secure file on the researcher's drive and the original copy maintained on the recorder for contingency purposes. The digital recorder and software were also safeguarded in the same filing cabinet for convenience and easy access within the office. The organised study documentation and audio files served an important purpose in demonstrating compliance, facilitating smooth management of the project and providing the internal auditors the ability to confirm the validity of the research and integrity of the data collected.

3.4.5 Data Analysis – Transcription & Procedural Steps

The following section outlines the analytical process which I undertook to examine the data. Reference in this section has been made to the Ritchie and Spencer (1994) thematic framework for data interpretation. Prior to any form of analysis there was an administrative process put in place which was set up with the assistance of the doctoral supervisory team to enable 'in-house' transcription of the telephone interviews. Therefore after a series of interviews which usually coincided with the main time-points, batches would be sent to the administrator: Ms Michere Beaumont. Depending on the workload of the administrator, the quantity of files in the batch and the size of the files the turn-around process could take as long as several weeks. The audio files would be transcribed verbatim and returned via secure link to the researcher's database.

3.4.6 Content Analysis: Thematic Analysis (Richie & Spencer Framework)

The next phase included printing out the interview transcripts to be manually coded using a pen and highlighter and following this five-step process: *Familiarisation with Data, Identification of Framework, Indexing of Transcripts, Charting* and *Mapping*. The framework was developed at the National Centre for Social Research and chosen because it's robust and well-established method of analysis. The mapping phase equated to the interpretation element (ascertaining meaning) of the process as the data was mapped to NPT in order to 'translate' the research findings (barriers, facilitators, lessons learned) into concrete propositions and conclusions to be made from implementing a national large-scale, complex digital health intervention into routine daily use by service users as 'consumers'.

3.4.6.1 Familiarisation with the Data

A quality check of transcribed files was the first step in becoming familiar with this large volume of data. This involved listening back to the audio files whilst concurrently proofing the transcribed files. This process ensured that on occasions where a word or sentence could not be transcribed for reasons outside of the administrators' capacity, then I would be able to most likely be able to fill-in the missing data. This constituted a 'completeness' check which also helped to identify key ideas and themes which were readily apparent. Spencer and Ritchie's framework encourages the user to immerse themselves into their data, and in line with this I triangulated (brought together in an organic fashion) the disparate data sources: observation notes, documentary evidence and interview transcripts to get a feel for the body of data as a 'whole' and make handwritten notes on the

margins of documentation. This is an important element of the first step as it directly feeds into the next stage of the process in identifying a thematic framework [93].

3.4.6.2 Identification of Framework: Priori Codes & Challenges

The major themes identified in my literature review served as a useful basis upon which to build on. The development of the thematic framework relied on two elements namely a) the primary data and b) the research objectives of the study which are linked to theoretical framework formed from the literature review [93]. During the telephone interview process, notes were made on the topic guides themselves which proved to be valuable in returning back to the data and making judgements about the meaning, relevance and significance or emerging issues. In addition, due to the large volume of data, I typed-up hand-written notes onto the electronic copy (equivalent) of the file. This included all telephone interview transcripts and observational notes, and from this point forward the use of Microsoft Word © facilitated the analytical process. The framework approach at this stage helped to ascertain 'links' between issues and major themes in order to address the original study aim.

3.4.6.3 Indexing of Transcripts

The majority of the transcribed interview files were tabulated according to the interviewer's questions and the interviewees' response. Electronic notes had been made in reference to key themes and sub-themes that emerged; these were noted in the margins of the electronic transcript and in line with the corresponding data 'quote' (an additional column). Four Microsoft Word documents were created to represent the overarching NPT framework and each interview transcript was given a number from 1 – 30. The next step was to present a holistic picture of the data as a whole and this required charting the data.

3.4.6.4 Charting the Data Excerpts

The charting process required data to be transferred from its original context in the source files and re-arranged thematically. The Control, Copy and Paste function was used to find data within the interview files which related to each theme. The relevant 'quote' was then transferred to one of four host files along with an identifier, a unique number for the data source (which enabled them to be traced). Sub-themes that underpinned a major theme were the essential quotes that were transferred to the suitable host file. A summary table was created to list theme and the data source file number which linked to the theme.

3.4.6.5 Mapping to NPT as an Explanatory Framework

The process of mapping the data consisted of referring back to the 16 sub-constructs (See Table 3B — Coding Framework) of NPT and reviewing the connections in the host data files. This involved comparing and contrasting data, specifically the barriers and facilitators which related to the same theme. Connections and explanations (causes and effect) were also part of the mapping process to assist in making sense of the data. Quotations and notes were separated according to the sub-constructs and this provided clear data paths in

linking good and bad examples of factors which help or hinder the large-scale implementation process. Selecting the most interesting factors to be presented in the findings was a challenge due to the complexity of choice. This manual mapping system was laborious however it was a method which I was comfortable and confident in using. As mentioned previously, thematic analysis was initially used to make sense of the major themes and their development during the analytical process (inductive reasoning). The overarching themes were generated from the findings of the scoping review. The use of the thematic approach helped to readily discern barriers and facilitators to implementation as well as positive and negative examples of each. Emerging themes were then mapped onto the 16 sub-constructs of NPT. The use of this framework provided added value in helping to think through and better understand the intricacies of implementation processes and the mechanisms underpinning impacts. In turn, it helped aid understanding of whether a factor should be considered positive, negative or either in terms of the influence on embedding of the intervention in routine practice.

3.5 Ethical Considerations – Privacy and Security

Ethical approval for the study was obtained from the University of Glasgow, College of Medical, Veterinary and Life Sciences, Research Ethics Committee on 20/01/2014 (Application Number: 200130029). The approval consisted of a completed application form, the researcher's resume, primary supervisor resume, a participant information sheet and consent form. The committee noted that a summary of the accomplished project should be provided within three months of completion. Permission to cover the period of observations carried out was secured in a separate application (DALLAS) as the researcher was noted as part of the collaborative evaluation team. The following sections outline the steps taken to uphold ethical principles within the study. Within this study consent was obtained from participants and ethical guidelines followed to maintain confidentiality and integrity whilst safeguarding data against access by unauthorised personnel.

3.5.1 Consent

Prior to each telephone interview, an email was sent out to each participant explaining and providing two file attachments. The first was a participant information sheet which provided a summary of the study and a question and answer section in relation to likely concerns such as how their information will be safeguarded. The second file was a consent form only to be initialled against each clause of the form and signed at the bottom. The form also granted permission to record the upcoming interview and to retain the data. Consent forms were also provided to participant of the sit-in focus group as this was a recorded session and to provide participants the choice. A copy of the consent form can be seen in the appendix section.

3.5.2 Confidentiality & Anonymity

During telephone interviews with participants, interviewees were reminded that their responses would remain anonymous. I adhered to the Data Protection Act (1998) principles, to ensure that data collected about participants remained confidential. All personal identifiable data were removed and pseudo-anonymized

(allocated a unique reference) to ensure remarks could not be traced back to a participant. This was a crucial component of the study as many of the participants held high political and organisational positions and with these measures in place helps to combat any negative ramifications such as deciphering a person working in a particular role within a particular sector.

3.6 Role of the Researcher

Reflective practice is very much encouraged being part of the everyday fabric of an independent researcher. During the course of the studentship I experienced a steep learning curve and a great deal of challenges which in turn created valuable learning opportunities. The following sections detail how I was able to overcome barriers and press forward given personal limitations.

Table 3B - The Normalisation Process Theory Coding Framework used for Qualitative Data Analysis

Coherence (Sense-Making)	Cognitive Participation (Buy In)	Collective Action (Enacting Work)	Reflexive Monitoring (Appraisal)
Differentiation Is there a clear understanding of how the Living It Up programme differs from previous efforts within implementation?	**Enrolment** Do service users actively participate and 'buy into' the services within the Living It Up programme?	**Skill-set Workability** How does the implementation of Living It Up affect division of labor of work practices, training or roles and responsibilities?	**Reconfiguration** Do participants develop a 'work-around' or try to alter a technology, product or service?
Communal Specification Do the stakeholders, service users and service providers develop a shared understanding of the aims and objectives of the Living It Up programme?	**Activation** Can service users who participate in the Living It Up project sustain its implementation?	**Contextual Integration** Is there organisational support for resource allocation? In terms of ways that users enact a new set of practice	**Communal Appraisal** How do service user groups judge and determine the value of the Living It Up programme?
Individual Specification Do all stakeholders have a clear understanding of their specific roles and responsibilities in achieving the vision of the Living It Up programme?	**Initiation** Are individuals willing to drive the implementation forward? Who are they? Local Champions?	**Interactional Workability** Does the Living It Up Programme make existing routines of practice easier?	**Individual Appraisal** How do individual participants appraise the effects of the implementation of Living It Up on them and their work environment?
Internalisation Do all stakeholders understand the significance of this intervention and its future value?	**Legitimation** Do participants believe it is right for them to be involved? Do participants feel they can make a valid contribution?	**Relational Integration** Do participants have confidence in using Living It Up technologies, products and services?	**Systematization** How do participants determine the effectiveness (benefits & limitations) or useful ness of Living It Up? And how can this be measured?

3.6.1 Project Challenges: Dynamic Real World

"*There is more than one way to skin a cat*". The basis of this research consisted of three prospective strategies (A, B and C). Plan A – each implementation site would constitute an individual case study, Plan B – a contrasting case study comparing a rural implementation site and an urban implementation site. Both plans would have enabled cross-case comparisons within the local environments and between cases capturing the influence of wider environmental factors and the diversity of experiences. Plan C – take a 'whole systems' approach to identifying implementation factors on a broader landscape.

Plans B set out to compare stakeholder perspectives of a traditional telehealth service to a bottom-up co-designed service as part of the LiU programme. This meant that data collection would drill down to catchment area, health provider, and patient. This plan seemed to be feasible and the most desirable, therefore an NHS Research Ethics Committee (REC) form was required to be completed (approximately 70 pages). The NHS REC form had been drafted and ready to be submitted when several project challenges emerged which affected the likely direction and prospective strategy. This included the following: *Recruitment Challenges* of patients and consumers and low uptake levels. *Agreeing Definitions* – defining what and who constitutes a 'service user' was quite a lengthy process. This was due to the fact the project aimed to target 10% of the Scottish population 55,000 people and the need to clarify the definition of a one-time user, regular user (member), and a sustained user was required to feed into the UK Government reporting of the project and the sister innovations (community seeds) across the country. A unified measure agreed by all the community seeds took time to achieve and this had a direct impact on LiU because a shared vision of what counted as a fully engaged user was not achieved across the programme until February 2014.

Additionally, the backing of the Scottish Government to support the ministerial launch of LiU was postponed for six months from May 2013 to November 2013. The first recruitment target of 1,500 consumers by the end of May fell short and it was therefore envisaged that additional time would be required to enable the public to become aware and grow an affinity to the co-design concept in time for the re-scheduled date. It was therefore agreed with the doctoral supervisory team that reframing this study to go with Plan C would be the most suitable option at that time since the recruitment of service users was completely out with the control of the researcher and in the hands of LiU. This was to prevent a situation where data collection could be seriously affected due to limited access, time and resource constraints. These challenges signified a steep learning curve for me as a researcher, with the need to be proactive and adaptable at all times, willing to accept changes outside of my control but most importantly learn from all situations albeit negative or positive.

3.6. 2 Personal Challenges: Nvivo vs. Manual Method

The use of QSR Nvivo ® Version 10.0 facilitated part of the analytical process however I struggled with 'losing' myself through the process and becoming distant from the data. This was probably the most trying decision to make given the fact that I had undergone specialist training at an early stage of the studentship although without any research data. The notion of coding a line to a node almost became a systematic procedure without

regard for links within a transcript. This proved to be even more restrictive as active coding in the source file window does not enable simultaneous relationships to become apparent between the nodes. However in Microsoft Word ©, I experienced greater flexibility by simply being able to type and follow up the relationships between themes in a single transcript without having to run a query or report. In many cases, to run a query such as to quantify the barriers and facilitators, the complete dataset had to be present but my data was collected gradually and therefore the convenience and easy access of Microsoft Word © was suitable in meeting the study design.

3.6.3 Personal Limitations

Your PhD is not just about your project, it is about developing the skills to become a competent early career researcher! . On several occasions during the doctoral process, I was reminded that it was not expected that I know 'everything' but the essence of a studentship is to learn and to develop one-self. The practice of holding high expectations and aiming to meet them at every opportunity has been a beneficial life approach however at times it was important to make a mental note that not meeting an expectation was not complete failure. Maintaining a research journal diary has helped in reflecting on key learning points and transferable skills that I have obtained during the course of the studentship.

3.7 Quality Criteria

Quality and trustworthiness of the findings from this study is imperative in making a sound contribution to knowledge. Lincoln & Guba (1985) developed criteria to assess study rigor and particular reference in this study is related to the credibility and transferability dimensions [91]. Credibility refers to whether the findings from the study provide a true representation of the research phenomena. Whilst transferability refers to the applicability of the findings for study in general, for other researches and policy makers.

3.7.1 Credibility

The credibility dimension in qualitative research is the equivalent to internal validity in quantitative research. There were various occasions during the research to provide feedback in terms of understanding the evolving picture from the analysis of observations, documentary evidence and baseline interviews. Additional feedback in relation to major themes from midpoint onwards was provided at internal seminars (eHealth GPPC) and in preparation for National Conferences (British Computer Society Scotland). The Strategic Lead was the main point of contact and filter for feedback which helped to clarify any misunderstandings and to ensure the interpretation was a true representative of the LiU implementation journey. It is now very common to use qualitative research in process evaluations for complex intervention studies. The use of data triangulation (multiple sources of data), methodological triangulation (multi-method approach) and time triangulation (various time-points) significantly reduces systematic bias in the data and therefore also promotes the credibility of the research findings [92].

3.7.2 Transferability

This study represents a single case, which in general is reported to offer a poor basis for making generalisations, however given the novelty of this digital health programme, assessing the transferability of the implementation model to a similar setting is certainly worthwhile and most likely to be of high interest. In using NPT as the underpinning theoretical basis for the study this demonstrates that the findings have broader theoretical significance to the field of implementation science. This study therefore provides a grounded basis upon which the subsequent propositions are able to influence and contribute to future digital health policy and practice.

3.8 Chapter Summary

This chapter presents details of the theory, approach, and methods used along with accompanying text which explains the rationale for choosing each respectively. I have also provided some discussion of potential limitations and alternative approaches that could have been considered to undertake this work. Key strengths of the approaches include the use of a robust theoretical framework to conceptualise the data, the use of a range of qualitative data sources along with the longitudinal nature of the work. There are however a number of limitations. Participants were those identified by key personnel involved in the implementation of the national programme, which provides the potential for bias in those participating. Additionally, there was no formal respondent validation from participants which some might deem to be a potential limitations but I did seek to check and clarify comments with participants during interviews to ensure that I was accurately grasping and appreciating the inferences and ideas they were trying to convey. The following chapter provides an overview of the LiU project, it's development over time and implementation insights into the issues affecting scalability.

CHAPTER FOUR
LIVING IT UP PROGRAMME

THE BACKGROUND, CONTEXT & DEVELOPMENT JOURNEY

4.1 Introduction

The purpose of this chapter is to provide an insight into the case of Living It Up (LiU). Contextual and background information is provided which is essential to fully understand and interpret the data in the following chapters on barriers and facilitators to implementation of LiU. The key methodological element supporting this chapter has been the immersion of the researcher in 'real time' into the project work environment over a three year period. This very unique opportunity provided a means to capture the entities, people, processes and activities which underpin this national endeavour. The objectives of this chapter are addressed as follows:

1. **Project Background**: section one describes why a change in the global digital health landscape needs to be directed towards upscaling and an introduction into a suggested solution (dallas). The high level vision and mission of the project is described in addition to a competitive tendering process to make dallas a reality.

2. **Project Description**: section two provides a 'description' of the Living It Up (LiU) case study. An overview of the case is presented; with the scope of the project outlining the objectives, collaborative consortium model, organisational and governance structure, implementation strategy, products, services and the sustainability and exploitation models.

3. **Project Development Journey**: section three describes the journey of the LiU development from inception. This includes an in-sight into the innovative co-design and engagement methods used as well as the underpinning community insight research activities which fostered scalability. The LiU implementation journey is viewed at a glance with the deliverables and key factors highlighted as affecting deployment at scale.

The data supporting this chapter are the extensive ethnographic, documentary evidence and participant observation (shadowing) carried out over the three year period which was thematically analysed as detailed in chapter three. A total of 403 pages of data were reviewed which made up this dense and rich data source. The use of field work notes and documentary evidence combined served as a key facilitator in creating a 'thick description' of the inner workings of LiU. The data helped to support this chapter to standalone due to the rich quality information it provided. Data was collected through attending unique events such as pop-ups (temporary events held in public spaces), interactive workshops at libraries, shopping centres, churches and places of interest. Leaflets, confidential documents and information were scanned and the data examined to identify key themes of interest. The data was used to develop a broader understanding of the context and development of the LiU project.

Documentary evidence was analysed using the framework approach which is the same approach used for the entire qualitative dataset. Using an example of a 'Quarterly Report' the following steps were taken: 1) Reviewing the document and familiarising the contents of the quarterly report 2)Highlighting areas of interest as concepts and emerging themes to generate the basis of a thematic framework i.e. factors affecting engagement, participation, recruitment and buy-in 3) indexing excerpts that correspond to this theme and corresponding sub-themes i.e. the

co-design process, 4) Charting the data – creating an appropriate display format to chart the themes and sub-themes in an accessible format for example Table 5B illustrates this by charting according to whether sub-theme is an implementation barrier or facilitator. 5) Mapping the data – interpreting the coded data using NPT to foster understanding and help make sense of the dataset.

4.2 **Project Background**: The Call For Change and To Do Things Differently

A total initial investment of £23 million was made available UK-wide in an open competition on the 7th June 2011 to attract innovative proposals from a variety of public, private and third sector organisations. Applicants were invited to provide responses to the global unprecedented demographic shift which is affecting supply and demand requirements of the growing older population in the UK . The challenge for the different sectors (political, social, economic, private and public) was to 'think outside the box' and develop solutions to meet the consumer demand for healthy ageing, independent lifestyles and prolonged quality of life. The 'call' came from the Technology Strategy Board (TSB) now known as Innovate UK, a '*business-led government body which works to create sustainable economic; growth by ensuring that the UK is a global leader in innovation* .

Innovate UK, is an agency sponsored by the UK Government's Department for Business, Innovation and Skills (BIS)".The aim of this body is to fund and support science and technology innovations that will grow the UK economy. Technology being an agent of change evidently has an important role to play in shaping the future of services across all sectors. The need to reap the foreseeable benefits within health and social care is needed now more than ever in view of the aforementioned changing population demographics and concomitant increasing pressure on health services. Previous efforts in the provision of technology to support the self-care and self-management agenda have provided little evidence of effectiveness [94]. Randomised Control Trials (RCTs) are widely seen as the gold-standard in assessing clinical and cost-effectiveness of health interventions and therefore they have been advocated as the most appropriate means to evaluate digital health programmes [94]. The Whole Systems Demonstrator (WSD) is a prime example being the world's largest RCT of telehealth and telecare technology. However, the evidence base to support decision makers in the use of technology is mixed as illustrated by the WSD as it did not appear to be a '*cost effective addition to standard support and treatment*'.

Poor uptake and low adoption rates of technology only exacerbates the uncertainty of the value of digital health implementations. Therefore the need for creative, robust and theoretically grounded methodological frameworks have been promoted as a reasonable means to 'test out the waters' in providing sufficient evidence for large-scale roll out . New design methods are being advocated as a way to unlock creativity and a way to produce exciting ideas that will challenge existing assumptions. Getting innovative solutions aimed at re-designing the delivery of health and social care services into routine practice is a complex issue and therefore it is important to ensure that factors affecting implementation processes are considered in any large scale effort to promote service innovation. The UK Government reports that this issue requires an understanding of the '*social and intergenerational issues, business*

and economic models, interoperability, standards, design (of services and products) and the changing socio-political climates' - TSB, Innovate UK.

4.2.1 The Suggested Solution: Delivering Assisted Living Lifestyles at Scale (dallas)

Delivering Assisted Living Lifestyles at Scale (dallas) was the government's solution in 2011, seen as the next step towards integrating the provision of healthcare, social care and wellbeing services across all sectors using digital health. The project was part of Innovate UK's Assisted Living Innovation Platform (ALIP) which set out to establish up to five implementation sites or 'communities' across the UK. The term 'communities' recognises the fact that it is communities of people along with their *families and carers, public and private services, industry, voluntary, health and social care* which play an important factor in creating social innovation. Successful proposals for these communities were set to receive a Small Business Research Initiative (SBRI) development contract with funding for a maximum of 36 months [95]. The emphasis was centred on strategic direction and ambition to explore new models of service in order to progress a sector that had previously been dominated by pilots and demonstrators [94]. Applicants were encouraged to adopt a visionary approach in fostering two key principles, the first being that it had to be service orientated rather than product orientated and secondly the focus needed to be on creating social innovation rather than technical innovation. Harnessing existing technology alongside significant advances towards interoperability rather than developing new technology is where Innovate UK set out to gain the greatest value .

4.2.2 The Vision: The Big Picture

There is a need to understand the readiness of citizens, professionals and the market for digital self-care. Therefore the dallas programme aimed to provide an opportunity to think beyond the traditional boundaries of health and social care to consider *how new technologies and services can be used to improve the way that people live* . This involves taking a look at the full life-cycle of 'implementation' which begins with *engaging with communities to co-design and re-design services*, looking at ways to develop and deploy solutions supporting self-care, identifying how to promote digital awareness and finding ways to successfully sustain these interventions . Time and time again, the evidence base demonstrates that it is not enough to look at individual outcomes from individual stand-alone projects and services. Therefore Innovate UK set out to gain an understanding of the large-scale national context of the implementation of digital health and wellbeing technologies in the UK. The main aims of the dallas programme were to: a) create a consumer-market for digital health and wellbeing products and services; b) to empower people to take ownership over their health and wellbeing; and c) to roll-out innovative technologies and services at scale.

4.2.3 The dallas Consortia: Winners of the Tendering Process

Successful applicants were informed on the 30th April 2012 having made it through a ten-month selection process. This competitive three stage process required applicants to: 1) submit a business case detailing their background and capabilities in meeting the government's vision which were assessed by a panel of experts (Stage 1); 2)

attendance at a compulsory workshop in order to identify a core consortia (Stage 2); and 3) shortlisted candidate communities were required to submit a full proposal alongside a presentation to a select panel (Stage 3) [95]. The four applications from organisations across the country selected as beacons to spearhead this British endeavour were: Living It Up (LiU), More Independent (Mi), Year Zero (YZ) and i-Focus. My thesis examines the digital health deployment undertaken by LiU, which was the single community located in Scotland.

The official start and end dates for dallas were 1st June 2012 – 31st May 2015. This gave LiU a two month window to prepare themselves for the project. In this time, the government set up a series of networking events and knowledge sharing opportunities for dissemination across the programme using the government online platform "_connect" Knowledge Transfer Network available at https://ktn.innovateuk.org/web/dallas. Management personal from Innovation Centre Scotland (ICS) facilitated the process by ensuring that the communities and individuals involved in dallas could communicate effectively to share knowledge across the programme and with the wider health and social care sector. LiU was ultimately awarded £10.375 million in joint funds, coming from Innovate UK, the National Institute for Health Research (NIHR), Highlands and Islands Enterprise, Scottish Enterprise and £5M from the Scottish Government. In addition, the communities themselves raised their own financial contributions bringing the total programme funding to £37 million .

LiU set out to work independently within their catchment areas and collaboratively with the other communities across the UK where appropriate. LiU set out to engage with the Scottish citizens to redesign services; to foster the delivery of innovative solutions to support self-care in the digital age, to promote and increase digital inclusion, and to explore how to successfully mainstream "*normalise*" and sustain the implementation and adoption of digital health products and services. This endeavour therefore became a large scale digital health programme in Scotland, testing and creating new ways of delivering technology enabled care services (TECS) at scale. Living it Up (LiU) was a national digital service designed to help the citizens of Scotland to get the best out of life, to live happier, healthier and safer lives using technology as an enabler (https://www.livingitup.scot/). Key target impacts included the design and deployment of the largest co-design initiative in Europe, the creation of a digital platform for consumers and a marketplace to test innovation and digital services.

4.3 Project Description: The LiU Case Study

This section presents a description of the Living It Up case study; a national platform for Scottish citizens to access digital tools and services to enhance their health and wellbeing. The section is concerned with the "what" and "how" thesis objectives regarding '*what was the LiU development process*?' and '*how was LiU developed over time?*'. In this case the interpretivist approach enabled the researcher to explore and

gain a deeper, richer and more complex understanding of the LiU programme. The goal of this section is to describe the LiU development process, such a description is needed to assist in contextualising and to fully understand the implementation issues involved in this complex, large scale deployment of digital health. Figure 4.1 – LiU Platform, Products and Services

4.3.1 What is Living it Up? – Novel Digital Health & Wellbeing Platform

Living it Up (LiU) is an award-winning online self-management hub which aimed to empower older people aged 50+ to use technology to manage their health and wellbeing; and also to be better connected to their local communities (www. https://www.livingitup.scot/). The platform was hailed by Alex Neil the Cabinet Secretary for Health and Wellbeing as a 'National Ground Breaking Service' being the recipient of the 2014 'Digital Service of the Year', a finalist in the 2014 Scottish Health Awards and 2015 AXA Health Tech & You Award', shortlisted as a 2015 UK Digital Leader Award and nominated for the 2017 'Mobile Innovation Award'. The government representative launched the £10.375M three year project in 2012 at the Peak Sports Complex in Stirling. LiU was designed to cater to and tackle the increasing financial burden related to caring for an ageing population living with long term conditions and complex needs through a series of early intervention initiatives and preventative care measures. This unique project enlisted local communities across Scotland to help in the design and development of new and innovative ways to provide personalised, person-centred tools and services to support digitally-enabled self-care at scale.

4.3.2 LiU Vision: Project Aims & Objectives

The vision for LiU was to create a multichannel self-service platform with the potential to transform the digital health sector in a similar way that advances in technology have transformed other sectors such as banking and aviation. For example, airline passengers now dictate their own travel experience by becoming an 'active' recipient with increased choice about the ideal value holiday suited to meet their needs. In addition mobile banking offers account holders the opportunity to take control of their finances, manage transactions and use services at their fingertips, accessible twenty four hours a day, seven days a week. This social technical change is in great contrast to how services were delivered previously with consumers playing a traditionally passive role in both sectors.

The Scottish government aimed to be at the forefront of innovation in becoming a "world class digital nation by 2020" with policy intending to help people to live longer and healthier lives at home or in a homely setting using digital technologies as an enabler [96]. Therefore government officials set out to ensure that LiU aligned and built upon a range of existing policies which included the national eHealth strategy for Scotland 2011 – 2017. This strategy supports the overall NHS Scotland goals as set out in the Better Health, Better Care Action Plan, "ensuring patients get the right care, involving the right clinicians, at the right time, to deliver the right outcomes" [97].

Additional policies include the 'Digital Strategy for Scotland', the '20:20 Vision for Healthcare in Scotland' and the 'Reshaping Care for Older People'. These policy documents are significant as they build on the use of 'Technology Enabled Care Services' (TECS) to support moving the balance of care from institutional to community settings, improved outcomes for service users and wealth creation.

LiU set out a number of deliverables to meet this ambitious vision. These were to a) create a digital platform accessible across a range of modalities with personalised, integrated and customisable support on offer related to health, social care and independent living; b) form vibrant self-sustaining communities across Scotland motivating 55,000 people to improve their health and wellbeing; c) create a market place to encourage open innovation and allow industry to promote and test innovative offerings to the LiU community and d) to develop a scalable business model and partnership vehicle to support long term sustainability. Ultimately, LiU set out to promote increased choice for service users, increased control over the care they receive, improved community cohesion and improved collaborative working between individuals and organisations .

4.3.3 LiU Collaborative Consortium & Partnership Model (Stakeholders)

LiU is a large-scale collaborative partnership led by NHS 24 and the Scottish Centre for Telehealth & Telecare (SCTT) which are government bodies' established with a purpose of facilitating the shift towards how health and social care services are provided, perceived and consumed. This group consists of stakeholders across six sectors: industry, health and social care, housing, education, voluntary and statutory, all working together as a collaborative consortium. This is illustrated in Figure 4.2 below.

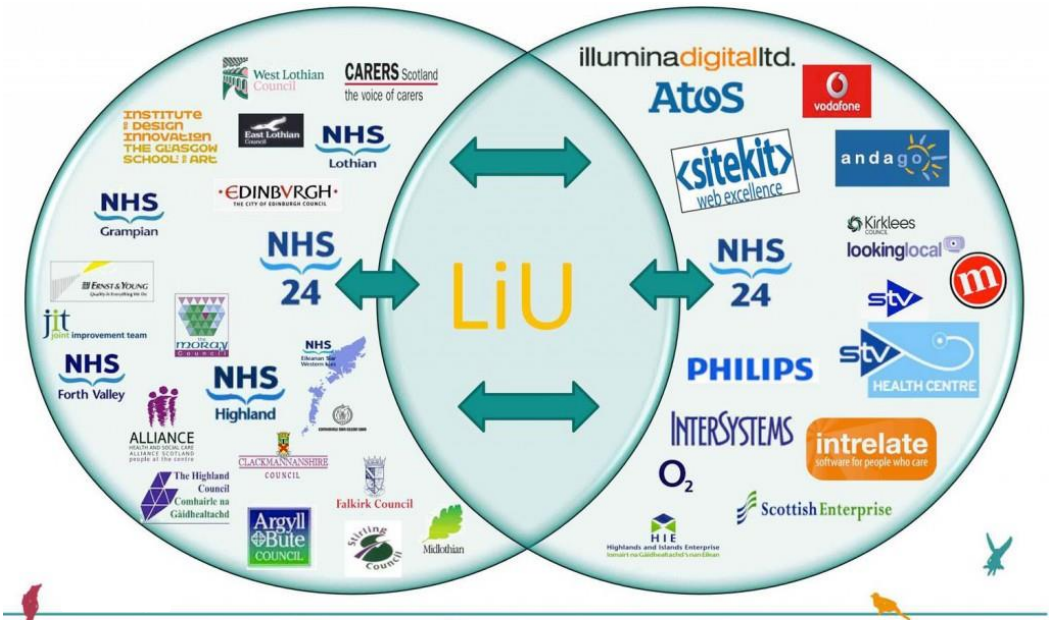


Figure 4.2 – International Stakeholders for Living It Up.

The partnership includes 5 *Health Boards* namely; NHS Lothian, NHS Highland, NHS Forth Valley, NHS Western Isles and NHS Moray CHSCP. In addition to a range of *Programme Stakeholders* including The Long Term Conditions Alliance Scotland (now knowns as The ALLIANCE Scotland), Carers Scotland and Glasgow School of Art. *Project Management and Business Modeling* were undertaken and managed by Ernst & Young, whilst the *Technology Platform and Integration Partners* included Sitekit, Intersystems, Atos, Intrelate and Phillips. *Telecommunication partners* consist of Maverick TV, Illumina Digital, STV, Looking Local, Vodafone, O2; and the S*trategic & Economic partners* consists of a partnership between the Scottish Assisted Living Programme (SALP), Scottish Enterprise, Highlands & Islands Enterprise and Scottish Development International.

4.3.4 LiU Implementation Pilot Sites & Geography

LiU has established 5 implementation sites, also known as 'communities' in *Lothian*, *Forth Valley*, *Highland*, *Moray* and the *Western Isles*. These diverse geographical locations capture a mix of urban, rural and remote rural areas. LiU set out to engage with a total of 55,000 people over the course of the programme through an active membership model and recruitment strategy aimed in the first instance at the over 50's plus their wider intergenerational support network and circles of care. The proportion of users being targeted from each community can be described as follows; Lothian = 26,950 people (49% of the target population), Highland = 13,200 (24%); Forth Valley = 10,450 (19%); Moray = 3,300 (6%) and Western Isles = 1,100 (2%). The plan was to recruit members using a variety of modalities and methods (Web, TV, Organisations). The LiU implementation is based on a membership model and the projected benefits included a community that is befitting to all members by providing a platform to have increased *control* and *choice* of services and products to enable users to *contribute* to their *community*, *collaborate* and maintain *connected* within their community. The main goal for users was to provide access to the right information, the right products and services at the right time. The target population includes 5 groups (A, B, C, D and E) which have been particularly identified as groups that require additional support to cope with global changes (increasing older people, coping with LTCs and living with disabilities). Group A: General Population and circles of care (Family, Friends, Carers). Group B: Active and generally

healthy people aged 50 – 70. Group **C**: People aged 50-70 with/or at risk of having a chronic condition (Chronic Obstructive Pulmonary Disease and Heart Failure the main conditions). Group **D**: People aged 75+ with existing LTC's/frailties/social isolation/ people with disabilities and Group **E**: Formal service providers (statutory, voluntary and independent). See above, Figure 4.3 – Map of Implementation Pilot Sites & Geography.

4.3.5 LiU Organisational & Governance Structure

Each LiU community was assigned a Project Manager to oversee the implementation process and ensure that high quality data is collected at ground level for various interventions, products and services which were to be used to fulfill the multiple aims of the programme. The data is then submitted to an internal Living It Up steering group responsible for maintaining internal governance. The Scottish Assisted Living Platform (SALP) is a body which is ultimately responsible in reporting the progress of the implementation. NHS 24 has been required by the Scottish Government to provide overall leadership, coordination, programme management, and financial governance to Innovate UK. See Figure 4.4 below which illustrates the LiU Structure.

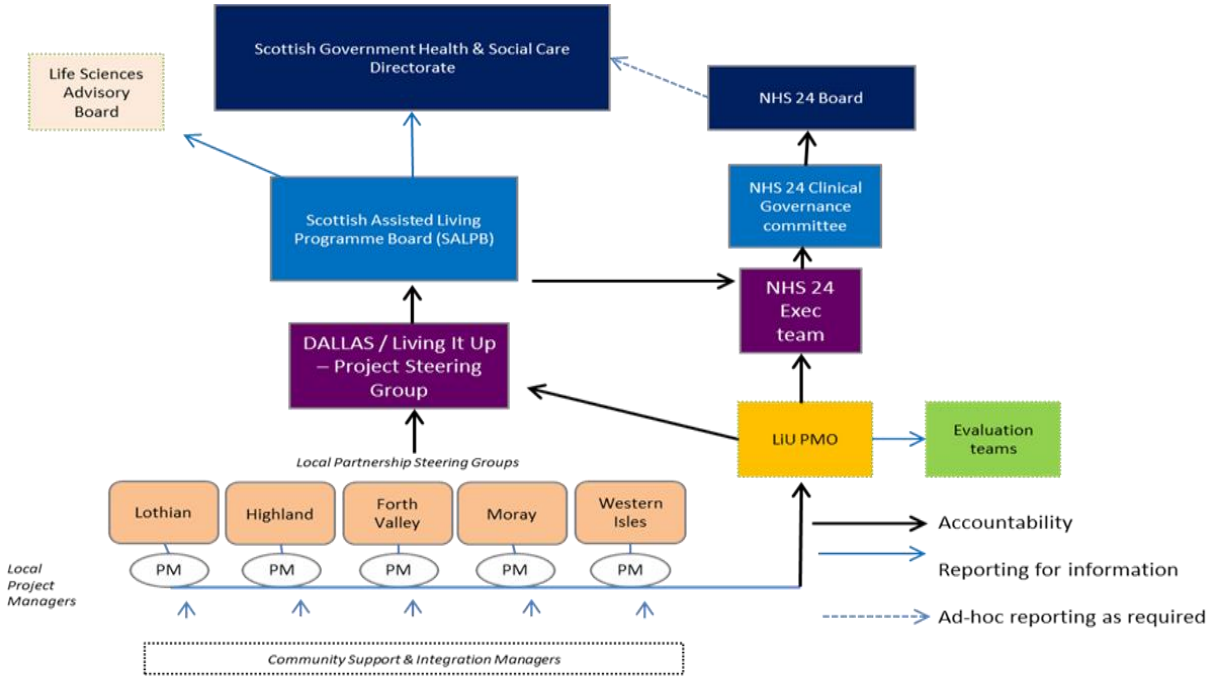


Figure 4.4 – Detailed LiU Governance Structure

4.3.6 LiU Programme: Products and Services

The self-management hub provides four core services, a range of unique tools, advice and a wealth of information to support people living with a long term condition and those who care for them. The platform hosts everything

from localised event information, technology user guides to assist with monitoring your health to inspirational video content to support on-going care. The following sub-sections describe the products and services available for users. Particular focus is on the ability to encourage users living in remote rural areas and also those with limited IT skills to use LiU as an educational tool as well as a social collaborative tool. Users of LiU can access the entire platform free of charge and there is an opportunity to become a member which will present them with a personalised dashboard.

Connect (Digital Participation) The first being a service which supports digital participation among communities in providing a means for people to remain 'connected' with their friends and family as well as an opportunity to up-skill and learn how to go about using technology. This service enables users to remain 'connected' to their care-giver via Cisco Jabber Client video conferencing (VC) suite. The second service 'Discover' is based on asset mapping national and local information about organisations, services, activities and groups which consumers may find useful in meeting their needs. This service is powered by a national database called ALISS (A Local Information System for Scotland). This provides a personalised search and collaboration tool for users and enables organisations themselves to use it for sign-posting. Users also have the ability to 'rate' services in an open format and share recommendations.

The third service, Flourish (Self-Management & Independence), provides a suite of interactive tools to support people in self-managing their chronic condition. This includes approved health information and advice, text messaging alerts and remote-monitoring services to help support people with conditions such as Heart Failure (HF). The final service 'Shine' centres on community capacity building. It is advertised as the 'front door' to LiU. This service taps into the value of the contribution that citizens can make to society. The service provides a 'profiling tool' which enables people to identify, nurture and refine their individual skills and experience in a way to 'give back' to their local community. This approach is being used to help contribute to improved wellbeing and stronger, more connected communities.

4.4 **Project Development Journey**: A National Scottish Endeavour

LiU aimed to create both service and technical innovation and has set out to do the following: **1)** Change the way health, well-being and social lifestyles are perceived, consumed and managed by adopting person-centered approach (PCA). **2)** Foster the concept of '*Shared Responsibility*' to enable people across Scotland to look after themselves and their communities. **3)** Enable a large scale and sustainable transformation in the provision of public services as well as raising awareness of the value of technology-enabled environments and **4**) Provide a platform to enable enterprises to invest so as to foster wealth creation with increased potential within a global market.

4.4.1 Co-Creation and Co-Production Methods (CET)

The LiU management board established a *Community Engagement Team* (CET) to work on the ground level in order to ascertain user requirements and encourage the development of collaborative solutions with potential end users. The team consists of a representative from Glasgow School of Arts, the Long Term Conditions Alliance Scotland (now The ALLIANCE Scotland) and Carers Scotland. The notion is that CET would be used to gather ideas on ground level and report back to the co-design steering group (every month) which consists of designers, professionals, industry partners and various representatives of the LiU consortium members. Quarterly reports are then supplied to TSB on the progress of the implementation.

4.4.2 Community Engagement Toolkit

The CET has engaged with approximately 1300 users across Scotland through community pop-up events in a range of locations. Participants engaging with LiU are characterised on a set criteria which includes: gender, age, health and wellbeing status (LTC, disability or impairment), region (rural or urban location), access to existing services and familiarity with technology. The team has also conducted in excess of N=50 targeted one to one interviews and focus groups with participants and professionals around the community and N=8 prototyping workshops to encourage progress with particular focus around 'Shine' as the gateway to the other 3 key services. LiU launched a *'Come Join Us Co-design Community Engagement Website and Blog*' www.livingitup.org.uk. The LiU Engagement Toolkit is a set of tools (newly created by CET) which was used to engage users from the 5 communities to become involved in the design process of products and services to meet their needs. The toolkit consists of 4 components:

1) Tree of Talents Tool: The toolkit originally begins with an umbrella tool to identify what talents people have by simply asking them "What is your hidden talent?" and whether they would like to share that with their local community. Individuals were also asked about what they thought could make their life better. Individuals would then write this on a paper leaf and hang it on a paper tree with other people's submissions.

2) A little Birdie Told Us Tool: the CET went out into the community to public spaces to be able to engage with people and find out what would make their life better. They asked individuals what they valued within their community, what organisations, what people and what they view as a highlight in being a part of that community. Individuals were then asked to write this down on a LiU Postcard and post it into a bird's house-like-box. The CET later reviewed submissions and contacted individuals and invited them to join LiU.

3) Technology Tool: the CET asked people what technology has influenced their lives and what technology has helped them to do things the most in the past, and how they see technology helping them in the future (so, what will be useful going forward). The team set up a number of boxes representing different technology products and asked participants to rank them.

4) **Recruitment Tool:** It's a challenge game. Participants were asked to tell the CET what they know about their community and what their ideas might be for improving their community as volunteers. 3 colored counters were given to participants: yellow, green and red; and through those questions they were able to identify if the individual could be (a) *Community Champion*: a person interested in working for the good of their community, (b) *Community Apprentice*: a person eager to make a difference in their community and (c) *Community Imaginer*: a person who can identify opportunities within their community. Participants were then encouraged to sign up and get involved to be a part of the design team.

4.4.3 Co-Design Toolkit & Prototyping Workshops

The CET and LiU dallas Leads used traditional co-design methods to design all 4 LiU services specifically prototyping sketches, storyboards, affinity diagrams and character profiles. **Prototyping Sketches**: 4 Sheets of A3 Paper are placed on 4 tables (1 on each table) to represent the 4 services. This method was used on ground level with potential participants and the general public in various locations such as shopping centers. A series of questions were written by the CET under each heading e.g. what do you think about the profiler tool? How could you improve that? (*Shine*) or what keeps you well? Who and what inspires you to be healthier? (*Flourish*). Participants were guided from table to table in time slot formats to discuss the topics. Thoughts, ideas and concerns were written on the piece of paper and post-it notes were also provided. This creative brain-storming exercise was designed to gain information from prospective participants to inform future design of LiU services. Many positive responses were recorded as well as constructive feedback such as "I thought exchange meant like a place to swap things… it's not clear". The information gathered from prototyping sketches at grass root level was then inputted into the 'feedback loop' and presented at the next stakeholder co-design meeting.

Storyboards: a widely used tool to describe how each of the target group users (A,B,C,D,E) could engage with the hidden talent service. LiU aimed to provide both service and technical innovation. The use of storyboards as detailed in their service specification provides a unique sequence of pictures for each group. It is intended to market the benefits of hidden talents as the gateway to the other key services as well as aid recruitment. **Character Profiles**: are developed as small case studies to be discussed at stakeholder co-design meetings. The LiU character profile consists of a dummy person's name, age, where they live, health status (LTC's), family background and dynamics, how the person lives day-to-day and how that person may want to contribute to their community.. The stakeholder group is divided into teams to discuss 4 character profiles which relate to one or more LiU service and notes are recorded.

4.4.4 Implementation Journey Timeline

Implementing new technology in health and wellness is complex, as it requires a significant amount of change at all levels of the health and social care systems. It is inevitable that there will be a number of barriers and facilitators

throughout the process. Figure 4.5 illustrates the three year LiU implementation timeline at a glance with highlights of key change events. The ability to track these 'activities' has provided a unique insight into key issues as they arose and how these barriers were circumnavigated. The following section provides a summary of how products and services developed over time, in addition to key implementation activities. One key theme which emerged from engagement events early on was that of 'Giving Back', which later shaped the design of the 'Hidden Talents' service specification [Quarter 1-2, Solution Exploration Stage] and this later became the 'Shine Service'. Following on from these events, the 'Hidden Talents' service and technical specifications were further developed. ‘Asset mapping’ begun at a local level, and a need for four key services was identified from the co-design workshops. A soft launch of the LiU platform was discussed and a target date was set for March 2013 alongside the first community recruitment target. All project managers were then recruited and in place, with plans to recruit Community Managers and office staff at base (Support Office) being discussed [Quarter 2-3]. A community workshop date was set to test a change in the initial branding and design of LiU for Nov 2012 as discussions were arising regarding the suitability of the initial branding.

The first version the LiU platform was launched live (www.livingitup.org.uk) with static content as a Community Engagement website and to aid recruitment of potential users [Quarter 3]. The aim was to then add dynamic content in the near future. LiU focused on enabling industry partners to build close working relationships. New community engagement tools were also developed such as Tech pop-up and the LiU Challenge to foster recruitment. A working group was established for service development with a sustainability sub-group and IP exploitation steering group created (Quarter 3). Towards the end of the first year, a new version (1.1) of the technical platform had been developed, with three initial service prototypes developed: Hidden Talents, Exchange Profile, Keeping Connected (Quarter 4). There was also a discussion being held around the development of 'MyCare' as a service for Quarter 5-6 which was scheduled to feed into V2.0 of LiU scheduled for autumn 2013.

Version 1.1 usability and load testing was carried out to facilitate the transition to the portal (Quarter 5). After consultation with potential users, formal sign off was achieved for the following re-branding of services (Quarter 6) as mentioned in the LiU Case Study earlier:

- Shine, (formerly 'Hidden Talents')
- Discover, (formerly 'Exchange')
- Connect, (formerly 'Keeping Connected')
- Flourish, (formerly 'MyCare')

These sub-brands were scheduled to be incorporated into Quarter 6 marketing. However, usability and user experience issues with the Discover service were identified and actions to improve functionality were undertaken to establish a way forward for the service (Quarter 7). Discover later integrated with the ALISS (A Local Information System for Scotland) toolkit. The LiU Version 2.0 was delivered during Quarter 6 and included the 'Profiling'

functionality which aimed to tailor the LiU offerings to individuals' contexts. The official portal launch was conducted in November 2013 in Stirling led by the Cabinet Secretary for Health and Wellbeing, Alex Neil. Clinical engagement remained low at this stage and therefore additional efforts were made to identify and recruit clinical champions and a clinical lead (Quarter.8). During the last year of the programme, a new Version (4.0) was completed and due to be launched in November 2014. A new 'Get Active' service was also developed in partnership with Storm Health with a planned release date set for October 2014 (Quarter. 9). The 'Get Active' service aimed to encourage people with – or at risk of developing - a chronic condition to increase their levels of physical activity. Nearing the end of the implementation period LiU gave a range of presentations on the programme progress to national and local conferences including the Scottish Centre for Telehealth and Telecare Digital Health and Care Conferences, the King's Fund Self Care in the Digital Age Conference in June 2014. LiU gained national attention with the platform being awarded numerous innovation awards and securing further sustainability funding through Scottish Government for 2015/6. It is clear to see that the implementation of LiU illustrates it was dynamic, constantly changing and a complex programme and therefore the ability to capture this serves as a unique contribution to knowledge.

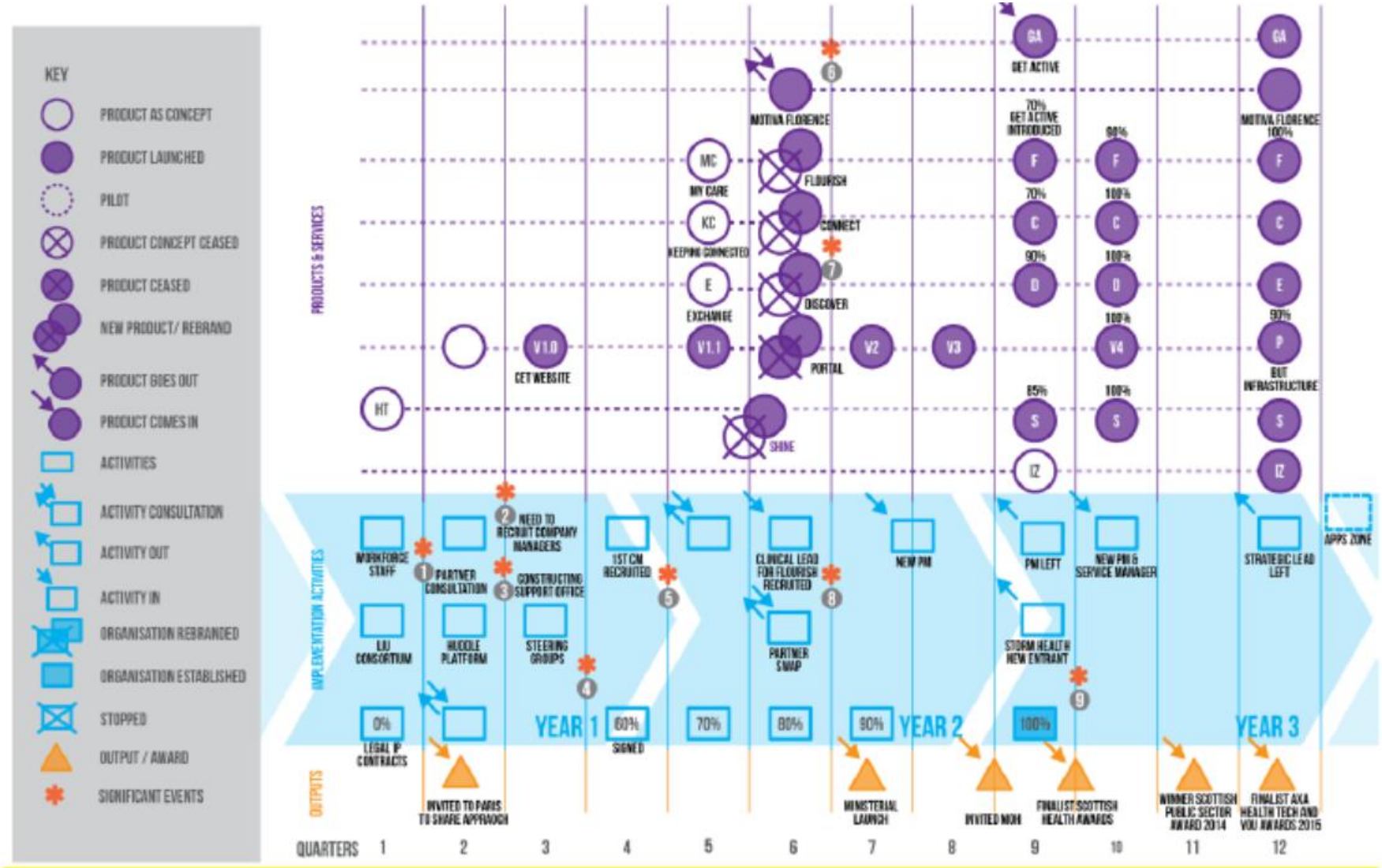
4.5 Chapter Summary

The ground work within this chapter is essential to support understanding of the subsequent results and discussion chapters which focus on: a) highlighting the factors which can promote or inhibit successful implementation at scale – *so explicitly identifying the key implementation issues* and b) to develop an explanatory framework which can shed light as to 'how' and 'why' these factors can contribute to some or all services becoming embedded, integrated and sustained. The opportunity to capture how the programme changed over time and whether perceptions regarding the barriers and facilitators shifted during the implementation process is crucial to knowing what worked well, what was less effective and what might need to be done differently on an international level in any future national or large scale digital health deployments of this kind. More importantly understanding how the perceived barriers can be overcome (successful strategies) in order to enable products and services to become mainstream is critical in fostering a successful digital self-care agenda.

This chapter has served to illustrate how the LiU programme evolved, particularly the way in which services and branding changed over the life of the programme in response to iterative feedback loops. It also shows how LiU, which was originally targeting older individuals, expanded to include services for younger individuals too. This was partly as a response to meet challenging recruitment targets and also a reflection of a willingness to grasp new opportunities as they arose.

The following chapters now go on to explore implementation barriers and facilitators in detail.

Figure 4.5 LiU Timeline Implementation Journey



CHAPTER FIVE RESULTS PLANNING & ENGAGEMENT WORK

5.1 Introduction

The following results chapters five and six present findings that have emerged from the in-depth analysis of the data collected during the three year life of this digital health programme. This aim of this chapter was to explore the early phases of digital health programme initiation and therefore the chapter has been divided into two sub-sections which explore the range of factors affecting a) the 'Sense-Making Work' and b) the 'Relational Work' that was required on an individual level (consumer, patient, champion, carer, stakeholder) and collective level (organisations, consortium, government and policy makers) during the course of the LiU implementation in Scotland. The rich understanding around the work required to implement at scale and the factors affecting the process is the most unique and valuable element of this thesis in terms of impact on future digital health policy and practice but most importantly understanding how the introduction of a novel initiative influences how people think, act and organise themselves; shedding light on personal duties and activities as part of their social context.

Chapter Aims and Objectives

The aim of this chapter is to address research objective three:

To identify and explain the underpinning factors which promote or inhibit successful normalization (implementation, embedding and integration) of the LiU programme. The underlying methods used to support the analysis and interpretation work underpinning chapter 5 has been detailed fully in chapter three. The data being used to evidence this chapter are the extensive interviews carried out over the three year period (See Table 5A for details) which was analysed using a thematic approach underpinned by NPT as described previously. Key themes will be presented with exemplar illustrative quotes to help develop an understanding of the complexity of LiU and the factors unique to this major digital health implementation endeavour.

Section One – Thinking About Doing: The Sense-Making Work

5.2 Factors Affecting Planning, Organisation, Shared Understanding, Vision and Strategy

This section explores the experiences and views of the participants involved in the implementation of LiU over time. Particular attention is paid to the positive and negative factors affecting the preparatory activities required to facilitate development of shared understandings and readiness for this large scale digital health deployment.. There were five factors identified which affected planning and engagement and these were as follows: 1) the challenge of developing a shared understanding of the political landscape and need for change; 2) the need to ensure that there is a cohesive understanding of the overall vision of LiU supported by central leadership and management; 3) identifying how to organise, plan and work across individual, professional and organisational boundaries; 4) the difficulty of developing clear communication channels and 5) the need to cement plans within an agreed legal framework pre-implementation. Figure 5.1 shows how the identified themes as outlined below map onto the Sense-Making NPT constructs.

Longitudinal Interviews	Number of Items	Number of Participants	Number of Pages
Time Point: ***Baseline*** Participants: 5 Project Managers, 1 Strategic Lead Dates: January 2014	7	6	113
Time Point: ***Mid-Point*** Participants: 4 Project Managers, 1 Strategic Lead Dates: June 2014	5	5	97
Time Point: ***End-Point*** Participants: 5 Project Managers, 1 Strategic Lead Dates: January 2015	6	6	105
Subtotal	**18**	**6***	**315**
Cross-Sectional Interviews	Number of Items	Number of Participants	Number of Pages
Participants: 1 Clinical Specialist Physiotherapist, 1 Weight Management & Physical Activity Specialist Dates: March – April 2015	2	2	32
Participant: 1 Consumer Get Active 1-1 Interview Dates: May 2015	2	1	29
Participants: Champions 1 Lay Rural Champion, 1 Lay Urban Champion. Dates: November – December 2014	2	2	49
Participants: Stakeholder Interviews with LiU Consortium Members. 5 Industry Professionals, 2 Voluntary Professionals, 1 Local Authority, 1 Government Official, 1 Academic Professional. Dates: July – October 2014	11	10	169
Subtotal	**17**	**15**	**279**
Focus Group	Number of Items	Number of Participants	Number of Pages
Participants: 5 Get Active Consumer and 2 Voluntary Sector Professionals. Dates: May 2015	2	7	19
Subtotal	**2**	**7**	**19**
Grand Total	**37**	**28**	**613**

Table 5A – Cross-Sectional, Longitudinal and Focus Group Dataset (*=Repeat Interviews Same Participants)

5.2.1 Theme 1 – Political Landscape and Rationale for Change

While there was a political imperative to embrace change and new ways of working as documented in the scoping review, it is important to bear in mind that the LiU deployment began at a time when Scotland and the

NHS in Scotland was experiencing a period of austerity on a background where major cuts were being made to existing services. This context in itself could serve as a potential implementation barrier as the comment from a LiU implementer illustrates:

"*[It] can make it difficult for people to see the value in something else that has been developed when it's not about a replacement for what's been cut but it's a different way of working…there's that kind of cautionary*" – *Project Manager*

In addition, the fact that resources were already stretched to cater to population demands meant that negative attitudes towards change extended to the practicalities of this change and the uncertainty ahead. Implementation facilitators included helping to shift mind-sets by ensuring local needs are in line with national priorities and highlighting the added value and beneficial difference of LiU in comparison to traditional solutions and ways of working whilst reinforcing the wider objectives of the project.

5.2.1.1 – Subtheme 1 – Streamlining National and Local Priorities

It is noteworthy that at the time of the LiU deployment in the background there was considerable political uncertainty because the Scottish Independence Referendum debate was underway In the midst of this discussion, it was largely agreed by consortium members that the outcome would neither positively or negatively affect the project. Many stakeholders involved in the project wanted to be seen as being at the forefront of innovation and saw LiU as a ground breaking endeavour attempting to provide solutions that were scaleable on a national level:

"*we are proud of living it up being a Scottish project but it's going to reach wider than the referendum…it's going to be an international project…the model it's been built on people are going to be interested about…people are going to be interested in us as a country, creating this model*" – *Government Representative*

The need to map the local needs of the community within the various LiU implementation sites with national policy such as the wellness agenda was a key part of demonstrating to the population that their concerns were actively being addressed at government level in a new and creative way:

"*So looking at how do we get all what people are saying on the ground and telling us, how do we make sure that aligns with policy and objectives that are coming from top down*" – Lead Manager

In addition, the need to explore a range of strategies that would promote successful adoption and utilisation of LiU was a point of contention amongst stakeholders. There was a strong consensus that an element of compromise and meeting in the 'middle' would be required in order to drive forward local service needs from the bottom to align with top-level policy makers enforcing national priorities.

"*To a certain extent we are always wrestling with this bottom up and top down approach so from the Scottish Assisted Living Programme (SALP) perspective and the various other government bodies sitting on that it is very*

much about ok, this is where policy is moving to so adult social care integration a key policy agenda you need to show how what your doing is actually driving that forward. Whist at the bottom up we have very much said it is always about local partnerships and that those local partnerships feed the definition that the Joint Improvement Team (JIT) have been working on for quite some time, so it's not just health and social care on the ground its very much about the voluntary, independent sectors etc. So it's both, we are trying to work across to meet in the middles" – Government Representative

5.2.1.2 – Subtheme 2 – The Need to Create Choice: Added Value [Pooling Resources: Optimization]

The need to create choice within health and social care is very much welcome as a means to promote personalised self-care in the digital age. Various stakeholder groups such as carers, clinical professionals and voluntary service groups were often able to identify potential long-term benefits such as reduced hospital admissions, the potential to enable independence and control, person-centred care self-management, prevention, trusted information, reducing social exclusion, providing peer-to-peer support and identifying service gaps through co-design and how to bridge them. What made LiU distinct from previous projects was the move it was making towards integrating health, social care and wellbeing. A bonus for consumers and care providers was that the LiU service operated free of charge and therefore those with a lower socioeconomic status would not be excluded from the reach of this initiative. At the very top of the political agenda included creating a sustainable health and wellbeing service available any time, any place, anywhere via digital means.

"*We are also looking for ways to cope out with the kind of 9–5 of the normal service hours. So as well as the very healthily orientated information; people are looking for information about wellbeing things, things that can help them manage pain or places they can get support when maybe all the other services are closed*" – Project Manager

Early implementation facilitators included the notion that it is a service developed for you and by you on the largest scale the country has ever seen; with 'you' being consumers, clinicians, third sector, statutory care providers and industry experts. Additional facilitators included incorporating user interaction and creating opportunities for dialogue between users both on the digital platform but also within their everyday local communities. This stimulated the creation of a two-way service where personalised information is 'pushed' to the users finger-tips and at the same time providing means to 'pull' information in an accessible way.

Lastly, what was considered to be the 'star-quality' and revolutionary was the premise that the platform was being setup to pool various sources of information into one place and so members of the LiU community coined the term 'one-stop-shop'. This concept is a model which has flourished in other industries providing choice for consumers to get the best deal for their car insurance, the best deal for their gas and electricity and the best deal for their mobile phone for example. Likewise, LiU sought to offer users the opportunity to get the best 'deal' for their health and wellbeing by providing trusted information at the right time, in the right place, on the right device suitable to them (multi-channel) all in one place. Instead of having to go online and visit various

individual websites the 'added value' is that solutions to community needs are harnessed in one place. The potential to 'franchise' the LiU business model in the future community was also considered to be the most valuable asset of the platform.

"*I suppose it's about…how can we do it so that it suit's people's needs better. It's just about giving people options, I suppose, and letting them have a wee bit more control over their kind of daily routines…people should always have the option…Living It Up should start to become the norm as well as one of the very valid options and popular options as well, that hopefully people choose*" – Third Sector

5.2.2 Theme 2 – Working across Individual, Professional and Organisational Boundaries

Initial efforts in coming together to plan and organise how 'work' was going to be carried out encountered some challenges and covered three main areas as described here. This included the need to align differences in approach and different ways of working across public, private and third sector organisations, the need to establish roles and responsibilities early-on so that individuals involved are clear about what specific tasks will be required of them during the implementation of. The need to develop a common language in order to foster a shared understanding and the challenge of developing a clear channel for dialogue between stakeholders early on. These preparatory activities took a great deal of time to put in place however once they were established and a way forward was created the outcomes that enhanced multi-disciplinary working included a variety of learning opportunities, adoption of new ways of working and a reliable source for innovation.

5.2.2.1 – Subtheme 1 – Complex Multi-Stakeholder Environment: Private, Public & Third Sector

Various obstacles affected initial efforts in developing a shared understanding of the work requirements across individual, organisational and professional boundaries. This included the heterogeneity of the consortium stakeholders coming together and the sheer size and scale of the consortium as a whole. The call to be innovative and demonstrate a progressive agenda implied that at the very core of the project would be a rich diversity of players. This brought along opportunities for open collaboration with innovative ideas that would meet community needs. The dynamics of the consortium consists of stakeholders from a wide range of backgrounds and expertise spanning across six sectors of society: third sector, statutory sector, industry, health and social care, housing and academia. Each stakeholder group held a different set of priorities, expectations, organisational cultures and ways of working. For instance, public and private sector partners clashed in particular as the working dynamics and pace of work almost entirely conflicted.

"*the difficulty is that you've got a large consortium, lots of different partners, lots of different agendas and perspectives, and the other thing is the way that we've structured ourselves*" Lead Manager.

"*I've certainly learnt that a statutory provider has quite a different approach to a private company. A private company you can do deals with them and not really have to worry about it. You can just, if you like another*

organisation you sit down and say, yes, we'll work with you. Whereas a statutory provider has to have a much more arm's length approach. And that's been a learning point for me, if nothing else" – Industry Tech

Further to cultural and organisational differences was the fact that there was a great deal of difficulty in developing a common language to communicate between consortium members. This was a major constraint and barrier in organising how consortium members were going to operate during the lifecycle of the project as a whole. Several stakeholders inherently used professional acronyms alien to others and therefore there was a need to develop a common 'language' or manner of communication that would be understood by all members

"*One of the biggest challenges has been communication with a number of partners that we've had and just how within the depth of the project, there's almost two or three different languages go on. There's a very health focused language, there's a very technical language, and that took quite a while to do some of the jargon busting around that, and I remember in some of the early co-designs, we thought we were going away having made decisions and quite often, people's understanding of what we'd agreed were different because they had different understandings of what the terminologies meant*" – Project Manager

In the interim, the Project Management Office (PMO) informally played the role of 'translator' between consortium stakeholders although this approach was not practical in the long-term. Therefore, consortium members made efforts to learn the 'basics' of each stakeholder group language, speak in lay terms as much as possible and also produce a standard glossary which helped to provide a strong foundation with which to communicate.

"*We've all just had to learn each other's terminology…different professions use different languages within their own organisations…and it is just a bit about learning each other's, learning and understanding each other's language and terms and descriptions. I think there is a glossary…the more you're involved in it the more you tend to pick up the differences and the more we try and talk in lay speak*" – Project Manager

An additional factor that required due consideration was that ordinarily many stakeholders would be working in competition as opposed to collaboratively and this new set of dynamics of being collaborative working in the best interest of a consortium was seen as a challenging concept to digest at first. Industry partners in particular found the concept to be challenging in the planning stages. The need to adapt their thinking and ways of working defied the traditional customer-supplier boundaries.

"*There was certainly tension in the early stages of the project, whereby NHS 24 were definitely seen to be the client. We were subcontracted by NHS 24, but very early on they, kind of, kept saying to us, oh, you're the consortium; you've got to come up with solutions, which was a very difficult way to go about organising things. You've basically got half a dozen commercial companies, you know, each trying to win business, being told to*

work together, collaboratively, you know, and that's to a relatively wide open vision. It's a very difficult thing to do. We're effectively competitive businesses" – Industry Technology Firm.

However, retrospective and longitudinal reflections from stakeholders working across boundaries included the wealth of learning opportunities that multi-agency working has introduced.

5.2.2.2 – Subtheme 2 – Establishing Roles and Responsibilities

Several issues arose in the early stages of the project with efforts being made to recognise how stakeholders were going to 'come-together' and work collaboratively within the confines of their various organisational standpoints. Exemplar:

"*It was important and crucial for stakeholders to identify a collective purpose in meeting the objectives of the programme: Just getting everybody in the room … to develop their relationships across the different organisational structures and to develop a shared vision. So … what is it we are really trying to do? How does that meet everybody's agendas? Are you engaging with us and are you going to drive it forward from your different organisational perspectives?*" – Manager

In the first instance, some project managers demonstrated anxiety as roles and responsibilities were yet to be established. This anxiety was exacerbated as concerns arose with regards to 'whose voice counts', be it who shouts the loudest, who is considered to have most influence or who would be the likely decision-maker. All of these concerns were major issues which programme leads took time to address in order to encourage free participation, fairness and equality amongst the consortium. However, in the meantime the 'show must go on' and therefore effects of the initial disarray led to a mismatch in roles and responsibilities with some consortium members taking up responsibilities which did not necessarily match their professional or organisational expertise.

"*There was a kind of confusion or blurring of roles and responsibilities" … I think sometimes the term 'co-design' or 'co-production' has been confused and what sometimes has happened is that we've failed to acknowledge or to draw on the expertise that particular people have*" – Project Manager

It was also the case that when roles and responsibilities were established, the ethos that the project operated using an agile and flexible approach (not usually adopted within the NHS) meant that a) the demands of some implementation activities were underestimated and b) this required further learning on the job. For instance, project managers of LiU implementation sites were in the main seconded to this position from the NHS or Local Authority and it was largely expressed that they had to learn to adapt to 'wear several hats' from the very beginning and as the role evolved in order to understand their individual requirements as part of the collective implementation process.

"*I know I can't be a perfectionist but I feel like jack of all trades and absolutely master of nothing!*" – Project Manager [S3].

Longitudinal reflections on establishing roles and responsibilities demonstrate that for future large-scale complex digital health projects, commissioners would need to be mindful and factor in additional time into the funding period in order to accommodate for crucial sense-making activities.

"*I think in terms of, you know, responsibilities...I think it is much better now than it was, like, a month and a half ago when I started. I think it's much clearer, there's been a restructuring of the support office, I think that makes things much clearer. But I think previously we would have been very confused about, you know, we're making a leaflet, can we just make it? Do we need to send it to someone? Who do we send it to someone to check? Have we sent it to the right person? It seems to have disappeared into the abyss. And I think, yes, so, but I think that was mainly a result of there being a lot of work, there not being a huge amount of people doing it. It being a bit multi-board thing*" – Project Manager

5.2.3 Theme 3 – Difficulty in Developing Clear Communication Channels

The inconsistency of general communications throughout the project was another point of contention and factor affecting sense-making activities. Implementation barriers included inconsistency between national and local communications across the project, repetitiveness of planning and reporting activities a feeling of communications being a one-way street imposed from top-down, a loss of control with project-planning in the 'dark' and general miscommunication. However, implementation facilitators included developing an understanding of the 'bigger picture' and a sense of the knock-on effects from inadequate project communications as a whole.

5.2.3.1 – Subtheme 1 – Disconnect between National and Local Communications

Several stakeholders highlighted the practical difficulties that they faced when trying to implement national objectives into actionable activities on the ground in relation to service specifications and service developments. There seemed to be a great disconnect between national communication plans and local plans which led to several implications on the ground. For example, LiU project managers strongly expressed the view that delays with the national communications plan hampered local progress and even this impacted the level of trust and relationships forming in some of the local communities. Project managers at times were eager to press forward with particular key messages and priorities of their respective region, although it was largely agreed that professional autonomy was negatively impacted due to delays with national communications.

"*We've waited so long for the national communications plan and the content plan from the support office to come out. What's happened is we've been held back on doing things locally which has made it difficult for us… I think the, sort of, general communications throughout the project has maybe been a bit of a barrier in that often there's uncertainty around particular things and sometimes these things actually, you need an answer one way*

or another because it's having an impact locally on some of the different partners and that can be difficult and I think that's where we've potentially, where we've built up relationships and established them we've then sometimes lost a wee bit of trust because we've not been able to keep going at the same pace as what we thought we would be able to" – Project Manager

Longitudinal reflections illustrate the importance of establishing clear channels of communication early on. The co-design and co-production meetings themselves presented opportunities to develop relationships between stakeholders and collective growth as a consortium. These meeting points also helped stakeholders to reflect on their position in the project 'supply chain'.

5.2.4 **Theme 4** – Challenge in Cementing Legal Contracts Pre-Implementation

Planning and readiness efforts were greatly undermined at the beginning of the project due to difficulties in cementing legal contracts with stakeholders and in particular with industry companies tasked with developing digital health products and services. These contractual difficulties stemmed from issues in relation to the legal clauses and language used to 'set in stone' agreements from the traditional customer-supplier language to a partnership language, concerns regarding patients and intellectual property (IP) rights and changes of the traditional tendering process Implementation barriers included having to 'work at risk' which refers to contractual difficulties which were problematic and which meant companies had to accept delayed finanacial payments however implementation facilitators included the development of trusted relationship and drafting a letter of intent between programme managements and stakeholders in order to overcome contractual difficulties posed by "working at risk".

5.2.4.1 – Subtheme 1 – The Art of Negotiation

During the early phases of the project, drawing up the legal boundaries in which to commence the 'work' of implementing LiU proved more challenging than originally envisioned. LiU programme leads experienced setbacks from the very beginning due to the complex nature of the consortium and therefore this task required more time and attention to enable negotiations to take place. These 'setbacks' included an overlapping existing agreement with a stakeholder organisation and disagreements in relation to Intellectual Property. Industry stakeholders were pushing for the use of 'Lambert Agreements' which have been endorsed by the UK patent office where there is potential for unique innovation to be created, this would enable organisations to have ownership and protection over their intangible works; whereas programme leads took the position of using the traditional customer-supplier template for works within the project. A particular industry organisation was awarded the opportunity to work across Scotland and England and therefore made a key comparison in how this choice in some respects hindered the collaborative ethos of the consortium.

"*It's been painfully long, and it's maybe simply that NHS 24 is used to being...It's used to a customer supplier relationship, and all the contractual stuff that came out at first was all written in customer supplier language…dallas is really trying to get this partnership and it's taken us a long time to sort of batch this contract from the user or customer will do X, Y and Z to one which sounds much more like we will do this together. So, it took us a long, long time. If I can contrast to Liverpool, Liverpool were much more recognising that this was a consortium, and that it was a collaboration. And the contract we signed with Liverpool, it took us about three months of negotiations. Whereas with Scotland, sorry, with NHS 24 it's taken us more like a year and a quarter*!" – Digital Health Industry .

Legal agreements with all stakeholders were only finalised and signed approximately two years into the project. The delay was as a result of limited stakeholder engagement and complicated internal administrative procedures within some stakeholder organisations. This was a time of great uncertainty and high risk as there were concerns that limited or non-participation could lead to withdrawal of a stakeholder and limitations for the project. This was the case for one industry partner that seemed to disengage during this process and further action was required to enable open dialogue whilst legal negotiations were still occurring.

"*There was a huge bureaucratic delay in getting the thing set up and a contract out… The project was officially meant to start in June…you know, as a delivery partner, we did not get a contract until the following January. So, you know, we worked at risk. You know… to try and be a good partner but, you know, for a business that's not satisfactory and that means that you can't commit all the resources you would like to when you don't know if you're going to get a contract*" – Digital Health Industry

Understanding how to plan and operate within unstable realms was very much a challenging task. Several executives of industry organisers therefore agreed to proceed only with a 'Letter of Intent' in place.

"*We can't do this [Working at Risk] anymore. We have received instruction from our parent company we've not to do it …they put a halt yes so very quickly there was kind of various high level I won't say panic meetings but high level meetings and quickly a kind of written agreement was given so …what's called a letter of intent"*– Information Technology & Consulting Company.

Having a written '*promise*' in place meant that work was authorised to be actioned whilst there was on-going discussion regarding the resolution of the legal agreements. Although the effects of the delay in resolving these extensive legal issues led to several financial implications that hampered morale among stakeholders within the consortium. The financial approval process for work that was complete was so far behind that many stakeholders raised concerns about progress all together. However, the use of the written 'Letter of Intent' proved to be a key facilitator in fostering the development of LiU from being effectively stationary to one that was now making progress. Consultation with the SALPB management board and Innovate UK was another

success strategy that helped to circumnavigate difficulties and this re-enforces the importance of having flexible dynamics within such an innovative project.

5.2.4. 2 – Subtheme 2 – Developing Trusted Relationships

The notion of trust between stakeholders was a significant factor that helped stakeholders to develop a professional but friendly bond that changed the dynamics of the traditional customer–supplier relationship and the tendering process. Industry stakeholders expressed that operating within the confines of a collaborative consortium provided a greater deal of freedom in relaxing some of the formalities in working across individual, professionals and organisational boundaries. For example: the selection process for community seeds to become a part of dallas was judged within EU law [Script: 29]. Therefore for the duration of the project and the period of the contracts "*we can work together without the need to do any further tendering*". This introduced new ways of working which helped to drive the collective vision of the LiU platform forward.

"*Normally that relationship is one of customer–supplier, and the public service has a very thorough obligation to treat all private organisations equally. You know, no favours, no special conditions and that's fine when you're trying to buy… It's just a question of who makes the cheapest [product] that passes the requirements.* – Health Information Technology Company

This industry stakeholder in particular further explained that in order for there to be innovation there needs to be trust; hence the need to develop trusted relationships as part of a cohesive unit early on is crucial.

"*But it's not a good way of handling things when you want to do innovation, because with innovation you need trust, you need a relationship, you need the ability to be able to say, in a trusted way from one side, this is what we want, and the other side says, well this is what, at the moment what I can deliver, but maybe I can move towards that over the next six months. "And that's the only way that you can do joint innovation. And that's basically what Dallas has delivered. We've moved from a customer supplier relationship to a more of a partner relationship. And I think that's absolutely essential to solving some of these problems that we have in using technology to provide health care. So I don't want to just be the telehealth guy. I'd hope we can be broader than that. I'd hope we don't go back to customer- supplier"* – Health Information Technology Company.

Many of the stakeholders had no previous joint working history and therefore the concept of trust set precedence in working collaboratively. In many instances where stakeholders would normally be fierce rivals, they were in fact actively thinking in the best interest of the project. A large part of fostering a successful implementation depended on identifying the right stakeholder with the right expertise to take on appropriate work even if it was originally allocated to a different stakeholder. In the following example, the industry stakeholder was explicitly honest and took on the concept of being '"*my brother's keeper*" by actively recommending another consortium member to lead managers as an appropriate partner to take up that work.

It is highly uncommon for a business to pass up an opportunity to generate additional revenue under usual circumstances and therefore this was an interesting finding.

"*The technical partners have shown they are willing to be flexible. So they have perhaps for very high level reasoning for the greater good of the society …we had an example two weeks ago whereby one supplier was asked to do a piece of work and we said yes we can do it and we'll charge you for it but they suggested another supplier would be better placed to do that work. Rather than just saying oh great it's more revenue for my company. They are saying well actually given the history the relevant partners this type of thing is better done by B instead of A and it was A that was saying that!*" – Information Technology & Consulting.

5.2.5 Theme 5 – Central Leadership and Management of Vision and Strategy

The challenge of establishing a shared vision that is understood across working boundaries and levels: local and national is a crucial component of coherence. In addition, mindful management of 'work' to be completed and the associated organisational processes is an important factor in the co-ordination and direction of a project. In relation to complex digital health innovations, establishing central leadership at the very beginning is key for all stakeholders involved. There were several barriers experienced by stakeholders working at grass roots levels such as the perception that there was no clear national plan to spearhead the endeavour, mismatch between service re-design expectations, ever-changing project scope and a lack of central leadership felt by stakeholders operating on ground level. However the setup of steering working groups proved to be a key enabler in developing a clear working strategy to meet the overall LiU vision. Another facilitator was the way in which the PMO was structured which enabled close working relationships to develop between local partnership area leads . The project structure in line with the ethos of the collaborative consortium was also setup in a way to prevent one partner 'monopolising' the project.

5.2.5.1 – Subtheme 1 – Creating a Clearly Understood Vision across Working Boundaries & Levels

It is important for the LiU implementation team (all stakeholders involved) to have a clearly defined shared vision for innovation. It became evident during the course of the LiU implementation that the central vision was not clearly understood by all stakeholders, especially those working on the ground For example a project manager explained that the national plan was not clear enough to enable her to ensure that the local plan meets national priorities as well as local user needs. In addition due to the grand scale of the endeavour there was a clear consensus and feeling amongst all project managers that some key project tasks emerged spontaneously which caused further uncertainty.

"*I don't think there has been a clear plan, a national plan so that we could then draw up our local one and know what's coming…if we had a national plan that sort of said right in this month we are going to be looking at*

benefits and realisation and this month we are going to be looking at something else. We would know and we would be able to plan for that. We haven't been able to plan; firefighting really would have dealt with it!"

– Project Manager

An additional barrier which was considered by project managers to impede the pace of progress was having an understanding of the required individual and collective *workload responsibilities* from the outset. Working on a large-scale project at such a dynamic pace in itself requires a defined skill-set to manage competing demands and to prioritise work. It was felt by one participant in particular that there was a sense of confusion at times due to insufficient time to factor in and make sense of the individual work they have been asked to do and how that fits into the wider frame of work. Given this degree of uncertainty, many stakeholders felt that the scope of the project seemed to creep and become more complex. It seemed challenging for implementers to balance the commitments of the role in line with the overall vision of the project. Although due to the iterative nature of the project there was an initial assumption that the scope of LiU was largely going to evolve overtime and therefore as time passed the scope became more defined and clearer.

"*Lessons learned…I think…probably about scope, the scope of the project. I think it took us quite a while to scope the projects, so I suppose it would really be a lesson learned there, but it's difficult, because it's based in community engagement…but we maybe should have perhaps thought about the scope of the project before, early on, but these are just… these are hindsight things. You don't really know these, because it's such a journey*"

– Project Manager

Industry stakeholders largely expressed the view that due to the ever-changing scope, their general work practices were affected. It was clear that their involvement became fragmented and information was distributed on a need-to-know basis. These findings suggest that it is crucial to ensure that when planning, designing or commissioning a digital health service, that there are sufficient provisions made to uphold a coherent vision across all working boundaries and levels. Most importantly, all stakeholders need to understand and be fully on-board with their required input from the outset. Reflective accounts from industry stakeholders with regards to creating a clearly understood vision illustrated that careful consideration is required to prevent different translations of the same vision occurring. In the case of LiU, early insights demonstrated a mismatch between stakeholders and the service re-design expectations

5.2.5.2 – Subtheme 2 – Formal Leadership, Management and Governance

In the case of LiU, there were clear national and local leadership structures in place, with the setup of several boards and committees to maintain accountability and stakeholder responsibilities. The reporting and governance structure set out to ensure a clear and transparent flexible hierarchy with the establishment of local partnership steering groups, a life sciences advisory board, an NHS 24 clinical governance committee, and the Scottish Assisted Living Programme Board (SALPB) all of which are ultimately accountable to the Scottish

Government, Health and Social Care Directorate. However, there were mixed feelings that were experienced by project managers, industry professionals and clinicians regarding available support on the ground; as a lack of support was seen as a detrimental factor with several implications. These included changes in key figures such as the loss of two regional project managers, the loss of key industry stakeholder partners and difficulty securing a common ground with clinicians. A few project managers for instance seemed to be struggling with the demands and responsibilities of the role as it was largely expressed that a strong leadership presence was absent for quite some time in the early phases of the deployment.

One regional project manager expressed her anxiety in having to press on reluctantly without adequate support in place. Exemplar: "*Personally, and I may be just a one-off but I struggled because I didn't have support. I didn't have strategic leadership for a long time. And I plodded on, on my own for a long, long time and it was quite demoralising- Project Manager*

Another regional project manager expressed that clear lines of communication failed to be established between programme organisers, strategic leads and stakeholders quite early on in the project, and that this was largely due to the structures in place as well as and a lack of committed support as felt by project managers. A lack of communication also proved to incite additional frustration for project managers and industry professionals, particularly when they were not able to internalise the value of work that had been delegated to them.

"*For a period there was this, kind of, two-sided thing, where, on the one hand we were told that NHS 24 wasn't a client, but whenever anybody wanted to do anything different, or, you know, slightly differently, if NHS 24 came in and said they did want it or they didn't want it then their word was final. A little bit of confusion, even amongst themselves, as to what their role was. You know, they kind of… They didn't want to have to make the decisions, but they also made that making decision"* – Digital Health Industry.

A lack of formal leadership, support and strategic direction are factors which were seen by the majority of implementers to hamper a shared vision and strategy in the realisation of LiU in practice. A wide range of implementers including third sector professionals in particular felt that the way in which LiU had developed over time had strategic benefits, such as creating capacity for knowledge translation in terms of the ability to be made aware of the progress of local implementation initiatives by being able to share and compare activities; furthermore it was felt by some that the structure of LiU provided clear channels for feedback lending itself nicely towards developing a shared understanding.

To ensure stronger programme leadership, the setup of several steering groups: service, technical, exploitation and sustainability were established with a number of key partners tasked with responsibility of formally reviewing governance. For example the Digital Health and Care Alliance (DHACA) were responsible for developing interoperable standards concerning the implementation of systems, services and products. These

governance changes helped to improve communication between stakeholders in developing a stronger support and accountability network.

"*Having things like our service steering group, where we go for a day once a month, with... as product owners, and we hear about other products, as well as your own product. So I hear about Discover and Shine, and the other services, and I know what's happening... You know, it's like you're reporting on your... on your progress, you know, things that may be an issue, things that are going well, things that are complete, and it also enables us to think about links, where our different services might have links, so they link up... I think we all get so much out of that service steering group that helps our understanding of the broader Living it Up, and not just the product that we're working in"*. Project Manager.

A consequence of having a large and complex consortium naturally raises concerns over the degree of stakeholder involvement. Statutory and third sector stakeholders in particular were concerned about being locked into a particular supplier and project leads were equally concerned about managing demands. Therefore, the need to uphold a strong visionary presence overall proved to help prevent the 'monopolisation' of the consortium as a whole. The focus shifted towards increasing local autonomy and ownership of delegated work as opposed to dealing with inherent 'politics of implementation' in the midst of a large multi-stakeholder environment.

"*So the politics we are managing right now with [Manufacturer A] and [Manufacturer B] are pretty significant. So there are things that we can't do just because someone says it*" – Project Lead

5.2.5.3 – Subtheme 3 – The Need for Start-Up Organisational Support

Identifying the appropriate resources to ensure that preparatory implementation activities such as ensuring that there are sufficient start-up funds, personnel and adequate time to support implementation plans proved to be an important factor. Few project managers voiced their concerns regarding the division of the initial funds. Some project managers felt that the allocation of funds to the implementation sites were disproportionate. For example one project manager in particular mentioned that their implementation site was much larger and geographically challenging in comparison to another, furthermore they experience issues with technology and mobile network coverage to greater extent than the other.

I do feel that even the national sort of resources weren't divvied up fairly … I don't know if you know the size of [Area]. Well it's the size of Belgium. So it's a massive area with a lot of islands…It's huge it's got a lot of mountains; we've got [Land] in the middle … so we don't do well with technology; we have a lot of problems with mobile phone signal coverage [S15] – Project Manager

It was clear that this was an issue early on in the implementation process that required a significant investment in terms of providing the support for start-up activities and the people working on the ground. However, the set-up of the PMO office early on helped to facilitate this issue by listening to the concerns of the project managers and making plans to resolve it in line with the project milestones. The recruitment of 'Community Support Managers' during the subsequent buy-in and engagement phases helped significantly as discussed in the next section.

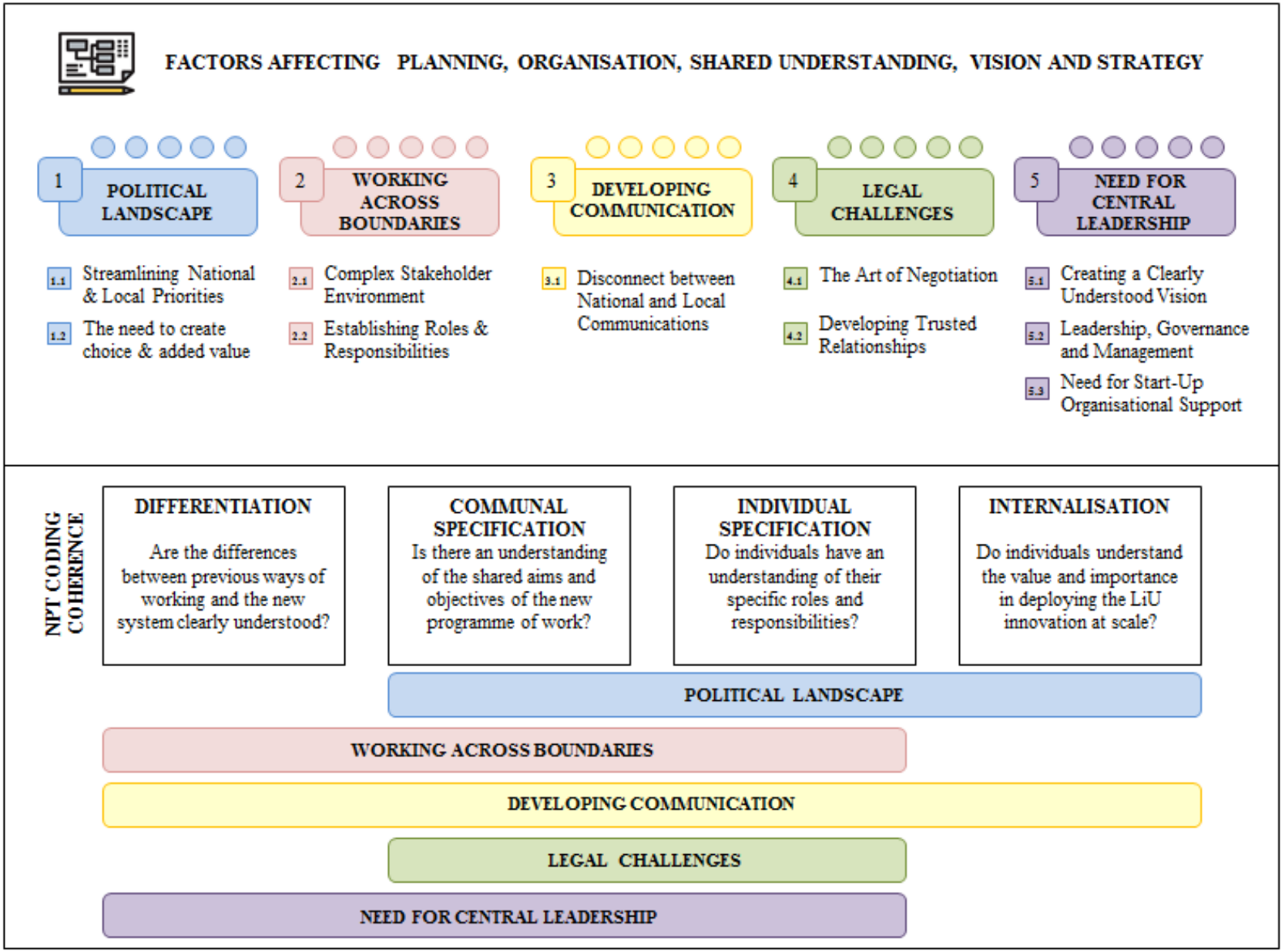

FACTORS AFFECTING PLANNING, ORGANISATION, SHARED UNDERSTANDING, VISION AND STRATEGY
1 POLITICAL LANDSCAPE
1.1 Streamlining National & Local Priorities
1.2 The need to create choice & added value
2 WORKING ACROSS BOUNDARIES
2.1 Complex Stakeholder Environment
2.2 Establishing Roles & Responsibilities
3 DEVELOPING COMMUNICATION
3.1 Disconnect between National and Local Communications
4 LEGAL CHALLENGES
4.1 The Art of Negotiation
4.2 Developing Trusted Relationships
5 NEED FOR CENTRAL LEADERSHIP
5.1 Creating a Clearly Understood Vision
5.2 Leadership, Governance and Management
5.3 Need for Start-Up Organisational Support
NPT CODING COHERENCE
DIFFERENTIATION
Are the differences between previous ways of working and the new system clearly understood?
COMMUNAL SPECIFICATION
Is there an understanding of the shared aims and objectives of the new programme of work?
INDIVIDUAL SPECIFICATION
Do individuals have an understanding of their specific roles and responsibilities?
INTERNALISATION
Do individuals understand the value and importance in deploying the LiU innovation at scale?
POLITICAL LANDSCAPE
WORKING ACROSS BOUNDARIES
DEVELOPING COMMUNICATION
LEGAL CHALLENGES
NEED FOR CENTRAL LEADERSHIP

Figure 5.1

5.3 Factors Affecting Engagement, Participation, Recruitment and Buy-In

This section explores the positive and negative factors affecting the engagement, participation and buy-in elements impacting the implementation of LiU in practice. There were five factors identified which affected the engagement work and these were as follows: 1) Methods of Consumer and Patient Engagement; 2) Identifying the Need or "Hook" and Retention; 3) Re-Branding Living It Up , 4) the Need to Engage Clinicians Early on to Secure Clinical Backing / Endorsement and 5) Champions: Community Individuals and Community Organisations and 5) Methods of Consumer and Patient Engagement. The findings discussed in the next sections and how they map onto the Buy-In Constructs of the NPT conceptual framework are outlined in Figure 5.2.

5.3.5 Theme 5 – Methods of Consumer and Patient Engagement

5.3.5.1 – Subtheme 1 – Face to Face Engagement & Novel Tools

The strategy used to facilitate engagement, participation and buy-in focused on four areas which were face to face, the use of the local media, creating means to upskill and socially include and lastly large-scale initiatives. The face to face element accounted for a large proportion of the initial start-up resources as well as implementation as a whole. It presented many benefits such as the ability to explain the concept of LiU being developed using co-design and co-creation with members of the general public and a wide variety of stakeholders.

But I think given that the early stages of recruitment we can see that what's actually worked has been face to face contact. Yeah, that to me suggests that there is a good bit of trust and relationship building that needs to be done within each of the areas and I think to do that you do need to have a physical presence there – Project Manager [S2]

However because LiU was still being actively developed it was a difficult concept for people not involved in the implementation process to grasp, so there were problems posed by having a constantly evolving product as described in Chapter 4. The one-to-one interaction helped to initiate engagement and then participation with the portal platform; however it was insufficient in terms of retention of users to the portal. Therefore it was clear to see that there were different approaches to consumer engagement that needed to be considered whilst adopting an agile methodology. Importantly, the large scale of recruitment required as a programme deliverable also presented challenges as it was clear one to one engagement for recruitment was not a viable way to recruit tens of thousands of users as the comments below illustrate.

"I think the face to face element we are able to explain what we are doing and the potential of feeding back on their experience of using the portal but the challenge is if somebody else comes along because they've just seen an advert or they have just heard about it… or somebody has told them about it and they come on and they have a look and if there isn't a clear message at the moment on the site anywhere to say this is in development. we

flagged that up and they are looking at what they do about that but there's also there is maybe not enough things there to keep people coming back or the other issue at the moment with service is that they don't have to sign up to use most of it so there is very little that they actually need to register for so they can go on and do lots of things on it and not actually have to register." – Project Manager [S6]

" I think so far just about all of the recruitment has been through face to face and that's not sustainable and it's, we are not going to make the, we are not, well in area x we have eleven hundred but across the five areas, 55,000 people aren't going to be recruited by face to face contact– Project Manager [S2]
Once they walk away then you've lost them. – Project Manager [S6]

While it is clear that the face to face strategy provided great benefits in facilitating the 'word' to spread about the LiU programme throughout communities, particularly small remote or rural ones due to the novelty of the concept it proved to be a real challenge on the ground due to the scale of recruitment required and therefore additional methods of engagement had to be explored to help build upon all the work that had be done during the face to face stages.

5.3.5.2 – Subtheme 2 – Local Media and Press

The use of local media and press within the five geographical areas was thought likely to enable a larger impact on the ground. This strategy was used in addition to face to face as a way of creating an opportunity for 'locals' to identify and network with others in their community and to encourage a community spirit that would help to increase the chance of a scalable innovation.

"*Because at the moment it has very much been local messages and we've not advertised particularly using any of the press yet at all so we are going to be doing that just in the next month or so and I think both of those things together will help us deliver that message at scale" – Project Manager [S1]*

5.3.5.3 – Subtheme 3 – Early Recruitment: Upskilling and Social Inclusion

Social inclusion and the need to digitally upskill potential users proved to be challenging at first but the efforts and investment in upskilling and inclusive approaches which promoted access to technologies reaped many benefits. Some of the implementation sites served underserved communities, and those living in remote-rural areas with difficulty accessing health and wellbeing services as well as many older people. One clear facilitator which helped to build the confidence of users was the ability to network with local libraries in the area as a means of creating a space for people to 'meet' and take up a 'free' IT Class. In this capacity the strategy used here was to integrate the use of the portal with everyday activities.

"I think some of the barriers have been around when you first start talking to some of the older people, they say, oh, you know, that's not for me. I don't have an email, or I don't have… I don't have time to do that. But once you start talking to them you begin to realise they are using bits of technology and they are interested in finding out how to do more… They just need somebody sitting beside them, I think, and just chatting them through some of the steps – Project Manager [DA10]

I mean we've got, we've got an older person's development officer who at the moment they are doing a body project so they've got school age children linking up with older people and showing them how to use [technology]. But I've also made links with the local library because they offer IT literacy courses and basically trying to bridge the digital divide. They are going to be trying to recruit people and as part of their literacy course they are going to give people living it up to go and try and comment on so it's almost like a little exercise for people who are just getting into computers. And that sort of thing so I've made links with them so that we can sort of try – Project Manager [S3]

I've hooked in locally with digital participation, they can spread the word, and libraries, they do adult IT literacy courses, and they're using Living it Up as an example website" – *Project Manager [DA10]*

The use of 'coaching' for staff members and implementers on the ground proved to be a successful strategy adopted by the community engagement team to help boost recruitment of users to the platform. It also served as a means for sharing of skills and efficient use of man-hours and resources to enable a 'train the trainer' approach to be established.

"In my role, I'm managing a small team and they're involved in community engagement and going out and promoting parts of the website that has been developed and asking people for feedback so that we can develop the website further. We're involved in recruiting people, so we show them what the portal can do and how it can support them to find things locally on their doorstep or find better health information, or just things to do in the community. So we do a little bit of coaching with people about how to use the portal and how to use the different services that… and we also do workshops locally and we facilitate those." – Project Manager [S7]

Lastly, one project manager in particular identified a unique and innovative method to embed and link the recruitment of users to statutory services. This model was then further adopted in other implementation sites. The Project Manager approached third sector and community organisations such as 'Job Centre Plus' to encourage claimants to think about their talents and how it could be used to the benefit of others. The idea was this 'passion' is likely then to form the basis of a long-standing and fulfilling career.

So, for example, as a result of that I've now developed the partnership with Jobcentre Plus because they encourage their long-term health claimants to do a spot of volunteering or work experience or that sort of thing.

So they have to do that as part of their statutory requirement so we slipped in there and said, oh, actually if you tell them about Shine and they can take up the quiz. And that might help lead them into sort of some sort of voluntary action. ..There is a sort of appetite that people do maybe want to do something but they're not sure what they've got to give or, you know, where to give it to. It may help just push somebody in the right direction. – Project Manager [S15]

5.3.5.4 – Subtheme 4 – Large Scale Recruitment Strategies

Identifying an opportunity and strategy to create a scalable digital health programme was one of the key milestones outlined in the initial plans and documentation for the project. The CET on the ground partnered with a marketing company in order to help create awareness and encourage large-scale engagement and recruitment. This strategy was adopted due to the potential of this option to have a large impact on the implementation sites. Several stakeholders especially the project managers were accepting of this engagement and recruitment strategy early on and were eager for the assistance due to the specialist marketing skills that the company offered.

"A marketing company are coming in and they are specialist in terms of marketing because I don't think any of the project managers are. And called creative and creative are doing some recruitment road shows for us in a few of the areas including my own and they are reckoning that in a week they can get 1000 recruits…We are very interested to see what methods they are using. Because obviously if their methods work then those are things that hopefully, skills that we can acquire and copy as well" – Project Manager [S5]

However, it became apparent during the course of this large-scale campaign that the sales approach and style used in the health and wellbeing sphere on a local level was not as successful as initially thought. It was felt by some consumers themselves that it was a 'hard sell' and therefore it became apparent that there needed to be a compromise in approach to ensure that engagement and recruitment efforts encompassed a level of personalisation on the ground.

"It didn't actually work as well as they expected it to, because it was just a different approach that they took, because they're obviously – the roadshow teams were obviously used to, sort of, selling products and they weren't taking as much time as some of our community engagement staff would, just to find out what the person's interests were and they were doing quite a hard sell and it just didn't sit comfortably with the approach we had used previous to that. You know, it, kind of, jarred with it, so the decision was that actually our own community engagement skills were more effective" – Project Manager [S16]

Therefore, the strategy adopted moving forward was to combine the effective community engagement insights from the initial efforts to be used alongside social media in order to leverage impact and facilitate scalability.

"We've now got a social media policy, so we are building our local Facebook and Twitter sites, so we're building good reach through those media. We're engaging with those local organisations to help them advertise events and activities that they've got going on"– Project Manager [S7]

"I think the support office are working on a campaign to see how that can be used to drive people to the portal and then to sign up. That's one thing. And our local Facebook page has got over 500 likes just now. So, we've got a good following there" – Project Manager [S9]

5.3.2 Theme 2 – Identifying the Need or "Hook" and Retention

5.3.2.1 – Subtheme 1 – 'One Stop Shop' – Pooling Resources into Single Source [Optimization]

Identifying the underlining incentives to engage with the platform was one major theme that emerged during the course of the implementation process. A key aspect of the LiU service, unlike many platforms and websites previously on the market, is the ability to enable a 'two-way service' and two-way communication so that consumers are not merely passive participants but also active participants. In addition, the LiU platform set out to create added value by becoming a 'one-stop-shop' for consumers for all their health and wellbeing needs. Similar to a comparison website in other industries, LiU was designed to pool information and services into a single resource to ensure that the user is able to receive the best 'deal' and information, at the right place and time, suitable on the right device and in the right format.

"The added value is it's a one stop shop. It offers citizens the opportunity to interact and be communicated with by the Living It Up support managed service. Most sites located in Scotland that promote health or promote care or promote wellbeing are a one-way service, as they give information and the user gives them information. We went the next step on from that by actually allowing interaction so using things like the experience guides, using some of the tools, building a profile... we can then actually interact with them on a monthly basis, a daily basis, you know, and they can get a personalised experience" – Project Manager [S1]

"So whilst you can with NHS inform and indeed... what's the other one whose names escape me right now, the difficulty is that you as a user have to have been told about all these websites or know about all these websites, whereas now you can just be told about one website, so I think it's a lot easier to remember and are much easier to access as well" – Voluntary Third Sector [S20]

An additional aspect of the LiU platform which proved to be a unique selling point was the ability for the platform to cater to the needs of people outside the usual 9-5 working hours and 7 days a week. This degree of flexibility proved to be a popular incentive to encourage buy-in during the course of the recruitment and engagement activities. LiU branding started to be seen as a "trusted friend"

"And are also looking for ways to cope out with the kind of 9 to 5 of the normal service hours. So as well as the very healthily oriented information people are looking for information about well-being

things, things that can help them manage pain or places they can get support when maybe all the other services are closed" – Project Manager [S1]

5.3.2.2 – Subtheme 2 – Selling a Concept: Motivation to Engage

The novel aspect of the LiU project was the very nature of its concept, design, implementation and continuous evaluation. Adopting an agile methodology to enable 'everyone' in essence to come around the table and begin to create dialogue within the digital health, wellbeing and self-management sphere was new and exciting for all involved. However identifying the best way forward in harnessing all contributions and creating an effective strategy proved to be a 'work in progress' due to the very nature of the methodology adopted. The use of the co-design approach presented both challenges and opportunities that impacted the implementation process. The first being developing creative solutions from scratch requires a great deal of co-operation and patience from all involved especially intended users to enable their perspectives to be open towards a developing proof-of-concept service.

"*Often recruit to something that's finished and I think we've already talked about this at lots of different meetings, but it's difficult to recruit somebody to something that's not done yet. So I think it's becoming easier because it's becoming much clearer what the service will ultimately be and it's easier to recruit when you actually have something concrete to sell. So I think the barrier is it was very conceptual, it was ambitious, it was unclear and we actually needed the people to come with us on a journey and they don't often see themselves as being part of that from an early stage*" *– Project Manager [S8]*

Recruiting to a concept also proved to be challenging with the bulk of resources and efforts being used to engage from the start however at the early stages some initial recruitment efforts were seen as being 'wasted' and it was thought to be more efficient to delay recruitment efforts to once a substantial product had been developed. As while one could "engage" or "discuss" a concept and evolving product, getting someone to register and sustain engagement till the finished product was ready proved more difficult. So over time the programme implementers aimed to enable future users to be able to effectively grasp the concept and design whilst leaving as little time in between recruitment and launch of the final product.

"*So I suppose the project at the beginning was focused on like what is Living It Up, trying to shape it, also at the same time trying to bring in co-designers and recruit to a service that didn't exist and I think that was a big lesson learned. You can't really recruit to that and I think a lot of resources was, wasted would be the wrong word, but a lot of resources were focused on that too much at that point in time. So, again, if I was to start again I would push recruitment way ou*t" *– Project Manager [S8]*

"I think they come with the view that oh this doesn't look finished and you think no, it's not finished.

That's the whole point of it! But I think they struggle with that concept because everybody is so much easier to criticise something that is developed than it is actually influence the development of it so people are very good at criticising ideas that are you know somebody has taken the risk in developing. I think we've actually done well with the community engagement team to actually get their head round how they can influence the design" – Implementation Lead [S6]

The LiU programme in Scotland compared to the other dallas communities across the UK was the only innovation which set out to co-create and co-design from scratch. Selling a concept and recruiting users along the way proved to be most challenging compared to recruiting to a 'finished product' which doesn't require the user to par-take in its development. However they began experience different issues regarding retention of users.

"I think a lot of the other dallas communities came with finished products early on so it's interesting that they're still finding it difficult to recruit to a product that was developed. So I think it's a different issue that Living It Up face because Living It Up very much came from a blank page and then had to try, you know, try to recruit to that blank page where how Year Zero is an example; they had things that they had developed that they were then trying to recruit to and it's interesting that they also had or are experiencing the same challenges" – *Project Manager [S8]*

5.3.1 Theme 3 – Re-Branding Living It Up

5.3.1.1 – Subtheme 1 – Trusted Branding and Marketing

The preliminary scoping work carried out by implementers meant that in order for the LiU programme to resonate with future users, a conceptual model of each service was required with the idea that they will be further developed alongside the ethos of LiU "to be developed for and by the people". However after preliminary community engagement outreach it was clear that the initial names of the services were not readily meaningful to members of the public. It became evident that re-branding work was necessary to help build trust with consumers by enabling them to readily see the 'added value'. For example the '*Exchange'* service which was later re-branded to '*Discover*' was perceived to be a service to exchange goods as opposed to an opportunity for people to ascertain community assets.

"I thought exchange meant like a place to swap things' it's not clear" – User, Documentary Evidence

"*Shine is probably more subtle than actual volunteering if you get my drift. If you volunteer you tend to, you know to tend to make a conscious effort about volunteering. Yeah in my spare time! And you know that's because I know I've got certain set of skills that they find useful. I think we probably need to do a little bit more on that to draw out that more subtle element of hidden talents. Because you know what we are trying to say is yeah it's not as statutory or conscious as actually volunteering it maybe that you are not aware that you've got*

anything useful to give back to the community but it may be that just being able to drive a car at that moment in time." – Project Manager [S3]

The key aim of LiU is to promote healthy living, active lifestyles and independent living. Improving health and wellbeing is at the forefront of the national agenda in Scotland in order to reduce health inequalities via preventative measures. LiU was led by NHS 24 in partnership with 5 NHS regional health boards and therefore in the eyes of implementers it seems that this provides a platform for potential users to trust and value what is essentially being sold to them. Implementers strongly agreed that building 'trust' was a facilitator.

"As soon as you fit something within NHS, under the NHS banner people assume that it's trusted" – Project Manager [S3]

5.3.3 Theme 4 – Need to Engage Clinicians Early on to Secure Clinical Backing / Endorsement

5.3.3.1 – Subtheme 1 – Innovators and Need for Senior Support

It proved more difficult for project managers to engage with health professionals and get them on board initially which was a key issue for users particularly targeted at the Flourish service. Clinicians clearly would have preferred clinical trial evidence of clear benefits before embracing the new digital services. However a key facilitator for encouraging clinicians to become actively engaged in the development of LiU was to demonstrate the benefits perceived by patients and also to their daily workflow.

"Professionals are much more cynical…..they are looking for the evidence behind all this before actually getting engaged despite the fact we are gathering the evidence as we are going…the evidence is coming from our community engagement and people saying this is what they want. That's the evidence" – Project Manager [S5]

The use of clinicians as champions or 'innovators' facilitated the process of engaging health professionals. Community engagement teams across the implementation sites created opportunities for 'innovators' (champions) to be involved in the design and development of LiU.

"*The innovators to do a lot of that kind of work with them. Within living it up in Lothian we've got innovators who they spend a day a week with our project so their clinicians who work with them. So we've got someone who works with COPD, diabetes, heart failure, video conference, physical activity and gaming so they've got their own job and they just spend a week on the project" – Project Manager [S13*]

A key lesson and learning point at a local level, is the need to secure senior level buy-in to be able to then drive forward service developments. Endorsement by influential clinical peers was seen as an important facilitator to clinician engagement.

"We're working with our respiratory nurse to look at embedding Living it Up into her service. She's trialled some video conferencing. She's going to start some home monitoring. She's looking at starting a Better Plan. So, she's looking at home some of the Living it Up tools can be used to support her patients" – Project Manager [S13]

5.3.3.2 – Subtheme 2 – Financial Incentives

The use of financial incentives as mentioned in previous literature is widely known to support implementation activities. Within the realms of this project this factor proved to be a facilitator once again. Essentially, investment of resources is needed to enable engagement by busy clinicians with competing priorities. Such resources could, for example, enable employing others to take over their day to day clinical work temporarily to allow time out to engage with the LiU programme.

Well, they're backfilled, so, all their roles are either backfilled so their department will get money for them spending time with us. Yes, no one's spending time with us for free. So, you know, they maybe have a part time role but they're very interested in this area – Project Manager [S12]

5.3.4 Theme 5 – Champions: Community Individuals and Community Organisation

5.3.4.1 – Subtheme 1 – Third Sector 'Link' Person and Organisation

There was a consensus among Project managers to that the recruitment tool was used by the community engagement team as a means of identifying champions. Participants were asked what they know about their community and what their ideas might be for promoting volunteering within their communities and through this line of reasoning were able to identify if the individual could be (a) a Community Champion: a person interested in working for the good of their community, (b) a Community Apprentice: a person eager to make a difference in their community and (c) a Community Imaginer: a person who can identify opportunities within their community. Once such individuals were identified, project managers were able to effectively leave the bulk of engagement efforts down to the local community whilst directing efforts and resources elsewhere.

"What I've done is I've been very lucky and I've got a great group, a core group of local community champions, who are basically... in a way, I'm leaving it to them, because I think it sells it better if it's coming from actual users. So we've got one guy who's writing a regular blog about living with long-term conditions, you know, he gives practical advice based on his own experiences, and that's been very popular with people, given it a human edge, if you like" – Project Manager [10]

Creating community and third-sector champions equally proved to be a facilitator towards driving the implementation forward. Users within the communities took it upon themselves to get involved in spearheading engagement activities and creating awareness.

"I see Living it Up as being a good idea…the intentions are honourable…I got involved with it by accident, I think. I was already planning to do something resembling the tablets thing that was involved with…because in the cancer group we had people who were fairly isolated geographically. This is, this is a rural area basically; Elgin's a town but the rest of us are, you know, relatively small. And there are a lot of people live in the country. And quite often they'll be pretty isolated. And it seemed to me that tablets offer a way to get them involved with computing" – User [S21]

"*Well, what we do is we offer to go - two of us, my friend Jim and I - we offer to go to, you know, groups and to introduce them to tablets and to show them that any fool can use them. They're aimed, I think, to be usable by people who don't care about computing. So I'm quite convinced that tablets have a big possibility with people who are frightened of computers I'd already had a go at computing, already converted something like a quarter of our cancer support group, which was maybe… The total group would be something like 80. I converted about 20 of them to using computers, mainly laptops*" *– User [S21]*

Figure 5.2 shows how the themes discussed in the section above map onto the theoretical concepts of NPT.

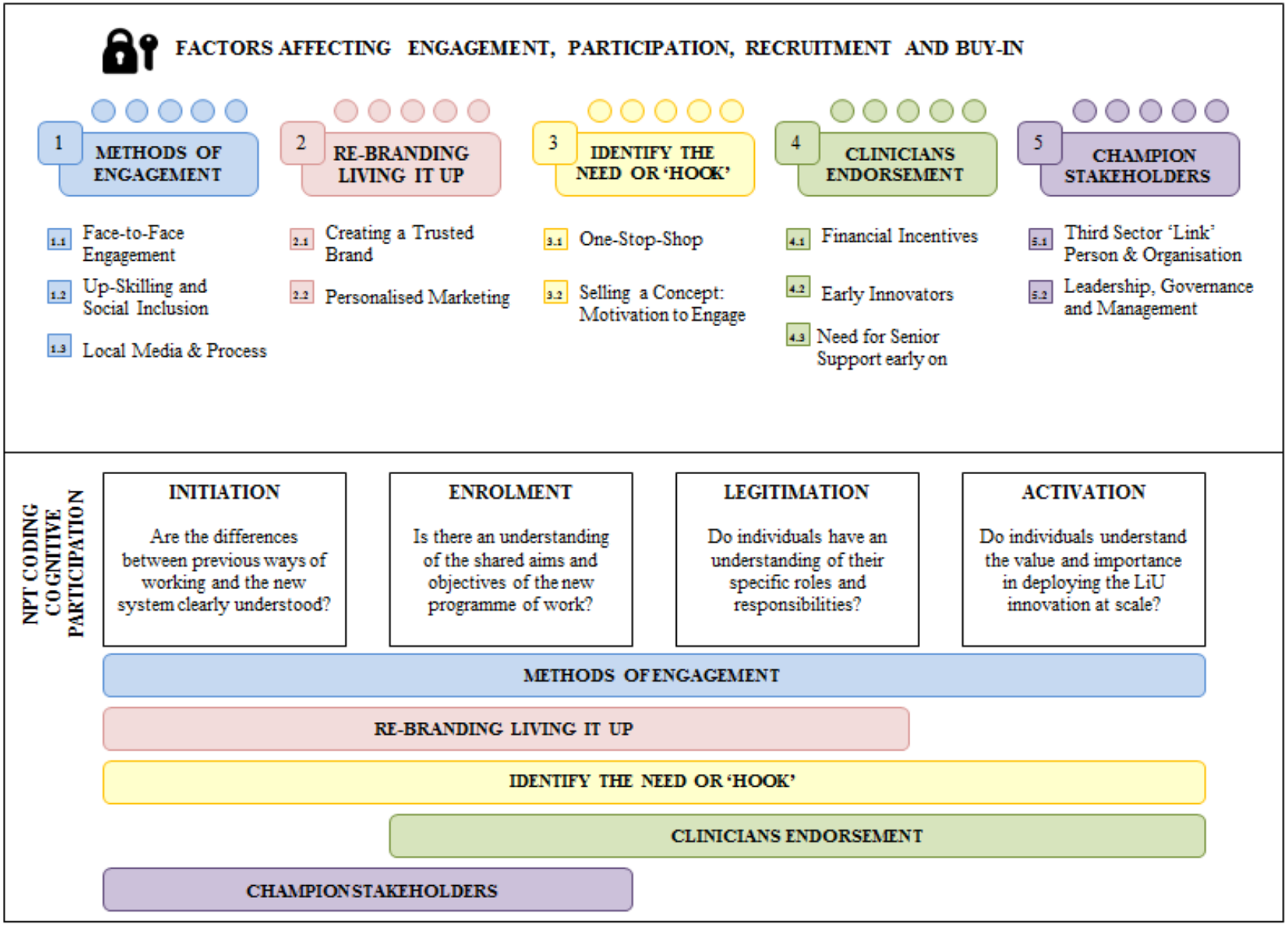

FACTORS AFFECTING ENGAGEMENT, PARTICIPATION, RECRUITMENT AND BUY-IN
1
METHODS OF ENGAGEMENT
1.1 Face-to-Face Engagement
1.2 Up-Skilling and Social Inclusion
1.3 Local Media & Process
2
RE-BRANDING LIVING IT UP
2.1 Creating a Trusted Brand
2.2 Personalised Marketing
3
IDENTIFY THE NEED OR 'HOOK'
3.1 One-Stop-Shop
3.2 Selling a Concept: Motivation to Engage
4
CLINICIANS ENDORSEMENT
4.1 Financial Incentives
4.2 Early Innovators
4.3 Need for Senior Support early on
5
CHAMPION STAKEHOLDERS
5.1 Third Sector 'Link' Person & Organisation
5.2 Leadership, Governance and Management
NPT CODING COGNITIVE PARTICIPATION
INITIATION
Are the differences between previous ways of working and the new system clearly understood?
ENROLMENT
Is there an understanding of the shared aims and objectives of the new programme of work?
LEGITIMATION
Do individuals have an understanding of their specific roles and responsibilities?
ACTIVATION
Do individuals understand the value and importance in deploying the LiU innovation at scale?
METHODS OF ENGAGEMENT
RE-BRANDING LIVING IT UP
IDENTIFY THE NEED OR 'HOOK'
CLINICIANS ENDORSEMENT
CHAMPION STAKEHOLDERS

Figure 5.2

5.4 Chapter Summary

This chapter has highlighted the immense challenges faced from the outset of the LiU digital health programme. The key issues identified are illustrated in Table 5B. This work has highlighted the importance of both shared vision for the project and an emphasis on engagement issues. While it has made the difficulties encountered during the initial stages of the LiU programme visible it has also shown the actions taken to circumnavigate a range of challenges. These findings are novel as many reports focus mainly on barriers to digital health uptake and do not describe facilitators to digital health uptake in detail nor describe precisely what steps are taken to overcome barriers to uptake and utilisation [98]. The importance of good leadership and effective governance processes as well as flexibility, especially by industrial partners were clear facilitators of the programme.. However, this large scale digital deployment has also illustrated how the size and nature of the consortia, consisting of partners with quite different backgrounds, experiences, and perspectives was a real challenge and that developing good communication channels was essential. In addition, it was clear that practical issues for example, relating to contracts were a major issue which caused great difficulty and consumed much time and energy. The importance of investing in training and upskilling of communities and improving access to technologies through a range of approaches as described in the preceding sections is also an important finding which suggests that greater attention to such issues need to be considered when planning to implement digital health initiatives at scale. Equally, time spent on engaging with the public about a range of issues, including branding, seemed to be time well spent to promote engagement and uptake in the longer term.

Strengths and Weaknesses

The LiU programme provided a unique opportunity to be the "fly on the wall" observing the implementation journey of a national digital health deployment. A wide range of data were collected and analysed that provided insights into the dynamic and evolving LiU programme. While this study has enabled identification of potential barriers to implementation it has also provided useful information about the nature of the barriers, why they occurred and strategies that were used to overcome identified challenges. The interview guides and qualitative data analyses were underpinned by a strong theoretical framework, NPT, something which has been recommended as good practice for implementation evaluations of this kind . There are however, a number of limitations with regard to this work. For example, the stakeholders who contributed to the research were people who were either tasked with implementing the LiU programme or were engaging with the initiative to some degree. Consequently, the data collected does not include the views or perspectives of people or groups who did not engage with the LiU programme. Understanding reasons for non-engagement and disengagement with a national deployment of this nature would obviously have provided additional knowledge. In addition, while the qualitative data does include some input from health professionals and patients this was relatively limited and most of the data comes from those tasked with implementing the LiU programme (which included NHS staff, government or industry personnel and members of the voluntary sector). So this should be considered another limitation of the work. Despite the large volume of data collected, relatively little came directly from health professionals and patients/members of the public. This was because the LiU programme

was mainly focused on development and engagement activities for the first two years, when the bulk of the data collection for this thesis was undertaken, with most active use of products and services not occurring till the final phases of the project in the third year of the life of the programme.

How this Fits with Existing Literature?

A lack of formal leadership and management support has been mentioned recurrently within existing literature as one of the most important implementation factors contributing to the failure of digital health innovations in practice. The findings from this evaluation of the implementation of the LiU programme in Scotland has shown how having clear leadership, management and a governance structure was a facilitator of success for the programme. In addition, the importance of 'consensus building' has been noted previously by others discussing the key factors for successful implementation and adoption of large scale health information technology programmes [99]. Similarly, here it is clear from the data collected that developing a "shared vision" and a suitable collaborative environment was crucial to the success of the LiU programme.

The sheer scale of this national deployment has permitted novel insights into the challenges that can be encountered when large, multi-agency partnerships have to deliver digital health at scale. This is a relatively novel finding and certainly less well described in the digital health literature. Although, the importance of issues such as flexibility which was clearly necessary to overcome such problems have been suggested previously as a key issue in e-health implementation or when integrating implementation and evaluation of telehealth [100, 101]. The importance of "champions" has also previously been identified in the digital health and wider health service implementation literature and again this was also an important finding in this work.[102]

Conclusion

This chapter has illustrated the key 'Sense-Making' and 'Relational' work that was required on an individual level (consumer, patient, champion, carer, stakeholder) and collective level (organisations, consortium, industry, government and policy maker) to enable the implementation of the LiU programme across Scotland. The next chapter will now address 'Active Deployment' and Appraisal' factors that emerged during the course of the implementation.

Factors Affecting Planning, Organisation, Shared Understanding, Vision and Strategy		
	–	+
Theme 1: Political Landscape and Rationale for Change	The need to map the local needs of the community within the various LiU implementation sites with national policy (i.e. wellness agenda) was time consuming	Creating choice and opportunities for dialogue within local communities. Thus stimulating the creation of a two-way service
Theme 2: Working Across Individual, Professional and Organisational Boundaries	Complex multi-Stakeholder Environment and working across individual, organisational and professional boundaries. This heterogeneity of the consortium stakeholders and the sheer size and scale of the consortium as a whole presented challenges.	Coming together to develop a common language. Valuing the contribution of each consortium member. In addition the creation of a standard glossary helped to provide a strong foundation with which to communicate.
Theme 3: Difficulty in Developing Clear Communication Channels	Disconnect between national communication plans and local plans which led to several implications on the ground	Establishing clear channels of communication early on + use of the co-design meetings themselves
Theme 4: Challenge in Cementing Legal Contracts Pre-Implementation	Setbacks due to the complex nature of the consortium and this required more time and attention to enable negotiations to take place. These 'setbacks' included overlapping existing agreements and Intellectual Property	Developing a professional but friendly bond that changed the dynamics of the traditional customer–supplier relationship and the tendering process.
Theme 5: Central Leadership and Management of Vision and Strategy	Setup of several boards and committees to maintain accountability and stakeholder responsibilities. The reporting and governance structure set out to ensure a clear and transparent flexible hierarchy with the establishment of local partnership steering groups [POSITIVE FACTOR]	
Factors Affecting Engagement, Participation, Recruitment and Buy-In		
	–	+
Theme 1: Methods of Consumer and Patient Engagement	Build the confidence of users with the ability to network with local libraries in the area as means of creating a space for people to 'meet' take up a 'free' IT Class. Personalised approach. [POSITIVE FACTOR]	
Theme 2: Identifying the Need or "Hook" and Retention	Recruiting to a concept that was not fully developed at the beginning also proved to be challenging with the bulk of resources and efforts being used to engage.	Pool information into a single resource to ensure that the user is able to receive the best 'deal' and information, at the right place and time, suitable on the right device and in the right format.
Theme 3: Re-Branding Living It Up	Initial names of the services were not readily meaningful. It became evident that re-branding work was necessary to help build trust with consumers by enabling them to readily see the 'added value'. Creating a trusted brand help to overcome initial barrier.	
Theme 4: Need to Engage Clinicians Early on to Secure Clinical Backing / Endorsement	Proved difficult for project managers to engage with health professionals and get them on board initially looking for the evidence base	The use of clinicians as champions or 'innovators' and financial incentives facilitated the process of engaging health professionals.
Theme 5: Champions: Community Individuals and Community Organisation	Creating opportunity to identify key members within the implementation site communities to become local champions. [POSITIVE FACTOR]	

Table 5 B – NOTE: Factors spanning ' + and –' can be either plus or negative unless explicitly specified otherwise

CHAPTER SIX RESULTS DEPLOYMENT & EVALUATION

6.1 Introduction

This chapter follows the same fashion as the previous in presenting a holistic overview of the factors affecting the implementation of the LiU digital health programme. However, this particular chapter focuses on the collective action and reflexive monitoring aspects of the implementation. Therefore emphasis is paid to 1) the requirements to make the LiU programme work in routine practice and the factors inhibiting or enabling the enacting work (collective action) and 2) the work required to assess and evaluate the value and use of the platform at scale (reflexive monitoring). Again, the factors which either impede of facilitate this process are examined under the lens of the Normalisation Process Theory to help foster an understanding of the implementation factors and to promote a move from description (presented in chapter 4) to explanation (chapters 5 and 6).

Firstly this chapter sets out the study aim, which largely focuses on gaining an in-depth insight into the actions and work of stakeholder implementers over time, and how their experiences could be used to understand more clearly the factors influencing implementation at scale. The methods are briefly referenced with full justification for their choice described in chapter three. The results are presented thematically along with visual diagrams illustrating major themes and sub-themes that emerged during the analytical process. In addition the same visuals are used to explain how the findings are conceptualised and 'map' onto NPT, the theoretical framework which underpins this thesis. Summary check lists are provided to quickly highlight the key barriers and facilitators being discussed, and a chapter summary is provided which makes reference to the existing literature and discusses the significance of the chapter findings.

Chapter Aims and Objectives

The aim of this chapter is to address research question three: To identify and explain the underpinning factors which promote or inhibit successful normalization (implementation, embedding and integration) of the LiU programme. Again, the underlying methods used to support the analysis and interpretation work underpinning chapter 6 have been detailed fully in chapter three. The data supporting this chapter are the extensive interviews carried out over the three year period (See Table 6A for details) which was analysed using a framework approach underpinned by NPT as described previously.

Longitudinal Interviews	Number of Items	Number of Participants	Number of Pages
Time Point: ***Baseline*** Participants: 5 Project Managers, 1 Strategic Lead Dates: January 2014	7	6	113
Time Point: ***Mid-Point*** Participants: 4 Project Managers, 1 Strategic Lead Dates: June 2014	5	5	97
Time Point: ***End-Point*** Participants: 5 Project Managers, 1 Strategic Lead Dates: January 2015	6	6	105
Subtotal	**18**	**6***	**315**

Cross-Sectional Interviews	Number of Items	Number of Participants	Number of Pages
Participants: 1 Clinical Specialist Physiotherapist, 1 Weight Management & Physical Activity Specialist Dates: March – April 2015	2	2	32
Participant: 1 Consumer Get Active 1-1 Interview Dates: May 2015	2	1	29
Participants: Champions 1 Lay Rural Champion, 1 Lay Urban Champion. Dates: November – December 2014	2	2	49
Participants: Stakeholder Interviews with LiU Consortium Members. 5 Industry Professionals, 2 Voluntary Professionals, 1 Local Authority, 1 Government Official, 1 Academic Professional. Dates: July – October 2014	11	10	169
Subtotal	**17**	**15**	**279**
Focus Group	Number of Items	Number of Participants	Number of Pages
Participants: 5 Get Active Consumer and 2 Voluntary Sector Professionals. Dates: May 2015	2	7	19
Subtotal	**2**	**7**	**19**
Grand Total	**37**	**28**	**613**

Table 6 A – Cross-Sectional, Longitudinal and Focus Group Dataset (*= Repeat Interviews Same Participants)

Section One – Doing the Doing: The Rolling Out Work

6.2 Factors Affecting Operational Rollout, Deployment and Active Implementation

This section explores the work performed by individuals, groups of professionals and the consortium as a whole to operationalize the different aspects of the LiU programme. There were five factors identified which affected the rollout and active deployment and these were as follows: 1) issues concerning the underpinning technical infrastructure; 2) differences in working styles and the subsequent impact on the consortium functioning; 3) division of labour; 4) resource constraints and the need for organisational support, and lastly 5) the need to create a foundation for open innovation. See Figure 6.1 – Factors Affecting Operational Rollout, Deployment and Active Implementation

6.2.1 **Theme 1** – Underpinning Infrastructure

The first theme relates to inadequate technical and operational infrastructure in place across many of the implementation sites which greatly affected the rate at which the new LiU services were being rolled out. There were three main sub-themes that fell under this category and these included: Difficulties with Broadband,

Bandwidth, Network & Configuration; Issues concerning Interoperability, Standards and Governance; and concerns with Security, Privacy and Trust.

6.2.1.1 – Subtheme 1 – Broadband, Bandwidth, Network & Configuration

A key barrier which impeded implementation efforts was the lack of broadband connectivity to enable people to connect to the LiU portal especially for those in in remote or rural locations which made it very difficult to access any services or to become involved in the creative process early on. This affected both interest and engagement activity with the main LiU platform (website) and the rate of individuals signing up to the LiU Platform of services. In some areas, the broadband speed was so slow that using any service became a challenging task. Therefore although the LiU platform (website) was able to provide access to potentially innovative services (such as the connect clinical video conferencing service) the underpinning infrastructure acted as a barrier towards implementation. In one case a care home in one implementation site, where the ideal target users for critical care services such as flourish and connect resided , Wi-Fi was not installed and therefore not available at all, thus restricting use of the service that relied on being effectively connected to the internet.

"We have since discovered that Wi-Fi is not installed in any of the council-paid for in old folks home. You know, we now know; didn't know that before. Didn't know to ask" [S22] – Consumer, Older Person

The lack of broadband connectivity and poor mobile reception impeded efforts to rollout some LiU services, and this became one of the most frequently cited implementation barriers among project managers in particular. It became clear that in order for them 'to do their job' effectively the issues concerning infrastructure needed to be addressed.

"I think one of the other barriers certainly in this area is we've got you know poor reception, we've got poor bandwidth. You know I tried to do a video conference last week and my bandwidth just wouldn't support. So you know and that's an issue right across apart from the five major towns but even so our, I can't remember what our, what our speed is, it's under 2 meg [megabytes] I think. Yeah it's like a hamster and you know ... so the infrastructure is a big barrier". [S3] – Project Manager 3

We have a lot of problems with poor band widths. Lots of areas that don't have broadband at all we do have some real challenges even in some of our towns we have some challenges with this broad band access as well so as far as the technology is concerned yes we have had lots of problems. [S6] –Implementer

It seemed that the problems with infrastructure were deep-rooted and required intervention from government in order to bring about the required change needed to help Scotland to become the pioneering digital society outlined in policy documents such as the '2020 Quality Strategy Vision'. Recently a programme has been established to increase connectivity and to enable those who are currently digitally excluded to be

able to get online. This initiative which is open to implementing fibre optic capabilities is an explicit facilitator which is happening now.

"Well these aren't problems that living it up can sort. These are problems that need to be sorted nationally by the Scottish Government. And there is a programme to, in place to increase broad band, band width, broad band access and band width across Scotland and some areas of [implementation site] that will impact on some of that might not happen until the end of the project time" [S6] – Implementation Lead

Investment in infrastructure is clearly necessary to facilitate successful digital health deployment. Despite ambitious digital health aspirations, inadequate infrastructure remains an obstacle to making digital health services ubiquitous in Scotland, and is something which needs addressed in the coming years.

6.2.1.2 – Subtheme 2 – Interoperability, Governance & Standards

The lack of broadband connectivity issues coupled with technical and service interoperability issues meant that progress was difficult to achieve throughout a large part of the delivery cycle. Ensuring that the platform was interoperable with existing systems (such as established NHS systems and consumer technology) required additional organisational support in terms of building an end-to-end testing environment. LiU aimed to provide consumers with an integrated seamless journey of care. There was a consensus amongst stakeholders that delivering this vision was a complex process. This was due to the fact that some partners worked in 'silos' within their respective organisations and concentrated on a particular piece of work which meant that difficulties were only recognised when that piece of work became integrated within the wider programme.

"So basically what happens is a supplier, a technical partner is used to the principle of building something and then they put it into their test environment and test it. Right…now the problem is until you have interlinked them you don't know they are going to work. So supplier A could build product 1 and test it but when it goes live it might not work because of something that supplier B has running on their website…now it would cost a lot of money to build a complete end to end test environment"[S20] – Industry Professional

Even more of a challenge for consortium members working within NHS Organisations were firewalls and how they frequently prevented easy access to the sites needed to access the full functionality of all the LiU services. Measures such as firewalls are certainly needed to protect the NHS from malicious attacks for unauthorised access to network security computers and patient confidential information. However, the LiU platform was designed using a Firefox browser as opposed to internet explorer which is the standard operating browser within the NHS. In addition, to access services that LiU depends on to widen their reach such as YouTube video content, there would need to be a formal governance process of retaining an approved NHS security certificate to permit the content which would otherwise be easily accessible to people outside the NHS. This is because the NHS is risk adverse to the use of modern approaches to allowing access using simple straightforward security certificates; however this led to a large degree of frustration amongst NHS workers.

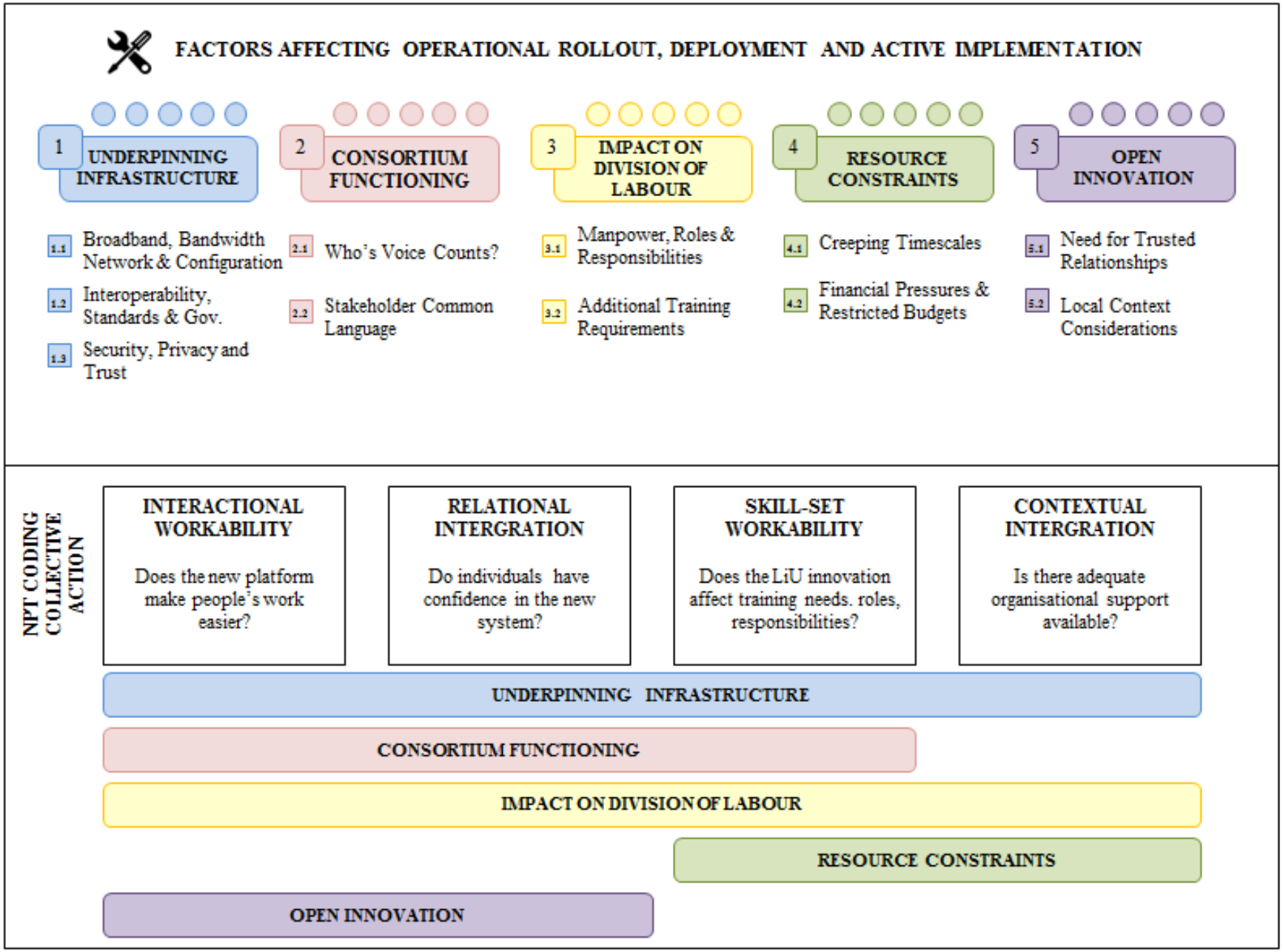

FACTORS AFFECTING OPERATIONAL ROLLOUT, DEPLOYMENT AND ACTIVE IMPLEMENTATION
1 UNDERPINNING INFRASTRUCTURE
1.1 Broadband, Bandwidth Network & Configuration
1.2 Interoperability, Standards & Gov.
1.3 Security, Privacy and Trust
2 CONSORTIUM FUNCTIONING
2.1 Who's Voice Counts?
2.2 Stakeholder Common Language
3 IMPACT ON DIVISION OF LABOUR
3.1 Manpower, Roles & Responsibilities
3.2 Additional Training Requirements
4 RESOURCE CONSTRAINTS
4.1 Creeping Timescales
4.2 Financial Pressures & Restricted Budgets
5 OPEN INNOVATION
5.1 Need for Trusted Relationships
5.2 Local Context Considerations
NPT CODING COLLECTIVE ACTION
INTERACTIONAL WORKABILITY
Does the new platform make people's work easier?
RELATIONAL INTERGRATION
Do individuals have confidence in the new system?
SKILL-SET WORKABILITY
Does the LiU innovation affect training needs. roles, responsibilities?
CONTEXTUAL INTERGRATION
Is there adequate organisational support available?
UNDERPINNING INFRASTRUCTURE
CONSORTIUM FUNCTIONING
IMPACT ON DIVISION OF LABOUR
RESOURCE CONSTRAINTS
OPEN INNOVATION

Figure 6.1

"Some NHS PCs have some difficulty in accessing some of the information like the digital postcard, some people in the NHS PC's can't see it. Well because it's basically that the digital postcard, the security certificates that they are using are not NHS approved so they need to go back and get a security certificate that is NHS approved" [S4] – Project Manager

6.2.1.3 – Subtheme 3 – Security, Privacy & Trust

Some users raised concerns in relation to the perceived integrity of the LiU platform in terms of the security procedures in place regarding the personal information that they provided in the sign up process, or medical details required to use certain services such as 'Flourish'. Privacy and security was a major concern among users of the 'Get Active' digital exercise referral scheme in particular. The majority of users felt that although they were making efforts to improve their health and wellbeing, this in actual fact could be detrimental to their financial wellbeing as there could be perception that if they are 'fit' to exercise then they are fit in all other aspects of life and they might consequently lose access to essential benefits.

"This is one of the big fears amongst people of my generation, it's not secure, people will find out about me" [S21] – Consumer, Older Person

There's this paranoia, as well, that somebody is going to report you, so that's another thing that might come up, if you're putting all your steps in....You're trying to improve your health, but at the same point, that might be seen as detrimental. The benefits thing, the Universal Credit stuff, it's such a biggie for people [Focus Group] – Facilitators, Get Active Service

Clinicians expressed concerns in relation to the robustness of services supporting the LiU platform. Health professionals identified the need to view the system as an 'enabler' to support their clinical practice and not a system that could be trusted wholly to be the 'magic bullet' in providing the much needed service transformation in health and social care provision.

"There are some assumptions made that, you know, technology is going to be the saviour of everything in health settings. But the actual application of technology, like Flow, you know, it has to be underpinned by a degree of clinical decision-making, especially with an unwell group of patients. In other areas where there's maybe more black and white it might be different but I think within this group of patients there are lots of variables for patients becoming unwell and, you know, it isn't something that can just be applied to a team or a patient without really a kind of bed of knowledge of, you know, previous use, what's worked, what hasn't, how to make it easier, what do patients like, what do they not like, what's gone well, what hasn't". [S18] – Clinician

6.2.2 **Theme 2** – Consortium Functioning

The second theme relates to the implementation challenges that arose as a direct result of challenges with the functioning of the consortium in practice. There were two main sub-themes that fell under this category and

these included: the challenge of coming together and understanding each other in order to complete work tasks, and secondly, the notion of whose voice counts, and takes precedence among a large collaborative consortium. Although consortium working is complex and these difficulties occurred, strategies such as developing a common language and working terminology ameliorate this initial barrier and facilitate implementation.

6.2.2.1 – Subtheme 1 – Stakeholder Common Language

Working collectively in practice proved to be a challenging task in the early phases of the LiU implementation given the differences between organisations and sectors, as well as differences in existing terminologies and working language between stakeholder groups such as clinical terminology versus industry professional terms. Therefore, existing work practises were challenged which required a degree of flexibility in order to ensure that the system requirements were able to be met. In some cases, the barrier posed by differences in working practices meant that there was a mismatch between service and technical requirements, however once a common stakeholder language was developed in addition to a collective working culture, a compromise was reached which helped to foster a smoother working transition. A collective working culture was achieved using the stakeholder meetings as an opportunity to use project leads to translate they translate the requirements and create a shared language.

"I know that there has been issues and problems with the technical company and I think that's I mean I don't think that's uncommon I think it has been a real learning curve for all of us. Working in the public sector with private industry and again you know the cultures are completely different. The language is completely different. So we have you know it has been challenging to get or to communicate a service requirement that they can translate into the technical requirement. And I think the technical partners idea of psychological profile is really very different to the NHS. But I think they have reached a sort of happy medium I think. And we are probably on the right track." [S3] – Project Manager 3

6.2.2.2 – Subtheme 2 – Who's Voice Counts

There were clear challenges in terms of group dynamics, and effectively co-producing in practice. Determining and deciding the importance of stakeholder voices and views was a key challenge. The group dynamics in the early stages of the implementation demonstrated a period of learning and growth. Therefore the need to value each contribution was imperative within the consortium regardless of the standings outside of the consortium. It is important to note that this theme is not limited to the healthcare context alone.

"Just getting everybody in the room…to develop their relationships across the different organisational structures and to develop a shared vision. So…what is it we are really trying to do? How does that meet everybody's agendas? Are you engaging with us and are you going to drive it forward from your different organisational perspectives?" [S5] – *Implementation Lead*

Further to this, in line with developing a shared sense of understanding it was even more evident that this was significant in shaping the future implementation as stakeholder's views and concerns varied quite widely and there was an urgent need for each party to obtain a tangible 'sense of belonging' in direct terms this relates to how a stakeholder fits into the wider picture of the LiU programme. This seemed important to enable stakeholders to identify a collective aim in meeting the objectives of the programme.

6.2.3 Theme 3 – Impact on the Division of Labour

The third theme relates to issues that affected the allocation of work tasks and division of labour. There were two sub-themes that fell under this category and these included the need to create new roles to support project objectives and additional training to support new and existing staff skill-sets. Given the novelty and scale of the project, this prospect in itself was unprecedented and therefore this process slowed down the implementation process significantly..

6.2.3.1 – Subtheme 1 – Manpower: Need for the Creation of New Roles

Inadequate staffing and division of labour were recurrent issues that put pressure on the majority of stakeholders. The consensus was that there was a lack of support on the ground in terms of personnel and manpower. Some positions required others to fill in as a courtesy in order to meet the project aims. The scale of the implementation was unprecedented so there was a need for additional organisational support in terms of manpower in order to relieve the pressures on existing services. The backdrop of austerity affecting the NHS and social services was partly an issue here which called for new ways of working and the subsequent development of additional roles and responsibilities.

> *"All this is perhaps going to take a new way of working and a new way of thinking and perhaps new job roles within statutory and voluntary services to help people help each other out."*
>
> *[S20] - Community Engagement Team*

However, the time it took to advertise, recruit, train and get a new members of staff on board proved to be more challenging than expected. This was particularly true for positions to support those working in statutory organisations such as the NHS. Project managers and industry professionals both voiced concerns around 'bureaucracy' and too much 'red tape' affecting the pace of implementation.

> *"I think I actually wrote the job description eventually last June or July, so it's a year. we actually advertised it around February/March this year, and we didn't actually get anybody; we did get people applying for it, they just didn't have the skills that we needed. Whereas this time we've got probably about four people that we would have quite happily employed, so I think it was just the luck of the draw, it shouldn't have taken as long as it did. These processes take time, and there's also internal sort of organisational issues as well, because you've got the*

budget held by the NHS, and then the actual post being advertised through the council, so we had to set up an agreement whereby that we could recharge the NHS for the salary and all that, so yes, it was internal politics that took the time" [S10] – Project Manager 4

"But I think from a, sort of, capacity and that perspective I would always gladly have more staff in the support office but obviously there are budget constraints and development processes through up-scaling a team and stuff like that. I think that the state [?] that we're at the moment with the five territories we are just about covered off with the staff that we've got. It would always be a help because we are very, very busy, as you know" [S28] – Implementer

It was thought that the programme wide recruitment of community managers to support project managers locally on the ground would ease the manpower pressures that they were facing. However, it became clear during the course of the implementation that their role at times became an additional 'burden' as they worked remotely as opposed to on the ground.

"Well, personally, I mean, our community manager is down in Edinburgh, who doesn't drive, who very rarely comes up to [Implementation Site], so how can they be a local manager if they don't even live in the area, number one? And that's, I don't mean that in any bad sense, but that, to my mind, just isn't right, and I know she probably is very good at her job and all the rest of it, and I have no qualms about her job, but why have a local manager when they're not even in the… they don't even live in the area? Yes it would be great if we had some more help, do you know what I mean and more manpower because there's lots of activity going on and you just try and strive to do your best" [S23] – Council Representative

6.2.3.2 – Subtheme 2 – Additional Training Requirements

During the course of the deployment, it became apparent that there was a widespread lack of knowledge and digital skills regarding the potential of technology. Insufficient digital skill-sets and resource gaps can limit progress and reduce the confidence of the workforce in actively investing time and effort to support the roll out of digital health. Therefore proactive decisions were made to address these gaps by organising additional training to reduce strain and pressure on existing resources. In a multi-stakeholder environment, the need for all LiU consortium members to have a shared sense of understanding required a level of learning. It was clear that some stakeholders required more 'training' than others which slowed down the implementation process.

"There was a lack of understanding of digital technology and what it can do now. A lot of the people were not familiar with the use of digital technology and, you know, on the service side, the people that were designing the services did not themselves use this type of technology, so they were not pushing the boundaries" [S30] – Digital Health Industry Expert

"I think staffing in each of the local areas still do need bigger teams, with focus on different things and whether that's like buying-in services...People are struggling to do their work with less resources than what they have had before … then it's very difficult for them to start to think about new ways of doing things"

[S2] – Project Manager 2

6.2.4 **Theme 4** – Resource Constraints & Organisational Support

The fourth theme relates to implementation barriers concerning resource constraints and organisational support. There were two sub-themes that fell under this category and these included efforts to chase targets in the face of creeping timescales and the challenge of operating under restricted financial budgets. The importance of having adequate resources to support implementation at scale in practice was also a key implementation factor.

6.2.4.1 – Subtheme 1 – Challenge of Creeping Timescales

In some instances, given the scale of the LiU endeavour, a degree of leeway in terms of meeting quarterly milestone deadlines was permitted. Although this seemed to have a 'domino effect' in terms of maintaining project pace and meeting targets. Therefore time as a resource was an impending factor which required a great deal of consideration locally as it seemed to have amplified implications on the national level.

"They were supposed to have gone live in March. So basically in March they [LiU Services and Portal] just didn't work at all and so they couldn't go live with it because they weren't working at all and rather than saying okay we haven't gone live in March we'll set a deadline for June they let it drift on and on and on and eventually they said well let's coincide it with the ministerial launch …." [S4] – Project Manager

The majority of project managers in particular felt that there was a burden placed on them given that there were several targets that had to be met during the course of the project. The implications of failing to meet these targets included a lack of morale and a negative mis-interpretation of community performance and all the 'good work' being done locally. There was therefore a move towards capturing local positive impacts on the ground.

I'm not a fan of targets at all, because I think it skews performance, you know, if you're too focused on targets for the sake of targets, then it does, and I think that's what we were guilty of in the early days, you know, it was sort of like, numbers, numbers, numbers, we need to get these numbers [S10] – Project Manager 3

The financial approval process for industry professionals to actually do the work in practice became a challenge at times due to contractual difficulties which distorted the traditional tendering process. On several occasions in order for stakeholders to proceed with their involvement in the project they usually had to 'work at risk' and

this meant that they had to obtain a 'letter of intent' in relation to delayed financial payments. This was to ensure and guarantee payments to be received for approved works in advance.

"There was a huge bureaucratic delay in getting the thing set up and a contract out… The project was officially meant to start in June…you know, as a delivery partner, we did not get a contract until the following January. So, you know, we worked at risk. You know… to try and be a good partner but, you know, for a business that's not satisfactory and that means that you can't commit all the resources you would like to when you don't know if you're going to get a contract. So, there's a slow start but what made it worse… was it took far too long to decide what LiU would be, you know…our job was delivery of the requirement. Now, it took probably a year to decide on what the requirement was" [S29] – Technology Industry Professional.

"LiU works in quarters. The financial approval process is so far off the pace of the work process that it's not only late it's almost at the end of the process…There's two things you can do as a supplier, one is you can say I'm not moving until I get approval…or else you can proceed at what's called…working at risk. I'd say it's uncommon" [S19] – Digital Representative

6.2.4.2 – Subtheme 2 – Financial Pressures & Restricted Budgets

There was a consensus among all project managers responsible for local implementation, that operating within the confines of restricted budgets meant that in some cases innovation was stifled. For example, it was the case that the budget had been adequately planned at the start of the project although each implementation site budget was different as documented in the Project Initiation Documents (PID). However, some project managers felt it did not reflect the work required to implement in their particular region. This was evidence by the fact that the goal posts and requirements of the project changed as the programme was being implemented. Therefore resources were stretched quite thinly across the entire LiU programme. Taking into account local context and needs, the importance of adequate financial allocations to support deployment efforts was a major concern amongst all stakeholders, in particular industry professionals.

" I guess it's just time and money, resources, yeah I guess there is lots that we could more but we are obviously on a budget and we have to make decisions based on that and we've also had different launches so the launches time wise ... what we would have liked to do hadn't happened or yeah I guess at deployment it was staged so things were not quite finished for one and would be held for the other ..." [S25] – Third Sector

6.2.5 Theme 5 – Scalability and Open Innovation

The final theme relates to implementation factors regarding 1) the need to develop trusted relationships during the course of active implementation and 2) the need to take into consideration local context whilst deploying digital health at scale. Scalability and 'Open' Innovation proved to be key implementation factors with positive impacts. Open innovation simply refers to the degree of flexibility during the course of the programme.

6.2.5.1 – Subtheme 1 – Need for Trusted Relationships

The first being that over the course of the implementation, stakeholders developed a professional but friendly bond which changed the usual dynamics of the customer-supplier relationship. This introduced new ways of working in which representatives from sectors such as housing, healthcare and voluntary indicated that it helped drive the implementation forward.

> "*Normally that relationship is one of customer–supplier, and the public service has a very thorough obligation to treat all private organisations equally. You know, no favours, no special conditions and that's fine when you're trying to buy… [you know…it's a plaster. It's just a question of who makes the cheapest plaster that passes the requirements]*". *[S29] – Digital Technology Lead*

Several industry partners in particular noted that this change in dynamics was special given that it was created within and under the notion of the 'LiU Consortium'. Therefore a great deal of 'trust' developed over time which enabled innovative ways of working to be achieved. This might not have occurred if traditional ways of working which required a customer to be explicit with their tender and a supplier to match these requirements had persisted. A great deal of flexibility and trust was introduced within the consortium which has created future business and working opportunities for partners.

> "*We've moved from a customer–supplier relationship to a more of a partner relationship. And I think that's absolutely essential to solving some of these problems that we have in using technology to provide health care… With innovation you need trust, you need a relationship, you need the ability to be able to say, in a trusted way from one side, this is what we want, and the other side says, well this is what, at the moment what I can deliver, but maybe I can move towards that over the next six months. And that's the only way that you can do joint innovation*."*[S29] – Digital Technology Lead*

6.2.5. 2 – Subtheme 2 – Local Context Considerations

The need to acknowledge context has been well noted already in previous literature as an important key aspect of successful implementations from small scale endeavours. This held to be true and even more significant on a large scale. Project managers of the various implementation sites raised concerns about the need for the national project resources to be distributed equitably. Community Support staff reiterated that this distribution must take into account and accommodate the needs and size of the geographical areas.

> *"I think the lesson really is to, not just to break it down by numbers, but to consider the geographical size and population, and the dispersed nature of the population needs to be taken more into account. I think, from the [Area], perspective, what they should have done at the start was put in some additional project management support. I think that might have helped, and also not to underestimate the requirement of service development*

support. I think, because maybe, that, you know, that's something which should be factored in a bit more, as well, in the local partnership areas" [S13] – Project Manager

Section Two – Doing the Doing: The Appraisal Work

6.3 Factors Affecting Appraisal Work and Large-Scale Evaluation

This section explores the appraisal work carried out to enable adequate assessment and evaluation of the LiU innovation. There were four factors which influenced appraisal work and these were as follows; 1) the need to evidence the platform, 2) the challenge of demonstrating success against projected figures, 3) capturing and measuring the projected benefits and finally 4) defining an approach to support future sustainability. Figure 6.2.

6.3.1 Theme 1 – Evidencing Innovation

The first theme relates to the need to capture the evidence supporting this real world evaluation, in order to understand how to better provide digitally enabled self-care initiatives at scale. There were three main sub-themes that fell under this category and these included: the development of multi-channel feedback mechanisms, the development of a continuous improvement cycle and the need to timeline such initiatives to demonstrate benefits realisation.

6.3.1.1 – Subtheme 1 – Multi-Channel Feedback Routes

Consumers have a crucial role as stakeholders within the consortium as they are continuously consulted throughout the life cycle of the project in various ways both online and offline for their feedback; and this provided an opportunity for sustained grass-root level engagement and innovation to occur such as the creation of personalised services to meet individual needs.

"Sometimes they'll be giving the feedback on a one-to-one basis at workshop events and that goes through…we consolidate that…to shape the development of LiU. If they go through the digital portal then…that goes directly to support office who then again push that out …and see if things can be improved " [S5] – Project Manager

Creating multiple avenues of feedback for users enabled pockets of refinements and improvements to be made to the developed services and products. This became a key indicator of whether the needs of consumers were being met whilst demonstrating the prospect of long-term sustainability. It is important to note that this is something that would not usually happen in the NHS. The most notable and unique aspect of LiU, is that it is not a single product or service and therefore this had to be reflected in terms of assessing and evaluating the platform. Industry professionals in particular used this opportunity to gain 'free' feedback from the pool of LiU users as it was agreed that there is a considerable amount of value to be gained in being able to harness user feedback.

"Feedback would constantly be collected, and if we're then required to make changes on the basis of that feedback there is a process for doing that." [S24] – Industry Professional

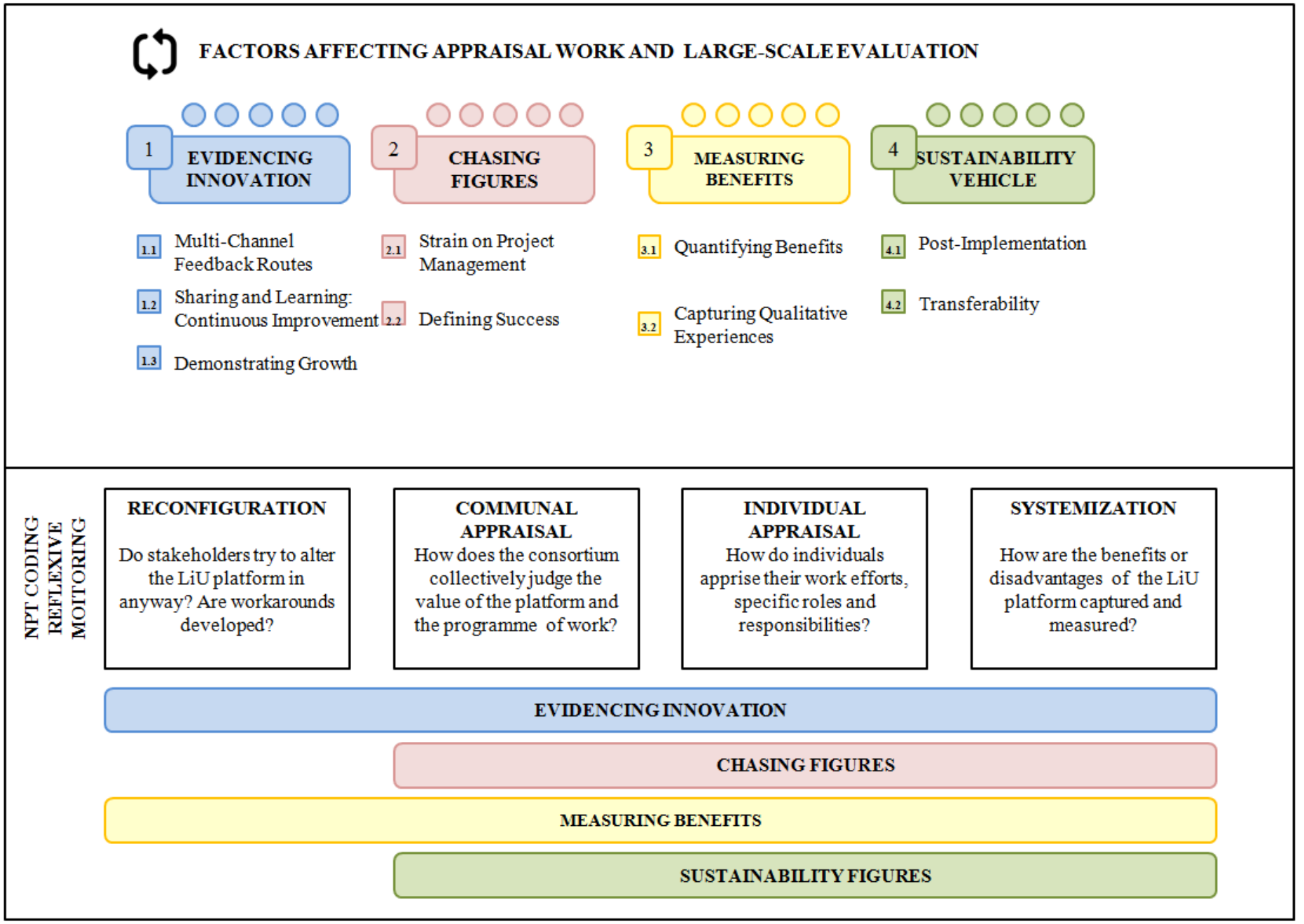

FACTORS AFFECTING APPRAISAL WORK AND LARGE-SCALE EVALUATION
1
EVIDENCING INNOVATION
2
CHASING FIGURES
3
MEASURING BENEFITS
4
SUSTAINABILITY VEHICLE
1.1 Multi-Channel Feedback Routes
1.2 Sharing and Learning: Continuous Improvement
1.3 Demonstrating Growth
2.1 Strain on Project Management
2.2 Defining Success
3.1 Quantifying Benefits
3.2 Capturing Qualitative Experiences
4.1 Post-Implementation
4.2 Transferability
NPT CODING REFLEXIVE MOITORING
RECONFIGURATION
Do stakeholders try to alter the LiU platform in anyway? Are workarounds developed?
COMMUNAL APPRAISAL
How does the consortium collectively judge the value of the platform and the programme of work?
INDIVIDUAL APPRAISAL
How do individuals apprise their work efforts, specific roles and responsibilities?
SYSTEMIZATION
How are the benefits or disadvantages of the LiU platform captured and measured?
EVIDENCING INNOVATION
CHASING FIGURES
MEASURING BENEFITS
SUSTAINABILITY FIGURES

Figure 6.2

6.3.1.2 – Subtheme 2 – Sharing and Learning: Continuous Improvement

During the initial stages, LiU consortium members invested considerable efforts in developing strong links and communication mechanisms between service designers, providers and target users. This certainly had a positive impact on the programme implementation efforts to resolve difficult and challenging occasions. For example, a clear tension emerged over the course of the programme that related to the difficulty of both innovating and scaling up at the same time. This process proved to be lengthy however, during 'sprint' operations which are short bursts of product and service developments; lessons learned were collated in terms of best practice.

"And the other thing that has worked really well for me, and I picked this up through some of the project management stuff that I criticised earlier on, is the sprint meetings. That's stuff that we have learned through the [Industry Company] involvement around the project management, and it's a regular thing that happens with technical partners, but it doesn't... it's not how we normally operate in the NHS" [S13] – Project Manager 3

This continuous notion of sharing best practices and harnessing lessons learned really helped to prevent previous mistakes in the implementation process from being repeated. This is a finding which is not entirely new within existing literature - 'the need to harness lessons learned' - and therefore this finding proves to be just as crucial on a large scale.

6.3.1.2 – Subtheme 3 – Period to Demonstrate Growth: Three vs. Five Years.

The most challenging factor in terms of evidencing innovation relates to the timeframe of the LiU programme. A period of three years was given to demonstrate the innovation benefits (if any) and scalability from the outset. However during the course of the implementation it became clear that this time was insufficient. It was agreed during the course of deployment that a longer period would be more appropriate to demonstrate the effects of up-scaling in particular.

"I think with three years I think there's a certain amount of growth that can happen within three years and is it possible for that to be from the list of ideas to something concrete in three years? I think that's too short" [S12] – Project Manager 1

The clear learning was that for such digital health programmes with ambitious aims for scale, there should be a longer time between project initiation and efforts to up-scale with a minimum of five years timeline ideally to allow successful deployment and enable adequate uptake to be evidenced.

6.3.2 Theme 2 – Impact of 'Chasing' Recruitment Figures

The second theme relates to the impact of having ambitious recruitment figures and the belief of having to chase them as felt by several stakeholders for evaluation purposes. There were two main sub-themes that fell

under this category and these included: 1) the negative strain put on the project momentum during the course of the implementation process and 2) the need to demonstrate success at both local and national level.

6.3.2.1 – Subtheme 1 – Strain on Project Momentum

It seemed that from the outset, being able to meet recruitment targets played a key role in being able to demonstrate success. The need to be flexible however proved to be more challenging in practice and on reflection there was a consensus that the absence of flexibility puts a strain on the project momentum and staff morale.

"You've got to be flexible. And I think that there should've been some flexibility built in to say, you know what, that's what we thought when we first made the bid but actually it's turning out to be more like this, and can we renegotiate with the TSB, you know, what they need from us. And, you know, I think that buttered… well it certainly buttered my morale. I'm not going to speak for other people but I do remember the conversations I had at the time, and I think everybody's morale was pretty low at the time" [S15] – Project Manager 2

6.3.2.2 – Subtheme 2 – Defining Success

Secondly, not being able to reach the target figures was initially seen as an indicator of failure. For example, in the early to mid-point stages project managers in particular took on the bulk of recruiting consumers to the point that it started to hinder the project performance. There was a clear view amongst stakeholders that a definition of success within the project meant being able to recruit and secure the recruitment target figure of 55,000 people. Failure to do so, even in small increments was deemed to be a defeat however coming together to discuss 'what' success looks like and 'how' this could be captured proved to be a positive facilitator amongst consortium members.

"I'd say number one is that in the early days of the project there was far too much emphasis placed on target numbers, you know, getting the recruited 55,000 because we didn't have a product. So you know, we just didn't have a prodder .Yet we were wasting a huge amount of man hours trying to get people to sign up to something that didn't actually exist. So that to me was a big waste of time. I mean, it absolutely buttered my morale and motivation because I just felt like I was on a hamster wheel and not actually producing anything"
[S15] – Project Manager 2

This 'metric' of success permeated throughout the consortium. Many industrial professionals, clinicians and consumers feared that focusing on target numbers alone was problematic and thought it should not be the only indicator of success.

"I think to me the biggest risk still somehow, as I said earlier, is around recruitment. You know, at the end of the day if we fail to recruit the number of people that we set out to recruit, then it will be judged as a failure. What will also be a failure is if we have people recruited, but not actually using the resource. And I think the target as

well, just in a general way, has been completely over-ambitious, I think. Because as I say, we've had to declare those numbers long before we actually knew what we were going to deliver. "[S27] –Industry Professional

6.3.3 Theme 3 – Measuring the Benefits to Stakeholder Groups

The third theme relates to the need to demonstrate impact and measure the benefits to stakeholder groups and there were two sub-themes that fell under this category 1) the need to quantify the benefits to the wider eco-system and 2) the need to capture user stories and experiences.

6.3.3.1 – Subtheme 1 – Quantifying the Benefits to Wider Eco-System

During the course of the implementation process, it was deemed to be of high value by all consortium members that there was a need to map out the projected benefits of LiU and also 'track' them accordingly so that it could feed into the continuous evaluation cycle of the project and feed into future works. However there was not a clear process in place initially to feed back to implementers working on the ground regarding the impact of their work. In term of feedback and communication channels project managers in particular felt that they were able to effectively capture benefits on a local level but they wanted to be able to see the impact of this 'work' across the programme as a means of encouragement and motivation. It also served as a means of being able to make comparisons between the various geographical implementation sites.

"*We're passing our reach figures every month, you know, i.e. how many people were at this talk that I did, or we put an article in the paper, so that will have got, you know, 30,000 people circulation, I would like to see something coming from PMO to sort of say, well, actually, yes, that was worth it because, look, our numbers swelled around it. You know, I think if we're being asked to do benefits, I think there should be some benefits coming out of the national side as well*". *[S5]* – Project Manager

Although it is worth noting that the sheer scale of the LiU programme really had an impact on project managers in terms of the ability to manage and meet ongoing expectations. In time the metric for benefits realisation was established although this occurred during the mid-stages of the implementation process.

"I still have faith that the benefits will be realised, but I think it's the time pressure. There's just not enough time to develop something blue sky, think it, co-design, co-produce with a big consortium and then also recruit 55,000, then also make sure that we've done all the benefits realisation"[S10] – Project Manager

One readily available 'benefit' that was realised by small and medium-sized business (SMB) stakeholders was that working in such a collaborative environment created opportunity for new business ventures and

partnerships among consortium members. This helped to provide a platform in which the vision of wealth creation and innovation could be achieved. More importantly SMB stakeholders were identified as product owners in different elements of LiU and therefore this enabled them to showcase their work as well as a 'collection' of individual works within their respective organisations; an opportunity they may not have had without being part of LiU.

"As a company we've had great benefit from being a part of this project because it has allowed us to establish a position in the individual health market and you know, we're working for Living It Up, we're working for all the Dallas projects. So, we're not restricted to Living It Up, although that's given us opportunity" [S24] – Industry Representative

6.3.3.2 – Subtheme 2 – Capturing User Stories & Experiences

The ability to capture the real user experience of LiU as 'user stories' or case study examples were identified as implementation facilitators due to the fact that it 'personalizes' the user interaction of LiU as being suitable to be for anyone, anywhere at any time. Even more importantly it serves as a means for new users to identify with any given 'case study'. For example, the case of 'Jimmy' with Multiple Sclerosis presents his condition, circles of care and how he has used LiU to empower him to live independently. Examples such as 'Jimmy' prove to be a useful evaluation tool.

"We've just done a range of case studies with people that have been through different parts of the journey with us. So for example, here some people that we've filmed, some people who have been at development workshops, those kinds of things, to give us their opinion of Living It Up and what it means to them. So we've evaluated it through those". [S13] – Project Manager

6.3.4 Theme 4 – Sustainability Vehicle Model

The push towards scaling-up and sustaining LiU far beyond the official end date of 2015 positively influenced the implementation process. Stakeholders themselves were thinking long term but more importantly in 'real-terms' as to how LiU could be integrated into daily practices. This was a key overall positive factor in ensuring the success of project as a whole.

"So we will be kind of running workshops in all of the areas just on how we can do that, and actually just get them to implement it in as part of their daily working" [S23] – Third Sector

"I think sustainability for where we are sitting just now with the strains on the statutory service, the only way we can see a sustainable service moving forwards is to actually utilise the community assets. You know you are not going to be able to have another 100,000

nurses and twenty more hospitals etc so we need to look at what we have within the community and actually build the communities up. To be able to cope with the demands in five, ten, fifteen years" – [S30] – Industry Professional

6.4 Chapter Summary

Table 6 B summarises the key issues identified as barriers or facilitators to the deployment of services by the LiU programme. Inadequate infrastructure at both national and local levels served as clear barriers to deployment. This is something that has been highlighted in UK government documents as an important issue to address but clearly is a persistent problem that remains a major consideration for anyone seeking to deploy digital health products and services in the UK [103]. Interoperability issues, in particular the way in which digital health services or products interface with existing systems (such as established NHS systems) created considerable additional work and consumed precious time and effort, slowing the deployment of digital health services and products during the life of the LiU programme. Interoperability has long been recognised as an issue of importance in digital health but clearly is a "mission critical" factor when trying to deploy digital health services at scale and across a nation as was the case here.

Safety and security of personal data was a major concern for consumers engaging with LiU products or services. There were concerns how information might be used or perhaps misused by statutory agencies. Such concerns are not unreasonable given the more recent use by Immigration services of NHS Digital data to identify illegal immigrants [104]. Consumers were concerned about the potential for data sharing that would not be in their personal interest and might even prove detrimental. This suggests that if e-health services are to flourish and policymakers really wish to encourage uptake and utilisation of new e-health services then statutory protections of such data may well be necessary beyond that which currently exists.

The importance of developing a "shared language" and gaining an understanding of different ways of working proved an essential for the success of LiU. It was clear that large multi-agency consortia had groups with completely different backgrounds, expectations and ways of working and efforts spent facilitating enhanced understanding were definitely well spent and proved to be a facilitator. The importance of upskilling to enable use of digital health technologies was also an important finding. It illustrates that skill deficiencies are not insurmountable obstacles but need to be addressed if digital health deployments at scale are to be successful. The importance of upskilling to enable digital health uptake and utilisation is one that has been identified as an issue in recent publications [105].

In terms of resources, insufficient man-power, centrally controlled budgets and limited time, bureaucracy proved to be a barrier to progress and these have already been highlighted in previous literature as key issues to consider. The need to evidence the success if a new intervention is ultimately a key implementation factor and the ability for LiU to develop multi-channels avenues of feedback proved to be a key implementation facilitator. Although identifying adequate funding periods to demonstrate 'success' has been mentioned time and time again in the literature. An extended period of five years may have been more suitable in this case. Lastly, it is

clear that forward thinking consortium members especially the industry and technical sphere proved that innovative partnerships could be created as a means of sustaining the current work and encouraging future works. This novel theme seems to have become unearthed due to the very nature of the consortium alone.

Factors Affecting Operational Rollout, Deployment and Active Implementation		
	–	+
Theme 1: Underpinning Infrastructure	Broadband Speed and Bandwidth Interoperability: No end to end testing environment. Firewalls issues preventing NHS access to content outside of IE.	New programme and initiative launched by the Scottish Government as documented in the 20:20 Quality Strategy for the use of Fibre Optic cables
Theme 2: Consortium Functioning	Mismatch between service and technical requirements. The need to manage expectations opinions and voices	Coming together to develop a common language. Valuing the contribution of each consortium member
Theme 3: Impact on Division of Labour	Inadequate Staff Training, Division of Labour, Time taken to recruit and train candidates. Bureaucracy affecting pace of implementation	Creation of additional roles and further organisational support. Proactive decision making to address resource gaps
Theme 4: Resource Constraints & Org. Support	Challenging creeping timescales, lack of morale, and negative interpretation of community performance.	Importance of adequate financial allocations to support deployment efforts as a 'means' to assist in reducing resource constraints
Theme 5: Scalability and Open Innovation	Taking into account local context of each implementation site as a means for 'successful ' implementation	Developing trusted relationships, means to encourage innovative thinking scale-able LiU strategy
Factors Affecting Appraisal Work and Large-Scale Evaluation		
	–	+
Theme 1: Evidencing Innovation	Lack of clear and effective communication channels for feedback. In addition to the tight funding period not enough to demonstrate 'growth'	Multi-Channel Feedback opportunities and the continuous learning cycle feeding into refinements and improvements.
Theme 2: Impact of 'Chasing' Recruitment Figures	Ambitious recruitment figures at times served as a barrier in reduced moral among members	Identifying various metrics to define 'Success' and not only rely on the numbers
Theme 3: Measuring the Benefits to Stakeholder Groups	Lack of recognition on the ground for 'benefits' realised and the impact on a national level for users and stakeholders.	Creation and value identified In the emergence of new and innovative partnerships between SMB's consortium
Theme 4: Sustainability Vehicle Model	A lack of foresight in terms of a sustainability strategy. The need for an appropriate sustainability and scalability plan needs to be made available early on	Forward thinking consortium members with the eagerness and will-power to sustain the LiU programme for future generations.
Table 6 B -NOTE: Factors spanning ' + and –' can be either plus or negative unless explicitly specified otherwise		

CHAPTER SEVEN
DISCUSSION & CONCLUSION

7.1 Introduction

This thesis set out to understand the barriers and facilitators affecting the implementation of digital health innovation on a national scale. This was done through undertaking a detailed exploration of the implementation processes at play during the design, development and deployment of the nation's first large scale health, wellbeing and self-management programme in Scotland. Special attention was focused on exploring the impact of this innovation and the 'work' undertaken by those involved in the implementation of the programme over a three year period [dates]. In order to meet this aim the following research objectives were set:

OBJECTIVE ONE – Evidenced in Chapter Two

To conduct a 'Structured Literature Review' to examine the existing literature regarding the implementation of national digital health projects in practice and to identify the factors affecting large-scale endeavours.

OBJECTIVE TWO – Evidenced in Chapters Three and Four

Explore the attitudes and experiences of 'implementers' as key stakeholders involved in the national deployment of the LiU programme over time. [Adopting use of multi-methods case study to explore the LiU Programme]

OBJECTIVE THREE – Evidenced in Chapters Five and Six

Identify and explain the underpinning factors which promote or inhibit successful normalization (implementation, embedding, and integration) of digital health innovation. [Original PhD Contribution]

OBJECTIVE FOUR – Evidenced in Chapter Seven

Produce a set of recommendations and lessons learned to inform future large-scale implementations, national digital health policies and practice. [Synthesis + Integration of Findings, Lessons Learned & Recommendations]

7.2 Summary of Key Findings

Firstly, a 'Structured Literature Review' was conducted in order to identify studies which had been conducted and published in relation to the large-scale implementation of digital health projects in practice. The study aims were to ascertain what the published literature tells us about the barriers and facilitators which impact the process of implementation, the lessons learned and what if any, research gaps exist. Five main factors were identified from this review of the literature which were organisational, technical, human and social, political,

and economic. These factors were mapped to the Normalisation Process Theory to help understand these factors and the 'work' underpinning implementation. It was clear that there was a great deal of overlap concerning factors which impacted the cognitive participation (engagement) and collective action (operationalisation) components of the theory. Identifying an adequate patient and consumer engagement strategy, supported by the use of champions proved to be a highly effective method promoting implementation success. In addition the need to align national and local priorities as well as identify a sustainable funding model was a key factor which was mentioned by several studies. The weakest elements within the literature stem from a lack of attention regarding evaluation and appraisal mechanisms. Furthermore, coherence appeared to be an under explored subject which highlighted the need for readiness assessments, ensuring that organisations have the digital framework and maturity to commence and succeed with implementation, as well as the need to identify roles and responsibilities and lastly to ascertain start-up resources to support initial preparatory and planning activities. The methods employed to report the respective studies were mostly qualitative and 'before and after' studies. This led to exploring a study design which enables the researcher to conduct a process evaluation to actively capture and gain a unique perspective during the course of the LiU programme implementation. Therefore Chapter Three discussed the suitability of such an approach as a 'Single Explanatory Case Study' using the interpretivist approach and qualitative methods (including ethnographic approaches as well as semi-structured interviews and analysis of documentary evidence). The aim of Chapter Three was to outline and justify the methods used to explore the attitudes and experiences of 'implementers' as key stakeholders involved in this national digital health deployment. Therefore a synthesis of key theoretical frameworks was conducted in order to ascertain the suitability of the chosen theory to support the thesis objectives. Due to the sheer scale of this endeavour the use of a multi-method approach; a) ethnography (participant observation), b) the collection of a wide range of documentary evidence and c) conducting longitudinal semi-structured interviews supported the vast and rich exploration of the experience of implementers during the course of the programme. The use of triangulation helped to create a rich dataset and chronology of the unique components which make up digital health innovation programmes such as the LiU programme. The researcher was given access to government documents and other information which helped to support the formation of Chapter Four – the description of the background, context and development journey. The ground work within this chapter (mapping the implementation journey timeline) was an essential component of this thesis as it highlighted the factors which can promote or inhibit successful implementation at scale on the ***surface level*** (the key implementation issues) in order for the subsequent chapters to illustrate and 'explain' 'how' and 'why' these factors can contribute to some or all services becoming embedded, integrated and sustained in practice.

Chapter Four provided a detailed and holistic account of the factual aspects relating to the context in which the LiU programme operated, in terms of organisations involved, management structures and contractual issues, and the specific activities and products delivered by the LiU digital health programme over three years. This chapter served to describe and explain how the programme itself developed and evolved over the three year period of observation. The main goal of this work was to set the scene and illustrate the dynamic and

evolving nature of the programme to aid understanding of the key implementation issues which chapters five and six explored in detail. The findings of this chapter included insights into the intricacies of the 'behind the scenes' work undertaken as well as crucial contextual information. This included details of the set-up of national and local structures to support wide-scale implementation, financial issues, the collaborative partnership model of working, branding and rebranding issues as well as the procurement and delivery strategy. In addition, further contextual information is provided in terms of the gradual development of products and services supporting the platform, as the researcher was essentially able to be the "fly on the wall" that could document and describe key issues and activities over the course of the initial three years of operation of this national digital health programme.

Chapters Five and Six presented the results of an in-depth longitudinal qualitative study performed to meet objective three of the thesis: to identify and explain the underpinning factors which promote or inhibit successful normalization (implementation, embedding, and integration) of the LiU digital health innovation. Implementation issues affecting sense-making and buy-in were discussed in Chapter Five where there was a special focus placed on the initial planning and engagement 'work' required to deliver this national initiative. The purpose of this was to examine how key stakeholders and organizations involved in the implementation process made sense of a new digital health innovation and how they encouraged user buy-in. Barriers included difficulty in cementing legal contracts pre-implementation, challenges in developing clear communication channels, establishing roles and responsibilities and working across individual, professional and organisational boundaries. Facilitators included creating additional choice for consumers as part of national and local needs, the development of trusted relationships recruiting local champions and the use of agile co-design methods. Although the use of these methods were naturally time consuming and impeded the pace of implementation at times, the co-design methodology also promoted effective engagement and 'buy in' by the public. Early challenges that the LiU programmed faced during the course of the implementation included the need to secure clinical endorsement from the outset. The findings suggest that sense-making and buy-in work requires a considerable amount of time and effort from all involved in order to create a solid foundation on which to carry the innovation forward.

Chapter Six again drew on the previously described qualitative work and the factors affecting deployment and appraisal. Here, data collected was used to examine the practicalities and the 'work' that key stakeholders and organisations do in order to ensure that LiU is operational in practice. In addition, informal and formal appraisal of LiU once in use was assessed and explored to understand the barriers and facilitators affecting the LiU innovation and also sustainability issues. Barriers included inadequate infrastructure, resource constraints, lack of training, difficulties evidencing the benefits of the digital health innovations and difficulty chasing recruitment figures to demonstrate scale. Facilitators included developing a common stakeholder language, the creation of new roles and multi-channel feedback routes for consumers. Early facilitators that worked in favour of the programme during the course of the implementation included the 'means' of defining success and sustainability efforts. The findings suggest that the enacting and appraisal work mechanisms are somewhat dependant on the

planning and preparatory work that is required at the very beginning of the programme to create a strong foundation.

7.3 Synthesis and Integration of Findings

Having identified key implementation issues relating to large scale deployments from an examination of both the literature and the longitudinal study of the LiU national digital health deployment the next key activity was to synthesise the key implementation findings. Figure 7.1 – presents the **Digital 'ATLAS' Conceptual Model** of implementation issues 'At Large Scale'. The model was developed by integrating all the findings of from this thesis and mapping them onto the components of the normalization process theory. It makes reference to the key issues that have been raised and key factors that need to be considered when implementing digital health at scale. This model can be viewed as a checklist of things to think about when embarking on such a large scale digital health initiative. It is important to be clear that the author is not developing a new theory but instead proposing a new toolkit and model for those embarking on implementation at scale. It is evident from the model that there is an element of overlap between the findings from the literature review and that from the analysis of the data from the LiU case study. The model illustrates that several findings identified within the existing literature resonated with those found from examining the experiences of deployment on a large scale as part of the LiU national programme. This suggests these are generic issues that are amplified in digital health deployments at scale and therefore it is important to factor these in to preparatory activities. The model is presented as circular, recognising that implementation is not a linear process and there are parallel and overlapping issues at play that may interact, throughout the life of any digital health implementation project. Lastly, while the model highlights key implementation factors the relative weighting of each factor is not represented, and this is an issue, which may merit future investigation. Each domain may not be equally weighted and whilst this work provides preliminary evidence about which aspects are likely to be particularly crucial this will remain a topic worthy of further investigation. The model was developed using an iterative process by aggregating the key findings, learning and summary points identified through the research activities undertaken within this thesis. It is important to clearly illustrate the links between the a) theoretical groundings, b) existing literature and c) identification of knowledge gaps and unearthing new findings. Therefore an explanation of the development of this model helps to provide a greater level of transparency between the analytical process and the added value of NPT. The Digital ATLAS Model was developed four-fold. The base layer also known as the 'theoretical layer' represents each construct of NPT which is the theoretical framework underpinning this thesis.

- **Quadrant One**: 'Sense-Making' – reflects the factors that need to be considered when coming together to adequately create an at-scale implementation strategy. Findings from existing knowledge base (Red) illustrate for example start-up resources, defining roles and responsibilities, education and training that need to be considered. Findings from this thesis indicate that it is also important to consider the need to

work across multi-agency and heterogeneous boundaries effectively, to develop clear communication channels and strong leadership.

- ☐ **Quadrant Two**: 'Buy-In' – reflects the factors that need to be considered when attempting to engage and recruit users to your digital health innovation at scale – the factors which need to be considered from the existing knowledge base was the need to engage clinicians and patients early on, to identify clinical champions, and perhaps the use of financial incentives. Findings from this thesis demonstrate that these exact findings are exemplified at-scale. For example the use of consumer engagement strategies were a notable facilitator however as the implementation process progressed the sheer scale of the endeavour meant that additional time was required to enable users to fully participate in the engagement and recruitment journey.
- ☐ **Quadrant Three**: 'Operationalising' – refers to the work required to enable the innovation to be implemented in practice 'what needs to be done'. Findings from the existing literature points out the need to consider ethical-legal practicalities, technical infrastructure, the need to align your at-scale implementation with that of the needs of users and the subsequent impact on working practices. Findings from this thesis indicates that 'context' and 'scalability' requires due consideration in addition to ensuring that users are sufficiently up-skilled to enable them to fully participate in the implementation journey.
- ☐ **Quadrant Four**: 'Appraisal' – refers to the work required to evaluate the implementation process at scale. Findings from the existing literature already suggested that for complex interventions greater consideration should be placed on enabling longer funding periods in order to demonstrate 'success'' , thus enabling sufficient time for the embedding processes to take place. Furthermore, this project highlighted the need to consider the impact of ambitious targets on implementers' performance. It was equally important to identify a sustainability 'vehicle' as a measure of success.

Having catalogued the barriers and facilitators to implementation at-scale and conceptualised them through the lens of NPT, each component and their sub-factors are made up of underpinning processes which affect how implementers and users progress through the implementation journey at scale. Again, as previously mentioned further research would be required to determine the relative '**weighting**' and thus importance that should be placed on different elements of the model. The next section summarises strengths and limitations of this work, the key learning and the outstanding research gaps.

7.4 Strengths and Limitation of Thesis

This section provides an overall appraisal of the multi-method approach used throughout this thesis: Chapters 2, 4, 5 and 6. The use an interpretive line of inquiry as part of a case-study approach provided an opportunity to explore how implementers (social actors) attribute meaning to their 'work'. This approach was deemed to be the most appropriate given the aim and objectives of the thesis. The ability to gain an insight into the subjective behaviours and beliefs of implementers was key in efforts to understand how and why normalisation occurs or not across the board. A clear strength was the use of a range of qualitative methods (qualitative literature

review, focus groups, interviews, observation, documentary evidence) and data sources which has resulted in a broader understanding and gives richer credibility to the findings. In addition, the fact that the study is not just cross sectional but rather longitudinal in nature, over three years, again should be viewed as a strength as the findings provide a more complete picture of the implementation experiences throughout the life of the programme. The work was also undertaken prospectively in parallel with the LiU service deployment across Scotland, rather than retrospectively as has been the case in many other implementation research projects. Participants were therefore describing issues affecting implementation in real -time, as they arose, rather than simply reflecting on past events which might have produced different and potentially less accurate reflections. Such a prospective approach was likely to minimise recall bias and also meant participants were sharing opinions about implementation issues without prior knowledge of the final outcome of their efforts.

The innovative co-design and user engagement approach developed as part of LiU was very much welcomed as a positive method to incorporate citizens' views into the development of health and social care services in Scotland. Hailed as the largest collaborative and engagement approach used in Europe it was important at the very beginning to ensure that participants understood that LiU was a project 'in development' and not a finished 'product. Therefore emphasis was placed on the value of participants in shaping products and services. Although this novel approach was warmly received it did have some drawbacks with regard to the length of time that it took to carry out. This was partly due to ensuring that all stakeholders were able to have an input into the development process. This approach was considerably different to that of the other 'dallas' communities which either adopted a limited use of co-design as many of the products had already been developed (Liverpool, eRedbook) or none at all (Canary Service, DHAHA). The time taken on this co-design was seen by some as important but also as a barrier to meeting the tight timelines and expectation of the funder in relation to dallas deliverables. The LiU programme was the only community that used such an intensive, large scale co-design approach. LiU claimed to be engaged in the largest co-design process in Europe, and the first of its kind to develop engagement and participation tools for such widespread use. In contrast the other communities mostly had readily available products that just needed minor tailoring and therefore the approach in Scotland was quite distinct and warmly received. In addition, the LiU co-design approaches were the recipient of multiple awards.

Conducting a Process Evaluation meant that one had to be proactive as digital health innovations are dynamic in nature. I was able to gain a unique insight into the inner workings of LiU and this insight was very beneficial because outcome studies are unable to shed light on how effects come about which is a strength of carrying out a process evaluation. This was a key learning point as process evaluations that address causality of complex interventions in the 'real world' and at scale are rarely reported. An additional strength of adopting a Process Evaluation approach to investigate the implementation of LiU was that it was the creation of feedback mechanisms which enabled implementers to pin-point strengths and weaknesses within the program to enable adjustments to be made accordingly to help improve the chances of positive outcomes and future sustainability and scale-up efforts. However, a challenge of utilising Process Evaluation to investigate LiU was the need to not

jump to any conclusions as the outcomes were unknown and the project was still developing. It was important to 'wait' to place judgement.

Many aspects of the LiU innovation are no longer operational. Early findings identified from baseline interviews indicated the challenges facing implementers. The sheer scale of the LiU programme added to the complexity of this ambitious project. In reporting my findings, it was important to remain true to the data and from the very fact that I was required to change the entire course of my PhD attests to these challenges and difficulties. Early 'Red Flags' were issues regarding gaining access to speak with patients and health professionals, the need for upskilling of potential users and lack of infrastructure and broadband for example which had major negative effects on implementation efforts in rural areas. Many of these issues remain issues even after the LiU had been implemented and while efforts have been made to improve infrastructure some of these problems are unresolved and persist to the present time.

The use of the Normalisation Process Theory as the underpinning theoretical framework for this thesis has been a key strength of this research. It provided a crucial foundation on which to analyse and interpret the findings from the Literature Review Chapter 2 and Data Chapters 5 and 6. This provided scope to compare and contrast the findings from the data collected in relation to the LiU deployment to that of the qualitative systematic review in Chapter 2. The iterative mapping of the themes identified against the NPT framework aided reflection and understanding of the key concepts identified. NPT is now well documented to be a theory of implementation that is very appropriate to use to answer the types of questions posed in this thesis. [106] Using NPT helped to describe and explain processes identified through analysis of the data collected during the life of this PhD programme. Using such a theoretical lens to reflect on qualitative data is thought to help better explain the key issues underpinning success or failure of a particular implementation project [106]. Certainly it has enabled a large volume of disparate implementation data to be drawn together into a coherent model that summarises the many factors that affect digital health implementation. It has the potential to provide a useful tool to assist anyone considering a large scale digital health initiative to think through key steps that will be worthy of consideration in advance of embarking on such a venture.

The use of NPT as a theory-based evaluation framework helped to explain the factors that enabled and inhibited the implementation of LiU at scale. In addition it also helped to identify the underpinning generative mechanisms likely to enhance its sustainability. A challenge of its application however was the overlapping nature of the core constructs. This means to say that the data could be coded to one or more NPT constructs. Again, the constructs of NPT do not describe a linear process and instead are meant to capture implementation processes which are dynamic in nature and therefore in the event that data mapped onto more than one construct then a decision was made to be explicit and state that where relevant. Strengths of using NPT throughout this thesis were that it helped to provide a level of consistency in the mapping process given that data was collected at different time points over three years. Furthermore, the use of NPT helped to maintain a

consistent approach throughout the lifecycle of this thesis from informing the planning phases and topic guides through to analysis and evaluation.

However, this thesis also has a number of limitations. A key limitation of this thesis was the lack of inclusion of user voices. Due to the heavy focus on co-design and delays in the early stages of the programme which have been described in the earlier chapters, the recruitment of participants to the programme was greatly delayed which meant that the researcher, who had originally intended to include data collection from users, had to amend their study plans and limit data collection to other key stakeholders in this national deployment (e.g. implementers). A further important limitation relates to the lack of input from the professionals who declined to engage with the LiU programme and this meant that the researcher only obtained data from those who engaged with LiU. So a clear gap is the lack of data from those who did not engage with the LiU programme. Data from such individuals might have provided additional useful insights and different perspectives to those who participated in this research. Undertaking longitudinal and prospective work of this kind is also time consuming and therefore limited the scope of the work that could be done. Also while a robust approach to data analysis was undertaken with careful attention to thematic coding and mapping onto a recognised theoretical framework, resource limitations meant that the data was not double coded. Although the researcher, checked coding with supervisors and participated in "coding clinics" with members of her supervisory team to ensure the robustness of her approach to coding this could also be seen as a study limitation. In addition, respondent validation of the analysed transcripts was not undertaken which could be seen as a limitation. Respondent validation refers to the practice of allowing interviewees to comment on the interview transcript and whether the final themes and concepts adequately reflect the phenomena being investigated [107]. Time and resource constraints meant that such checking was not undertaken. Finally, while the use of NPT can be seen as a key strength, some might argue that there is a danger of 'shoe-horning' or the use of NPT as a framework for analysis might limit conceptualisation of data that falls outside the framework. In the case of this research the use of 'coding data clincis' facilitated transparency and the thematic analytical process also prevented inappropriate 'shoe-horning' of data.

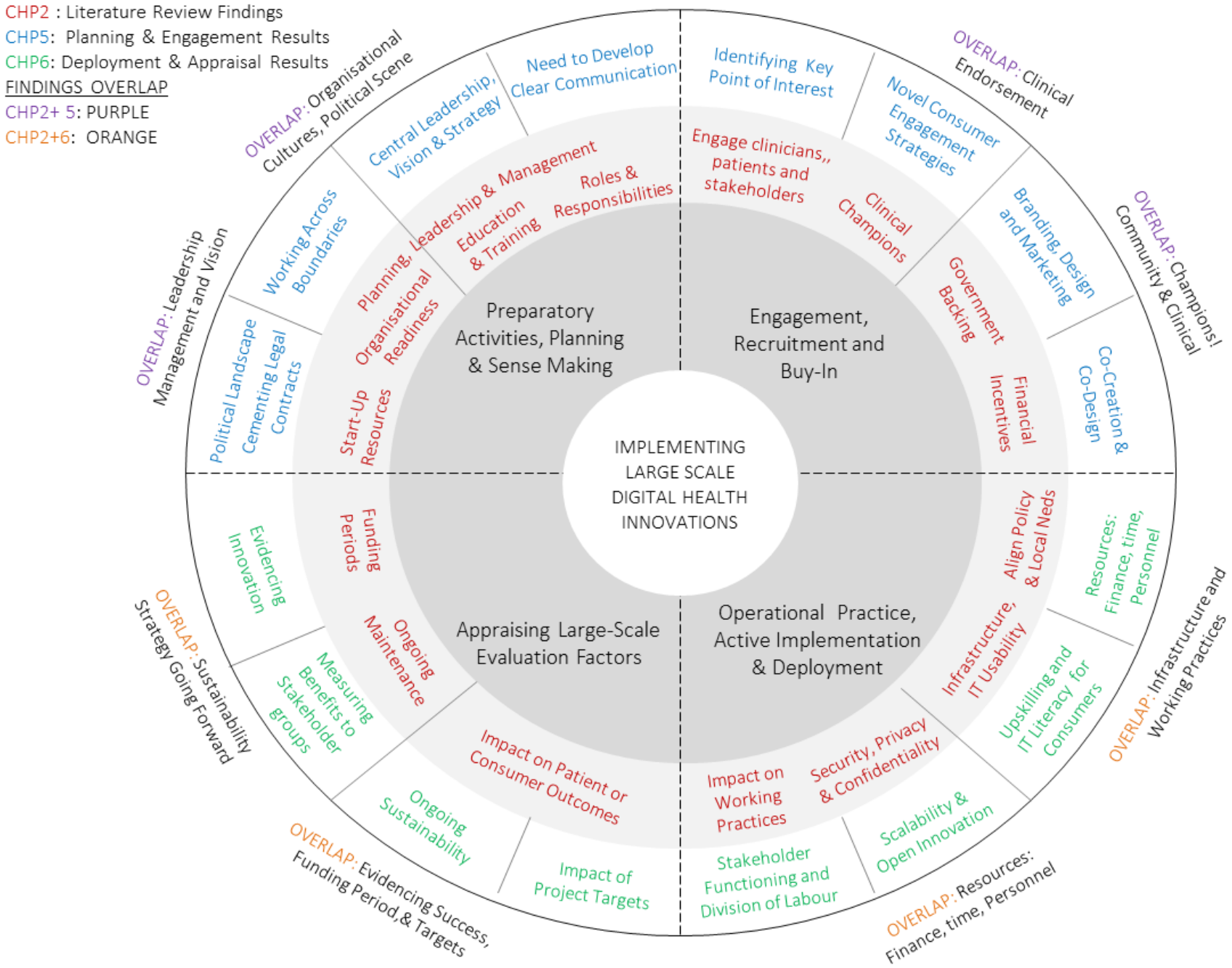


Figure 7.1 – Digital 'ATLAS' Conceptual Model of Factors Affecting Implementation of Health Innovations at Scale

7.5 Consideration of Findings in Relation to Existing Literature

A summary of what was already known versus what this study adds is provided in this section. This thesis set out to make a unique contribution to knowledge by being able to shed light on the enablers and obstacles faced when a national digitally enabled self-care initiative is rolled-out and scaled-up in the real world. A service evaluation of this kind is unique given the fact that the literature is overwhelmed with data from small scale pilot and demonstration projects and there is far less known about large scale deployments and none that look at deployment of such a range of digital health services as described here. Therefore the opportunity to gain an insider's view of Scotland's first national digital health programme presents the perfect test-bed and opportunity on which to capture the complex and multi-faceted nature of implementation at scale. In addition, obtaining evidence to capture sustainability at scale is a unique aspect which is an under-researched area but important indicator for normalisation .

While many of the issues identified here clearly resonate with the existing digital health implementation literature this body of research makes a distinct contribution because of the scale and diversity of the services being studied. In addition, it is clear from the analysis of the work undertaken throughout this PhD, that there are generic implementation mechanisms at play that merit consideration in any digital health deployment. The areas of overlap with the existing literature are clearly highlighted in Figure 7.1. However, there are certainly also important new insights about facilitators of implementation highlighted by this work., particularly in relation to the intensive co-design and engagement work that was undertaken as part of this programme which seemed to promote engagement and seems likely to have the potential to underpin longer term sustainability.

In addition, there has been longstanding concern that digital health may potentially increase inequalities in health due to problems associated with the "digital divide" which relates to the gap separating people who have access to new technologies compared to those who do not [108]. This digital divide might be related to socioeconomic status but could also be a result of geographical location, for example, relating to the poorer accessibility of broadband services in remote and rural areas. A key feature of the LiU implementation related to the efforts to increase accessibility of new technologies to people in different areas and from different backgrounds. This investment in upskilling and promoting digital access was a unique feature which appeared to have positive effects and enabled engagement. The wider digital health implementation literature has certainly advocated attention to such issues but this is the largest scale digital health programme to have put this level of effort and investment into upskilling and this is particularly noteworthy. This work has demonstrated the importance of allocating sufficient time to adapting ways of working to make new systems work in practice. This research was not only able to identify the work underpinning implementation at scale but also the 'reasoning' behind it. Previous research into large-scale innovations in the UK by Sheikh, Cresswell, Greenhalgh and colleagues support the findings that have emerged from this thesis [46,99,100].

LiU was part of a wider dallas programme involving three other communities. The work presented here was a more in depth case study, providing a deeper dive into the details of the programme than was possible for the wider dallas programme.. The findings from this PhD work resonated with findings from the other dallas communities but provided unique insights particularly due to the challenges of providing digital health to remote and rural locations and also due to the national support of the work, which was quite distinct from the other communities. In addition, the LiU community was the only community to adopt such an intensive co-design and community engagement approach and to try to set up a national level resource. In addition, more detailed ethnographic work was possible in this single community case study than was possible as part of the wider programme.

7.6 Implications of Findings Going Forward

Valuable information has been gained throughout this thesis which provides a useful starting point for future exploration. The 'Digital ATLAS' model of factors to consider whilst implementing health innovations at scale provides a useful toolkit for researchers and the work of this thesis has resulted in a number of key lessons learned and recommendations regarding critical success factors that merit consideration in future digital health deployments.

7.7 Future Research Directions

The Digital ATLAS model described in this Chapter (**Figure 7.1**) highlights a range of factors that will be important for any large skill digital health implementation. However, as mentioned previously there remain many unanswered questions which merit future exploration.

1. It will be important to prospectively test the factors identified here in future large scale digital health deployments and determine if the concepts identified are indeed generic and to explore whether there are gaps in the model. This is clearly a preliminary conceptual model and there may well be other important issues that need to be added. In addition, the relative importance of different components of the model remains unclear and this issue needs further investigation. Importantly, it will be vital to identify whether any particular elements of the model are particularly crucial and whether inattention to one or two specific issues could be deemed an implementation killer or not.

2. This study of a large scale digital health deployment focused predominantly on stakeholders involved in implementation. It would be important for any future work in this area to explore public perceptions of large scale digital health deployments. Such research would need to include data collection from those who engage with such digital health services but also those who do not to determine outstanding barriers to engagement.

3. Similarly any future research of this kind would need to engage more intensively with health professionals, both those who engage with a digital health deployment and those who seem reluctant to do so to determine if there are any additional features not captured in the present model.

4. It will also be important to examine how to judge implementation success. Here issues that were deemed to promote implementation were considered as important facilitators. But how does one measure implementation success? New measures of implementation such as the newly developed NOMAD tool may help in this respect but this remains a relatively unexplored topic which deserves further attention.

7.8 Key Learning Points and Recommendations

Key considerations for future large scale digital health service deployments should include the following.

1. ADEQUATE PLANNING AND PREPARATORY ACTIVITIES ARE ESSENTIAL

   From the beginning it is important to have adequate start up resources. There is a need to ensure that there is sufficient time to invest in preparatory activities pre-implementation. It would be worth carrying out a readiness assessment to ascertain digital maturity of organisations that are going to be involved in a digital health deployment and to have evidence of suitability to carry out the project.

2. PROOF OF CONCEPT

   Funding should be sought for at least a five year period to demonstrate the effectiveness of sustainability, scalability and mobilisation of any digital health intervention. Realistic efforts should be made when costing and time lining such initiatives.

3. THE IMPORTANCE OF STRATEGIC VISION

   It is clearly important to have clear goals and also to have a clear implementation and sustainability plan from the outset. Implementations that fit well with the wider policy and service goals have a great likelihood of success.

4. COMMUNICATION & GOVERNANCE

   Investing in and creating a clear communication plan supported by a defined governance structure to ensure that there is a coherent and shared strategy in place are likely to be important features to enhance the likelihood of a successful digital health deployment.

5. DESIGN: The use of co-design and co-creation methods presents several benefits for all stakeholders involved however it would be worth setting a defined time for 'creativity' in order to enable smooth

integration towards recruitment of potential users. Ensure that users understand the level of commitment required from the outset in order to maintain buy-in and support for any intervention.

6. RECRUITMENT

   'Phased Recruitment' would be worth delaying recruitment till after any 'creative' work has been undertaken. This is necessary in order to ensure that digital health services are fully defined and have developed sufficiently for users to grasp the potential benefits or disadvantages of any planned digital health services

7. SENIOR BACKING: It is crucial to gain the support of senior levels of management to help spearhead the adoption of a digital health intervention early on, and help to sustain levels of engagement and participation

8. CHAMPIONS: It is clear from the literature and the experiences of the large scale LiU deployment that it is important to be able to identify people with a vested interest in championing a specific digital health intervention.

9. FLEXIBILITY: A great deal of flexibility is needed in order to circumnavigate obstacles as they arise. Identify strengths and opportunities early on as a means of creating an effective contingency strategy.

10. ROLES AND RESPONSIBILITIES

    Implications for role and responsibilities of health professionals should be considered as this may influence training or support requirements and impact on workload which can serve as an important barrier to uptake and utilisation.

11. BRANDING & MARKETING

    Use clear language and undertake testing of any branding and marketing efforts in advance of widespread dissemination to ensure any digital health product, service, or innovation can be understood by the planned target audience.

12. TECHNICAL FACTORS

    It is essential to scope out the technical abilities of those expected to use digital health services (both professionals and public). It will be important to attempt to scope and visualise scalability and what this would mean in real terms and to various stakeholders involved. There should be sufficient investment in both national and local infrastructures. Additional guidance should be offered to local level implementers within public services attempting to implement across interoperable, security and governance structures.

13. UPSKILLING: Considerable investment should be made to increase public and professional awareness and to upskill and train professionals and members of the public about the capabilities of digital health to promote health and wellbeing. Equally, there needs to be consideration of potential barriers to access of digital health services and any such barriers need to be addressed.

14. DEVELOPING SYSTEMS FOR MONITORING AND EVALUATION

    While Randomised Controlled Trials may be neither feasible nor desirable when considering digital health deployments there do need to be mechanisms and processes in place to monitor benefits and dis-benefits if any, of new digital health services. Any such evaluations should consider the effects, if any, of any digital health deployment on inequalities in health. Will the deployment ameliorate or exacerbate these? In addition, systems for feedback and iterative development are important. Potential mechanisms might include creation or development of multi-channel feedback routes.

7.9 Conclusion

The large scale deployment of digital health undertaken by the LiU programme provided a unique opportunity for research and learning. However, the LiU programme as originally developed is no longer operational. There were many novel aspects of the LiU programme, particularly relating to the public engagement and co-design work that was undertaken. The work undertaken through this thesis has enabled the development of evidence based, theoretically grounded conceptual model of implementation to be developed which can serve as a checklist for Policy Makers, Researches, Digital Health Implementers and Influencers regarding the factors to be considered when considering large-scale implementations. Even more importantly the model can be used to assist implementers from the outset as they progress forward from planning, to implementation and evaluation to ensure or be mindful of these factors, if anything is missing (which may seem obvious or perhaps not have occurred to them).

It would be valuable for the LiU programme to endeavour to share information about their tools and services as widely as possible to maximise learning and to ensure the maximum benefit is gained from the investment in the programme to date. There is evidence that programme has endeavoured to share learning in Scotland and across Europe. Data generated from this body of work informed the on-going development of the wider dallas project, providing an opportunity to compare and contrast findings among the respective communities. Furthermore, these findings collated over a longitudinal period of time and were able to be reviewed by LiU implementers thereby becoming an indicator of quality. The co-design process itself was highly welcomed by communities across Scotland and the use of novel engagement tools and techniques proved to be attractive. Going forward it will be important to monitor utilisation of the LiU services to determine whether the service is used by all sectors of society or not and to explore what future actions need to be undertaken to widen participation.

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University of Glasgow | College of Medical, Veterinary & Life Sciences

20th January 2014

Dear Professor Mair

MVLS College Ethics Committee

Project Title: Exploring the Implementation of a National e-Health Programme in Scotland
Project No: 200130029

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project, subject to the following conditions:

- Project end date: **28th February 2015**
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.
- If the study does not start within three years of the date of this letter, the project should be resubmitted.
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

Dr Dorothy McKeegan
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Implementing a National Scottish Digital Health & Wellbeing Service at Scale: A Qualitative Study of Stakeholders' Views

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Abstract

Digital technologies are being used as part of international efforts to revolutionize healthcare in order to meet increasing demands such as the rising burden of chronic disease and ageing populations. In Scotland there is a government push towards a national service (Living It Up) as a single point of reference where citizens can access information, products and services to support their health and wellbeing. The aim of the study is to examine implementation issues including the challenges or facilitators which can help to sustain this intervention. We gathered data in three ways: a) participant observation to gain an understanding of LiU (N=16); b) in-depth interviews (N=21) with stakeholders involved in the process; and c) analysis of documentary evidence about the progress of the implementation (N=45). Barriers included the need to "work at risk" due to delays in financing, inadequate infrastructure and skill-set deficiencies, whilst facilitators included trusted relationships, champions and a push towards normalisation. The findings suggest that a Scottish ehealth service is achievable but identifies key considerations for future large scale initiatives.

Keywords:
eHealth; Chronic Disease;Wellness Programs; Implementation

Introduction

Population ageing in the 21st century is a major issue with the World Health Organisation (WHO) forecasting that the number of people aged 60+ around the world is set to reach 2 billion by 2050 [1]. This represents the fastest growing age group anywhere in the world. While, this can be seen as a cause for celebration, ageing is changing the shape of society and therefore introduces enormous challenges, particularly in relation to the provision of health and social care services to a population with increasingly complex needs. A consequence of this demographic shift is the increased prevalence of non-communicable diseases (NCD) associated with ageing; also known as chronic diseases. Each year NCDs are the cause of 36 million deaths; in Scotland 60% of all deaths are attributable to a chronic condition and they account for 80% of all general practice consultations [2,3,4]. This has major implications for primary care provision within the United Kingdom (UK) as 90% of all patients' interaction within the National Health Service (NHS) 'starts and ends in primary care'[5]. Current models of care are unsustainable, costly and inadequate. There is a need for innovative approaches and solutions which can meet the demands of a fragmented system. The Scottish government aim to be at the forefront of innovation in becoming a "world class digital nation by 2020" with policy intending to help people to live longer and healthier lives at home or in a homely setting using digital technologies as an enabler [6]. The focus within primary care is on prevention, supported self-management and patient-centred holistic care. Healthcare is a lucrative and expanding market and the call to revolutionize it using digital technology has been seen as a key driver in creating innovation. However one of the most critical issues impeding previous efforts has been the gap between what we know can optimise health and wellbeing to what actually gets implemented in everyday practice. This has been referred to as a 'translational gap' where the normalisation of an intervention commonly fails [7]. The *purpose* of this study is to report on the *mid-point* views of stakeholders' on the factors which can promote or inhibit successful implementation of a large-scale digital health and wellbeing programme (Living It Up) across Scotland.

Materials and Methods

Participant Recruitment & Data Collection

In order to gain a wide range of perspectives and obtain a holistic picture of the implementation journey we contacted via email a purposive sample of stakeholders (N=16), representing local, national and international organisations. This sample spanned six sectors (industry, health and social care, housing, education, voluntary and statutory), all working together as a collaborative consortium within the Living It Up (LiU) project. Qualitative studies of stakeholders views are important to understand factors which affect implementations on the ground, for example a study on EHRs in Sweden identified discrepancies between the views of professionals and consumers which affected EHR utility and uptake of a national system designed to improve health provision [8].

Data Collection

Ethical approval for this study was obtained from the University of Glasgow, College of Medicine, Veterinary and Life Sciences Ethics Committee (2000130029). We collected and triangulated multiple sources of data through: a) prolonged participant observation; b) semi-structured interviews; and c) collection of a wide range of documentary evidence. Participant observation in this study involved two components: 1) observing monthly stakeholder meetings and 2) collecting data from quarterly meetings held between stakeholders (key informants) and researchers which served a primary purpose of capturing the changing face and shape of a digital health and wellbeing service which started as a 'blank

canvas'. These translated to a total of N=16 participant observation sessions over a period of 14 months (October 2012 to December 2013) and approximately 62 hours of interaction. Secondly, we conducted a total of N=21 semi–structured interviews (January to July 2014) which helped us identify and understand the barriers and facilitators to implementation. In order to capture both breadth and depth within the study we collected both a longitudinal and cross-sectional dataset. The longitudinal data included follow-up interviews conducted with N=6 participants (project managers) at baseline and mid-point (after 6 months). N=1 project manager resigned after 6 months and therefore we were not able to carry out their interview and this was not part of our final dataset. The cross-sectional dataset included mid-point interviews with N=10 participants that were service and technical partners involved in high-level strategic decision making. The interview questions were informed by Normalisation Process Theory (NPT) [9] and each interview lasted approximately 60 mins. All interviews were transcribed verbatim and coded in addition the research team undertook 'data coding clinics' where coding was discussed and agreed to ensure consistency and validity of the coding framework. Lastly, we collected N=45 multiple sources of documentary evidence such as Quarterly Progress Reports, Service Specifications, Alignment Interviews, Recruitment Reports and Evaluation Updates that were synthesised in order to capture and map out the implementation journey and to create a 'thick description' of the project over time. These methods maximized our ability to grasp the subjective behaviours of a multi-stakeholder environment.

Data Analysis

Each transcript was subject to theory-led qualitative analysis with reference being made to the Ritchie & Spencer (1994) thematic framework for data interpretation (familiarization; identifying a thematic framework; indexing; charting, mapping and interpretation)[10]. NPT was used as the theoretical framework underpinning our study as it is widely advocated and cited as a robust explanatory framework which captures the 'work' of implementing, embedding and integrating new technologies or services into routine practice [11]. The framework makes reference to four key domains namely: Coherence, Cognitive Participation, Collective Action and Reflexive Monitoring. The first domain looks at the '*sense-making'* work that people do individually or collectively in order to develop a shared understanding of a new intervention. The second domain reflects on the '*relational*' work that people do to encourage people to engage, buy-in and sustain a new intervention. The third domain simply refers to the '*operational work*' that people do and what needs to be done to ensure that the new intervention works in a real-life setting. The final domain looks at the '*appraisal*' work that people do to assess and understand the impact of a new intervention. We mapped our thematic findings to NPT in order to help us understand our data. The analytical process as a whole was facilitated using QRS Nvivo ® Version 10.0.

Results

The Makeup a Scottish Digital Health & Wellbeing Service

Living It Up (LiU) is part of a £37 million UK-wide project titled Delivering Assisted Living Lifestyles at Scale (dallas). The aim of dallas is to demonstrate how innovative technologies and services can be used for 'preventative care to promote independent living and improve peoples lifestyles' between June 2012 and May 2015 [12]. LiU is a digital platform (www.livingitup.org.uk) accessible via various modes of familiar technology, which aims to impact 55,000 people aged 50+ approximately 10% of the total Scottish population to improve their quality of life and independent living. The project targets 5 specific geographical locations namely; West Lothian, Moray, Highlands & Islands, Forth Valley and the Western Isles capturing a mix of urban, rural and remote rural areas. LiU has been hailed as a 'national ground breaking service' by government representatives. It aims to help the citizens of Scotland find local, trusted and personalised information on services which can support health and wellbeing [13]. The platform was developed using a co-design approach with intended users (members of the general public), creatives, technology designers and over 30 organisations (Figure 1). The LiU deployment is being led by the Scottish Centre for Telehealth and Telecare (SCTT) and NHS 24 which are government bodies' established with a purpose of facilitating the shift towards how health and social care services are provided, perceived and consumed.

Figure 1 –International Stakeholders for Living It Up

LiU is a platform that provides consumers with access to four key services: Connect, Discover, Flourish and Shine. The first being a service which supports *digital participation* among communities in providing a means for people to remain 'connected' with their friends and family as well as an opportunity to up-skill and learn how to go about using technology. This service enables users to remain 'connected' to their care-giver via Cisco Jabber Client video conferencing (VC) suite. The second service 'Discover' is based on *asset mapping* national and local information about organisations, services, activities and groups which consumers may find useful in meeting their needs. This service is powered by a national database called ALISS (A Local Information System for Scotland). This provides a personalised search and collaboration tool for users and enables organisations themselves to use it for sign-posting [13]. Users also have the ability to 'rate' services in an open format and share recommendations.

Flourish provides a suite of interactive tools to support people in *self-managing* their chronic condition. This includes approved health information and advice, text messaging alerts and remote-monitoring services to help support people with conditions such as Heart Failure (HF). The final service 'Shine' centres on community *capacity building*. It is advertised as the 'front door' to LiU. This service taps into the value of the contribution that citizens can make to society.

The service provides a 'profiling tool' which enables people to identify, nurture and refine their individual skills and experience in a way to 'give back' to their local community. This approach is being used to help contribute to improved wellbeing and stronger, more connected communities. Users of LiU can access the entire platform free of charge and there is an opportunity to become a member which will present them with a personalised dashboard. The final aspect of this platform is the 'Innovation Zone' which provides a space for enterprise where companies can advertise new solutions, apps or products which require testing or exposure ultimately fostering wealth creation [13].

Implementation Barriers

Working at Risk

This section provides an overview of the key mid-point themes that emerged as barriers during the national deployment of the LiU platform. A challenge amongst stakeholders in the beginning was to identify an agreed approach and direction. Due to the ambitious nature of the programme it was deemed important to engage with a wide range of different types of stakeholders. However, as this collaborative consortium combined a large number of organisations (local, national and international) from various backgrounds and with varying expertise, this introduced a degree of tension when voicing opinions, settling agreements and making decisions. This, coupled with the use of a co-design approach prolonged the design phases a great deal. For example, it was anticipated that a 'soft launch' of LiU would be live by March 2013 but in reality this occurred in November 2013 this attests to the scale of delay. Further to this, there were contractual difficulties which distorted the traditional tendering process and in order for stakeholders to proceed with their involvement in the project they usually had to 'work at risk' and obtain a letter of intent in relation to delayed financial payments. "*There was a huge bureaucratic delay in getting the thing set up and a contract out… The project was officially meant to start in June…you know, as a delivery partner, we did not get a contract until the following January. So, you know, we worked at risk. You know… to try and be a good partner but, you know, for a business that's not satisfactory and that means that you can't commit all the resources you would like to when you don't know if you're going to get a contract*". "*So, there's a slow start but what made it worse… was it took far too long to decide what LiU would be, you know…Our job was delivery of the requirement. Now, it took probably a year to decide on what the requirement was*"[LiU11]. "*LiU works in quarters. The financial approval process is so far off the pace of the work process that it's not only late it's almost at the end of the process…There's two things you can do as a supplier, one is you can say I'm not moving until I get approval…or else you can proceed at what's called…working at risk. I'd say it's uncommon*"[LiU20]

No Complete End-to-End Testing Environment

LiU aims to provide consumers with an integrated seamless journey of care. There was a consensus amongst stakeholders that delivering this vision was a complex process. Some partners worked in 'silos' within their organisations and concentrated on a particular piece of work which meant that difficulties were only recognised when that piece of work became integrated within the wider programme. This impacted the implementation process because there was no complete end to end testing environment across the entire programme. "*So basically what happens is a supplier, a technical partner is used to the principle of building something and then they put it into their test environment and test it. Right…now the problem is until you have interlinked them you don't know they are going to work. So supplier A could build product 1 and test it but when it goes live it might not work because of something that supplier B has running on their website…now it would cost a lot of money to build a complete end to end test environment"*[LiU20].

Inadequate Infrastructure – Challenging Boundaries

In some cases, the ability to deliver the innovation meant that transformational re-modelling of the current care model was required. This meant that LiU was being impeded in some aspects as current infrastructure was not suitable to adopt some elements of the platform."*I think we're certainly ahead of the game. Looking at international markets and speaking to our counterparts in the UK I think this is very much a pioneering project. ..We've actually moved to a kind of model that's maybe five years ahead of its time*". [LiU06]

Educating Stakeholders

In a multi-stakeholder environment, the need for all LiU consortium members to have a shared sense of understanding required a level of learning. It was clear that some stakeholders required more 'training' than others which slowed down the implementation process as well as the concept of innovation as a whole. "*There was a lack of understanding of digital technology and what it can do now. A lot of the people were not familiar with the use of digital technology and, you know, on the service side, the people that were designing the services did not themselves use this type of technology, so they were not pushing the boundaries*" [LiU11]

Designed for Local vs. International

This national platform aims to become Scotland's premier source for health and wellbeing; and stakeholders wanted to become a beacon for other countries but faced a challenge in identifying how to go about that. Several issues emerged in identifying the customer and market which led to concerns that the consortium might be taking too myopic a standpoint. "*The requirements were gathered from people in Scotland. Now, the market is not people in Scotland. The market is outside Scotland...for LiU to be commercialised…to become a product or service that people will buy…it needs to meet the needs of people outside Scotland. The current users are in Scotland but the future users are not in Scotland…""A big assumption was made that what suits Scottish people in the Scottish context will suit a world market and I think that's wrong". "There's a fundamental mismatch.* [LiU11].

Implementation Facilitators

Trusted Customer – Supplier Relationship

This section provides an overview of the key mid-point themes that emerged as positive enablers, or facilitators during the deployment of the LiU platform. The first being that over the course of the implementation, stakeholders developed a professional but friendly bond which changed the usual dynamics of the customer-supplier relationship. This introduced new ways of working in which representatives from sectors such as housing, healthcare and voluntary indicated that it helped drive the implementation forward. "*Normally that relationship is one of customer–supplier, and the public service has a very thorough obligation to treat all private organisations equally. You know, no favours, no special conditions and that's fine when you're trying to buy…you know…it's a plaster. It's just a question of who*

makes the cheapest plaster that passes the requirements". "But it's not a good way of handling things when you want to do innovation, because with innovation you need trust, you need a relationship, you need the ability to be able to say, in a trusted way from one side, this is what we want, and the other side says, well this is what, at the moment what I can deliver, but maybe I can move towards that over the next six months. And that's the only way that you can do joint innovation. And that's basically what Dallas has delivered…""We've moved from a customer–supplier relationship to a more of a partner relationship. And I think that's absolutely essential to solving some of these problems that we have in using technology to provide health care". "So I don't want to just be the telehealth guy. I'd hope we can be broader than that…""I'd hope we don't go back to customer- supplier". [LiU08]

Iterative User Feedback Shapes Development

Consumers have a crucial role as a stakeholder within the consortium as they are continuously consulted throughout the life cycle of the project in various ways both online and offline; and this provided an opportunity for grass-root level engagement and innovation to occur such as personalisation of health and wellbeing services. "*Sometimes they'll be giving the feedback on a one-to-one basis at workshop events and that goes through…we consolidate that…to shape the development of LiU. If they go through the digital portal then…that goes directly to support office who then again push that out …and see if things can be improved* "[LiU05]

Local Champions Driving Implementation

A key facilitator has been the establishment of local champions who are people that live in the target communities that either a) have a vested interest in co-designing LiU or b) have identified the value of LiU as part of their daily lives. They have been identified as a key driving force in creating awareness and encouraging regular people to buy-in to LiU. *What I've done is I've been very lucky and I've got a great group, a core group of local community champions, who are basically... in a way, I'm leaving it to them, because I think it sells it better if it's coming from actual users. So we've got one guy who's writing a regular blog about living with long-term conditions, you know, he gives practical advice based on his own experiences, and that's been very popular with people, given it a human edge, if you like*. [LiU07]

Product Ownership & Business Opportunities

It was largely agreed by small and medium-sized businesses (SMBs) that working on a large national collaborative project such as LiU created new business opportunities and ventures. This helped to provide a platform in which the vision of wealth creation and innovation could be achieved. More importantly stakeholders were identified as product owners in different elements of LiU and therefore this enabled them to showcase this work as well as a 'collection' of individual works within their respective organisations; an opportunity that they may not have had without being part of LiU. "*As a company we've had great benefit from being a part of this project because it has allowed us to establish a position in the individual health market and you know, we're working for Living It Up, we're working for all the Dallas projects. So, we're not restricted to Living It Up, although that's given us opportunity*" [LiU11]

Push Towards Sustainability and Normalisation

The push towards scaling LiU and making it sustainable far beyond the official end date of 2015 has positively influenced the implementation process. Stakeholders themselves are thinking long term but more importantly in 'real-terms' as to how LiU can be integrated into daily practices. This is a key overall positive factor in ensuring that the project as a whole is a success. "*We're going to run some workshops, actually, just to see how health and care professionals can implement if there's some of the tools. I mean, not all of them, but we're going to have just some of the tools that are relevant to them and their clients or their service users. So we will be kind of running workshops in all of the areas just on how we can do that, and actually just get them to implement it in as part of their daily working*" [LiU_15]

Discussion & Conclusion

This study explored the views, knowledge and understanding of stakeholder personnel and organisations involved in the deployment of an on-going national digital health and wellbeing project at scale in Scotland. The results of the study show that obtaining stakeholders views on factors affecting the implementation process provides valuable insights which can help to inform its future development in becoming a sustainable service for Scottish citizens. A limitation of our work is the lack of data from end-users of the LiU services and the fact that we are describing a deployment still "in process", however a strength of this study has been the use of the NPT framework in capturing the 'work of implementation' as well as providing a basis for learning and critical reflection in understanding the valuable lessons that have been learned throughout this journey of implementation. The use of the NPT framework has helped us to highlight barriers and facilitators and we apply it here in order to interpret and synthesise our findings.

Coherence

This domain refers to the '*sense-making'* work that people do individually or collectively in order to develop a shared understanding of a new intervention. It is clear that there was some difficulty experienced by stakeholders in developing a shared direction of travel due to several factors such as the number of stakeholders involved in the process, identifying requirements to match future need and having to 'work at risk'. Although facilitators such as the creation of 'trusted' relationships and the move towards embedding this intervention into everyday practice has helped to overcome this barrier. It seems that these risks were necessary when implementing a project which is at the forefront of innovation. Recent research has confirmed that having good existing relationships or links between senior management or strategic level players helps to improve communication among implementers as well as securing long lasting change [14]. Our findings within this domain clearly demonstrate the need to understand organisational cultures as a key ingredient and basis for any innovative digital health and wellbeing project.

Cognitive Participation

This domain refers to the '*relational*' work that people do to encourage people to engage, buy-in and sustain a new intervention. A key barrier that needed to be addressed was lack of knowledge/skill-set deficiencies and the need to educate, upskill and train stakeholders in digital technologies as it was clear that not all stakeholders had the same level of understanding. This finding unearthed a link between the 'Collective Action' domain and the 'Cognitive Participation' domain due to the fact that this process was required to take place before stakeholders actually engaged with LiU in order for them to go on to endorse or promote it themselves. Local champions however helped to overcome the barriers that

stakeholders faced by not concentrating on the technology but on personalising the benefits to demonstrate to potential users how this product can help them in their daily lives. Previous research in Australia has shown that use of clinical champions can play a critical role in helping to promote uptake and sustainability of telehealth; with the authors pointing out that it is more important to get the service model right rather than the technology itself [15]. This is key as there is a lack of evidence in relation to participation and engagement within the field of ehealth and wellness [16].

Collective Action

The third domain refers to the '*operational work*' that people do and what specifically needs to be done to ensure that a new intervention works in a real-life setting. Barriers which affected the practical application of LiU included inadequate infrastructure, constraints on resources (including finances) and limited testing environments which are key findings that align with available evidence from the United States of America [17]. In Scotland there remains a challenge in delivering services to people living in remote locations which compounds the existing burden on the system. The need for adequate infrastructure and resources to support digitally enabled self-care has been recognised and the Scottish Government have recently launched a national programme to enhance the current broadband and fibre optic capabilities.

Reflexive Monitoring

The final domain looks at the '*appraisal*' work that people do to assess and understand the impact of a new intervention. A challenge was designing to meet all needs but positive themes such as the creation of business opportunities and iterative user feedback emerged as key facilitators in assessing the impact of LiU. Particular focus on the latter finding is significant as it illustrates the value of input from Scottish citizens in dictating their own care and becoming 'active' recipients with increased choice about how and where they receive services as opposed to the traditional passive role that is played. There is a considerable amount of value from capturing the process and journey of implementation at scale. Lessons that have emerged as key learning points include the need for flexible and trusted working environments to support multi-sector working partnerships and the need for policy to support innovative business models. This report highlights difficulties faced in delivering new digital health and wellbeing services at scale and the need for further research to help understand implementation issues in order to a) bridge the 'translational gap' and b) inform future ehealth policy and practice.

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Delivering digital health and well-being at scale: lessons learned during the implementation of the dallas program in the United Kingdom

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ABSTRACT

Objective To identify implementation lessons from the United Kingdom Delivering Assisted Living Lifestyles at Scale (dallas) program—a large-scale, national technology program that aims to deliver a broad range of digital services and products to the public to promote health and well-being.

Materials and Methods Prospective, longitudinal qualitative research study investigating implementation processes. Qualitative data collected includes semi-structured e-Health Implementation Toolkit–led interviews at baseline/mid-point ($n = 38$), quarterly evaluation, quarterly technical and barrier and solutions reports, observational logs, quarterly evaluation alignment interviews with project leads, observational data collected during meetings, and ethnographic data from dallas events ($n > 200$ distinct pieces of qualitative data). Data analysis was guided by Normalization Process Theory, a sociological theory that aids conceptualization of implementation issues in complex healthcare settings.

Results Five key challenges were identified: 1) The challenge of establishing and maintaining large heterogeneous, multi-agency partnerships to deliver new models of healthcare; 2) The need for resilience in the face of barriers and set-backs including the backdrop of continually changing external environments; 3) The inherent tension between embracing innovative co-design and achieving delivery *at pace and at scale*; 4) The effects of branding and marketing issues in consumer healthcare settings; and 5) The challenge of interoperability and information governance, when commercial proprietary models are dominant.

Conclusions The magnitude and ambition of the dallas program provides a unique opportunity to investigate the macro level implementation challenges faced when designing and delivering digital health and wellness services *at scale.* Flexibility, adaptability, and resilience are key implementation facilitators when shifting to new digitally enabled models of care.

Keywords: consumer health informatics, eHealth implementation, assistive living technologies, electronic health records, mHealth

RESEARCH AND APPLICATIONS

BACKGROUND

Healthcare systems globally recognize the need to adapt in order to accommodate unprecedented changes in population demographics and related increases in incidence of chronic disease.[1–3] Interactive, person-centered digital tools and services offer a vehicle to promote a more citizen-led, self-care and preventative health and well-being agenda.[4–6]

Previous studies in the evolving interdisciplinary field of health informatics have highlighted the complex nature of implementing digital health and well-being tools in practice.[7] This is due in part to the breadth and complexity of the systems, processes, and stakeholders involved in implementing e-health interventions.[8] A recent study by Cresswell et al.[9] highlighted 10 key considerations for implementing e-health interventions at scale, including: clarification of the problem being addressed, building consensus, planning, addressing infrastructure, and evaluation. However, to date, most of the evaluation literature focuses on single digital tools or systems at a time, such as the implementation of electronic health records,[10–13] computerized decision support systems,[14] or the implementation of telemedicine services.[7,15] In contrast, the Delivering Assisted Living Lifestyles at Scale (dallas) program aims to deploy a broad portfolio of digital tools and services and represents the next stage toward deployment of such technologies for health and well-being at scale in the United Kingdom.

The dallas program is a pan-UK program that was funded by Innovate UK (formerly the Technology Strategy Board) (https://www.gov.uk/government/organisations/innovate-uk), the National Institute for Health Research, The Scottish Government, Scottish Enterprise, and Highlands and Islands Enterprise. The total investment of £37 million (over the period 2012–2015) reflects the current emphasis being placed on developing digitally enabled healthcare and wellness globally. The funding was delivered via Small Business Research Initiative to 4 lead contractors and the projects developed in conjunction with a highly innovative group of sub-contracted organizations, mostly private sector business and small companies (referred to as SMEs). The dallas program is highly ambitious and aims to deliver health and well-being services (to 169 000 individuals) using a wide range of technologies including interactive, person-centered digital portals; telecare;

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electronic personal health records; and Mobile applications (Apps) *at scale* and across remote, rural, and urban areas of the United Kingdom. It consists of 4 multi-agency consortia or "communities": *More Independent*; *i-Focus*; *Living it Up*, and *Year Zero* working in new collaborative partnerships and distributed across the United Kingdom (Figure 1). Each community involves health and care services, industry (including small-, medium-, and large-size companies), nongovernmental, third-sector and voluntary organizations, as well as academia and government bodies (see table in online Appendix). As such, dallas aims to harness new knowledge across traditional boundaries and disparate systems to introduce interoperable, person-centered digital tools and enable more adaptive systems to provide a new "space" for interactive, person-centered, digital health and wellbeing products and services.

OBJECTIVE

The objective of the present study was to report on the qualitative evaluation conducted, which aimed to identify the barriers and facilitators in the dallas implementation journey and to share implementation lessons learned within and across the unique dallas program.

MATERIALS AND METHODS

We have a multi-disciplinary team with expertise in General Practice and Primary Care, Computing Science & Human Computer Interaction (HCI), Health Informatics, Nursing, Health Economics, Statistics, and Social Sciences. The team is working closely with the dallas communities to conduct an independent evaluation.

Data Collection

Our evaluation adopts a socio-technical approach,[16–19] using a mixed methods evaluation framework consistent with evaluations of complex interventions.[20] Qualitative data has been collected longitudinally from the four communities. Table 1 outlines the breadth and extent of the data collected.

The present study draws on the evaluation alignment interviews, the barriers and facilitators reports, and the in-depth e-Health Implementation Toolkit (e-HIT) led semi-structured research interviews held at baseline ($n = 17$) and approximately 12–14 months later (midpoint; $n = 21$) of the implementation process. The e-HIT is a tool to aid consideration of implementation issues in e-health, underpinned by Normalization Process Theory (NPT).[21,22] Stakeholders sampled represent a cross-section of those involved in the dallas digital service redesign and delivery and include professionals from public sector health (NHS) and social care, business and industry leads, technical ICT personnel, voluntary and third-sector organizations, academia, and other government bodies.

Research Governance and Ethics

University of Glasgow ethical approval was granted for this study. All respondents provided consent for participation. Identities are protected

Figure 1: The 4 multi-agency dallas consortia.

Table 1: Summary of Qualitative datasets collected (as of 23 January, 2015).

Qualitative data collected	Number of items	Number of pages
e-Health Implementation Toolkit (e-HIT) baseline research interviews	17	257
e-HIT midpoint research interviews	21	454
User stories	9	12
Evaluation alignment interviews	5	14
Semi-structured research interviews	9	111
Barriers/facilitators/ lessons learned reports	6	18
Product/service development planning documents	18	245
Contract/bids and appendices	13	74
Observation research logs	10	34
Reach recruitment and membership documents	14	59
Quarterly technical reports	38	262
Quarterly evaluation reports	25	190
Focus group/workshop reports	3	36
Local evaluation reports	4	207
Other: (Initiation report/Dissemination report/Eval planning doc/Outline brief)	9	125
Total (as of 23 January 2015)	201	2098

and are assigned a confidential generic descriptor to ensure anonymity.

Theoretical Framing of Qualitative Data Analysis

In order to conduct a meaningful evaluation of the complex socio-technical processes involved in the implementation of digital tools and services within dallas, we have drawn on NPT, which has been used in e-health implementation projects.[16,21,23,24] The judicious choice of a robust underpinning theoretical framework is known to aid with conceptualization of analysis in complex adaptive systems such as healthcare settings.[25] NPT has 4 constituent constructs (Figure 2).

Qualitative Data Analysis Procedure

All baseline and midpoint research interviews were transcribed verbatim and transcripts checked for accuracy. Transcripts were coded and analyzed in an inductive manner.[26] Codes and themes were then mapped to NPT, as a conceptual framework and system of organizing the data (Table 2).

Data coding clinics were conducted at regular intervals among the team using samples of coded transcripts at baseline and mid-point to ensure accuracy and consistency of coding. We then mapped the results from each community in order to capture 5 of the significant challenges and navigation processes implemented across dallas as follows:

1. Challenges related to working as part of a large multi-agency, heterogeneous consortium.
2. Challenges related to the wider socio-political and economic environment.
3. Challenge of co-design at scale.
4. Challenge of branding and marketing.
5. Challenges related to interoperability and information governance (IG).

Emergent findings were shared with key leads and related stakeholders who concurred with the findings. The mapping of the 5 main challenges and navigation processes to the fine-grained NPT codes is presented in Figure 3. Results are presented and organized according to overarching themes as identified within dallas, and data presented drawing from the cross-section of stakeholders involved in order to provide depth and breadth to the findings.

RESULTS

Here we provide details of 5 key implementation themes identified from the early phases of the dallas program.

1. Challenges and Learning to Work within New, Multi-agency, Heterogeneous Partnership Models

One of the strategic aims of the dallas program was to support new partnerships to foster innovation, drawing on a diverse range of organizations including the NHS, local authorities, SMEs, voluntary and community organizations, as well as academia. However, challenges emerged related to forming and sustaining such heterogeneous partnerships with little shared history of working together. Reservations were expressed across sector boundaries, with perceptions of inertia and resistance to change in the NHS compared to the speed of change in the business world (Table 3, Q1). There were also cultural differences between NHS organizations and the retail or technology/ business partners. Examples included the way in which each viewed dallas as a scaled-up and live project, adherence to governance, and focus on developing finished digital products (Table 3, Q2).

Some communities struggled initially to communicate across the diverse array of partners and had to work toward understanding new processes and ways of working. For example, the voluntary sector is comfortable with "grass-roots" community engagement whilst technical/digital technology partners feel more comfortable with progressing directly to build an actual product (Table 3, Q3). Other partnerships involved different NHS organizations, which varied in terms of their digital readiness (Table 3, Q4). This lack of strategic knowledge was communicated by stakeholders as being, at least partially, due to the unusual initial contractual procedures with tension related to the speed with which the lead and sub-contractors had to sign off the contract (Table 3, Q5). Stakeholders reported it took some time for the contracts to be fully understood and embedded and understanding of roles and commitments to crystallize (Table 3, Q5, Q6). This experience led some stakeholders to reflect on what would help across multi-agency partnerships if this type of contracting arrangement was implemented in the future including, e.g., a much clearer articulation of roles at the beginning (Table 3, Q7).

Each community overcame barriers differently, but the issue of "choosing the right partner" arose across all communities (Table 3, Q8). Suitable partners should be able to implement action at the level of the operations within their own respective organizations as well as balance the "visionaries" with the "pragmatists" to prevent aspirations outrunning ability and capacity of the consortium as a whole (Table 3, Q8, Q9).

Figure 2: Representation of the 4 constituent NPT constructs which attend to the 4 key aspects in e-health implementation. (From May and Finch, 2009).[16]

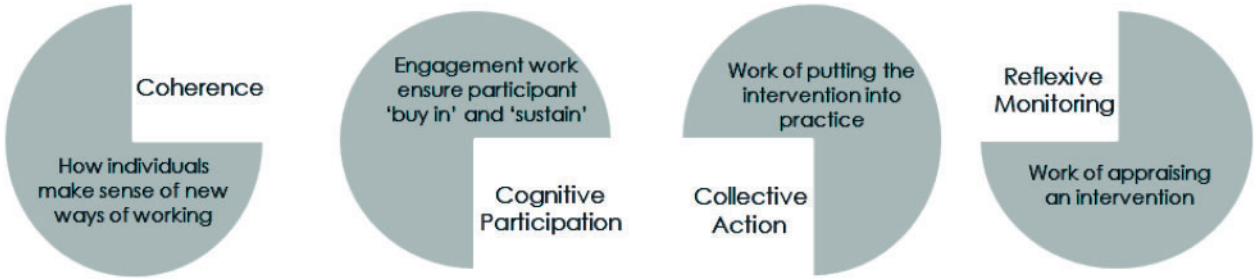
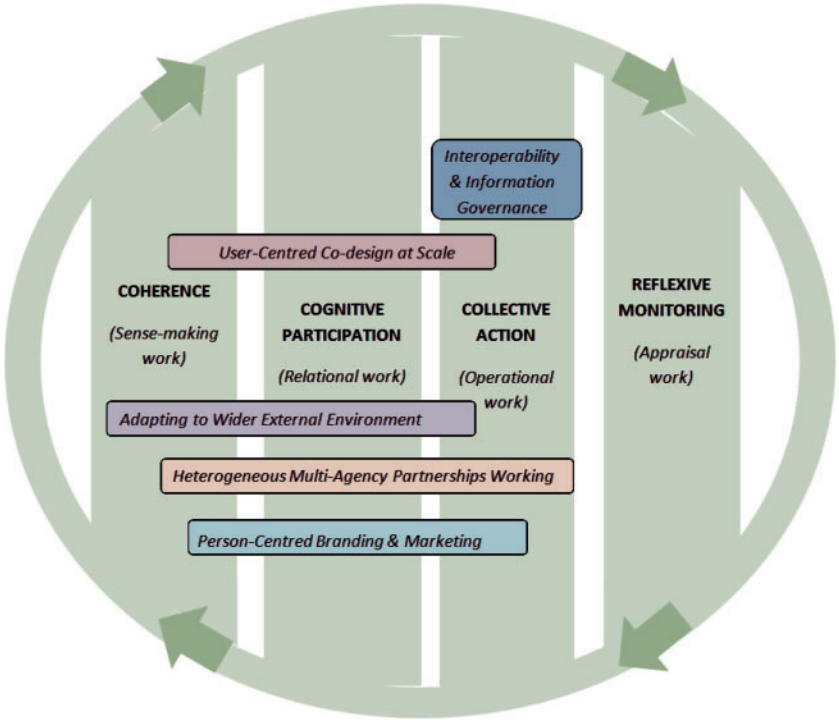


Table 2: Normalization Process Theory coding framework used for qualitative data analysis.

Coherence (sense-making work)	Cognitive participation (engagement/buy in work)	Collective action (enacting work)	Reflexive monitoring (appraisal work)
Differentiation	Enrollment	Skill-Set Workability	Reconfiguration
Is there a clear understanding of how the dallas technology products, tools, and e-health services differ from existing, current practice and services?	Do implementers, service providers, service users, and other partners "buy into" the dallas technology developments, tools, and e-health services?	How does the implementation of the dallas services and products affect division of labor of work practices, roles and responsibilities, or training needs?	Do participants (service user/service provider/other individuals) try to develop a "work around" or somehow alter a dallas service, technology, or product?
Communal Specification	Activation	Contextual Integration	Communal Appraisal
Do the dallas implementers, stakeholders, service users, service providers, business leads, third sector, voluntary, and other partners have a shared understanding of the aims, objectives, and expected benefits of the dallas e-health products and service(s)?	Can implementers, service users, service providers, and other partners who participate in the dallas communities/program sustain its implementation?	Is there organizational support in terms of resource allocation to enable the service users and service providers to enact a new set of practices to implement the new dallas products or services?	How do service user groups/service provider groups/service leaders/other groups judge and determine the value of the dallas technology products and other services?
Individual Specification	Initiation	Interactional Workability	Individual Appraisal
Do all dallas stakeholders (in each community) have a clear understanding of their own specific tasks and responsibilities in achieving the implementation of the dallas product or services?	Are key individuals willing to drive the implementation of the dallas products, tools, and services forward? Who are they?	Do the dallas e-health service(s) and products make routines of practice easier or make people's work easier?	How do individual participants/individual service users/other individuals appraise the effects of the implementation of the dallas service, technologies or products on them and their (work/home, as in context of tool resource, etc.) environment?
Internalization	Legitimation	Relational Integration	Systematization
Do all dallas stakeholders understand the value, benefits, significance, and importance of the dallas products or services and their future value?	Do implementers and participants believe it is right for them to be involved in implementation of dallas services and products? Do they feel they can make a valid contribution to the implementation of the dallas products and services?	Do service users/service providers/other participants have confidence in using the dallas-technologies, products, and services?	How do participants and implementers determine the effectiveness (benefits and limitations) or usefulness of the dallas tool, service, or product? How can this be measured?

Figure 3: Diagrammatic representation of the 5 overarching dallas themes and the underlying mapping to the Normalization Process Theory constructs.



In spite of initial challenges, the multi-agency partnerships made significant progress and can now share their learning on what helps to facilitate new collaborative partnerships across traditional silos between different communities of practice. Most of the facilitators are typical of good project management and include keeping in constant dialogue across the partnerships, clear communication, negotiation, and active problem-solving skills. The importance of team work and understanding exactly what roles entail at an individual and collective level are of key importance as are astute, strategic leadership, and strong project management skills in ensuring that a shared vision or coherence emerges and stakeholders "buy into" the direction of travel (Table 3, Q10, Q11).

2. Need for Resilience in the Face of Challenging Socio-political and Economic Factors in the External Environment

Digital and technology based health interventions are not implemented in a vacuum, but are intrinsically related to the complex socio-technical features within organizations, as well as the wider political and economic factors in the external environment. Some dallas consortia had to work on digital innovation against the backdrop of NHS England undergoing a radical restructuring process. This resulted in uncertainty and disruption along with a fear of role redundancy (Table 4, Q1, Q2), which affected engagement and the operationalization of services (mapping onto coherence, cognitive participation, and collective action constructs of NPT). This was particularly challenging for one of the business-led dallas consortia in the initial stages when they were trying to engage with several NHS partners, each of which were facing structural changes within their own localities (Table 4, Q3).

The wider political environment of austerity and economic recession was thought to be an external driver with some suspicion voiced that the real motive for introducing digital tools and services was as a cost-cutting measure as opposed to improving person-centered healthcare and well-being (Table 4, Q2). However, in at least one of the consortia, work was invested in ensuring that the dallas program was in alignment with the ongoing strategic planning of the new NHS structures. Indeed there was recognition that many of the dallas aims and objectives were similar to those of the new organizations, with regards to technologies as an enabler of more integrated, personalized health and well-being systems (Table 4, Q4).

In addition to the challenge of navigating the restructuring of NHS England, there were some key retail partners who went out of business and into receivership against the backdrop of economic austerity. A large commercial partner also withdrew from a consortium, due to wider company-related issues. This was recognized as an inherent risk from the outset, but consortia had worked with such new partners in order to try and build consumer-based business models in the existing health economy. However, the reality faced by more than one of the multiple partnerships was the collapse of their "route to market" through well branded, trusted commercial partners going bankrupt or withdrawing. As a result, the dallas communities had to recover and actively find new solutions in order to overcome these significant setbacks and move forward (Table 4, Q5).

3. Inherent Tension between Embracing Co-design and Achieving Delivery at Pace and Scale

One of the major strategic aims of dallas was to innovate through the co-design of more person-centered, interactive digital tools and services and to do this *at scale*. The emphasis on more personalized tools and services was viewed as part of the solution to the challenges in current healthcare and well-being provision (see Table 5, Q1). The

Table 3: Illustrative data excerpts related to Partnership Working in Multi-agency, Heterogeneous Consortia.

Working across boundaries	Q1 *" . . . in the health service, there's a big inertia to bringing in a change and . . . the intervention in the consumer space, it's, you know, it's much more receptive to that."* (C4(b) Operations – Business).
	Q2 *" . . . there are NHS organisations and they're very keen on making sure governance is adhered to. I'm not saying that the retail or the manufacturing partners aren't, but we've got a very keen eye for that whereas they've got a very keen eye on finished products and getting things there. But that doesn't cause any issues, I don't think, I think it probably complements each other and it's a new way of working as well."* (C2(b) Manager, Informatics).
	Q3 *" . . . we are comfortable with—as community engagement partners—that they be strong for the people that are involved. The industry and technology partners are comfortable that a tangible outcome means they can get on and do something and build something."* (C1(b) Representative, Third Sector organization).
Differences in the local digital health economy	Q4 *" . . . we've gone from having four [name of product] deploying partners down to two and the contrast between [NHS organisation 1] and [NHS organisation 2] in some levels is quite striking. So [NHS organisation 1] seem to be much clearer on their process maps and their interactions and the benefits of the product. [NHS organisation 2] don't seem to understand the internal structural process . . . [NHS organisation 1], as I say, they're much further developed in terms of their own Digital Strategy as an organisation so their staff are . . . they do Mobile working, they have tablets and, you know, they're digitally enabled."* (C3(m) Manager 1 – Business).
Lack of shared understanding between partners	Q5 "*So . . . various things that took longer than expected and I think the contract, getting it one week and then expecting us to sort of sign it and start the, start within a couple of weeks, that was never going to happen."*(C2(b) Manager 1 – NHS).
	Q6 *" . . . and on the NHS side, thinking . . . about six months in . . . people started to talk about pilots . . . and we were going, it's not a pilot. It says that it's not a pilot. This isn't a pilot. It's not going to help you if you think, it's not going to help any of us to think of it as a pilot. We're supposed to be deploying these things into use, not talking about pilots, not inventing . . . you know, and . . . but that only occurred later. And they'd already started."* (C3(m) Manager 2 – Business).
	Q7 *" . . . in hindsight I think what should have been done is . . . each of those partners should have articulated those things much more clearly beforehand and been selected on that basis. You know . . . a clear position on where they're at within their own digital strategies, organisationally."* (C3(m) Manager 1 – Business).
Partners in the right spaces	Q8 *"It's all about partners working together, making sure we all understand what we're doing, who's doing what so we can then feedback to our teams to give people that kind of general understanding. But also I need to make sure that [Voluntary organization name], we're delivering on the champion's front, which is recruiting 150 volunteers to go and talk about health and wellbeing, but around the assisted technology as well. So, I manage that and underneath me you have a project manager and you have eight staff who are all working on it . . . "*(C2(b) Representative, Voluntary organization).
	Q9 *"I think [Name's] point about being—the disconnect—perhaps between the visionaries and the resource that's got, or the Management that's got to implement is an important lesson. It's about making sure that those people who are sitting at the table saying, my organisation can do X, Y and Z are actually connected with the people who've got to do the X, Y and Z and we can see that within the program in that all the partners so [Third sector organisation name], [Charity organisation 1 name], [Charity organisation 2 name], the people who are sitting around the table are the people who have it in their authority to go, will this work, yes, it will, we'll sign it off. Whereas within the NHS and the local authority the visionaries weren't necessarily directly connected or influential . . . To the operations bit of the organisation. So that's an interesting lesson."* (C2(m) Manager 2 – NHS).
Leadership and project management skills	Q10 "*We are not frightened of making decisions, there are clearly risks roundabout that and we've taken them on our shoulders and made sure that the right people are briefed but yes I think that's actually been quite a significant benefit to the project as well."* (C1(m) Manager 1 – NHS).
New collaborative working	Q11 *" . . . the thing that's more difficult to describe is the activity I think [Name] referred to earlier on, the activity that's starting to happen between partners so it's more about the relationship which we're starting to get here where people see mutual benefit in doing things differently together . . . "* (C2(m) Manager 2 – NHS)

dallas communities used a spectrum of "co-design" methodologies ranging from 1) "grass-roots" community engagement using creative, participatory co-design methodologies to enable end users to directly shape services (Table 5, Q3); 2) HCI technical co-design methodologies that are iterative and contribute to product or tool development via prototyping and refining; and 3) a wider, broad-based, community asset design methodology which involved creative modification of a range of digital tools and services and linking in with pre-existing, large networks.

Such collaborative digital design methods were at first foreign to the technology partners who raised concerns about the time commitment required. In one community, extensive input from end users via

Table 4: Illustrative Data Excerpts Relating to the Challenging Wider External Environment.

Restructuring of NHS England	Q1 *" . . . the health services are going through this tremendous upheaval. It's beyond anything that any of us have experienced. I've been in the health service now nearly 40 years. I mean, it has . . . I think it's well evidenced that nothing like this has happened since the health service was incepted. So people are trying to deal with the here and now, and understand what's happening., in their own sphere of work in health service-land. I think the local authority are doing the same, against a background of massive efficiencies and so, they can be very distracting, understandably. . . . So I think people, in their hearts, understand them and want it promoted and be sponsors for it, but I think because there's so much going on, they're just distracted from that . . . "* (C2(b) Clinicial – NHS).
Fear of role redundancy	Q2 *Interviewee " . . . ..but I think there is some negative . . . negativity among different staff groups thinking technology will be replacing people."* *IV "What staff groups are you sensing that among?"* *Interviewee "Carers."* *IV "The social Carers, that they'll be made redundant by this . . . these technologies?"* *Interviewee "Well, yes. I think that's quite a big initial thought of a lot of different care groups, that they'd be made redundant by the introduction of technology."* (Interview with C2(b) Representative – Charity organization).
	Q3 *"I think there's been, particularly the first year, there was almost no focus, it was very hard to get attention from the NHS, where everybody whom you thought who could have become a Champion was . . . was worried about what their next job was. You know, the whole thing, you it's hard to imagine, [. . .], how disruptive that was."* (C3(m) Manager 2 – Business).
Aligning with new organizational structures	Q4 *" . . . Because the clinical commissioning groups are now bought into dallas and they will drive this forward. I think the only concern is that there is a lot of change going on at the moment, but a lot of the change that is going on with the clinical commissioning groups involved are things that were suggested in dallas . . . "* (C2(b) Manager, Informatics).
Impact of wider economic environment	Q5 *" . . . and unfortunately they went bust so that was quite a setback for us. The alternative we came up with which was for online and telephone sales; that hasn't gone down brilliantly . . . and what we've done since then is we've re-grouped and reconsidered; well, should we be selling them?[. . .]. We've just sort of moved into that because we've lost our Retail so we've regrouped now.* *We are back where we wanted to be, I think, which is we will vet products, make sure that the products are reliable, etc., before we actually feature them . . . and so on. But we would look to proper Retailers to actually sell them rather than trying to sell them ourselves."* (C2(m) Manager 1 – NHS).

face-to-face workshops and "pop-up" events was undertaken to shape all aspects of the service, foster ownership, and ensure the development of a digital health and well-being product that was "fit-for-purpose" (Table 5, Q2). However, the nature of iterative, agile, co-design caused a challenge because contractual arrangements with the communities required them to recruit large numbers of users simultaneously, which took time. Target recruitment numbers were perceived as overly ambitious and unrealistic to attain within a fixed 3-year timeframe (Table 5, Q4). There were also difficulties in engaging end users with a product undergoing iterative development. This conflicting tension of innovation and recruitment was a concern of all of the communities and seen as a real challenge (Table 5, Q4, Q5).

However, there were advantages and learning associated with working in new partnership models involving smaller business partners. These included more flexibility and the opportunity for active collaboration as compared to working with large multi-national companies (Table 5, Q6, Q7).

One consortium adopted a community asset based approach to co-design as their means of innovating, through drawing on pre-existing networks and resources (Table 5, Q8, Q9). This also allowed the consortium to build on some assisted living technologies which already existed. Some adopted a federated membership model or approach in order to address target recruitment numbers by partnering with pre-existing networks with significant reach in their local community.

Yet another approach to co-design involved more traditional HCI iterative methods with the overall aim of designing fit-for-purpose digital health tools. This partnership involved workshops with end users and service providers with the learning and feedback obtained from prototypes being fed back into the design of the digital health product. This also provided an important learning opportunity about person-centered design with the emergent learning being *written in* to form the basis of new e-health tool and service design processes (Table 5, Q10).

4. Branding and Marketing Challenges in Consumer Healthcare Settings

One of the strategic aims of dallas was to stimulate consumer and retail business models in order to drive innovation and economic growth in the United Kingdom. However, culturally, health is still not usually perceived as a commercial venture in the United Kingdom. All 4 consortia have carried out significant work in building person-centered brands and corporate identities, aligned to more personalized branding. However, challenges emerged—for example, one community discovered their brand was already in use by a pre-existing organization and they had to undergo a very expensive and time-consuming re-branding exercise.

In other communities, challenges existed since the grass-roots, participatory co-design process was time and labor intensive. A significant investment was made in this iterative co-design methodology which involved the end users in all aspects including choosing the colors and visual representation of the brand, resulting in a tailored, unique digital product (Table 6(A), Q1).

Another community invested significant time and resource in working toward the launch of a digital consumer version of a traditional health product only to face it not being endorsed by a

Table 5: Illustrative Quotes Relating to Challenge of Co-design at Scale.

Integrated care enabled by techs is welcome	Q1 *" . . . the new difference is that we will be doing things with people, and in some instances patients will be saying no, that's not what I want and I think technology can assist in that process, and it's to be welcomed. NHS is public service . . . It's about serving the public. And sometimes organisations . . . you know, services are wrapped round organisations and not round patients. [. . . .] So I think there is a fundamental shift . . . and the reforms . . . the NHS reforms and local authority support that shift, and it's to be welcomed. It's long overdue, in my humble opinion."* (C2(b) Clinical – NHS).
Participatory design	Q2 *"I think initially [. . .] the industry and technology partners couldn't really understand why they were engaging with people locally. Why they were engaging with real people, they already had the answers; they already had the product, why are they just not serving it to them. A very traditional if you like industry model of we've found a solution and let's just punt it out there."* (C1(b) Representative, Third Sector organization).
	Q3 *" . . . We are delivering community engagement and co-design so we are going out to talk to people who we hope will benefit from [community name] in . . . different regions. So we've gone out . . . to start conversations, in shopping centres, in hospitals, and we've really chatted to people about what they value about their community and themselves, and what they want to do more of . . . to, kind of, understand what [community name] can do to connect people to the resources that already exist . . . it's focusing on the opportunities that are there and people can see that designing around their lifestyles and around their needs, and people-centered services . . . so designing with them, rather than for them."* (C1(m) Researcher, Academia).
Ambitious recruitment numbers	Q4 *"I think they know that the overall, sort of, sign up target for dallas was hugely ambitious. I think also there's, kind of, what we realized and all the partners have realized is we've set . . . we have set a really high benchmark for ourselves . . . "* (C3(m) Manager 1 – Business).
	Q5 *"So I feel like I've been through it, stuck with it through all of that time where we had no idea what it was and kind of been up here in selling it to people without even being able to tell them what it actually is . . . A key lesson I've learned is . . . wait until you know what it is before you start to engage with people. It was really, really hard last year trying to talk to people and that's why our e-health department is only just now properly getting engaged because despite lots of conversations I wasn't able to tell them what we were doing."* C1(m) Manager 2 – NHS).
Co-design and learning	Q6 *"So we can make decisions a lot quicker, we can sign off funding a lot quicker than the traditional NHS projects so we have that flexibility . . . and the speed of decisions and getting things started and the other, big change I see is that the companies we are involved with they tend to be smaller companies . . . so the NHS very often have very big companies. You know multi-nationals so we have fewer of those here, we have more SME type of companies in this project."* (C1(m) Information Technology, NHS).
Collaboration	Q7 *" . . . I am the lead contact and [. . .] we are mainly interested in Telehealth deployment but eh, we are also interested in how the dallas projects help us understand how to deploy Assistive Living Technologies in a broader context. So the WSD . . . was strictly an RCT so eh . . . So it was very fixed and clear what had to be done, three million lives (3ML) was very commercially driven so the beauty of the dallas project is its collaborative aspect which allows us to be more innovative."* (C2(m) Researcher – Industry).
Community asset based approach	Q8 *"But . . . I think that [community name] approach has been very practical so it's been don't reinvent the wheel, if there's someone who's already doing it . . . then get in touch with the person who's already doing it. So we try to use existing resources and processes and, well, anything that we can rather than start from scratch and say, well, we're going to develop this big machine and it's going to do everything for you. We've looked to integrate with what's good out there in [city name] already."* (C2(m) Manager 1 – NHS).
	Q9 *"Yes, that's what [Charity organization name] are leading on. We've actually got our own mobile smart house, which we take and set up at events, it's got four rooms. Now that's always been, sort of, directed at learning disabled events . . . and things like that. But, now we're creating a more generic model in the [name of retail store] in [name of city] which is a big hardware store in the middle of [name of city]. So that's going to be a similar sort of model but with technologies that are not just aimed at people with learning disabilities."* (C2(b) Representative – Charity organization).
Traditional user testing	Q10 *"One of the biggest lessons for the [community name] project was . . . understanding the User Acceptance Testing that [name of Company 1]and [name of Company 2] do isn't sufficient on its own. It needs to come to health for us to test as well because we are testing it as a health professional would use it . . . or as a (person) would use it, they are testing it from the technical, and so that was a really important lesson to learn. That step has been put into the process now . . . sometimes it does delay products being released but it prevents any products being released that aren't fit for purpose."* (C3(m) Manager 1 – NHS).

key regulator (Table 6(A), Q2). Despite these challenges and set-backs the communities "*stayed the course*,"[9] and through agility and adaptive learning, have made significant progress toward achieving digital health brand recognition (Table 6(A), Q3, Q4). There is now growing European interest and wider recognition of the innovative, digital dallas services and products which provide exemplars of new models of collaborative, partnership working and perseverance in the face of seemingly intractable problems (Table 6A, Q5).

5. Facing the Challenges of Interoperability and Information Governance

The dallas program aims to facilitate person-centered, seamless digital healthcare and well-being; a key feature of this is the role of information sharing between services and the user and the need to open up proprietary/statutory IT systems in order to become more interoperable and flexible. One consortium in particular has been working on interoperability in order to open up the market and enable more customized technologies to be introduced that are tailored more closely to local needs. The technology companies believe that the current limited success of digital technologies may be partially related to a lack of customized products that people actually want and which take into account the organizations' and/ or the end user's needs, choices, and requirements (Table 6(B), Q1).

To achieve this, there is a need to design systems and products that are interoperable, which some traditional suppliers see as a threat since increased competition may result in them losing their market share (Table 6(B), Q2). In order to progress this interoperability agenda new guidelines and open architectures are being developed (Table 6(B), Q3), as well as the launch of the "Digital Health and Care Alliance" in the United Kingdom. Their aim is to try and reshape the current healthcare landscape to move the field forward from locked down proprietary systems to one of open sharing with digital products working across systems.

The information governance (IG) rules and regulations surrounding patient records, which are required to ensure patient confidentiality and security, also presented challenges. New person-centered, health and well-being digital tools that enable citizens to access and own parts of their personal digital health records also require new IG approaches. Within dallas, one consortium has been working to launch a broad range of digital health and care planning and management tools but are finding a lack of IG that would accommodate such tools (Table 6(B), Q4, Q5). There exists fear and a lack of understanding and clarity about security and associated issues of trust surrounding such new interventions (Table 6(B), Q6). Thus, IG represents a significant part of the process of trusted implementation that has yet to be addressed and represents a barrier toward implementation at the present time (Table 6(B), Q6). Initially, business partners did not fully understand the deeply embedded nature of IG rules in the NHS and its status on sharing information. However, the consortia have contributed to policy discussions and, although not a tangible operationalized product, this work is making new pathways and "in roads" as an important part of the wider dallas implementation processes (Table 6(B) Q7).

DISCUSSION

This article communicates key challenges and lessons learned across dallas, a large-scale, national, multi-agency, and multi-site deployment of a wide range of digital technologies for the promotion of health and well-being in the United Kingdom. Importantly, we report on the implementation challenges faced when rolling out a broad portfolio of digital tools and services nationally *at scale* and *at pace* (see table in Supplementary Appendix) as opposed to previous studies which describe implementation lessons arising from individual interventions (e.g., telecare or telehealth or electronic medical record implementations).[27] We have highlighted 5 key challenges: 1) establishing and maintaining large heterogeneous, multi-agency partnerships in the consortia; 2) the need for resilience in the face of barriers and set-backs including continually changing external environments; 3) the inherent tension between embracing innovative co-design and achieving delivery *at pace and scale;* 4) the effects of branding and marketing issues in healthcare settings; and 5) the challenge surrounding interoperability and IG, when commercial proprietary models dominate. These challenges generate a valuable evidence base about issues for consideration when embarking on any large scale digital health or well-being deployment. Key lessons for consideration include:

1. Successful, multi-agency partnership working requires robust management, excellent continual communication, and time to achieve coherence in order to influence health and care models.
2. The importance of resilience when embracing real risk in order to support and enable healthcare innovation.
3. The ability to navigate complex socio-technical change against a backdrop of challenging wider uncertainty.
4. The benefits of capitalizing on the opportunity to innovate locally with communities and implement person-centered design at scale.
5. How to build consumer-facing life enhancing health technologies and enhance digital health brand recognition.
6. The benefits, but difficulties in practice, of advancing interoperability and IG agendas.
7. The importance of brand trust and confidence as well as intervening and promoting at the right time and place—and with the right people—to increase meaningful uptake of digital healthcare services.
8. Mechanisms for innovating can be important for generating a sense of coherence across heterogeneous stakeholders, to facilitate traction in this emergent field.

Some of the lessons learned across the dallas program align closely with work reported by Cresswell et al.,[9] especially the importance of building consensus, which relates to issues raised in working in large, multi-agency partnerships; some aspects of infrastructure, particularly interoperability; the importance of maintenance, which was a constant feature across the dallas program and noteworthy in the work undertaken to maintain consortia; and finally, the importance of "*staying the course*" which has been a clear and successful feature of the dallas program. Furthermore, additional insights involve the need for agility in service re-design and adaptive learning to overcome seemingly intractable problems related to the wider socio-economic and political environment. The management of organizational change literature emphasizes the agency of people as a key factor influencing the implementation of change.[28] Technologies can be enablers of organizational change but only if the surrounding socio-technical factors are taken into account[28] and the dallas program has faced significant challenges posed by organizational restructuring and economic austerity. Our findings also resonate with current studies which recognize that a lack of integration and interoperability across traditional services is not conducive to flexible, joined up healthcare provision.[29] The importance of flexibility and adaptability and an iterative, agile approach to both development of digital systems *and* the implementation strategy highlighted here resonates with previous reports concerning national deployments of electronic medical record systems.[10]

Since the locus of healthcare is shifting to the home and community setting, there is an increasing need to adopt a broader approach across the traditional boundaries of health and social care in order to operationalize a more integrated and personalized healthcare service provision. Indeed, May et al.[30] have called for the need to form new partnerships across a diverse range of healthcare communities and to include nongovernmental, third sector and voluntary organizations in order to harness multiple skillsets and localized knowledge to deliver

Table 6: Illustrative Quotes Related to (A) Branding and Marketing and (B) Interoperability and Information Governance.

(A)	Branding and Marketing
Branding challenges	Q1 " . . . *we've done the branding work for [community name] and all the different services, so we've been doing that with the communities as well, and the aim of that is to make it feel that it's owned by the community . . . so that it could be made by the community, and I think the colours that we've used, as well, I think that demonstrated that the brand works, because people were curious about what it was, because . . . it doesn't say Health, and I think the fact that it wasn't selling anything was just, that's just weird. So, let's go in."* (C1(m) Researcher, Academia).
	Q2 *"Yes. What's actually happened is we've been dragged down an NHS, you know, service route which is basically it needs to comply with information governance, you know, and we've just gone down a vortex of bureaucracy."* (C3(m) Manager 1 – Business).
Digital health brand recognition	Q3 *"We've got a desire to engage our Creative and Digital sector in the city so that's small and medium enterprises that is thriving in the city, very much focused on technology and particularly the Creative Arts so Media, Music, Digital Content. They will start to become a Centre of Excellence for the Region, hopefully the UK, possibly the world . . . and I think the work that we've done [. . .] what it's done is it's placed this agenda, e-health, assisted living, whatever we'll call it; it's really placed it in the eyeline of the Local Enterprise Partnership who now see this as being one of the planks of city region growth. Em it's taken us a while to get here but we're here now and they will begin to major in this area."* (C2(m) Manager 2 – NHS).
	Q4 *"We have started to take our experiences from [community name] into our European dimension so . . . because we have very good links now within the commission and with a range of European projects European partners . . . industry players and indeed commissioners in some of our partner organisations very interested in what we are doing with [community name] and it aligns very well to some other approaches that are going on in different countries . . . "* (C1(m) Manager 1 – NHS).
	Q5 *"And I think, if I'm truthful, there's virtually nobody you speak to at Clinical Commissioning Group now that doesn't know about the [community name] program and whereas before I think when the [community name] program was first started and even when we were at the dallas bid stage it was like, oh, they didn't—you know, it'll never happen, it'll never happen. And now those same sceptics are now saying, but that's really good, that, I think we need to."* (C2(m) Manager 3 – NHS).
(B)	Interoperability and Information Governance
Person-centered technologies	Q1 *"So, [. . .] the technologies that have been proposed so far haven't really met the needs of the doctors, patients and the communities, and the social care providers and so on [. . .] so what we're trying to do is actually give them a user perspective and actually get the suppliers to see it from that point of view, so that they start providing things that people actually want . . . we hope that by working the way we'll give them more confidence to go out and buy systems, because they'll know that systems then on offer will be appropriate to the user's needs. That's what we're hoping to achieve."* (C4(b) Information Technologist – Business).
Interoperability/ market share	Q2 *" . . . And, the interoperability agenda that we're following is really about making sure that local authorities can buy from multiple sources. So the opinion, the resistance at the moment, we're finding is a little bit from the suppliers of technology, that would rather keep the market locked up in proprietary systems, whereas if we opened it up and made them truly interoperable, then they'll have to contend with a bigger competition field, and they don't like that idea. [. . .] if we just start opening it up and saying, well, you've got to design it in such a way that a competitor could come in and replace that bit of it, that you know, and then you'd lose some market share."* (C4(b) Information Technologist – Business).
	Q3 *"So, this year, we're focusing on topics around the personal health record, and about identity and consent, and also about devices that people will use to access services, so those three main topics that we are addressing. So, what [Group name] will do is, it might address those topics again, in the future, but it might address different topics that are related to what's needed by the communities and by assisted living as a whole, and it will produce guidelines on how to make systems that are interoperable."* (C4(b) Information Technologist – Business).
Information Governance	Q4 *" . . . Well information governance, regimes within the NHS [. . .] I think information governance we run across all the time because whilst the high level objectives certainly in the NHS constitution, which I suppose refers only to England, are about greater involvement . . . So involvement of the patient in co-decision making. But things like the information governance rules just don't understand the idea of the patient, or the citizen, owning the data."* (C3(b) Manager 2 – Business).
	Q5 *"I think a lot of information governance issues within the health sector haven't been designed with the idea that the citizen owns the data. So they find it very hard, so often we get people coming to us and saying this doesn't fit in with this information governance and you go, no it doesn't. And they go well you have to make it to, and we go no, you don't because your information governance is on the basis that how you govern information which you own and control, this is about how the user—so things like information sharing, it's up to the user who they share the information with, it's not up to—because it's owned by them. It's a complete shift in mind set . . . "* (C3(b) Manager 2 – Business).
Security	Q6 *" . . . My feeling is that it will be completely secure, and that's what we've got to sell to families, clearly, because that is the one concern that we've had from all of the focus groups, is around security."* (C3(b) Manager 2 – NHS).
Information Governance and policy debate	Q7 " . . . *the whole project is about the adoption of Personal Health Records, or Services based on personal health records . . . So . . . we work with all the partners to understand the Information Governance, and we say . . . it's a personal health record that it's the citizen, the patient..the citizen . . . is in control of the data, that's really fundamental. And, they're going, ah, but as soon as we see that person, we have to become the data management, and that's the Information Governance Leads . . . so we've gone to Dame Fiona Caldicott for a Ruling with a set of questions."* (C3(m) Manager 2 – Business).

more appropriate digital models of healthcare and well-being.[30] Here we have demonstrated the importance of building coherence and cognitive participation feedback loops across consortia in order to sustain engagement. Other lessons learned relate to the nuanced, yet crucial, shifts in shared understanding (coherence) between public and private sectors with one of the shared goals being the need to enhance interoperability.

One of the major challenges reported here was the need to innovate and recruit at the same time. Nonetheless, the number of users, *as reported by the communities* (in January 2015) was 24 588. However, importantly, the dallas program has resulted in the development and deployment of a wide range of digital tools and services across the United Kingdom (see table in Supplementary Appendix) with associated wider impact. These include a national digital health and well-being portal, which represents a new suite of interactive, web-based tools that can be personalized to each individual user; an electronic personal health record which has been endorsed by a key Regulatory body in the United Kingdom; and a consortium whose region is now recognized as a European Reference Site for innovation in digital healthcare.

Developing digital health and well-being products cognizant of users' needs that also had trusted brand recognition highlighted crucial differences in approaches to product design between the two principal communities of healthcare and digital technology. The dallas consortia aimed to innovate in the area of consumer-facing healthcare and well-being digital tools, resources, and services, which is a lucrative area of market growth. However, the program has shown how risks can manifest into reality and how difficult it can be in identifying the best "routes to market." This illustrates the perils of forging new routes to facilitate change within complex ecosystems when people and systems are not necessarily ready to change *at equal pace*.

Interoperability is needed to facilitate data and information sharing in alignment with more integrated, personalized healthcare and well-being provision but there is resistance from statutory suppliers who have dominated the market and which can be a barrier to innovation.[31] Person-centered, digital healthcare, and wellness records requires not only interoperable systems but also "real time" access to records. In the United Kingdom, the IG legislation is historical and deeply embedded in a culture of high security and confidentiality, with the concept of sharing still foreign. Experience from dallas suggests that the healthcare and well-being community would welcome better integration of health records but with some caution, perhaps due to the lack of legislation and system readiness for such change.

Strengths and Limitations

This study has a number of strengths and limitations. We have addressed the implementation processes and systems within dallas by drawing on NPT,[16,19,21] which served as a socio-technical analytical lens to help us analyze the implementation processes and emergent learning across the dallas program, and which is considered good practice by those examining implementation issues in the sphere of digital health.[32] We have also used "data coding clinics" to ensure the validity and robustness of our coding framework and we have drawn on data from multiple different sources to enhance confidence in our findings.[33] However, the dallas program is large and diffuse and the evaluation data presented here has focused primarily on macro and meso-level implementation issues and the perspectives of key implementers, with less information gained from professionals "at the coalface." In addition, we provide no data on the views of users of dallas services or products. Our use of theory to inform our coding framework may raise concerns that we "shoehorned" data to fit the framework or were unnecessarily constrained by the theory. However, we explicitly looked for data that fell outside the framework and did not exclude such data in order to conduct a rigorous and meaningful analysis of the implementation processes. Finally, while we describe here a national deployment, the work was undertaken across only 2 countries, Scotland and England, which both operate a system of free healthcare at the point of delivery. While this may be viewed as an additional limitation, we would contend that the issues we have raised and the resultant generic learning have widespread, international applicability.

Considerations for Future Studies

The present study suggests three key areas that should be addressed for future large-scale implementation of digital healthcare tools and services: 1) For a program of this scale, there should be a longer timeline between signing the contract to program initiation and a minimum 5-year timeline (5–10 year plan ideally) for the overall program of innovation at scale; 2) There should be significant time invested in assessing the digital readiness of the local health economies and a greater degree of intelligence gathering across partners before embarking on innovation at scale, and; 3) There needs to be greater attention paid to the current status of IG (and lack of interoperability) which still represents a barrier to the meaningful deployment of innovative digital healthcare services at scale.

CONCLUSIONS

As challenges have been overcome and alternative "routes" or pathways forged, dallas has gained momentum within each community and across the overall program, representing a significant network of expertise that is building capacity in this new interdisciplinary field. As far as we are aware, it is also one of the first programs in the world to undertake such *large-scale* digital health interventions and implementation, providing new evidence about creative partnership models, integrating new digital services, innovating, co-designing and delivering *at scale*, and navigating socio-technical change. Therefore, in conclusion, the identification of the key challenges in this unique program—and the mapping of the resultant solutions—provides rich learning that will benefit both future evaluation capacity and real world implementation of digital health and well-being at scale.

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CONTRIBUTORS

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COMPETING INTERESTS

None.

ETHICAL APPROVAL

The College of Medical, Veterinary and Life Sciences (Approval number: 200130141) and the College of Science and Engineering (Approval numbers: CSE01210 and CSE01096) at the University of Glasgow, United Kingdom approved this study.

SUPPLEMENTARY MATERIAL

Supplementary material is available online at http://jamia.oxfordjournals.org/.

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