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Exploring the Role of Design Thinking in
Improving Patient Adherence to Self-
Administered Treatment Technology
Volume 1-2: Thesis

Rafiq Refaat Elmansy
Doctor of Philosophy
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Exploring the Role of Design Thinking in Improving Patient Adherence to Self- Administered Treatment Technology

Volume 1-2: Thesis

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This thesis is submitted in partial fulfilment of
the requirements of the University of
Northumbria at Newcastle for the degree of
Doctor of Philosophy.

Research is undertaken in the Faculty of Arts,
Design & Social Sciences

February, 2021

Dedication

TO
MY PARENTS, THE LOVE OF
MY LIFE, RADWA, THE ROSES
OF MY LIFE, MALAK AND
HALA, MY BIGGER FAMILY
SAMIR, SUZY, SHADY, AND
HAITHAM THE CRAZINESS IN
MY LIFE, OLI THE COCKAPOO,
AND THE MILLIONS AROUND
THE WORLD WHO LIVE WITH
CHRONIC PAIN AND HEALTH
CONDITIONS.

Acknowledgment

In 2017, I moved with my family to Newcastle upon Tyne in the UK to start my PhD, a new course in our life driven by one of my design dreams, which is this PhD study. The study that I wish to provide an opportunity for millions who live with chronic diseases and pain (including myself) to live a normal life. During my research, I faced different personal, academic, and social experiences. Although some days were good and others were not, this PhD journey was the best thing in my lives.

I thank God, the designer of the universe system. Secondly, I would like to thank my parents that I hope they proudly see me from heaven. To the love of my life (Radwa) and the two gifts of my life (Malak and Hala), I would like to thank you so much for supporting and standing beside me through my study and the new life.

This study could not be done without the support of my supervisor, mentor, and friend, Dr Stuart English. I truly appreciate all your support, help, mentorship, and giving me the opportunity to learn about the philosophical approach of design. I genuinely enjoyed our discussions about design and related topics. I am looking forward to continuing to learn from him and doing further researches together. My secondary supervisor, Professor Gilbert Cockton, provided me with the opportunity to learn from him and his deep experience. So, I would acknowledge his mentorship and support. I was fortunate and honoured to learn from them, and I hope I was a good student.

During the study, a new member joined my family, Oliver the cockapoo, our lovely dog. He filled our life with joy and craziness.

Also, I would like to thank Professor Brigitte Borja de Mozota, who guided me and mentored me through learning design management. I learnt from our chat and discussion about design management, especially in the organisational structure. Also, I want to thank Dr Rodrick Adams for mentoring me to obtain the Higher Education Academy fellowship.

Furthermore, I would like to acknowledge the opportunity to work with the research collaborators from AHSN, CPI, Philips, NHS, NIHR, and the SMEs. I want to acknowledge my friends and mentors' support in my teaching in London campus (Dr Arshad Jamal, and Dr Sumesh Dadwal), and Newcastle campus (Dr Stuart English and Matteo Conte). Also, I would like to acknowledge and thank my friend and program leader Dr Lillian Clark for here support and help during my teaching in London.

Declaration

I declare that the work contained in this thesis has not been submitted for any other award, and that is all my own work. I also confirm that this work fully acknowledges opinions, ideas and contributions from the work of others. Any ethical clearance for the research presented in this thesis has been approved. Approval has been sought and granted by the University Ethics Committee on 27/6/2018. I declare that the Word Count of this thesis is 78397 words excluding references and appendices.

Name: Rafiq Elmansy

Signature:

Date:

7th February 2021

Abstract

Poor treatment adherence is an increasing challenge for healthcare, especially for chronic diseases and patient-administered treatments. This research has investigated how design thinking can improve adherence in self-administered treatment technology. The study has three main objectives. The first is to investigate the current state of adherence and its involvement in the design process. For this objective, literature about adherence theoretical frameworks, design thinking, and medical technology was reviewed. Also, in five SME case studies, interviews provided evidence of consideration of adherence during the design process. The second objective was to explore consideration of adherence at an early stage of a design process. Postgraduate students on an MA Design project were observed while applying design thinking processes to develop a medical solution. The third objective was to assess a framework through an eDelphi study that built consensus from panellists on adherence factors that influence patient adherence to a treatment technology regimen, and the importance of each factor.

A number of gaps were identified after addressing the first objective: 1) a lack of an adherence framework that considers the nature of self-administered treatment technology products, 2) There is a lack of a practical mechanism to consider adherence factors during the design and development of medical treatment technology, and 3) There is a need for a resource that can guide and help companies to consider adherence factors during the design process.

Based on the research findings, the study claims two contributions to knowledge: an adherence framework that identifies factors that affect patient-administered technology treatment adherence and their level of importance, and a design-focused adherence canvas, based on the adherence framework (1st claim), which is a practical resource that record how adherence factors are being consideration and their level of importance.

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List of Acronyms

AHSN	Academy of Health Science Network
AHSN NENC	Academy of Health Science Network North East and North Cumbria
BCW	Behaviour Change Wheel
CBT	Cognition Behavioural Therapy
COM-B	Capabilities, Opportunities and Motivation Behaviour model
CPI	Centre of Process Innovation
CRN	Clinical Research Network
D4D	Devices for Dignity Healthcare Technology Co-operative
DME	Diabetic macular oedema
DR	Diabetic retinopathy
FBM	Fogg Behaviour Model
GP	general practitioner
HBM	Health Belief Model
HERD	Health Environments Research & Design Journal
HTC	Health Technology Co-operatives
MAR	Missing at random
MCAR	Missing completely at random
MEMS	Micro Electro-Mechanical Systems
MPPF	Multi-Perspective Problem Framing
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NIHR	National Institute of Health Research
NMAR	Not missing at random
PAG	Patients Advisory Groups
PESTLE	Political, Economic, Social, Technological, Law, and Environmental
PDP	Product development process
QALY	Quality-Adjusted Life Year
ROI	Return of Investment
SCT	Social Cognitive Theory

SD	Standard Deviation
SRAQ	Self-Reporting Adherence Questionnaires
SME	Small and Medium Enterprise
SRT	Stimulus Response Theory
SWOT	Strength, Weakness, Opportunity, and Threat
UI	User Interface
UK	United Kingdom
US	United States
UX	User Experience
YPAG	Young patient advisory groups

Part 1

Introduction

Chapter 1: Introduction

This chapter introduces the study and includes an overview of the research, its aims, objectives and original contribution to knowledge. It furthermore provides an overview of the key terms used in the study that clarifies how these terms are used and interpreted. The limitations of the research, and how they might impact it, will be also highlighted.

Key Topics:

- 1.1 Introduction
- 1.2 Structure of the Thesis
- 1.3 Research Aims and Objectives
- 1.4 Contribution to Knowledge
- 1.5 Definition of Terms
- 1.6 COVID-19 Impact on Research
- 1.7 Conclusion and Summary

1.1 Introduction

The very early inspiration of this research project was based on my previously published article, 'Designing the 3D-printed prosthetic hand' (Elmansy, 2015), in *Design Management Review*. The article explored the design process of eNable the Future, a US-based charity. The company facilitates the open-source 3D printing of affordable prosthetic hands for children, especially those who have no access to traditional prosthetics medical care due to financial or geographical barriers. The article provided an opportunity to understand the importance of medical technology's contributions to patient welfare and the healthcare sector in general. My personal experience with chronic pain and high blood pressure furnished me with first-person knowledge of the critical importance of the research topic. The self-administration of chronic pain treatment provides an effective opportunity to take control of the treatment instead of waiting on long lists to see a physician. Additionally, medical technology (e.g. TINs) provides me the opportunity to avoid the side effects of pain killers. However, patients can't benefit from the self-administered medical technology without full adherence to the treatment regimen. Generally, the lack of compliance with the chronic disease's treatment led to catastrophic results, including death. The significance of this research lies in the opportunity it can provide for the increasing number of patients suffering from chronic diseases, especially those that have limited access to healthcare resources (Aldeer et al., 2018; Barnett, 2014; Haskard-Zolnieriek, & DiMatteo, 2009; Nunes et al., 2009; Sabaté, 2003; Viswanathan et al., 2012).

The healthcare system in the UK is facing increasing challenges, especially for chronic diseases (Wilson et al., 2005). These challenges include, but are not limited to, insufficient funding, lack of resources (Appleby et al., 2014), lack of staff (Buchan et al., 2017) and increasing demand on hospital admissions (Smith et al., 2014). These challenges became apparent during the COVID-19 outbreak that hit the world, including the UK, at the beginning of 2020 (Willan et al., 2020). Several studies have shown the benefits of adopting medical technology systems especially for the treatment of chronic diseases (Cutler, 2007; García-Lizana & Sarría-Santamera, 2007; Mirza et al., 2008; Ganasegeran et al., 2017; Wickramasinghe et al., 2011). The self-administered treatment technology can be as effective as the clinically administered treatments (Scogin et al., 1990), additionally, medical

technology can reduce medication costs (Hoppe et al., 2000; Scogin et al., 2003), hospital and General practitioners (GPs) admissions, the psychological impact of the disease, instances of surgical intervention and the side effects of using of pharmaceutical treatment.

However, various literature studies have shown that poor adherence to medication regimes is a persistent (van Dulmen et al., 2007) and involved problem in healthcare (Aldeer et al., 2018). An estimated 20% to 30% of patients do not take their medications (Viswanathan et al., 2012). This percentage increases to between 30% and 50% for patients with chronic diseases (Nunes et al., 2009; Sabaté, 2003; Barnett, 2014). The failure to achieve a significant level of adherence can lead to serious complications, including death (Viswanathan et al., 2012; Aldeer et al., 2018), increased healthcare costs and a negative impact on healthcare workforce productivity (Bosworth et al., 2011; Conn et al., 2016). Another consequence of poor adherence is that it blurs the actual effectiveness of the treatment and its success rates (Viswanathan et al., 2012). This gap may affect the accuracy of clinical trial results and, subsequently, the outcome of decisions related to the treatment. Additionally, the literature studies that investigated adherence have approached it from the traditional pharmaceutical perspective ignoring the unique nature of medical technology, and especially issues around self-administered intervention such as the design of the treatment device, usability issues and human-factor issues.

To this end, the research aims to investigate how design thinking can improve consideration of patient adherence during the development of self-administered treatment technology. Three main goals will contribute toward achieving this aim: 1) investigate the current design processes in treatment technology; 2) explore the contribution of design thinking to the development of the treatment; and 3) assess the impact of considering adherence factors during the design of treatment technology on the intervention outcome.

Based on the addressed aim and objectives, the research methodology of the study has three main stages: Investigate, Explore and Assess. The Investigate stage aims to identify the role of adherence in medical treatment technology from the perspective of the literature

and the view of practitioners and founders of self-administered medical technology companies. The Investigate stage includes two steps:

- Desk research, which reviews the literature related to design thinking characteristics, medical innovation, self-administered treatment devices and theoretical factors of adherence.
- Case study interviews. Representatives from five SMEs were interviewed to explore the design process inside the company and how adherence was considered.

The second phase, Explore, aims to explore how adherence could be considered while implementing design thinking in an early design stage. In this stage, MA of Design students at Northumbria University were observed during WearCare II, a practice-based design project. This stage aims to understand how adherence is considered in an early stage of product idea development and how the design process ensures an acceptable level of consideration of adherence during the design process timeline.

The final stage, Assess, implements a Delphi methodology. This stage aims to explore the agreement of a multi-disciplinary panel on the factors that affect adherence and the importance of each factor. This stage is the triangulation stage as the data collected from the literature, case studies and observation is presented to the panel that includes representative who answer the case study interview questions. The Delphi consists of three rounds:

- Round one: This round consists of interviews with the panel (15 panellists) who received an online link with open-ended questions to answer. This setup was planned to provide the panellists a flexibility to answer the questions especially during the Covid-19 pandemic. The panellists have expertise in medical psychology, medical design technology and design process and are representatives of the five case studies SMEs. The panel also includes representation of the healthcare system and medical research companies such as the Academy of Health Science Network North East and North Cumbria (AHSN NENC), National Health Service (NHS), Centre of Process Innovation (CPI), Philips, GraftWorx and ORCHA.

- Round two: The collected data from round one is analysed and presented to the panellists in the form of a questionnaire (Likert rating questions) to allow them to rate the importance of each adherence factor in terms of self-administered medical technology.
- Round three: The same questionnaire is presented to each panellist along with the complete panel answers and the panellist's own answer. This round aims to allow the panellists to change their answers after reviewing the full answers of all the panellists' responses.

To determine the significance of the data collected from round one and round two of the Delphi method, the Inter-rater reliability procedure and Wilcoxon test used to ensure the agreement between the panellists is not based on chance. The data collected from the Delphi study contributes to building a Design-Focused Adherence Canvas that companies can use to measure consideration of adherence during the design of a medical treatments.

The primary limitation of this research is the timeframe constraints of the study. The timeframe of a PhD study does not afford the opportunity to test the results of the research and its impact on the participated companies. Therefore, the study stopped at the assessment stage, which uses the panellists' answers to build an understanding of the factors that affect adherence and the level of impact or importance of each factor. Further research would provide the opportunity to test how the consideration of adherence factors during the design of the treatment technology affects the outcome of the self-administered treatment technology and the results of evaluating this outcome.

1.2 Structure of the Thesis

The thesis is divided into two parts (documents): The Thesis and the Appendices. The Appendices document was submitted separately of the main Thesis document as it was submitted as secure document as it contains information about the participants in both the interviews and Delphi panel. Therefore, the Appendices were submitted as a secure

document to ensure the anonymity of the participants information, and adherence to Northumbria University regulations.

The structure of this thesis is closely linked to the structure of the study itself. The thesis is divided into Parts and Chapters. The Parts reflect either a section related to the study (e.g., Part 1: Introduction and Part 2: Research methodology) or chapters related to a specific research stage (e.g., Part 3: Investigate and Part 4: Explore). The chapters listed in each Part are related to one another and form a specific part of the study. Each part has a specific colour, which will be the same as the chapter names in the header of each page.

The naming of the titles and sub-title heading was styled to ensure that the reader knows the current chapter and position. So, each heading starts with the chapter number (e.g. the first title in Chapter one is 1.1). Table 1.1 visualises the different parts of the study and the associated chapters:

Part 1	Chapter 1: Introduction
Introduction	
Part 2	Chapter 2: Methodology Introduction
Research Methodology	Chapter 3: Case Studies Methodology
	Chapter 4: WearCare II Observation Methodology
	Chapter 5: Delphi Method Methodology
Part 3	Chapter 6: Theoretical Frameworks of Adherence
Investigate	Chapter 7: Design Thinking
	Chapter 8: Medical Technology Innovation
	Chapter 9: Case Studies Interviews
Part 4	Chapter 10: WearCare II Project
Explore	
Part 5	Chapter 11: Delphi Method Application
Assess	
Part 6	Chapter 12: Discussion of Findings
Discussion and Conclusion	Chapter 13: Introducing a Suggested Design-Focused Adherence Canvas
	Chapter 14: Conclusion and Potential Contribution to Knowledge

Table 1.1 A visualisation demonstration of the structure of the study

1.3 Research Aims and Objectives

This research has two main aims. The primary aim is to investigate how design thinking can improve patient adherence in self-administered treatment technology. The secondary aim is to identify the factors that affect patient adherence during the design of the self-administered treatment technology. The two aims form the main hypothesis of the study, which is that building a Design-Focused Adherence Canvas can improve adherence in self-administered treatment technology.

To this end, the following objectives will be achieved:

- Investigate the current design processes applied in medical technology innovation and how adherence factors are considered during the development process.
- Explore the contribution of design thinking in the development of the treatment intervention and how the process is used to consider adherence factors, especially at an early design stage.
- Assess the impact of considering adherence factors during the design process on patient behaviour and the expected outcome of the treatment intervention.

The above three main objectives contribute to building three areas of knowledge:

Investigate, Explore and Assess. Below are the details of each area:

- The first area of knowledge, Investigate, includes investigating both literature studies and primary data (interviews) to explore the theoretical adherence framework, the design process for self-administered treatment technology and how adherence is considered during the design and development process.
- The second Area of knowledge, Explore, includes building an understanding of the adherence factors and how they are considered at an early stage of the design process. This stage presents a triangulation of knowledge from the previous one, and it will feed into the following stage, Assess.
- The third Area of knowledge, Assess, is covered during the Delphi method procedure in order to reach an agreement between panellists on the adherence factors that are most important to consider during the design of the treatment technology. The

usage of the assessment procedure is linked to study time limitations. This will be discussed later (Chapter 14: 14.3.2 Delphi Study Limitations).

Over the course of addressing the above aim and objectives, the questions below were prepared to guide the research in the following stages

Information about the study objectives and the knowledge that will be result from achieving each objective is discussed in more detail in later chapters of this study.

1.4 Contribution to Knowledge

This research claims two contributions to knowledge:

- An adherence framework that identifies factors that affect patient-administered technology treatment adherence and their level of importance.

The existing adherence theories and frameworks don't consider the specific forms of medical technology interventions. This finding presented the first gap in literature.

The interviews with case studies (Chapter 9: Case Studies Interviews) and Delphi method (Chapter 11: Delphi Method Application) contributed to formulate the first claim above.

- A design-focused adherence canvas, based on the adherence framework (1st claim), which is a practical resource that records how adherence factors are being considered and their level of importance.

Existing adherence theories don't provide a practical mechanism for companies to consider adherence in their product or service. This finding presented the second gap in knowledge. The interviews with the case studies, the observation of WearCare II project (Chapter 10: WearCare II Project), and the Delphi method have contributed to formulate the second claim above.

1.5 Definition of Terms

This study explores two main domains of knowledge: medical science and design science. To ensure the accuracy of the terms and their precise definition, the below section will:

1. Highlight the definition of key terms used in this study, and
2. Highlight how these definitions are used in the context of this research to reflect the nature of the research to explore the role of design in improving adherence in self-administered treatment technology.

The below definitions are categorised into two main sections—medical terms and design terms—to differentiate between the two domains of knowledge.

1.5.1 Medical Terms

The below definitions are related to the medical and health terms that will be used during this research.

1.5.1.1 Adherence, compliance, concordances and more

Literature studies have shown confusion between both the conceptual and operational definitions of adherence. As a result of this confusion, terms such as ‘compliance’, ‘concordance’, ‘cooperation’, ‘mutuality’ and ‘therapeutic’ alliance were used interchangeably to define adherence (Horne, 2006). However, the shared element between these definitions is that they describe coordination between the patient and clinicians (Haynes, 1979). These different terms were reviewed in this study to identify the most relevant term that fits with the research aims.

Adherence

The World Health Organisation defines adherence as 'the extent to which a person's behaviour—taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider' (Sabaté, 2003, p.3). However, this definition limits adherence to three aspects of medical intervention, eliminating other aspects such as medical technology treatments. Cramer et al. (2008, p. 46)

introduced a more inclusive definition of patient adherence: 'the extent to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen'.

Compliance

Haynes (1987, p.13) provided the most cited definition of compliance: 'the extent to which a person's behaviour [in terms of taking medication, following a diet, modifying habits or attending clinics] coincides with the medical or health advice'. While this definition aligns with the literature definition of adherence, the term 'compliance' reflects subservience (Bosworth et al., 2005) and passive reaction (Jette, 1982) from the patient. This superior attitude presents one of the reasons that caused a recent shift toward the term adherence (Martin et al., 2010).

Concordance

The term 'concordance' implies that both the patient and physician discuss and come to an agreement about the prescribed treatment (Aronson, 2007). A concordance can be defined as 'the consultation process, in which doctor and patient agree on therapeutic decisions that incorporate their respective views, to a wider concept which stretches from prescribing communication to patient support in medicine taking' (Horne et al., 2005. p. 12). The American Institute of Medicine defines the patient-centred approach as respecting patients' needs and preferences to improve the healthcare system, especially of patients with chronic diseases (Levinson, 2011, p. 823).

The term 'concordance' is usually confused with adherence and compliance. It is likely that this is because words like concord, accord, or agreement have been used as synonyms for compliance and adherence (Aronson, 2007). Horne et al. (2005) highlighted that term 'concordance' is confused and incorrectly used as a synonym for the term 'adherence'.

Based on the above literature, the term 'concordance' reflects the communication and conversation between the patient and clinician. Accordingly, the term 'concordance' can represent one of the factors that affect patient adherence such as communication (Haskard-Zolnierrek & DiMatteo, 2009; Martin et al., 2010; Martin, & DiMatteo, 2013) rather than defining the whole picture of the term 'adherence'.

Cooperation

The term 'cooperation' is used interchangeability with adherence and compliance. Previous studies tended to use this term to eliminate the passivity (Jette, 1982) and subservience (Bosworth et al., 2005) implied by the term 'compliance'. While the term 'cooperation' includes patient adherence to the medication, it is more than just this. The cooperation between the patient and clinician can extend to a wide range of activities in time and place during the treatment intervention.

Mutuality

Mutuality refers to the relationship between patients and service providers that is based on experience, respect and collaboration (Henson, 1997). The term 'mutuality' reflects the unique experiential characteristics of the relationship between the patient and clinician (Smith & Newton, 1984). Based on this definition, this relationship can have a positive impact on patient adherence to the treatment (Martin et al., 2010). Similar to cooperation, mutuality reflects the broad range of the patient-clinician experience that extends beyond patient adherence to the treatment.

Different terms are used to describe patient adherence to a prescribed treatment; according to the above exploration of the definitions of these terms, 'adherence' was selected because it most accurately represents this part of the patient-clinician experience.

1.5.1.2 Patient Empowerment

Self-determination theory is a cornerstone of patient empowerment as it aims to enable the patient to make decisions and solve problems (Bosworth et al., 2006). Patient empowerment provides a model of medical treatment that widens the scope of traditional healthcare systems to include the psychosocial aspects of patient experience, such as emotional, social and cognitive factors (Arnold et al., 1995). The evolution of medical technology and digital health—for example, e-health and web-based interventions—contribute to the extension of the role of patient empowerment and self-efficacy (Samoocha et al., 2010). Therefore, this study focuses on medical treatment technology.

1.5.1.3 Treatment and therapy

As this study aims to investigate patient behaviour toward medical technology, two terms have been explored to define this patient experience: 'treatment' and 'therapy'. According to the Merriam-Webster dictionary (2020), 'therapy' is defined as the dose or solution used to address a specific disease. On the other hand, 'treatment' is defined as the whole experience related to taking the medication. The word 'treatment' has a broader meaning that includes not only the medication but also the medication management and the regimen associated with it. In accordance with the above, this study will use the term 'treatment' to refer to the medical intervention and the environment associated with it.

1.5.2 Medical technology

There are a wide range of applications for medical innovation in the healthcare sector, which vary from treatment, monitoring or diagnosis solutions. This study focuses on medical technology innovation as it has an important impact on different aspects of the healthcare system including how it works, professional practice and the participation of patients in the treatment decision (Timmermans & Berg, 2003). The broad implementation of medical technology can bring varied benefits to the healthcare system. Healthcare technology has a wide range of medical devices that includes treatment devices, monitoring devices (Lehoux 2009) and communication technologies (Heath et al., 2003). Furthermore, medical technology is not only limited to physical devices, but also extends to digital and mobile systems (e-health), which can provide cost-effective, flexible and efficient solutions compared with the traditional interventions (Istepanian et al., 2006).

Medical technology contributes much to medical science and practice. It covers a wide range of equipment designed for the diagnosis and treatment of diseases (Moore & Zouridakis, 2004). The term 'medical technology' is broad and includes both medical devices and also the information technology associated with them. The application of medical technology includes the production of medical devices and diagnostic technologies such as digital imaging, instruments and test kits, surgical tools and implanted devices (Canadian

Healthcare Manager, Suppl. Health Research & Innovation, 2013). The coverage and the decisions to adopt medical technology fundamentally affect medical innovation (Institute of Medicine and Committee on Technological Innovation in Medicine, 1994).

Another definition of 'medical technology' was presented by De Miranda et al. (2005) as they defined it as usage and the application of energy forms to the body systems. The energy forms include physical forms such as magnetic energy, thermal energy, electrical energy and chemical energy. The implementation of these forms involves using medical devices such as x-ray machines, electrocardiographs, precision lasers and printed sensors. While this definition provides a solid understanding of medical technology from the energy perspective, it lacks the use of other physical forms, such as the implementation of 3D printing technology, in creating medical devices.

To position the term 'medical technology' in relation to its scientific contribution to the medical industry, a clear understanding of what medical science is required. Vandembroucke (2008) indicated two types of views of medical science; one view emphasises discovery and explanation, and the other emphasises the evaluation of the intervention. The first view focuses on the discovery and explanation of diseases, while the second view focuses on the evolution of the discoveries and how it reflects on patient welfare. Based on those two views of medical science, medical technology is closely linked to medical science and may contribute to medical science knowledge from different perspectives. Accordingly, this study will adopt both the broad scope of the definition by the Canadian Healthcare Manager, Suppl. Health Research & Innovation (2013) while also considering the later definition by De Miranda et al. (2005) from the perspective of a diversity of energy usage.

1.5.2.1 Medical technology vs Health Technology

'To believe that doctors and hospitals help keep people healthy is plain rubbish,' Lord Platt (Hegde, 2011, p.1).

The usage of the term 'medical' instead of 'health' in this research is based on both the difference in definition and the research scope. The terms 'health' or 'healthcare' refers to

the prevention of diseases in general and promoting health welfare within the community. Healthcare does not provide a cure to a specific disease. Instead, it aims to encourage people to live a healthy life. While healthcare focuses on public health, there are many applications that promote personal health such as mobile applications for weight loss and healthy lifestyle tracking devices. In contrast, 'medicine' or 'medical care' focuses on individuals who already suffer from a specific disease. In this case, the medical care focuses on diagnosing, treating and monitor patients suffering from a specific disease such as the mobile applications and insulin pumps used to treat Diabetes (T.H. Chan, N/A).

Based on the above, the term 'medical technology' will be used in this study because of the primary focus on adherence to treatment technology regimens for chronic diseases. The definition of this term will also reflect the type of case studies used to explore the design processes in SMEs working in the medical technology industry.

1.5.3 Self-Administered Treatment

As the term implies, self-administered treatment refers to treatment intervention that is administered by the patient. However, the level of dependency is essential to this study. For example, Scogin et al. (1990) defined the self-administered treatment as 'any therapeutic intervention that was presented in a written or audiotaped format and was designed to be implemented by the client'. This definition excluded therapeutic interventions that are administered by therapists or require therapeutic consistency contact. The above definition also excluded any form of communication between the patients and clinicians, which is one of the essential factors that influence adherence to treatment intervention as will be discussed later in 4.1.6 Treatment and Treatment Support. Accordingly, in this study, the term 'self-administered treatment' will include treatment interventions that are either fully- or partly-administered by the patients themselves. 'Partly-administered intervention' refers to a level of communication between the patient and the clinician. This relationship can be: 1) before the treatment to guide the patient in the use and administration of the treatment; and 2) during the treatment in order to follow-up with and provide consultations to the patient. Alternative strategies such as self-administered treatment can provide a solution to

overcome challenges faced by the UK health system, such as increasing number of appointments, short of staff and long waiting lists (Leigh & Flatt, 2015).

Glasgow and Rosen (1978) indicated four levels of communication between the patient and the therapist:

- Self-administered treatment, which is entirely administered by the patient with possible contact from the therapist for an assessment.
- Predominantly self-help, which includes which includes introduction to the treatment and materials and learning to the treatment, introduction to materials and learning how to self-administer the treatment.
- Minimal contact with some involvement of the therapist.
- Therapist-administered treatment, which is entirely administered by the clinician.
-

With the development of online communication tools, communication between the patient and the clinician is becoming more accessible and affordable. This communication can be done through telephone, online chat and mobile applications. Literature studies have shown significant benefits for self-administered treatment such as its effectiveness (Bandura, 1977), cost, affordability, convenience and suitability for some patients, especially those who do not want to take medications (Mains & Scogin, 2003).

1.5.4 Treatment and Treatment Support

This research focuses on two related medical technologies: treatment devices and treatment-support devices. The treatment devices are used as direct intervention to cure diseases or the health problem. The treatment support devices are used to facilitate the treatment to patients. While the support devices are not treatments themselves, they can be used to facilitate the delivery of the treatment, help patients to adhere to the usage of the treatment or improve patients' experiences with the treatment itself. Accordingly, the treatment support technology may have an impact on the patient adherence. Therefore, this research will consider both types of devices.

1.5.5 Regime and Regimen

While the term 'regimen' is relatively straightforward in medical science, experts from other fields may confuse it with the term 'regime.' According to the Cambridge Dictionary (2020), the word 'regime' is used to refer to a particular government or political system run by the government. Also, it can mean a particular way of operating a business or organisation. In addition to Cambridge's definition, the Merriam-Webster (2020) defines 'regime' as a regular pattern of occurrence or action, and the characteristics of a specific behaviour or natural phenomenon.

On the other hand, the term 'regimen' is defined in the Cambridge Dictionary (2020) as a set of rules and regulations related to health, food or exercise in order to improve health. In the Merriam-Webster (2020), 'regimen' is defined by a systematic plan (e.g., diet, treatment, therapy or medication) designed to improve health. The treatment regimen is defined by the treatment plan that aims to improve and maintain the patient's health (AIDSinfo, 2020). In this study, the term 'regimen' will be used to refer to the treatment plan used to improve patient health. This plan is either administrated by patients or clinicians.

1.5.6 Efficacy and effectiveness

The term 'efficacy' refers to the treatment intervention conducted under ideal or controlled circumstances. In contrast, 'effectiveness' refers to the treatment intervention in real-world conditions. In clinical trials, it is impossible to conduct pure efficacy or pure effectiveness studies (Flay, 1986; Singal et al., 2014). Accordingly, the efficacy studies test whether the experimental therapy generates specific therapeutic effects. The effectiveness studies aim to quantify the effects of several factors on the total therapeutic effect (Ernst & Pittler, 2006). The efficacy trials expect to facilitate different factors in order to achieve the main target of the trials; therefore, the intervention should be ready, there should be clear idea about the population and patients' adherence to the treatment intervention. For example, real-world conditions such as poor access to intervention and poor patient adherence make the highly-efficacious results less effective (Singal et al., 2014).

In this study, both terms are used based on the two definitions given above. Further usage, such as the theory of self-efficacy (e.g., Chapter 6: Theoretical Frameworks of Adherence), will be defined in the context.

1.5.7 QALY (Quality Adjustment Life Year)

The QALY (Quality-Adjusted Life Year) is a generic method of measurement that aims to measure both the quality and quantity of patients' lives. The QALY measurement is used to assess the outcome of a specific medical intervention by examining its impact on increasing the years' patients may live in good quality (Love-Koh et al., 2015). As highlighted in figure 1.1, a long life lived with chronic disease can be equal to a short life lived with good health. The QALY is calculated by the number of the life years lived multiplied by the weight of the quality of life where 0.00 means death and 1.00 is the best health level (Arnesen & Norheim, 2003).

1.5.8 Design Thinking

Literature studies conducted in the latter part of the 20th century contributed to defining the term 'design thinking'. One example was conducted by Peter Rowe, a professor of architecture at Harvard School of Design, in 1987 (Dorst, 2010; Nixon, 2016). Rowe intended to 'account for the underlying structure with those rather private moments of "seeking out", on the part of designers' (Rowe, 1987. p.1). Dorst (2012) defines design thinking as a practice that can be used to resolve issues with a broad approach in professional design practice and can be implemented to solve both business and social problems. In his article in the *Harvard Business Review*, Brown (2008) defined design thinking as the usage of designers' methods to address the people's need for solutions that are technically feasible and business viable.

Lawson and Dorst (2013) highlighted three types of thinking in design: 1) convention-based design thinking, where the response to the design challenge is based on the conventional wisdom; 2) situation-based design thinking, where the response to the design challenge is based on the study of the situation and the response is customised based on this particular

situation; and 3) strategy-based design thinking, where the response to the design challenge is based on a planned and effectively designed process that reflects the interpretation of the design situation. In addition to the above, more types of design thinking were introduced by Dorst (2010), such as choice-based and experience-based thinking, developing new schemata and refining the design arena. Strategy-based design thinking will be used in this study to examine the linkage between design thinking and strategic management.

However, Barsalou (2017) highlighted that design thinking involves the cognitive science perspective as its nature may change based on how the situation is seen from an explanatory perspective. Designers tend to change their design styles based on a reflective process, which makes it a challenge to find an absolute definition of design thinking. There isn't a single canonical form of Design Thinking, and that practices vary across projects and design teams.

In this study, the earlier definition of design thinking by Dorst (2010) was used with the focus on the strategy-based type of design thinking. The linkage between design thinking, business viability and technological feasibility will also be considered.

1.5.8.1 Creativity and Design Thinking

There have been several attempts to define creativity generally (Boden, 1996) and particularly in design (Gero & Maher, 2013). Hokanson (2007) suggested that creativity is the process that generates new ideas. Several studies have suggested that creativity has different levels that relate to the difficulty of the problem or novelty of the resultant solutions (Brown & Chandrasekaran, 1983; Gero & Rosenman, 1990; Westerberg, 1989; Gero & Maher, 2013). Creativity plays a crucial role in the design process, as it is necessary to achieve innovation (Mumford and Gustafson, 1988; Amabile, 1996; Howard et al., 2008). Literature definitions of 'innovation' have closely linked creativity to innovation, especially where ideas are transformed into commercial value (Thompson and Lordan, 1999; Culley, 2002; Cox, 2005). From the design thinking perspective, creativity is an essential factor in the co-evolution of the problem and solution spaces (Dorst & Cross, 2001) as it has a pivotal role that leads to framing and reframing problems (Schön, 1983). According to the above,

creativity plays an essential role in the design thinking process and is a pivotal driver of innovation. Therefore, this study will take into consideration the creative aspect of the design thinking process.

1.5.8.2 Innovation

'Innovation' is one of the most commonly used terms in different disciplines, yet many confuse it with 'invention'. While invention is the occurrence of a new idea, innovation is the first commercialisation of the idea. Although both are closely linked, there is a time lag between the two. It may take a long time to transform inventions into innovations (Rogers, 1995), which reflects the different requirements needed to transform ideas into innovative products or services (Fagerberg, 2004).

Bessant (2013) indicated that innovation is about change that can take a wide range of forms, from simple, incremental improvements of the product or service to radical changes, which may involve a varied level of risks and benefits. Innovation does not happen by accident. While the organisation may get lucky once, in order to repeat it, an organised and structured approach must be applied. Drucker (2002, p. 5) indicated that 'in business, innovation rarely springs from a flash of inspiration. It arises from a cold-eyed analysis of seven kinds of opportunities'. These opportunities include unexpected occurrences, incongruities, process needs, industry and market changes, demographic changes, changes in perception and new knowledge (Drucker, 2002).

Keeley et al. (2013) defined innovation as the process that creates a new, viable offering through understanding problems and providing solutions. This definition has four main characteristics:

- While innovation may involve invention, it also requires activities other than simply creating new ideas, such as understanding the consumer's needs.
- Innovation should provide a return value for the enterprise. To achieve innovation viability, it should sustain itself and return its weighted cost of capital.
- Innovation can vary from small improvements to radical changes. Most innovations are improvements based on previous advances.

- Innovation is not limited to the product or the service. It should extend its role to cover new ways of doing business.

The innovation process provides a result to the design process. It starts with creativity as a generator of new ideas and ends with an innovative product or service that is a result of the design process inside the enterprise (Cox, 2005). From the medical technology perspective, innovation has three dimensions: consumer-focus, technology and business model.

Consumer technology innovation aims to put the consumer at the heart of the development process by creating solutions that are more effective, more convenient and less expensive than current solutions. Technology innovation focuses on developing medical devices, diagnostic systems and drug delivery systems that are less expensive, less painful and less disruptive. Business model innovation aims to build a less fragmented healthcare system that solves the integration problem between all the stakeholders (Herzlinger, 2007). While this study aims to investigate innovation in the medical industry from the technological perspective, other dimensions of innovation in the industry will also be considered because all the three aspects of innovation lie under the umbrella of strategic design thinking interest and come together in the medical industry.

1.5.8.3 Small and Medium Enterprises (SMEs)

The definition of SMEs differs from country to country. These definitions vary based on a number of factors, the most important being the number of employees. Lukács (2005) defined SME as an independent business that is managed by its owners or part-owner. SMEs have a small market share. Until 1996, SMEs were defined solely by the number of employees, for example, micro-enterprises (1-9 employees), small enterprises (10-99 employees) and medium enterprises (100-499 employees). In 1996, a new definition was introduced by the European Union for SMEs; the definition was based on the following criteria (European Commission, 1996):

- The total number of employees
- The annual volume of turnover
- The total assets of the enterprise
- The ownership or the degree of independence

According to the above, the SMEs were categorised as shown in Table 1.2.

Category	Headcount	Turnover
Medium	< 250	£ 35.2 Million
Small	< 50	£ 8.2 Million
Micro	< 10	£ 1.7 Million

Table 1.2 The categorisation of SMEs based on the European Commission definition

Based on the UK Gov website (2012), SMEs need to meet two out of the three following characteristics:

- Employees: Less than 250
- Turnover: Less than £25m
- Gross assets: Less than £12.5m

The UK definition is based on the turnover of the SME, as £25m is the lowest level of the definition of a Mid-Sized Business (MSB), which has a turnover range of between £25m - £500m. Based on the above definitions, the study will adopt the UK definition of a SME and will focus the research sample characteristics on the SMEs.

1.5.9 Characteristics of Design and Medical Innovation

To identify how design can contribute to medical innovation, the research aims to explore the characteristics of the design thinking process and how it stands apart from other development processes.

De Mozota (2003) tried to identify the nature of design from the etymological approach by pointing out how design merges intention (need) with drawing (creativity). This definition aligns with the International Council Societies of Industrial Design (ICSID)'s definition of design. The ICSID highlighted two main characteristics of design:

- 1) Aim: Design is a creative practice that aims to create an object, process, service or other outcomes, and
- 2) Task: Design seeks to discover and assess the current situation to reach an improved state, such as enhancing global sustainability, giving benefits and freedom to people,

supporting cultural diversity and giving products and services an aesthetic form by appreciating the complexity (De Mozota, 2003; Manzini, 2006).

The above two definitions appreciate two main characteristics of design: 1) creativity, form and aesthetics of the product or service; and 2) moving from one status to an improved one (addressing needs). These characteristics were highlighted in Tim Brown's definition of design thinking as: 1) a human-centred approach; 2) innovative; 3) addressing people's needs; 4) producing a product that is aesthetically desirable; 5) viable technologically; and 7) feasible from the business perspective (Brown, 2011).

Cox (2005), Culley (2002) and Thompson and Lordan (1999) highlighted the nature of design as an innovative process that transforms creative ideas into innovative products. Cox (2005) saw design as a process that links creative new ideas and transforms them into innovative products and services. Therefore, design and innovation can't disconnect from each other, innovation is an outcome of the design process. Other definitions for design targeted the nature of design and how designers think to transform intangible ideas into physical products or services. Dorst and Cross (2001) and Dorst (2018) pointed out the problem frame/solution frame nature of design. According to the above literature, the below characteristics highlight the nature of design:

- a) A creative process that is used to transform creative ideas into innovative products.
- b) Acknowledges uncertainty and the move between both problem space and solution space.
- c) Human-centred, as it addresses people's needs in the context of use.
- d) Considers the aesthetical features of the product.
- e) Considers the business-related aspects of the product.

1.6 COVID-19 Impact on Research

In February 2020, the world was hit by the SARS-CoV-2 virus causing COVID-19 virus outbreak, which disrupted almost all industries as well as the healthcare systems in every country, including the UK. This outbreak impacted this study in the following ways:

- The outbreak lockdown occurred during the Delphi method; this moderately delayed, by an average of two months, the response time of the panellists.
- Panellists working in the NHS or companies closely related to it were given longer to respond to each round.
- My research plans were disrupted, especially at the beginning of the outbreak in February and March.

1.7 Conclusion and Summary

This chapter has presented the initial research aims and objectives. Information about the research's significant contribution to knowledge was provided. Additionally, the definitions of the terms used in the study were reviewed and clarified to ensure an accurate reflection of their meanings and interpretations. Finally, the impact of COVID-19 outbreak on the flow of the final stage of the research (Delphi method) was discussed.

Part 2

**Research
Methodology**

Chapter 2: Methodology Introduction

This chapter introduces the general methodology and research design of this study. It will review the research scope, philosophy and approaches. Then, it will highlight the research strategy, methods and process required to achieve the results of the strategy. Finally, research ethics will be discussed.

Key Topics:

- 2.1 Research Scope
- 2.2 Research Philosophy
- 2.3 Research Approaches
- 2.4 Research Methods
- 2.5 Research Strategy
- 2.6 Data Triangulation
- 2.7 Research Process
- 2.8 Research Ethics
- 2.9 Summary and Conclusion

This part of the thesis outlines the methodologies used in each of the research stages. The first chapter covers the high-level elements of the research methodology such as the research scope, strategy, and plan. This chapter presents the base of the following chapters who discuss the research.

2.1 Research Scope

The research aim of this study is to explore how design thinking can improve patient adherence to self-administered medical technology treatment developed by small and medium enterprises (SMEs). To explore the research's aim further, the healthcare challenging state was overviewed as following:

Healthcare Burden

Public spending on healthcare is a burden on many countries, including the UK. In 2006, at least 5 per cent of the UK's GDP was allocated to the healthcare system (Natarajan, 2006). This amount has been increased to 8.4 per cent in 2011 (Chang et al., 2011). Although some countries try to overcome this increasing pressure by facilitating private healthcare insurance, this solution may lead to inequality in the services offered (Timmins, 2005). The fact that the NHS provides equal healthcare service to both public and private patients (Oliver, 2005) increases its expenditure. The three main factors that cause this growing pressure are: 1) the financial load caused by ensuring that public sector wages remain comparable to those in the private sector; 2) increasing demands for healthcare; and 3) an increasingly elderly population (Emmerson et al., 2000).

Adherence

The adherence factor plays an essential role in different patient interactions with the healthcare system, including diagnosis, monitoring and treatment (Bosworth et al., 2006; Nunes et al., 2009; Sabaté, 2003). An estimated 20% to 30% of patients do not adhere to their treatment regimens (Viswanathan et al., 2012), and this increases to between 30% and 50% among patients with chronic diseases (Barnett, 2014; Nunes et al., 2009; Sabaté, 2003). Failure to reach a significant level of adherence can cause serious complications, including death (Aldeer et al., 2018; Viswanathan et al., 2012). Accordingly, this research focuses on the impact of adherence to treatments on: 1) the outcome of treatments; 2) the accuracy of treatment efficacy; and 3) evaluations of treatments during clinical trials.

2.2 Research Philosophy

To clearly state how this research philosophically addresses the phenomena studied, the philosophical approach to the study should be clearly defined (Saunders et al. 2008); therefore, this section provides an overview of the relevant research philosophies. In general, there are three philosophical approaches: ontological, epistemological and axiological (O’Gorman & MacIntosh, 2014; Saunders et al., 2008; Quinlan et al., 2019). Considering the nature of the study, the following provides a summary of the research philosophies and approaches that align with the nature of the research scope.

2.2.1 Ontology

Part of the branch of philosophy called Metaphysics, Ontology refers to research activities that aim to understand the ‘what is’ (Welty, 2003. p. 11). Ontology is a philosophical approach developed by the ancient Greeks and discussed by positivists such as Descartes through which the researcher aims to understand the nature around or the phenomena (Crotty, 2003); as Cocchiarella (2007) notes, ‘Ontology = the study of being as such’ (p. 3). Ontology informs two views of the nature of ‘reality’: objectivism and subjectivism. Objectivism regards phenomena as external to and independent of social actors. In contrast, subjectivism claims that the perceptions and actions of social actors form the world around them. Subjectivism and interpretivism are closely linked. Research that uses the interpretive approach explores the definition of the social phenomenon (Epstein, 2018). This is important because the researcher needs to understand the factors which affect participants’ beliefs and attitudes towards the phenomena being researched in order to accurately interpret the collected data (Wilson, 2010). Accordingly, the ontological approach will be utilised in this study to understand the adherence factors in the literature.

2.2.2 Epistemology

Epistemology is one of the oldest branches of philosophy. It comes from the Greek word 'episteme', which can be translated as 'knowledge'. Epistemology is concerned with what constitutes acceptable knowledge, such as how we see and deal with social phenomena. In this philosophical tradition, the researcher asks questions, such as 'how', that reveal knowledge (Steup & Ram, 2020). In this study, the epistemological approach will be widely adopted to understand the knowledge related to different elements of the research such as the theoretical frameworks of adherence and the design process.

The epistemological approach aligns with the study's scope and research design. Therefore, it is used in this study to reflect the study's phenomenological approach of understanding the phenomena (e.g. adherence) as they appear in our experience (Husserl, 2012). Smith (2018) suggests the phenomenological approach can be applied to understanding:

- The appearance of phenomena;
- The phenomena as they appear in our experience; or
- How we experience the phenomena.

Accordingly, phenomenology studies conscious experience as experienced from the subjective, or first-person, point of view (e.g. the point of view of the representatives of SMEs). While the research adopts a phenomenological epistemology perspective, the ontological approach cannot be ignored, especially in the early stages of the study where the phenomenon is defined. The ontological approach helps clearly explain the nature of the study elements. In this regard, the adoption of ontological realism can be considered a practice of critical realism (Fletcher, 2017).

- In addition to the overview of the related research philosophies above, how the data is handled during the research is crucial to clearly defining the researcher's position. As such, the below offers an overview of the different research approaches related to the current study

2.2.3 Axiology

Axiology is concerned with the nature of value and ethical issues within research, as well as the researcher's values and how these affect the study. Some approaches, like positivism, consider the research process to be value-free (Wilson, 2010). The way the researcher regards the values related to the research plays an essential role in how research ethics are considered during the research process (Saunders et al., 2008). The axiological approach will be adopted in the study in relation to the communication with the participants and the management of the data, which was described in the research ethics application.

2.3 Research Approaches

The approaches to how the collected data are considered within the study affect the research outcome. Below is a brief of the research approaches related to this study (Denzin & Lincoln, 2011; O'Gorman & MacIntosh, 2014).

2.3.1 Positivism

In this approach, the researcher regards social phenomena as objective reality and acceptable truth so that data collected from the research can be used to build a generalised theory. Accordingly, only observable phenomena can give rise to credible data. In this approach, the researcher uses previous research to build a hypothesis that can be tested. Positivism (also known as logical positivism or subjectivism) has three characteristics:

- Phenomenological: It distinguishes between the external world and the researcher who is observing it.
- Empirical: It uses observable evidence to establish 'knowledge'.
- Objective: It separates the scientific knowledge from the researcher's perspective, feelings, beliefs and values (Mäki, 2008; Payne & Payne, 2004; Williams, 2000).

However, positivism has faced criticism in the 20th century, especially with the rise of post-positivism movements that are inspired by scientific theories, such as the theory of relativity, which suggest that events in the world are not isolated from each other, but are in fact connected and unified. (Liamputtong, 2019).

2.3.2 Realism

Realism is similar to positivist approaches and is related to scientific enquiry. It shares the phenomenological nature of the epistemological position in that it holds that what our senses show us is real and true, and that objects exist independently of the human mind. In this approach, the reality of phenomena can be seen from two perspectives:

- **Direct realism:** In this perspective, we experience the world through our senses, which represent phenomena accurately.
- **Critical realism:** In contrast, critical realism maintains that reality experienced through our senses can be deceiving; thus, phenomena need to be observed from different perspectives to validate their accuracy (O’Gorman & MacIntosh, 2014).

While realism shares the phenomenological nature of the positivism, it is less fixed from the empirical perspective, in that it does not consider the truth of a theory essential to ensuring its accuracy (Bhaskar, 1998).

2.3.3 Interpretivism

The interpretive approach acknowledges the complexity of social phenomena. The researcher needs to be able to identify the role of human beings as social actors and differentiate between social phenomena which involve people and those which include objects. In this approach, the term ‘social actor’ is crucial to creating the need for interpretation: the person is considered an actor on a stage, which means that he or she interprets phenomena and transfers the knowledge to the researcher through the research methods adopted (O’Gorman & MacIntosh, 2014). The interpretivist approach is closely linked to phenomenological philosophy as it appreciates the subjective nature of describing phenomena.

In this research, the data collected reflected the experiences of the research sample. Therefore, the interpretivist approach will be adopted. However, during the early stage, a realist approach was used to handle the initial definitions related to the research phenomenon (e.g. adherence, design thinking and medical innovation). A realist approach was used to clearly define the different elements in the research. While these elements could be defined with a different approach in other studies, they were accepted as objective truth to focus on the main aim of the research.

According to the above overview of research philosophies and related approaches, the phenomenological epistemology approach was adopted in this study to understand the phenomenon of adherence and the factors affecting it. This understanding is based on an interpretive phenomenological approach, which was adopted in the study to understand the phenomenon (adherence) and its relationship with the social actors (patients) based on the feedback from the latter, including researcher observation. That said, the research showed evidence of the objective and ontological philosophical approach, especially in relation to understanding the phenomenon of adherence, based on the theories outlined in the literature that aimed to investigate the factors which affect it, as highlighted earlier.

2.4 Research Methods

In order to determine the most suitable type of data to collect during the research, three main approaches were explored: 1) qualitative; 2) quantitative; and 3) mixed methods. Each type is described below (Creswell & Creswell, 2017):

- **Qualitative approach:** This approach aims to understand how participants see and describe a specific social phenomenon from their subjective points of view. The researcher's role is to interpret the meaning of the data to build general themes. The nature of this research requires an inductive approach and acknowledges the complexity of social phenomena (Rocco & Hatcher, 2011).
- **Quantitative approach:** In this approach, the researcher aims to examine the relationship between measurable variables. The collected numerical data are analysed

using statistical methods. This type of approach has assumptions that are tested deductively (Rocco & Hatcher, 2011).

- **Mixed methods approach:** This approach combines qualitative and quantitative data. The development of this approach is based on the assumption that the combination of qualitative and quantitative approaches helps to build a complete understanding of a phenomenon (Creswell & Creswell, 2017).

Mixed methods will be utilised over the course of this study. While the Investigate (Chapter 9: Case Studies Interviews) and Explore (Chapter 10: WearCare II project observation) stages will be using qualitative data, the Assess stage (Chapter 11: Delphi Method Application) will adopt both qualitative and quantitative approach.

2.5 Research Strategy

The research strategy scopes a research design plan to achieve its main aims. To this end, the following research strategies were examined in order to identify the most suitable among them (Creswell, 2017; Denscombe, 2010):

- **Survey research:** This provides a quantitative description of the phenomenon by studying a sample of the population linked to it. The main aim of this strategy is to build a generalisation from the sample (Fowler, 2009).
- **Experimental research:** This is another quantitative strategy that aims to experiment with a specific practice, such as a treatment, and explore how this influences the outcome of the experiment (Keppel, 1991).
- **Case study research:** This aims to build an in-depth analysis of a case study bounded by time and activity. The researcher collects data about the case study and the people involved in it (Yin, 2011).
- **Ethnographic research:** This aims to understand the social behaviour of a social group and explore the shared patterns of behaviour and how these affect the cultural group in its natural environment (Creswell, 2017).
- **Grounded theory research:** This aims to build a generalised theory about the phenomenon from the point of view of the participants. This method involves multiple

stages of data collection and analysis until the saturation point is achieved (Charmaz, 2014).

- **Phenomenological research:** This is linked to philosophy and psychology. The study explores the phenomenon from the description of the individuals involved in it. This research strategy involves conducting interviews with the participants in order to explore and analyse their experience (Creswell, 2017).
- **Mixed methods research:** This involves the processing of both quantitative and qualitative data during the study (Creswell, 2017). However, various definitions were introduced based on the properties of the tool and the target of using it. The mixed methods were introduced as a systematic integration between quantitative and qualitative data, sequential or simultaneous use of qualitative and quantitative data, and two or more methods. While there are different views of mixed methods, the target of using it is almost the same that is building a more elaborated understanding of the phenomenon (Johnson & Onwuegbuzie, 2004). From the perspective of the sequence and integration of both qualitative and quantitative methods, Creswell (2017) defined main models. The first is convergent parallel mixed methods, in which the research starts with quantitative data and then moves to qualitative data in order to analyse the phenomenon comprehensively. The second is explanatory sequential mixed methods, in which the researcher starts the research by collecting and analysing quantitative data before collecting more detail using qualitative research. The third method (Exploratory sequential mixed methods) is similar to the second, but in reverse order: the researcher starts with qualitative research, after which the data are analysed before the quantitative analysis is carried out.
- **Action research:** This involves making a practical contribution to the research activity. In this type of research, the participants play an essential role as they are practically involved in changing or affecting the current state of the situation being studied. The other two characteristics of this research are its practical nature and the importance of the feedback loop in changing the current phenomenon (Denscombe, 2010).
- **Systematic review:** This research aims to gain objective insight into the phenomenon and evaluate the effectiveness of the research intervention (Denscombe, 2010).

Based on the brief overview of research strategies above, this study applied a mixed strategy approach, as follows:

- The core strategy of the research is adopting phenomenological philosophical approach due to the nature of the social phenomenon studied. However, from the perspective of the methods used, the research adopts a multiple mixed methods approach (interviews, observation, and Delphi method). The case studies step includes interviewing companies working in self-administered medical treatment technology as described in details in Chapter 9: Case Studies Interviews. Then, the observation method was used to observe how adherence is considered in an early stage of designing the medical technology (more details about the setup and usage of this method in Chapter 10: WearCare II Project). Finally, Delphi method will be used to collect panellists' agreement on adherence factors that can affect the usage of self-administered treatment technology. During the Delphi process, both qualitative and quantitative methods will be used (more details about the process is in Chapter 11: Delphi Method: Instrument Design and Application).
- The exploration of case studies was considered from a phenomenological approach as the collected data reflected the participants' points of view and reflections on the practice conducted during the development of the medical solution examined in this study.
- In terms of the type of data collected throughout the study, an explanatory sequential mixed method was applied. The early stages depended on the qualitative data collected through interviews, reflection on practice and observation. In the later stages (2nd round of the Delphi method), quantitative data were collected through a triangulation process using the Delphi method, as highlighted later in this chapter.

And based on the research approaches, this research adopted a mixed-method approach, collecting both qualitative and quantitative data as follows:

- Secondary data was collected from the companies, their products and the clinical trials conducted for these products, including both qualitative and quantitative data. For

example, the qualitative data included feedback from patients about the product, while the quantitative data included the percentage of patients that adhere to the treatment regimen.

- Qualitative data was collected in stage one (interviews), stage two (observation), and stage three (1st Delphi round). The aim of stage one and two is to explore the design process and how adherence is considered in the process from different perspectives and build a clear understanding of the companies' experiences from a phenomenological interpretive perspective. The aim of the qualitative data (collected using open-ended questions) in the 1st round of the Delphi method (stage 3) is to identify the factors that affect patient adherence in self-administered medical technology treatments.
- Quantitative data will be collected in the second and third rounds of the Delphi method (stage three) to identify the consensus between the panel members.

2.6 Data Triangulation

The data triangulation strategy refers to the use of mixed methods or data sources to understand the phenomenon related to the study (Patton, 1999). This strategy was not part of the initial study plan, yet it evolved organically from the main structure of the research design, which used three qualitative research methods in addition to the desk research. The knowledge accumulated as study moved from one stage to the next presented an excellent opportunity to triangulate data in order to better understand the research topic.

Understanding the role of triangulation in the study requires a review of the different types of data triangulation. Triangulation can take four forms (Denzin, 1978; Nancy et al., 2014; Patton, 1999):

- **Method triangulation:** This type uses multiple research methods to collect data about the same research topic. For example, it may include interviews, focus groups and observation.
- **Investigator triangulation:** In this type, two researchers independently investigate the same phenomenon and use the data collected by both to understand the phenomenon.

- **Theory triangulation:** In this type, different theories are used to interpret or understand the same data. Exploring the data from different perspectives may contribute to a better understanding or confirmation of the findings.
- **Data-source triangulation:** This type involves collecting data from two types of targeted population or research samples related to the main study. The collected data are then analysed from both sources to see the problem from multiple perspectives. For instance, the study can use data from both patients and clinicians about the same health issue.

Two types of triangulation have been utilised throughout the study:

- The stages before the Delphi method in Stage 3 (Assess) aimed to explore the phenomenon from multiple perspectives. Therefore, the data was triangulated between these stages and the Delphi method. Accordingly, both method and data-source triangulations were applied. Three methods were used (desk research, interviews and observation) to triangulate data in the Delphi method. The three main data sources used in the data triangulation were secondary data, case studies SMEs and the post-graduate students working in WearCare II Project.
- Both method and data source triangulations were used over the course of the research when proceeding from one step to the next. For instance, the secondary data collected via the desk research was used to refine the target of the interviews with the SMEs. Similarly, the data collected and analysed from the interviews were used to formulate the target of the observations.

The first three steps investigate and explore the design process, and how adherence is considered during the design process. Each step presented a view of the phenomenon from a different perspective. Accordingly, the triangulation of data contributed to building knowledge that was assessed in the final stage.

2.7 Research Process

As part of the research methodology, data was collected from case studies to analyse companies' experiences of developing treatment technologies. The sample companies offer both partially and fully patient-administered treatments. As adhering to the regimen is

challenging in self-administered treatments, this study focused on adherence and how it is considered during the development process, testing and clinical trials.

The research methodology was influenced by the study's main aim and the data required to make the planned contribution to knowledge (Denscombe, 2010). The phenomenological interpretative nature of the research directed the choice of research method toward qualitative methods (Kothari, 2004). However, quantitative data were also considered in order to build a clear understanding of the nature of the case studies, the results of the clinical trials and the information about the use of patient-administered products (Creswell & Creswell, 2017). To structure the research workflow, the process was divided into 'Stages' and 'Steps'. The Stages reflect the main aims of the research are 1) Investigate; 2) Explore; and 3) Assess. The steps represent the research activities: 1) Desk; 2) Field; 3) Analysis; 4) Action; and 5) Assess.

Within the Investigate phase, Steps 2 (Field) and 3 (Analysis) were considered 'mapping steps' as the data collected from the interviews was mapped onto the literature on adherence-related theories.

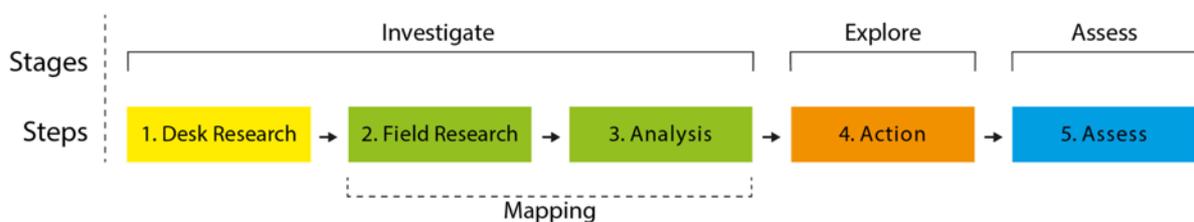


Fig 2.1 The research process diagram

2.7.1 Stage One: Investigate

The Investigate stage builds an understanding of each case study, its development process, consideration of patients' adherence and data collected from companies and clinical trials. This stage had three Steps: 1) desk research; 2) field research; and 3) analysis, as follows.

2.7.1.1 Step 1: Desk research

In the first Step (Desk), secondary data was collected from the company itself using documents shared by the company. Additional secondary data was collected from publicly

available information from the AHSN, National Institute of Health Research (NIHR) and NHS archives, clinical data results and published papers and articles. This step played a key role in the research as it helped the researcher to: 1) ensure that the company and its product aligned with the scope of the study; and 2) learn important details about the company, such as its size, structure, products, stage of product development and involvement in the healthcare innovation system in the UK. The data collected from this step played a crucial role in developing the questions asked during the semi-structured interviews in each case study.

2.7.1.2 Step 2: Field research

In Step two (Field), primary data was collected from each case study through interviews. This step builds a clear understanding of the companies, their products, their design processes and how they consider adherence. To meet this goal, the qualitative approach was regarded as the most suitable. To explore the research that may be used in this step, three methods were considered: 1) focus groups, group interviews and interviews (Gibbs, 2012). Both focus groups and group interview methods were excluded as: 1) they do not ensure the security of information which companies demand; 2) participants' answers can be influenced by the other participants in the focus group; 3) the accuracy of the collected data cannot be guaranteed; and 4) there were time and location limitations on gathering different founders of a single company or founders of different companies in the same place at the same time (Gubrium & Holstein, 2012). Accordingly, the most suitable method was the interview.

Three main types of interviews were considered: 1) structured; 2) non-structured; and 3) semi-structured. Structured interviews proceed by asking attendees pre-defined questions that are not altered during the interview. This type does not provide the researcher with the flexibility to adapt the interview questions based on the course of the discussion. Non-structured interviews do not use pre-defined questions, which reduces their benefits (Gubrium & Holstein, 2012). Semi-structured interviews provide the researcher more flexibility as the questions can be adapted to the specific situation either before or during the interviews, which gives the researcher the chance to maximise the benefits of the

interview by altering the course of questions to learn more about the specific company's experience (Harrell & Bradley, 2009; Rabionet, 2011). Accordingly, the semi-structured interview was adopted in this research to maximise the benefits of the discussions with companies. This type of interview allowed the researcher to predefine questions but also to elaborate on and alter them in order to explore every interviewee's unique experience in greater detail through online meetings via Skype. The meeting method was chosen based on the time and availability of each company's founders. Each interview lasted from one to two hours and was recorded. The interview transcripts were created using the Otter application on iPad. Due to the possible mistakes in the transcriptions, the transcribed manuscripts were reviewed and compared with the audio narration. Transcribing mistakes in the interviewees' answers were corrected to ensure accurate description for the answers. A backup audio recording version was created using the Apple iOS Memo application. While interview questions were previously prepared and shared with interviewees, they were altered, changed or modified based on the nature of the conversation during the interview.

The interviews were conducted in two batches—each batch consisted of three companies. Three companies were initially invited for interviews, after which their data were analysed (or partially analysed) before moving on to the second batch. This sequence helped to identifying exciting discussion points that could be discussed with companies in the next set. Further details about the observation setup in this research are covered in Chapter 4: WearCare II Observation Methodology.

2.7.1.3 Step 3: Data analysis

In the third step, Investigate stage, the data collected from the interviews were analysed. Different data analysis methods were explored. They differed in how they consider and interpret the data collected from the interviews, as follows (Denscombe, 2010):

- **Content analysis:** In this method, the interview data are broken into smaller components, such as words and lines. The researcher then develops relevant categories from the analysed data. As Vaismoradi, Turunen, & Bondas, (2013) highlighted, the content analysis considers the common issues in the data (Green & Thorogood, 2004) and tends to quantify the data (Braun & Clarke, 2006), which be considered a limitation

for applying the method in this study. Accordingly, this method is not the most suitable especially for exploring the detailed qualitative data about the companies' experience.

- **Theme analysis:** The researcher analyses the data and assigns codes (keywords) to each part of the interview, which may range from one word to a whole paragraph. The codes are then sorted into relevant categories which contribute to building hypotheses or inductive concepts. As this method aims to create a generalised theme or hypothesis that can be assessed, it presented a suitable approach for this study. Vaismoradi, Turunen, & Bondas, (2013) indicated that the thematic analysis aims to identify common themes in one or more interviews (DeSantis & Noel Ugarriza, 2000). Thematic analysis tends to quantify details bubbling out of the coded content (Braun & Clarke, 2006). According to the above.
- **Discourse analysis:** This method claims that the data gathered from the conversation during the interview should not be taken at face value; instead, the analysis should focus on the implied meaning of the words. There exists a debate about the reliability of this approach, because it cannot be proven that the analysis definitively represents the real meaning of the conversation. Therefore, it was not a suitable analysis method for the study.
- **Conversation analysis:** This method is a variant on discourse analysis as it focuses on the sample activity through the language used. It is influenced by the cultural backgrounds of both the participants and the researcher. As this method tends to explore everyday activities, it was not suitable for this research, which focused on a specific corporate experience through the development of medical technology.
- **Narrative analysis:** This approach explores the topic through narrative. The participants share their experiences in the form of a story using different media. This approach did not fit this research as the professional nature of the participants may be a barrier to their sharing their experiences in narrative form.

Based on the brief comparison of the four methods of analysis presented above, thematic analysis was deemed the most suitable form of data analysis to use in this study to understand the current state of design's contribution to product development and the consideration of adherence within the context of development and testing in companies.

In general, there was an overlap between steps because of the nature of the research timeline. The interviews were analysed using thematic analysis to identify the shared themes related to adherence among the case studies. The research was conducted using NVivo software version 12 for Mac. The anonymity of the case study participants and the confidentiality of the information were both considered during the thematic analysis and are discussed in more detail in Chapter 3 (3.4.1 Anonymisation of Data). Both step two (Field) and three (Analysis) form a mapping phase as the collected data from both Desk and Field research were mapped onto the literature related to the consideration of adherence during the development process (Taylor et al., 2015).

2.7.2 Stage Two: Explore

The second stage in the research process is the Explore stage, which involves observation for the WearCare II group project, a post-graduate project run for the MA Design students at Northumbria University. Details about the project and the Explore stage will be covered in Chapter 10: WearCare II Project. The project aims to design a medical solution to improve people's lives, so the students worked in groups to address the design challenge. Part of the limitations of the first stage is that the interviews with companies highlighted were already established and their products either in prototype stage or already delivered to the health market. The deployment of the observation method was decided because it provides the researcher the opportunity to observe the sample in the field (design practice room) and be able to observe sample's actions, practice, and their description for their project (Sapsford, & Jupp, 2012).

The second stage explores product ideas in an early design process's steps and how adherence is considered in this early part of the design process. This stage presented an opportunity to explore the consideration of adherence from different perspectives. The students were observed on weekly basis during the academic semester one 2019. The data of their progress in developing the design idea and the consideration of adherence factor were taken via notes by the research. During the weeks that the researcher didn't attend, groups were asked to fill an online questionnaire to document their activities.

2.7.3 Stage: Assess

Due to the research timeframe limitations highlighted in Chapter one: Introduction, testing the findings out of the previous stages is not feasible within the resources of this PhD study. Instead, the Assess stage identifies the level of agreement on the adherence factors that should be considered in the design and development of medical technology self-administered treatments. Delphi method will be used to identify the consensus (Keeney, Hasson, & Mckenna, 2010) of a panel that represent academic and professionals such as the NHS, AHSN, CPI, Philips, medical innovation companies and Northumbria University. The total number of the Delphi panel is 15 panellists.

The eDelphi will be used in the Assess stage to ensure the flexibility who are located in different locations in the UK (Hasson, & Keeney, 2000).

The Delphi process ran in three rounds; the first round will be an interview conducted through written online questionnaire using open-ended questions about the factors that affect patient adherence to self-administered medical technology treatment. The second round will be an online questionnaire that is collecting rating answers about the adherence factors. The final round will be similar questions as the second round with one different is that the answers from the previous round will be displayed anonymously to the panellists to give them the chance to change their minds. The answers from the first round will be evaluated through inter-rater reliability process which will be tested using Cohen Kappa (Cohen, 1960; Krippendorff, 2004). The significance of the final questionnaire's answers will be evaluated using Wilcoxon Signed Ranks Test (Taheri & Hesamian, 2012).

2.8 Research Ethics

The research ethics for this study were submitted with submission reference 10186. Below is a summary of the ethical information related to the level of risk, data management and data anonymity.

2.8.1 Research Risk

The research level of risk was considered to be “medium” as it met the university guidelines below:

- It included non-vulnerable adults, represented by the company founders;
- It did not include sensitive personal information; and
- It did include secondary data that are not in the public domain. These data are related to the companies and the products, including commercially sensitive information.

2.8.2 Research Data Management

Some of the data collected in this research may be commercially sensitive, such as internal company information that is not shared publicly. Therefore, the confidentiality and security of the data was considered. Data collected during the study were stored in a secure place: the printed data under lock and key, and digital data on Google Drive.

2.9 Summary and Conclusion

This chapter discussed the study research methodology and elements that affected the research design stages. The philosophical approach and research strategy were discussed in addition to determining how they would affect the study. Additionally, the way that the research methods that were used in the study fit with the research aims and objectives was discussed. The research methodology for each of the research methods highlighted in the research design in this chapter will be discussed in detail in the chapters three, four and five that follow.

Chapter 3: Case Studies Methodology

This chapter discusses the research methodology related to the case studies interviews. It discusses the design of the research instrument, case study recruitment, sampling techniques and the administration of interviews. The interviews' questions will be highlighted and mapped onto the main research questions.

Key Topics:

- 3.1 Aims and Objectives
- 3.2 Sampling Technique
- 3.3 Selection and Invitation for Companies
- 3.4 Case Studies Recruitment
- 3.5 Interviews Data Collection
- 3.6 Coding and Content Analysis
- 3.7 Summary and Conclusion

To explore the role of design in improving patient adherence to self-administered treatment technology regimens, this research explored SMEs working in medical technology innovation in the UK to: 1) learn about their products; 2) explore their product designs and development processes; and 3) investigate how adherence was considered before, during and after the product development process (PDP). The scope of the research, as highlighted earlier in this chapter, defined the specific characteristics of the companies considered as candidates for the research plan as follows:

- Small and medium enterprises (SMEs);
- Developing medical technology treatment; and
- Developing treatments which are fully or partially self-administered by the patient.

Accordingly, the above three aims formed the scope of the research, that is, SMEs working in patient-administered treatment technology.

3.1 Aims and Objectives

In this part of Phase one (Investigate), interviews were conducted as part of the research. These interviews aimed to: 1) investigate the state of medical technology innovation; 2) explore the role of design in developing innovative treatment technology; and 3) understand how adherence is considered during this development.

To realise this aim, the following objectives, which are also present in the main research questions of this study, were considered:

- Explore the current state of SMEs working in working in the medical technology innovation sector, including building an understanding of the barriers and opportunities they face.
- Explore how design thinking characteristics are adopted during the design and development of the treatment technology (including barriers to and opportunities for its application).
- Explore how adherence is considered during the design and development of the treatment solution.

- Explore how treatment products are considered in the clinical trials, including how adherence is considered during evaluation procedures.

3.2 Sampling Technique

To build an understanding of the recruitment of case studies, an overview of sampling techniques was conducted in order to determine the most suitable strategy for the current research. Overall, sampling falls into two main types: probability sampling and non-probability sampling. Probability sampling uses normal distribution statistical theory to ensure the researcher has no influence on the selected sample, and each element in the population has an equal chance of being represented (Etikan & Bala, 2017; Taherdoost, 2016). In contrast, non-probability sampling tends to build an exploratory sample, and the researcher may be involved in the selection process, for example, if specific criteria or aims require it (ibid). According to the above two classifications of sampling, the objective of this research was met by a non-probability sample. To identify the sampling technique which best aligned with the scope of the present research, the researcher explored the different non-probability sampling techniques and narrowed the choice to the following methods:

- Quota sampling
- Purposive sampling
- Expert sampling
- Snowball sampling
- Convenience sampling

The nature of this research played a crucial role in the choice of the sampling technique used to identify the case studies. This research focused on three main goals:

- 1) Investigating the current state of SMEs which are developing self-administered medical technology treatment interventions by building an understanding of how they operate, the role design plays in product development and considerations of patient adherence;
- 2) Exploring how design thinking can contribute to improving patient adherence; and

- 3) Assessing the adherence framework and gaining consensus as to its viability.

Sampling was used as an exploratory technique for a current phenomenon (Denscombe, 2010) with acceptance of the current state of reality (White, 2013).

This consideration dictated the use of non-probability sampling techniques in this research. There are five sample techniques, as outlined below.

3.2.1 Quota sampling

In this sampling technique, the main two considerations are: 1) easy access to the population; and 2) convenience, as the researcher is guided by visible characteristics that help in selecting the sample from the population. The selection process continues until the predetermined quota is reached (Kumar, 2014). The researcher has the freedom to choose the criteria used to select which participants will fill the quota, such as first to meet or last to visit a specific place (Denscombe, 2010). The foremost advantage offered by this technique is a low cost, as it does not require a sampling frame or information about the sampling, such as numbers and location. The disadvantage of using this technique is that the results collected from this sample cannot be generalised to the whole population, as there may be other elements in the population with unique characteristics for the participants in the population (Kumar, 2014).

This research had a clear idea of the sample companies involved in the research process regardless of the number of companies in the population. Therefore, quota sampling was excluded from the sampling techniques used.

3.2.2 Purposive sampling

Purposive sampling, also known as judgemental sampling, is based on the principle that the most useful data can be collected by focusing on a small sample which possesses specific expertise (Denscombe, 2010). In purposive sampling, the participants are selected based on their relevance to, and knowledge of, the topic, which qualifies them to produce the most valuable data (Kumar, 2014). This sampling technique is suitable to create an exploratory

sample as the experts will have the ability to provide quality information about, and insight into, the research topic (Denscombe, 2010).

In medical research, this sampling technique can be used to study groups with rare diseases or a specific ethnic group. In grounded theory research, a special type of sampling is called theoretical sampling. In this type, 20-40 people are selected who can contribute to evolving the theory. Data collection and analysis are conducted in parallel until the saturation point is reached (White, 2013).

In this research, purposive sampling was the main technique used to select the case studies involved in the research. During the collection of data, the selection was based on the following criteria:

- Size: Small- and medium-sized companies.
- Scope: Developing medical technology treatments that are fully or partially self-administered by patients.
- Location: United Kingdom.

The above criteria were the main target when the researcher started to search for companies through healthcare system archives or by attending medical innovation events.

3.2.3 Expert sampling

This technique is very similar to judgemental sampling. The only difference is that expert sampling requires participants to be experts in the field of the study. This sampling technique is applied by identifying people with expertise in the area, obtaining their consent to participate in the research and moving to data collection (Kumar, 2014). In this research, the participants represented each SME in capacities such as founders, co-founders, CEOs or managers. While they presented knowledge of the healthcare business in the UK, they did not necessarily have the expertise as regards the scope of this study, which was adherence within self-administered medical technology treatment.

3.2.4 Snowball sampling

This technique is also known as network sampling. The researcher contacts a small number of participants from the population who are then asked to locate other participants, who in turn nominate others. This process continues until the target number of participants is met or the saturation point has been reached (Denscombe, 2010). This technique is useful when the researcher has little knowledge about the population. As a small number of participants are contacted, they can guide the researcher to more participants (Kumar, 2014). There are disadvantages to this technique, such as the sample being affected by the choices of some individuals biasing the decisions of other participants (Kumar, 2014; White, 2013). In this study, the snowball technique was used by asking participants in the case studies to recommend other potential candidate companies that met the research aim. During meetings with healthcare organisations, such as the Academy of Healthcare Sciences Network (AHSN), National Institute of Health Research (NIHR) and National Health Service (NHS), and medical innovation companies at different events, the researcher asked them to recommend case studies. While those organisations and companies were not candidates themselves, the core principle of the technique, which is asking for nominated samples for the study, still applies.

3.2.5 Convenience sampling

In some situations, it is difficult for the researcher to access the sampling frame. For instance, it may be difficult to find people with the relevant experience, or there may be time limitations on reaching the targeted sample. In this situation, the researcher selects available participants who meet the selection criteria. Accordingly, the sample selection in this method is based on two main factors: accessibility and convenience. In healthcare, this sampling technique can involve patients attending a specific clinic or receiving a particular medical intervention (White, 2013).

In this study, time limitations have little impact on the selection of case studies involved in the research. The qualitative nature of the research directed the researcher to focus on relevance to the topic rather than the number of case studies involved.

3.2.6 Summary of Sampling Techniques Used in the Study

In section 4.2 above, probability and non-probability sampling techniques were reviewed to identify the most efficient sampling method. The applied techniques include the following:

- Purposive sampling: This was the main technique used in the study, as the scope of the research was clearly defined as SMEs developing self-administered technology treatments. The relevancy and knowledge of the participants were of higher priority than the number of participants. The timeframe of the study did not affect the sample selection process.
- Snowball sampling: This was used during the recruitment of case studies in both direct and indirect ways: directly, by asking companies to recommend other SMEs with the same criteria, and indirectly, by asking healthcare experts to recommend case studies for the research.
-

3.3 Selection and Invitation for Companies

Companies vary in terms of their size and operation. Therefore, a clear comprehension of the companies interviewed is crucial to understand how adherence is considered during the design process. This being the case, targeted companies had the following characteristics:

- Small and medium enterprises (SMEs). This size of companies plays an essential role in the national economy (Birch, 1989; Bommer and Jalajas, 2002; Lukács, 2005; Nauwelaerts et al., 2012; Oke et al., 2007). SMEs contribute to around 50% of the UK's GDP (Braams and Urlings, 2010).

- The company operates in the UK, and therefore share the same operation ecosystem.
- The firms focus on creating (fully or partially) patient-administered treatment (or treatment support) technology.
- The companies have implemented and practiced design differently. For example, one company (YMX) systematically implement the design thinking process using the double diamond (Design Council, 2015) and MPPF (English, 2010). Other companies applied design characteristics without systematic design (thinking) process. This was driven by the design background or the professional design expertise (Cross, 2011) of the founder. For instance, one of the founders had no design background, yet he applied prototype iteration through testing the product with the patients themselves (ESA). In LW7 company, the founder had design and gamification background, however, he did not apply systematic design process paradigm.

3.4 Case Studies Recruitment

Based on the above, invitations were sent to companies which met the sample criteria. The following channels were used to search for companies:

- Research collaborations with the School of Design at Northumbria University;
- Recommendations from friends, colleges or companies;
- Recommendations from healthcare organisations such as the AHSN, NIHR and NHS; and
- Different healthcare innovation conferences such as the AHSN, Govconnect, NIHR, NHS trusts.

Through those channels, companies were reviewed and filtered based on the research scope as follows:

- National Institute of Health Care Excellence (NICE): 196 case studies overviewed;
- AHSN network web archive: 119 case studies overviewed and filtered;

- Govconnect (Improving Patient Safety & Care 2019) event held 6th February 2019 at the Royal Society of Medicine, London: I visited each of the 29 attending companies and learned about their products; and
- Adoption of Innovation (National Pipeline and our Local Experiences event held by the AHSN NENC 7 June 2018 at Chester-le-Street): I watched and overviewed nine companies.

A total of 353 companies were overviewed and filtered based on the scope of the research (Table 3.2), of which 11 were contacted for collaboration. Of those:

- Five agreed to collaborate in the research;
- One agreed to collaborate but dropped out at an early stage of the study;
- Three refused to collaborate; and
- Two did not reply to the researcher's emails.

The companies who refused to participate were asked to clarify their reasons. They answered that either: 1) the company was small and lacked the resources, capacity and time to collaborate; or 2) they wished to avoid distractions for the development team.

Alternatively, they gave no reason for their decision.

Five of the recruited companies were micro- or small-sized companies and one was medium-sized. The process of inviting companies to join the study raises two interesting questions:

1. Why is it harder to persuade some medium-sized companies to participate in research collaboration than smaller ones?
2. Why do fewer companies offer self-administered treatment technologies than traditional pharmaceutical and surgical interventions?

The above questions can be considered by future research to understand how such companies operate in terms of research and development and fill technological treatment gaps in healthcare.

The first phase of this research consisted of three steps: desk research, field research and analysis. The aim of the field research was to explore how the companies working to design and develop (entirely for partially) self-administered treatment technology are working with a focus on two main elements:

- How these companies apply the PDP in the development their products; and
- How adherence is considered during the PDP.

To achieve this goal, the second step in this research was to meet with the companies and ask questions about the above two main points.

Table 3.1 also shows the companies who received an invitation to join the research. The blue rows show confirmed case studies, the green rows show companies that never replied, the yellow row shows companies who dropped in an early stage and the orange shows the companies who refused to collaborate in the study.

Code Name	Company Characteristics				Solution	Comments
	Est. date	Old	No. Employees	Capital		
YMX	2009	11	9	500,000	Diabetic retinopathy and diabetic macular oedema	
ESA	2016	2	3	700,000	Catheter supporting vest for renal and oncology	
LW7	2017	1	1	196,000	Encourage physiotherapy for children with Cystic Fibrosis	
3AB	2015	5	1	35,000	Treatment adherence support and behaviour change	
DE7	2018	2	1	N/A*	Treatment for sleeping problems either as a disease or a syndrome for mental health disease including dementia	
Z5W		3	1		Treatment and behaviour change for patients with dementia	Dropped in an early stage with no given reason.
C ₀₁	2011	7	60		Insomnia and anxiety	Rejected with no given reason,
C ₀₂					Non-invasive treatment for cluster headaches	Small company that did not have the resources and capacity at this time.
C ₀₃					Teach, change behaviour and manage treatment for chronic diseases: COPD, Cardio and Diabetes	Did not want to cause distract the design and development teams as they were in a very busy period.
C ₀₄	2016	2	13		Behaviour and lifestyle change for diabetes 2 (app + monitor device)	
C ₀₅					Cardiac, cancer and pulmonary rehabilitation program (app + monitor device)	

 Confirmed case studies
  Refused to collaborate
  No reply
  Dropped at an early stage

Table 3.1. List of the case study companies considered in the study, their solution and their status in the study.

*The interviewee did not provide information related to the source funding.

Code Name	Technology			Self-administered		Medical Solution				Educational (Behaviour change)	Patient-Centred
	Software	Hardware	Drug	Partly	Fully	Treatment	Treatment Support	Diagnosis	Monitor		
YMX		✓		✓	✓	✓	✓		✓	✓	✓
ESA		✓		✓	✓		✓			✓	✓
LW7	✓	✓			✓	✓			✓	✓	✓
3AB		✓			✓		✓			✓	✓
DE7		✓		✓	✓	✓				✓	✓
Z5W		✓		✓	✓	✓	✓			✓	✓
C ₀₁	✓				✓	✓				✓	✓
C ₀₂		✓	✓		✓	✓					✓
C ₀₃	✓			✓	✓		✓		✓	✓	✓
C ₀₄	✓	✓		✓	✓	✓			✓	✓	✓
C ₀₅	✓	✓		✓	✓	✓			✓	✓	✓

Confirmed case studies
 Refused to collaborate
 No reply
 Dropped at an early stage

Table 3.2. List of case studies with a focus on the nature of their product considered in the study.

In Table 3.1 highlights the characteristics of each treatment solution presented by the 11 companies. The characteristics indicate the nature of the treatment intervention based on:

- **Technology:** The type of technology used in the intervention—either software or hardware or both.
- **Self-administered:** The level of patient administration for the intervention.
- **Medical Solution:** The type of solution: treatment, treatment support, diagnosis or monitoring. While the study focused on treatment and treatment support, some products included one or more of the other solutions.
- **Educational (behaviour change):** Some interventions include educational (or behaviour) change features which can have a positive impact on adherence.
- **Patient-centred:** The product focuses on addressing the patient’s needs.

Together, the two tables show the following:

- Regarding the technology used, the majority of the companies depend on either software or hardware in developing the final treatment solutions. Many of these companies build their product solution to replace pharmaceutical solutions.
- Patients can fully administer most of the solutions. However, some products may need partial involvement of clinicians for installation, monitoring or both.
- Almost all the companies target changes in patients’ behaviour, especially in chronic diseases where the technology has to be used over an extended period.

3.4.1 Anonymisation of Data

The data collected from the case studies includes private corporate information. Different case studies highlighted that they would like this information to remain confidential and not be shared with other case studies for various reasons, including competitiveness, production plans, the current state of development and collaboration with other partners. Accordingly, the data collected from the case studies were anonymised and names and contact information were excluded. The names of the companies were anonymised by giving them a random code generated through (<https://www.randomcodes.co.uk>). The generated codes for the six companies are:

- Company 1: YMX
- Company 2: ESA
- Company 3: LW7
- Company 4: 3AB
- Company 5: Z5W
- Company 6: DE7

Companies who did not participate in the study (because they were rejected, did not respond to the invitation or dropped out from the course) were given the code name C_{01-n}

Table 3.1 provides details of the companies invited to participate in the research, including size, target market and product. Some cells were left blank with the aim to be filled during the first interview with the company. Understanding the company information and the nature of the product yields essential information that can drive the interviews and analysis of the collected data—for example, the current stage of product development. 3.5.2

Participants Dropped from the Study

Although there were initially six confirmed case studies, one company (25W) was dropped from study due to not responding to my email communications. Two meetings were conducted with 25W's founder, and we agreed to move forward and collaborate in the research. I subsequently tried to contact the founder multiple times through email and Twitter to arrange a meeting for the first interview; however, I received no reply. Accordingly, I had to drop the case study to move on to the next stage of the research. This decision was due to the time limitations of the research.

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3.4.3 Consent and Permission

All the companies' interviewees signed the consent form, which was approved by the University Research Ethics committee. Permission to record audio was also granted by all the five companies during the face-to-face and online interview sessions.

3.5 Interviews Data Collection

To achieve the goal of the interviews, the interview questions were designed to elicit answers that could contribute to answering the main research goals. The table below lists each interview question, the purpose of asking it and how it maps onto the main research questions. Tables 3.3 to 3.6 show the main questions and how these questions are linked to the primary research aims.

Group 1: General Questions	Associated Research Questions	Purpose
Tell me more about your company: date of establishment, size, number of employees, branches and capital.	1) What are the characteristics of the case study?	Understand the company's size, nature and age. Ensure it meets the research aim criteria.
How is your company integrated with the healthcare system in the UK?	1) What are the characteristics of the research case studies?	Appreciate the level of the company's involvement in the UK healthcare industry.
Explain to me your product and its current state, and how patients self-administer the treatment.	1) What are the characteristics of the case study?	Learn about the product and the stage of its development.

Table 3.3 Group one: General questions about the company.

Group 2: Design Process Questions	Associated Research Questions	Purpose
How did you find out about the health problem? And how did you come up with the solution (product)?	1) How does design influence innovation of patient-administered treatment technologies? 2) What are the current development processes applied in medical technology?	Understand how the problem was initially discovered and how the solution (product) was defined.
What type of research was carried out? And what is the product development process?	1) What are the current development processes applied in medical technology?	Learn about the exploration stage and the types of research used to define the product details.
What factors did you consider during the development process?	1) What are the current development processes applied in medical technology?	Identify the patient- and business-related factors considered during the product development process (PDP).

Table 3.4 Group two: Questions related to the design process inside the company.

Group 3: Design Benefits	Associated Research Questions	Purpose
How do you describe the development process from the innovation perspective? And what are the barriers?	1)What are the current development processes applied in medical technology?	Identify the level of appreciation of design inside the organization.
What factors influenced the product development? And how?	1)What are the current development processes applied in medical technology? 2) What are the barriers to and opportunities for adopting design thinking?	Understand the factors and the people that influence the PDP both inside and also outside the company.

Table 3.5 Group three: Questions related to the perceived benefits of design.

Group 4: Patient Adherence and Clinical Trials	Associated Research Questions	Purpose
Can you explain the status of the product from clinical trials?	1) How do treatment technologies are considered in clinical trials or alternative procedures?	Learn about the clinical trials applied to the product (if any) and the factors considered during it.
10. What barriers did the development process face and affected patient compliance with the treatment?	1) How does adherence is considered in product development and clinical trials?	Learn how the company ensure patient adherence during the clinical trials and as an approved treatment in the market.
How did the patients got involved in the development?	1) How does adherence is considered in product development and clinical trials?	Understand the clinical trial process and how it is used during the PDP.
What mechanism is/was used to evaluate adherence during long-term usage?	1) How do treatment technologies are considered in clinical trials or alternative procedures?	Understand if the company understand the correlation between long term treatment and adherence, and what are the procedures used to maintain it.
How did non-adherence affect the results of the clinical trials? And what are the adherence factors considered during the clinical trials?	1) How do treatment technologies are considered in clinical trials or alternative procedures?	Understand the impact of non-adherence on the results of the clinical trials or product testing procedures.

Table 3.6 Group four: Questions related to patient adherence and involvement in the design process.

The interview questions shared with the case studies were categorised into four groups:

- Group 1: General Questions
- Group 2: Design Process Questions
- Group 3: Design Benefits
- Group 4: Patient Adherence and Clinical Trials

Tables 3.3 to 3.6 maps the interviews questions to the main research questions and the purpose of each item.

The order of the interview discussion differs in this chapter from how it actually unfolded; for some questions, the way questions were asked was influenced by the previous company's answers. However, this order does not affect the discussion or answers.

The transcript was read several times in order to identify the information shared by each case study and to do thematic analysis to identify the content strands and merge them into themes. Detailed information about the application of content analysis is available in 3.6 Coding and Content Analysis.

This stage aimed to investigate how companies consider adherence during the design process. The findings of this stage and the following stage (Wear Care project observation) were triangulated during the first round of Delphi method, which was covered in the Assess stage of this research. Accordingly, no reliability procedures were applied to the content themes generated from the interviews' thematic analysis. At the first round (Interview) of the Delphi method, data collected from the panellists (including companies' representatives) was analysed using thematic analysis. Then the inter-rater reliability test was applied to ensure the two inter-raters in my interpretation agreed with the content and that this agreement was not due to chance.

3.5.1 Data Collection

This section covers how the data collected from interviews was managed and analysed. All the interviews were recorded, and transcripts were generated using the Otter application on mobile and desktop. Backups of the audio conversations were recorded using the Voice memos application on iPhone. As the interviews are semi-structured, during the talks, questions were altered or skipped. Items were added to the discussion to:

- 1) Let the interviewee elaborate specific points; or
- 2) Ask for further information related to the research topic.

The interviews were conducted through face-to-face and online meetings with the companies' representatives. The representatives were usually the founders and co-founders. In one interview (YMX), the interviewees were team members who had deep knowledge of the company's history and progress.

The meetings were held either at the company's location, on the university's campus or online through Skype. An interview with one company (LW7) was held online through Skype due to distance and time limitations. Two companies' interviews were held in the companies' locations in Durham (YMX and DE7). Finally, two interviews were held in other locations: a Northumbria university's meeting room (3AB) and a social meeting place in York (ESA).

The duration of the interviews ranged from one to two hours. The length of the interview depended on the interviewee's answers and the elaborated discussion after the original answer. One interview (YMX) was slightly more than two hours in length (two hours and eight minutes) because the interview was held with two representatives of the company; one with experience in the business side (interviewee one), and the other with experience in the technology side (interviewee two).

3.5.2 Management of Interviews

The process of administering the interviews included travelling to the interviewees, arranging online interviews and also facilitating the recording, backup and transcription of both the questions and the answers. I used several tools to record, document and transcribe the interviews which ensured the interviews were recorded clearly and accurately, taking extra care when meeting with companies' representatives in different environments with a variety of noise conditions. I also had administer interviews held with company representatives with whom it was hard to conduct in-person interviews due to factors such as distance and time limitations.

3.5.3 Technology Utilisation

To document the interviews, I used several software tools to ensure that the recorded sound was clear and could be heard accurately. The tools used include the following:

Apply Quicktime software: I used it for recording the online interview (via Skype). I recorded only the audio of the sessions for documentation and transcription purposes.

Otter: I used the app on an iPad to record the interviews and transcribe them in real-time. Otter app was the primary tool for transcription in all the interviews as it provided sound recording and accurate transcription even in places where there was unexpected noise

Voice Memos: This is a built-in app for iPhone. I used this app for back-up recording; during each interview, Otter was used as the main recording tool while, at the same time, Voice Memo was used to record a back-up version of the interview in case there were any technical problems with Otter such as failing to record, accidental stoppage, poor audio quality or a poor internet connection.

3.6 Coding and Content Analysis

The interview transcripts were refined and added to Vivo (version 12) for content analysis. I reviewed the transcript of the interviews three times as follows:

- 1) The first time was to review the interviewees' answers and fix any transcript issues;
- 2) The second time was to analyse content and explore the generated themes; and
- 3) The third time was to analyse the answers and explore the ways the companies considered adherence in the design process.

NVivo software for macOS was used for content analysis. All the transcripts were imported to NVivo from Otter. Minor modifications were made to the imported documents such as:

- Highlighting each question with bold text to quickly identify it and the answers.
- Fix incorrect transcription. This fix was mostly necessary for the transcription of my speech due to my accent
- NVivo allowed me to store all the interviews, the recorded audio and the codes in one project, which made the management of the process much easier.

Reliability and validation are crucial factors needed in order to maintain consistency in the contents analysis and avoid biases (MacPhail et al., 2016). In this stage of the research, interviews represented the first stage of primary data collection. These data were triangulated with data collected in stage two. The analysis of the interviews case studies and workshop observation present an opportunity to explore adherence from different perspectives. Finally, in the Delphi phase, a panel of case study representatives, industry professionals, academics and clinicians had the opportunity to answer open-ended questions and scaled questions regarding how adherence factors into self-administered treatment technology.

3.7 Summary and Conclusion

The case study interviews step is part of the Investigate stage that aims to understand the design process in SMEs working medical technology treatment, especially the self-administered interventions, and how adherence is considered during the design process. To this goal, sampling techniques were explored to determine the suitable technique for the research purpose, and both purposive and snowball sampling methods were utilised. As a result, 353 companies were reviewed against the study's scope (SMEs working in the UK in developing "fully or partially" self-administered treatment "or treatment support"

technology). Out of the overviewed companies, 11 SMEs fall under the study's scope. Five of the 11 SMEs agreed to join the research, which highlights two interesting questions that can be considered for future research:

1. Why is it harder to persuade some medium-sized companies to participate in research collaboration than smaller ones?
2. Why do fewer companies offer self-administered treatment technologies than traditional pharmaceutical and surgical interventions?

The chapter covers the recruitment of the interviews sample, which involves the search for companies that meet with the research scope and inviting them to the study. The characteristics of each company was highlighted the anonymisation of the data was covered. The research ethics, consents, and the dropping for the study were also covered.

The second part of the chapter involved the interview questions, the data collection from the participant including the management of the interview and recording the interviews' transcripts for data analysis. The final part covers the data analysis including preparing data for analysis and the process of code analysis using Nvivo 12.

Chapter 4: WearCare II Observation Methodology

This chapter discusses the methodology used in WearCare II observation project (Explore stage). The observation methodology will be reviewed to determine the suitable method to implement to achieve the goal of this stage. Description of how the data was collected and analysed will be overviewed.

Key Topics:

- 4.1 Stage Two: Explore (WearCare II Workshop Observation)
- 4.2 Observation
- 4.3 Reflection on practice
- 4.4 WearCare II Project
- 4.5 Observation Design
- 4.6 Findings and Summary

4.1 Stage Two: Explore (WearCare II Workshop Observation)

Stage two explored how adherence is considered during the early stages of the product design process for SMEs. While the interviews provided an opportunity to learn about how companies consider adherence, the very early stage of problem/solution arena could not be observed. Accordingly, both step 2 (interviews) and step 3 (observation) explored the phenomena from different perspectives to construct the knowledge that would be assessed through the Delphi method and the study contribution to knowledge. The Explore stage provided an opportunity to observe how adherence is considered in the early stage of the design process. This was not possible in the previous step because companies had already developed their product (or product prototype). The findings from the observation in this stage were triangulated as part of a process of synthesis in the final stage (Assess).

Project WearCare II was an assessed project for MA Design students at Northumbria University in semester one 2019/2020. This chapter describes the research observation design in order to achieve the aim of this chapter. In addition to the observation, reflection on the students' action was part of the documentation of students' practice during the semester.

The nature of the Explore stage contribution can't be properly perceived without clear understand to its role in the study and how the evidences related to the designers practice are strengths each other as the study evolve from one stage to another. Please refer to the Limitations section for more details about the nature of limitations.

4.2 Observation

The literature provides multiple definitions for the term 'observation'. Gorman and Clayton (2005) have defined observation as the systematic recording of observable phenomena, while for Spradley and McCurdy (1980) it is the work of describing a culture that can lead to an ethnographic description. These definitions agree on the characteristics of observation as

a research method, such as direct observation of data (Baker, 2006). Elements in the social environment such as actions and interaction, are all observable. Observation is a tool to understand complex social situations, as highlighted by Bowling (2014).

Observations can be classified based on three main categories: the nature of the data collected, the researcher involvement in the observed phenomena and if the sample know they are being watched or not. From the perspective of how the data is collected, observations can be either:

- Quantitative (Structured): The observation aims to collect quantitative data. Accordingly, the data may be collected using a checklist or structured questionnaire.
- Qualitative (Semi-structured or unstructured): The research aims to understand the phenomena in its natural setting, which reflects its phenomenological nature.

Based on the epistemological phenomenological nature of the research, the observation collected qualitative data using note recording (Marks, & Yardley, 2011).

Observations can be classified as either Over or Covert, depending on if the participants are aware they are being watched. During overt observation, the sample know they are being watched. In contrast, during covert observation, the participants do not know they are being watched. While overt observation brings with it the possibility that participants may change their behaviours when they know they are being watched, covert observation may be unethical, as the participants do not give their consent to be observed (Gray, 2013).

The third observation categorisation below is based on the research participant and involvement in the social act, which includes two types (Gray, 2013):

- Non-participant observation: In this type of observation, the researcher does not interfere with the phenomena and does not conduct any action that may change or affect the participants in the study. Although this method aims to eliminate bias and the effect of the researcher on the study, the isolation of the research from the flow of the observation is not 100 per cent. The method limits how much the researcher

affects the observations, yet the interpretive nature of qualitative data forces the researcher to be involved during the interpretation of the social act.

- Participant observation: In this type of observation, the researcher is involved in the social act. The participatory nature of this approach brings with it the risk of biasing the act being observed, and the flow of the study is affected by the researcher as much as any of the other participants in the social act. However, this type provides the researcher an opportunity to practice and take part in the phenomena, which can improve the reflection on the practice and therefore the qualitative outcome.

Gray (2013) defined four main roles for the observer (Figure 4.1) based on two main categories of observations: confidentiality and participation. These roles are:

- Announced participant
- Announced observer
- Undercover participant
- Undercover observer

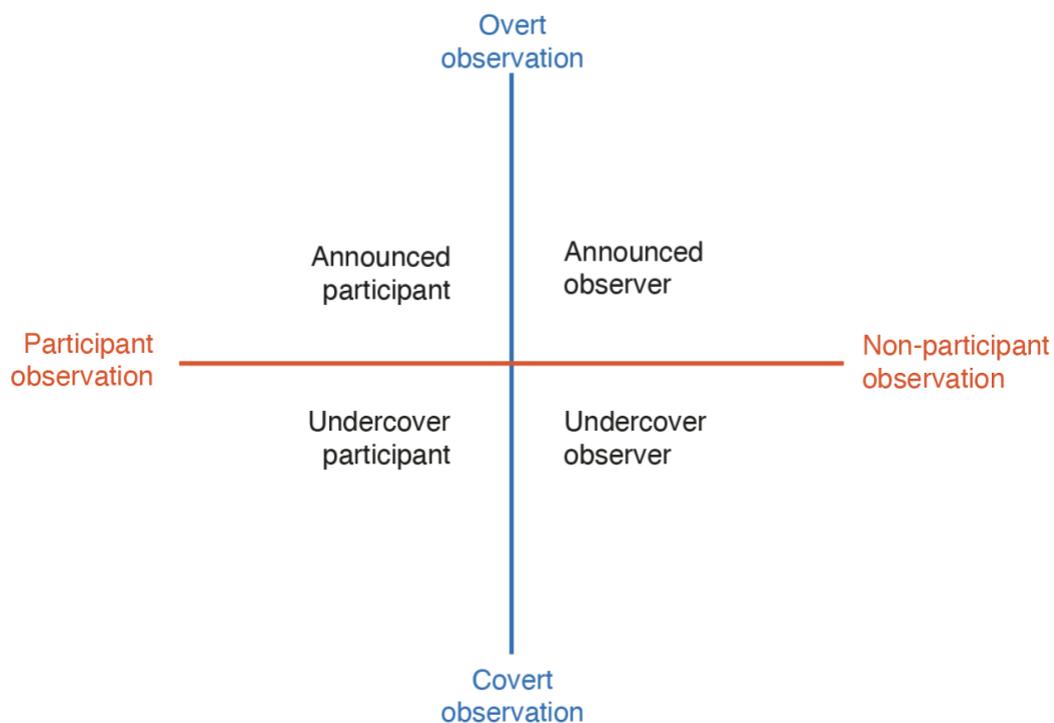


Figure 4.1 The role of the observer in each of the observation types. Source: (Gray, 2013).

These roles relate to the practical role of the researcher. In participant observation, the researcher acts as a participant, which brings with it unique advantages. Undercover participation and observation grant the researcher confidentiality, which may be needed depending on the nature of the involvement in the social act.

In this research, the participants were aware of the study as it was part of the module description and plan. Furthermore, in terms of the collected data, the qualitative data was addressed and collected, which aligns with the epistemological nature of the study. The collection and documentation of data are described in Chapter 10: WearCare II Project.

4.3 Reflection on practice

The notion of reflective practice in design was discussed by Schön (1983). He highlighted that designers construct the design world between two spaces: the problem space and moves to find the solution space. During this process, designers practise an experimental action and reflect on the practice and its results (Schön, 1983). In this research, reflection on practice applies to the information collected from interviews with companies. These data are used to formulate the questions that will be asked of the teams involved in the project, and the interpretation of their practice.

4.4 WearCare II Project

WearCare II was a student project conducted by post-graduate master students at Northumbria University School of Design during Semester One of the academic year 2019/2020, in collaboration with Northumbria University and Centre for Process Innovation Limited (CPI) and AHSN Network North East and North Cumbria (NENC). In this practice, seven groups were assembled, each consisting of 2-4 students from different disciplines. WearCare II project was introduced to the students, which aimed to design a patient-centric

medical innovation solution. The project focused on patient adherence, healthcare system and economic perspectives (Aldeer et al., 2018; van Dulmen et al., 2007; Viswanathan et al., 2012). During this project, the students were asked to consider patient needs, the NHS, technology, value networks and change factors. While developing their solutions, students followed a design thinking process using the Design Council Double Diamond model (Design Council, 2015) and the Multiple Perspective Problem Framing (MPPF) (English, 2007a, 2007b, 2008).

The aim of observing the WearCare II project was to 1) explore design characteristics, especially in the problem space and solution space (2015), and 2) explore how the solution for medical problem evolved in each of the observed groups, keeping in mind team members' backgrounds.

To analyse the data collected from observation, three main methods were explored:

- **Description as analysis:** This method depends on transforming observation (e.g. written, visual or audio) into a written text that describes the situation as it happens (Flick, 2013).
- **Inductive analysis:** An approach such as grounded theory is applied to analyse qualitative observation data. The research starts with a specific situation to build an inductive generalised conclusion (Charmaz, 2008)
- **Constructionist analysis:** Unlike inductive analysis, constructionist analysis aims to identify the meaning-making processes that people use to create their social worlds using spoken and written language (Flick, 2013)

The observation in the WearCare II project sought to explore the phenomenon rather than reach an inductive conclusion. Therefore, inductive analysis was excluded from the considered methods. Instead, the research used description as analysis and constructionist analysis as described below:

- The main observation analysis tool was description analysis. Each group's progress was observed and documented using notes to map design characteristics onto each group's practice.

- Constructionist analysis was used to understand the design practice based on how each group used words to describe their progress. As Cross (2011) highlighted, some designers may find it challenging to describe the development of their design solutions. Therefore, my industrial experience in the design field was used to underpin the description of design practice for each group.

4.5 Observation Design

The primary methodology in this stage was observation. I used participant observation (Denscombe, 2011) to observe and document the students' practice (Baker, 2006; Gorman & Clayton, 2005) within their teamwork (Spradley & McCurdy, 1980) as well as their reflection on that practice, as will be described in detail later in this chapter. Once the observation was completed, the collected data was analysed using both inductive and constructionist analysis (Charmaz, 2010; Flick, 2013) as highlighted earlier the Chapter 2: Methodology Introduction. This methodology involved reflecting on the practice as part of the observation analysis that was used to analyse the observation data. This analysis involved reflecting on the findings from the interviews in the first stage (Schön, 1983).

4.5.1 Aims and Questions

WearCare II project provides an opportunity to observe how teams progress from the problem space to the solution space, and the consideration of adherence factors. Therefore, the aims of the Observation stage were to:

- 1) Explore the design practice at an early stage of the product design (problem space) (Dorst, 2018); and
- 2) Explore how adherence is considered in the problem space and how it is represented in formulating the problem definition and possible solutions.

The above two aims map onto, and contribute to answering, the following two study questions:

- 1) How does design influence innovation in patient-administered treatment technologies?; and

2) How does adherence is considered in product development and clinical trials?

Teams needed to be aware of patient adherence and the significant impact it has on the accuracy of the health practice outcome. At the beginning of the semester, I introduced adherence and its impact to the students and provided ideas about the factors that affect adherence.

As highlighted in the Limitations section of this study (Chapter 14: 14.3.2 WearCare II Observation Limitations), observing the SMEs as they develop the product was not possible due to: 1) the companies had already developed the product or a high-fidelity prototype of the product, or 2) the limited timeframe of the study, compared to the long-term process of developing medical technology. The WearCare II project presented an opportunity to observe how a solution evolves based on exploring the problem space during the practice conducted by the class groups.

4.5.2 Methodological Approach

The observation aimed to understand a complex phenomenon involving human practice, which is the team working together to understand the problem space related to the health project. This phase aimed to observe and understand their practice with a focus on the consideration of adherence to self-administered technology. Therefore, the suitable philosophical approach was constructionism, which aligns with the main epistemological phenomenological approach of the study. Accordingly, each of the participants' interpretation for the data is based on number of factors such as experience and background (Jones et al., 2013).

The workshop was conducted within an educational environment. Therefore, the observation was semi-structured. While there were questions which were already prepared and planned, the sessions were flexible to consider altering questions or asking additional ones in order to further explore the groups' practice and project development (Gillham, 2008). The questions that had prepared for the groups are:

- What is the current stage of your idea development?
- What is the problem addressed?

- How do you use the design process and reflective practice to explore the problem space?
- How did you consider adherence in the project?

The observation took the form of participant observation, therefore, ideas and highlighted thoughts were exchanged with the different teams during the conversation between the research and team members (Gillham, 2008; Iacono et al., 2009).

4.6 Findings and Summary

This chapter discussed the research methodology used in the Explore stage (WearCare II observation). The main research method used is the observation with considering the reflection on practice. This research practice aims to observe the design process at an early stage, and adherence is considered. Toward this goal, the observation research method was overviewed to decide the research tool design and planning. The research questions that need to be addressed were also overviewed, and the limitations related to this research method.

This chapter briefly introduces the WearCare II project, which was used to apply the observation stage. The findings of the Explore stage contribute to building the big picture of the research outcome.

Chapter 5: Delphi Study Methodology

This chapter discusses the research methodology related to the Delphi Study applied at the Assess stage. It discusses the design of the Delphi tool, the selection of panellists, the design of the question rounds, the collection of the data and data analysis.

Key Topics:

- 5.1 Assessment Methods
- 5.2 Application of The Delphi Method
- 5.3 Delphi Panel
- 5.4 Ethical Approval and Consents
- 5.5 Process Management
- 5.6 Implementation of Delphi methodology
- 5.7 Timeline of the Delphi Phases
- 5.8 Summary and Conclusion

The final stage is Assess (Delphi method). Data observed from different perspectives was triangulated and fed into a Delphi method aimed to assess the integrated findings from the previous steps' analysis. This practice contributes to the main aim of the study, which is to explore how design thinking can contribute to improving adherence to self-administered treatment technology. As the stages before the Assess stage identified design and other factors that affect adherence to self-administered treatment technology, these factors were assessed using the Delphi method.

5.1 Assessment Methods

The decision to implement an assessment process rather a testing stage was due to the timeframe of the design, development and usage of a treatment device, which is much longer than this study's timeframe. Accordingly, the assessment was implemented at the last stage of the research. The decision to use the Delphi method was related to its properties as a tool that can be used to measure the consensus of the panellists and support the anonymity of the panellists. Generally, two main decision-making methods were explored to decide which is suitable for the study: the Delphi method and the analytic hierarchy process (AHP), as follows.

5.1.1 Analytic hierarchy process

Several research methods are used to determine future actions through decision making, such as analytic hierarchy process (AHP), which is used to measure priorities through the comparison and judgement of experts (Saaty, 2008). This tool and similar tools aim to make decisions by focusing on prioritising choices. Therefore, AHP was not applied in this study. Similar tools were investigated, such as the decision-making paradox, analytic network process and hierarchical decision process.

5.1.2 Delphi method

In this stage, two main factors dictated the use of this research method: 1) the confidentiality of information shared by the companies (Keeney et al., 2011); and 2) the target, namely assessing the proposed framework. Based on these two factors, the Delphi method was chosen to obtain a consensus about the factors that affect adherence in self-administered treatment technology.

In the Delphi method, two or more rounds of questionnaires are shared with professionals on an experts' panel. Firstly, a questionnaire asks the experts their opinions about the research topic, using open-ended questions. The answers are analysed by the researcher and sent back to the experts in the form of statements or questions. The experts rank the elements in the second questionnaire. The saturation point in the Delphi method is achieved once a consensus among the experts is reached (Hsu & Sandford, 2007).

There are several types of Delphi method which are used depending on the aim of applying the tool and the technical characteristics of the practice (Keeney et al. 2011). More details about the different types of Delphi method and the selected type are discussed later in 2.1 Types of Delphi Method.

5.1.2.1 Delphi Questionnaires

To explore the level of consensus of the expert panel on adherence factors that can form a proposed Adherence Canvas, three initial rounds of questionnaires are considered (Keeney et al., 2011).

- The first round consisted of a questionnaire about the adherence factors. The questions in this round were dictated by the research phases conducted in Stage one: Investigate, and Stage two: Explore.
- The second round of the questionnaire posed questions based on the answers received in the first round.
- The third round of the questionnaire was based on the second round and sent to the experts, along with the answers to the previous questions, to allow them to explore the responses of the rest of the panel and revise their own if needed.

The results of the Delphi method were used to confirm the adherence framework and introduce it for further research investigations, which may include testing or evaluating it for application in both product development and evaluation.

5.2 Application of The Delphi Method

The Delphi method is a research tool that is based on building consensus amongst a group of experts (panel) through a series of rounds. Each round involves a specific research method that varies based on the type of Delphi method (e.g. questionnaire, interview or focus group). During the last round, the panel members can review the results of the panel and build a consensus opinion about the study (Hasson et al., 2000). Delphi was initially developed by the RAND Corporation for scientific and technological forecasting and used by the United States Armed Forces (Manley, 2013). Since its introduction in the early 1960s (Gordon, 1994), it has been widely adopted in a variety of areas including policy-making, environment, social sciences, business, industrial research and medical and health research (Gibson, 1998; Hasson et al., 2000; Kirk et al. 1996; Williams & Webb, 1994). Medical and health research is the largest and most recent field to adopt this method (Gordon, 1994).

5.2.1 Types of Delphi Method

There are three main types of Delphi method: classic (traditional), decision-making, and policy (Linstone & Turoff, 1975; Manley, 2013). Most of the different varieties of the method is based on the traditional method (Manley, 2013). Several types of Delphi method can be identified, according to the aim of applying the tool and technical characteristics of the practice, as follows (Keeney et al., 2011).

- Classic Delphi: This is the most common method, which consists of three or more rounds and can be administered by email.
- Modified Delphi: This method replaces the first postal (or email) questionnaire with face-to-face or focus groups.

- Decision Delphi: This method differs from the classic type only in that it is used to make decisions.
- Policy Delphi: This method is used to agree on future policies.
- Real-time Delphi: In this method, the experts meet in an experts' session room.
- E-Delphi: This method differs from the classic Delphi only in that it uses a web-based questionnaire.
- Technological Delphi: This method is similar to the real-time Delphi, with experts using technology to immediately respond to the questions.
- Online Delphi: This method focuses on discussing arguments without the need to achieve consensus.
- Disaggregate Delphi: This method aims to agree on uses cluster analysis.

The type adopted in this study is the e-Delphi method because:

1. The experts are usually short of time and it is hard to ensure regular meetings with them. So, it is flexible in terms of sharing and collecting data through digital platforms (e.g. email and [SurveyMonkey.com](https://www.surveymonkey.com)) to obtain consensus on the adherence factors that can be considered in the medical technology treatment; and
2. Similar to the Classic Delphi, the first round can include open-ended questions which present an opportunity to allow panellists to share their experiences related to patient adherence. The eDelphi inherits the same limitations of the Classic Delphi, such as the amount of data collected from round one.

This study adopted the e-Delphi method because of its flexibility and feasibility, especially during the Covid-19 national lockdown in early 2020.

5.2.2 Delphi Rounds and Questionnaire Design

The Delphi panellists were asked a specific number of questions during each round. The number of rounds in Delphi studies can vary from two to ten rounds (Errfmeyer et al., 1986). However, most studies have between two-three rounds (Day & Bobeva, 2005; Milevska-Kostova & Dunn, 2010). The saturation point is where the research receives the maximum benefit from the sample and further rounds are meaningless. Therefore, reaching the

saturation point was considered when deciding on the number of rounds. While reaching the saturation point is normally achieved in the second or the third round, the decision of the number rounds was also affected by the study's time limitation (Keeney et al., 2010).

In traditional Delphi, the first round is usually an open-ended questionnaire that is the cornerstone of the research, as the data collected from the panellists in round one represents that crucial data used to construct the following rounds (Milevska-Kostova & Dunn, 2010). In round two, the data collected in round one is used to create 5-point Likert scale questions in order to create an anonymised questionnaire that explores the level of agreement between the panellists on the collected data. In the third round, the same questions are presented again, along with anonymised answers from the previous round, in order to allow experts to change their minds in ways which may affect the final agreement of the panel (Keeney et al., 2010).

5.2.3 Limitation of the Method

Similar to classic Delphi, one of the significant limitations of the open-ended questionnaire in e-Delphi is the amount of data collected and analysed (Gibson 1998; Hasson et al., 2000). A large amount can produce an extensive questionnaire in round two, which panellists may find time-consuming to complete (Keeney et al., 2011; Linstone & Turoff, 1975). As a result, the percentage of panellists participating in round two may fall relative to the number of panellists who completed round one. Therefore, the round one questions were limited to five and were targeted to collect data related to the adherence and factors that should be considered during the development of treatment technology.

5.3 Delphi Panel

The selection of the panel in Delphi was a crucial factor in the success of this stage (Linstone & Turoff, 1975). Therefore, the choice was based according to their expertise. Two criteria governed the panel selection:

- Panellists had to work in the UK healthcare system in the UK; for example, they could be company founders, experts working in healthcare organisations such as NHS, AHSN or NIHR, or academic experts; and/or
- Design experts had to have an understanding of the challenges within the healthcare system, for example, to be academic design experts with knowledge of the design process from one side or the healthcare system on the other.

Accordingly, the panel included case study founders, medical professionals, founders of medical research bodies in the UK such as AHSN and NIHR, design practitioners and academics. In general, the expertise involved included:

- Medical psychology behaviour change (adherence)
- Design for health technology
- Healthcare system
- Decision making
- Medical innovation

5.3.1 The Anonymity of the Panel

Anonymity of the panellists is essential to achieve the goal of the Delphi method because it reduces the occurrence of biased opinions and psychological influence (Linstone & Turoff, 1975). In this study, the identity and contributions of the panellists remained anonymous during the Delphi method process. Only the PhD supervisors and the researcher knew the identities of panellists and knew how they answered. We were also the only ones to follow-up with them regarding completing the survey or to engage in any further communication related to their answers. To avoid biased decisions, the names of the panel members were removed and replaced by serial codes P1 to P15, as listed in Table 5.1. The names of the experts who declined to join the panel or did not reply to the invitation were removed and replaced with codes P16 to P29, as listed in Table 5.2.

5.3.2 Size of Panel

The literature studies did not find any specific recommendation about the number of experts in the panel (Keeney et al., 2011). Some researchers suggested a small panel of less than 15 participants (Cavalli-Sforza & Ortolano, 1984; Delbecq et al., 1975; Malone et al., 2005; Novakowski & Wellar, 2008; Richey et al., 1985; Strasser et al., 2005; Turoff, 1970). Others recommended a larger panel of between 15-100 participants (Doughty, 2009; Miller, 2001; Rowe & Wright 1999), while still others suggested the panel to include hundreds (Back-Pettersson et al., 2008; Cyphert & Gant, 1971; Kelly & Porock, 2005; Meadows et al., 2005; Okamoto, 1999) or even thousands of participants (Aichholzer, 2001; Barnette et al., 1978; Drennan et al., 2007; Farrell & Scherer, 1983; Grundy & Ghazi, 2009; NISTEP, 1997; Jung-Erceg et al., 2007). In my research, the panellists' experience was considered a higher priority than the size of the panel. Table 5.7 shows the panel candidates, their expertise, affiliation and expertise.

5.3.3 Recruitment of the Panel

Panel member recruitment was based on the criteria highlighted earlier in the Delphi Panel Members section, as follows:

- A personal connection or the panellist is already a partner in the research as a case study;
- A representative of the Medical and health research organisations such as the AHSN, NHS and NIHR;
- Recommended designers with expertise in health technology; and/or
- Recommended faculty members in the School of Psychology at Northumbria University.

I reviewed the prospective participants' profiles, affiliations and positions in order to identify how their opinions might add value to the Delphi study. The total number of panellists considered was 28. From the nominated panellists, the participants were filtered as below:

1. Two were excluded as they did not have the required expertise;
2. Four replied that they were too busy to be part of the panel;

3. Two did not reply to my invitation email. Those panellists are excluded because one of their team had already agreed to be part of the panel; and
4. Six members did not reply to my invitation email or repeated follow-up messages.

Based on the above, the confirmed number of participants on the panel was 15. These are the panellists who received an invitation to answer the first-round questionnaire. Table 5.1 shows the 15 confirmed panellists and their expertise. Table 5.2 shows the initial candidates who didn't join the panel and the reason of exclusion.

Code Name	Position	Affiliation	Experience Mapping					
			Adherence and behaviour change	Treatment technology	Healthcare system	Med tech design	Decision making	Medical innovation
P1	Founder	Case study	✓	✓		✓		✓
P2	Co-Founder	Case study		✓	✓	✓		✓
P3	Founder	Case study		✓		✓		✓
P4	Founder	Case study		✓		✓		✓
P5	Clinical Operations Manager	Case study	✓	✓	✓	✓	✓	✓
P6	Innovation Manager	AHSN NENC		✓	✓	✓	✓	✓
P7	Innovation Manager	AHSN NENC		✓	✓	✓	✓	✓
P8	Senior Strategic Marketing Manager	CPI		✓	✓	✓	✓	✓
P9	Founder and CEO	GraftWorx	✓	✓	✓	✓	✓	✓
P10		James Cook University Hospital – NHS	✓	✓	✓	✓	✓	✓
P11	Founder	Movement Inc.	✓	✓	✓	✓	✓	✓
P12	Head of Design Strategy & Design Innovation	Philips	✓	✓	✓	✓	✓	✓
P13	School of Health and Life Sciences, Northumbria U	Academic (medical psychology). School of Health and Life Sciences, Northumbria University	✓					
P14	School of Health and Life Sciences, Northumbria U	Academic (medical psychology). School of Health and Life Sciences, Northumbria University	✓					
P15	CEO and Co- Founder	ORCHA	✓	✓	✓	✓	✓	✓

Table 5.1 Delphi candidate panellists and their expertise.

	Position	Affiliation	Experience Mapping						Comments
			Adherence and behaviour change	Treatment technology	Healthcare system	Med tech design	Decision making	Medical innovation	
P16	Co-Founder	Case study	✓	✓	✓	✓	✓	✓	Removed: the company is represented by another expert
P17		Case study	✓	✓	✓	✓	✓	✓	Removed: the company is represented by another expert
P18	Business manager	AHSN NENC						✓	Removed because of irrelevant experience
P19	Chief Executive	AHSN NENC						✓	Busy
P20	Research Operations Manager	CRN						✓	Removed because of irrelevant experience
P21	Chief Executive	Northern Health Science Alliance	✓	✓	✓	✓	✓	✓	Could not get in touch
P22	Director	NIHR	✓	✓	✓	✓	✓	✓	Busy
P23	Director of Research and Innovation	NIHR National Children's Specialty Lead	✓	✓	✓	✓	✓	✓	Agreed then could not move forward, possibly because COVID-19 NHS work
P24	Vice President, Design	Frog	✓	✓		✓	✓	✓	No reply
P25	Philips	Chief Design Officer				✓	✓	✓	Replied by forwarding to another representative
P26	Philips	Head of Design				✓	✓	✓	No reply back
P27	School of Health and Life Sciences, Northumbria U	Academic, psychology	✓	✓	✓		✓		Busy
P28	School of Health and Life Sciences, Northumbria U	Academic, psychology	✓	✓	✓				No reply
P29	University of Oxford	Professor of primary care	✓	✓	✓		✓		No reply

Table 5.2 List of the panel candidates who were not involved in the study and the reasons.

5.3.4 Invitation to the Panel Members

After preparing the candidates' list, an invitation email was sent to each candidate in order to introduce the research brief and research aims as well as to provide a summary of the Delphi method process and what was expected from each member. A copy of the message sent to the panellists is shown in Appendix 11.7.

5.4 Ethical Approval and Consents

This study was conducted under the Ethical Approval Regulation of Northumbria University. Panellists were asked to sign a consent form that was already approved by the university ethics committee (Appendix 1.1). Approval to join the study was collected through email invitations (Appendix 11.7) and communications between the panellists and me.

When the panellists visited the online questionnaire hosted on SurveyMonkey.com, the header of the questionnaire displayed a welcome message and information about the current round's survey. The brief indicated that, by clicking Ok and filling out the survey, the panel member gave consent to use their and data in the study.

5.4.1 Storage of Delphi Data

The storage of data related to the Delphi method stage followed the same regulations used throughout the study. A copy of the questionnaire and its responses was stored on the SurveyMonkey.com website database. I was the only one who had access to these data. The survey was shared with each of the panellists through a URL. The link was only shared with the experts who agreed to contribute to the study. I accessed and the questionnaires and data from my Apple computer, which was secured by a password and my fingerprint.

5.5 Process Management

The panel management represented a critical activity that ensured that the aim of the Delphi process was achieved. Accordingly, the process of managing the panel was as follows:

1. Identify the experts that could join the panel and provide insights and opinions related to adherence factors that affect self-administered treatment technology.
2. Build a list of candidates and map their different expertise onto the selected panel. The list (Table 5.1) includes: panellist name, position, affiliation, expertise, email and organisation represented (e.g. research case study, NHS or AHSN).
3. Email candidates to invite them to join the Delphi panel. In this email, information about the research was provided, including the Delphi method, planned timeline and required time commitment, along with a brief about the study's panel.
4. Ask the candidate to sign the research consent form and send it to me. It was then archived based on the research ethics regulations.
5. Select a sample of the candidates to share the first-round questions and get feedback.
6. Share the first round (open-ended qualitative questions) with all the panellists. The panellists were expected to answer the questions and send their responses back within one week.
7. Once the panellists answered the first-round questionnaire, the data was organised and analysed. At this point the inter-rater reliability process started, which involved hiring, managing and communicating with the inter-raters.
8. Based on the results from the analysis of the first round, I wrote the second-round questions and created the questionnaire on SurveyMonkey.com.
9. Once the second-round answers were collected and analysed, the third-round questions were created, which included the same questions as the second round but also showed the panellists the sum responses from the previous round and their answers. The process involved creating a separate questionnaire (with a unique URL) for each panellist to ensure the anonymity of their responses.
 - Once the data was received, it was analysed using the Wilcoxon test to define the level of agreement without the chance factor between the panellists.

5.5.1 Instrument Design: Questionnaires

The Delphi method aimed to explore the level of consensus amongst the panellists. Three initial rounds of questionnaires were planned (Keeney et al., 2011). The design of the survey aimed to achieve the following:

- Collect opinions from panellists related to adherence factors and how adherence is considered while designing medical and health treatment technology.
- Build a consensus on the different factors and their impact on patient adherence.

The Delphi study consisted of three rounds, as follows:

- The first round consisted of an open-ended questionnaire to collect qualitative data.
- The second round consisted of a quantitative questionnaire.
- The third round sought consensus on the questions from the second round.

The results of the Delphi method were used to confirm the adherence framework's factors and introduce the framework for further research investigations, which included testing and evaluating it for application in both product development and evaluation.

5.5.2 Questionnaire Timeframe

The Delphi method, which ran from March until May 2020, represented the last stage in this study. I understood the panellists' time was limited, so I planned a specific time between each round to provide a chance for the panellists to reply with answers and allow myself the time to analyse the data. The timeframe was as follows:

- A sample of three panellists were shared the test questions in order to evaluate the responses. This stage took around one week.
- Panellists were asked to complete each round's questionnaire within a specific time period (one-two weeks). Another two weeks was given to analyse each round.

5.6 Implementation of Delphi methodology

According to the design of the research methodology, the application of the Delphi method represents the third stage of the research, the Assessment stage. This stage aims to identify the consensus of Delphi panellists on the adherence improvement a proposed Adherence Canvas. The model is a result of analysing the earlier steps:

- Completion of the literature studies related to treatment adherence.
- Interview of the five case studies.
- Observation of the WearCare II project; and
- Completion of the open-ended questionnaire in the first round of the Delphi study.

5.6.1 Technological Utilisation

The eDelphi method presented an opportunity to facilitate the Delphi study and to overcome the limitations of time (both of the study and of the panellists) and place (as they were located in different cities around the UK and Northern Ireland). The questionnaire rounds were designed and created using SurveyMonkey.com (a website to design, create, distribute and analyse questionnaires). A link for each round was generated and shared with the panellists; this web-based questionnaire allowed them to answer the questions. The links were shared with the panellists through email before each round.

5.6.2 Pilot Delphi Round

'Pilot test' refers to the practice of sharing the first-round questions with a sample of the panellists (Gordon, 1994; Mitchell, 1991; Novakowski & Wellar, 2008). Although the pilot testing step has been viewed as optional (Moore, 1987), the majority of the literature highlighted various benefits of applying it (Miller, 2001). Some of the benefits of implementing a test stage of the first Delphi round include:

- The data collection is an opportunity to gather sufficient data from the panellists. Accordingly, implementing a testing step develops good practices and reduces the risk of missed chances (Teijlingen & Hundley, 2001)

- Identify any inaccuracies and lack of clarity in the wording used in the questions (Turoff, 1975), especially in the open-ended questions.
- Test the administration process (Jillson, 1975). This process involves tasks such as sending the invitation emails, reminders, collecting and organising panellists replies (Keeney et al., 2011).

In this study, the pilot round was shared with a sample of panellists in order to test the wording of the questions, the round's administration and the feedback from the panellists.

The sample selection was based on the following criteria:

- Understanding the nature of the research and the research method used; and
- Being able to test and provide comments regarding the design of the open-ended questions.

According to the above criteria, four panellists were selected to receive the questionnaire. For this sample, I sent an invitation email (see Appendix 11.7) to participate in the pilot study. Then, in a separate email, I highlighted why their contribution to the sample was significant and encouraged them to provide feedback regarding the questions and process. Panellists were given around a week to answer the questions and share their comments.

Some of the comments received were:

- The questions are wordy and need to be more straightforward.
- The usage of terms may not be precise, especially for the panellists without knowledge of the medical psychology theoretical terms used to describe patient behaviour.

5.7 Timeline of the Delphi Phases

Table 5.3 shows a summary timeline of the Delphi phase and how it was administered between the researcher, the inter-raters and the panellists

	Researcher	Panellists	Inter-raters	Tool Used
Pre-Delphi activities	<ol style="list-style-type: none"> 1. Define the aim of the Delphi study phase 2. Design and plan the Delphi study phase 3. Design round one questionnaire 			MS Word
	<ol style="list-style-type: none"> 1. Search for potential panellists 2. Evaluate and filter panellists 3. Build an invitation list of the panellists 			
	<ol style="list-style-type: none"> 1. Contact the panellists 2. Design the questionnaire on SurveyMonkey.com 3. Invite the approved panellists to round one 			SurveyMonkey.com – MS Word – Email
Pilot Delphi activities	Select pilot round panellists			
	Share with the panellists sample questionnaire			SurveyMonkey.com – MS Word – Email
		Pilot panel answers the questionnaire and provide comments		
	Consider the comments and improve the questionnaire			SurveyMonkey.com – MS Word – Email
Round One	Invite the entire panel to round one questionnaire			
		Panellists answer round one survey		
	Follow-up with panellists			Email

	Collect, organise and analyse the results			SurveyMonkey.com – MS Word – Email
	Contact any panellist for clarifications if needed	Some panellists clarify their answers		Email – SurveyMonkey.com

Table 5.3 Timeline of Delphi method process.

	Researcher	Panellists	Inter-raters	Tool Used
Inter-rater reliability	Content analysis			NVivo – MS Excel – SurveyMonkey.com
	Search and hire inter-raters			
	Brief inter-raters about the research and their tasks			Email – Web-based chat
			Inter-raters review and code round one data	NVivo
	Collect the inter-raters' content; analysis and organise			NVivo – MS Excel
	Calculate Cohin's Kappa reliability			MS Excel
Round two	Create round two questionnaire			SurveyMonkey.com
	Invite panellists to answer round two			SurveyMonkey.com – Email
		Panellists answer round two survey		SurveyMonkey.com
	Follow-up with panellists			Email
	Collect, organise and analyse the results			SurveyMonkey.com – MS Excel – SPSS
Round three	Create round three questionnaire. Same as round two with showing the panellists the sum results and their responses.			SurveyMonkey.com
	Invite panellists to answer round two			Email
		Panellists answer round two survey		
	Follow-up with panellists			Email
	Collect, organise and analyse statistics			SurveyMonkey.com – MS Excel – SPSS

Wilcoxon test	Apply Wilcoxon test			SPSS – MS Excel
	Analyse statistics and build a proposed Adherence Canvas			MS Excel

Table 5.3 Timeline of Delphi method process (continued).

5.8 Summary and Conclusion

This chapter provided a brief about the Delphi methodology that is part of the third stage of the study (Assess). Due to the limitations related to the study such as the timeframe of the study, testing the findings of the study was not feasible within a sample of live commercial product development. Accordingly, the Delphi method was deployed to assess the findings through the consensus of a panellists of professional in the fields involved in the study. The previous two stages highlighted two interesting findings:

1. There is a lack of adherence theories that focus on self-administered treatment technology
2. There is no practical framework for companies to evaluate the consideration of adherence factors in the design and production of self-administered treatment technology.

According to the above findings, the Delphi method was designed to collect panellists' consensus on adherence factors that affect patient adherence to self-administered treatment technology. Toward this aim, the Delphi method was designed and described in this chapter.

As a conclusion of this chapter, the eDelphi was selected as the method that will be used to ensure flexibility and accessibility for panellist to contribute to the study. The eDelphi involves three rounds: the first round is an open-ended questionnaire, the second is a quantitative (Likert) survey, and the third round the same survey of round two with one difference that is showing the anonymised replies of the whole panel for panellists to revise their answers if they want. The panel selection and invitation were also discussed along with details related to the anonymisation and running the rounds with the panellists.

The management of the process, storage of data, sending the invitations, and the timeframe of the process were also discussed. The application of the method and the results of the application is discussed later in Chapter 11: Delphi Method Application.

Part 3

Investigate

Chapter 6: Theoretical Frameworks of Adherence

This chapter explores the challenging problem of adherence, and its clinical and financial impact on the healthcare system. Furthermore, the impact of administration on treatment adherence will be discussed. The theoretical frameworks that consider how adherence is affected will be discussed in order to identify the factors that affect adherence and how it works. The relationship between adherence on the one hand and communication and technology on the other hand is reviewed in order to understand its impact on adherence. Finally, the variations in adherence for different diseases will be discussed.

Key Topics:

- 6.1 Adherence in Literature Review Search**
- 6.2 The Problem of Low Adherence**
- 6.3 Factors that Affect Treatment Adherence**
- 6.4 Theoretical Adherence Frameworks**
- 6.5 Communication and Adherence**
- 6.6 Patient Empowerment**
- 6.7 Patient Monitoring**
- 6.8 Information, Motivation, Strategy**
- 6.9 Adherence Factors in Different Diseases**
- 6.10 Behaviour Change**
- 6.11 Findings and Summary**

This chapter investigates adherence as a challenging factor and burden for today's healthcare systems. Furthermore, this part explores the factors that influence patient adherence and behaviour change. Exploring these factors requires a clear understanding of the literature and theories related to the topic. This chapter explores the literature to answer the research question: what are the theoretical frameworks of treatment adherence?

Baum et al. (2012) defined three types of adherence: adherence to a prescribed treatment, adherence to produce a clinical outcome, and adherence to behavioural treatments. However, there is a lack of studies that address adherence in relation to medical technology usage and particularly self-administered interventions. This lack is identified as a gap in knowledge that needs to be investigated, especially with the varied nature of medical technology interventions and other treatments such as pharmaceutical and clinically administered therapies.

van Dulmen (2007) stated that: 'Many interventions to improve patient adherence are unsuccessful and sound theoretical foundations are lacking. Innovations in theory and practice are badly needed' (p.1). The literature studies discussed in this chapter contributed to determining the research scope and the characteristics of the products that the case studies manufacture. This part of the research scoping focuses on the characteristics of the product based on the nature of the disease (chronic diseases) and the administration of the treatment (self-administered).

6.1 Adherence in Literature Review Search

The Desk Research stage explored adherence and its consideration in the self-administered treatment technology design. The results of this stage presented the base for the setup of the following steps in the research. Various sources were used to search for the literature. The keywords and phrases used in the search varied based on the target objective of each chapter. This chapter explored the psychological theories related to adherence.

The search through the literature was conducted through the following channels:

- Northumbria University library website and its connected service (i.e. Shibboleth)
- NICE (www.nice.com)
- AHSN (<https://www.ahsnnetwork.com>)
- Google Scholar UK website (<https://scholar.google.co.uk>). Also, it includes my saved library from previous research
- Google search website (<https://www.google.co.uk>)
- My previously saved library on Mendeley desktop application
- Medical research using MEDLINE, PubMed, PsycINFO, EMBASE and The Cochrane Library
- Design for Health conference publications
- Design Research Society

While conducting the research, related keywords were used to expand the possibility of exploring related literature as shown Table 6.1:

Main search term	Related terms
Adherence	Compliance, Concordance, Patient Involvement, Patients Centred Intervention, Mutuality
Design	Behaviour Change, Persuasive Design, Captology
Design Thinking	Design Process, Innovation Process, Human-Centred Design, Gamification
Treatment	Therapy, Intervention
Health Technology	Medical Technology

Table 6.1 Literature review main search queries and related queries used in the search.

The search for the above (Related terms) aimed to expand the findings from design, technology and HCI domains such as persuasive design and captology. Refer to 6.10 Behaviour Change.

6.2 The Problem of Low Adherence

The low adherence is a challenging problem for healthcare systems (van Dulmen et al., 2007). An estimated 20% to 30% of patients do not take their medications (Viswanathan et al., 2012). In prevention and disease management activities (e.g. diet, medical appointments or screening), non-adherence may reach 25% (Haskard-Zolnieriek & Dimatteo, 2009). As a consequence of non-adherence, a gap can be identified between actual treatment success rates and those which are realistically achievable (Viswanathan et al., 2012). This gap may affect the accuracy of clinical trial results and, subsequently, the outcome of decisions related to the treatment. The adherence to intervention plays an essential role in determining the intervention's effectiveness in improving patient health (Car et al., 2017).

While there is a lack of practical mechanisms which consider adherence, there are some practices which consider adherence. van Dulmen et al. (2007) reviewed 38 systematic reviews of the effectiveness of adherence interventions and defined three practices: 1) there are effective practices to improve adherence without a supported theoretical explanation; 2) there are effective adherence interventions based on the behavioural theories; 3) there are acceptable models that are able to define non-adherence, however, they are poorly effective in improving adherence.

6.2.1 Non-adherence in the Treatment of Chronic Diseases

The nature of the disease plays an essential role on the level of adherence. The level of non-adherence of patients with chronic diseases is between 30% and 50% (Barnett, 2014; Bourbeau & Bartlett, 2008; Nunes et al., 2009; Sabaté, 2003). Bowry et al. (2011) emphasised that improving the percentage of adherence can be far more effective in the treatment outcome than only improving the medical treatment itself. Accordingly, a widespread innovative solution is needed to improve patients' adherence to prescribed intervention. For example, DiMatteo et al. (2000) highlighted that depression as a chronic

disease can be a main factor in patient's non-adherence. The adherence drops by 27% from the normal ranges if the patient experiences symptoms of depression (Martin et al., 2005).

There are number of techniques that are used to improve adherence in the treatment of chronic diseases, such as the Micro Electro-Mechanical Systems (MEMS) that uses embedded microprocessor technology to record the time and date of the opening of bottles. Another technique is counting the pills during physician visits. However, these practices have a weak effect on adherence (Saini et al. 2009). The latter technique may not be effective for medical technology due to the nature of the treatment and its administration.

6.2.2 Impact on Clinical Outcome

The failure to achieve a significant level of adherence can have serious consequences for patient health, including relapsing, morbidity, health status, hospitalisation and mortality (Aldeer et al., 2018; Baum et al., 2012; Viswanathan et al., 2012). Mennini et al. (2014) investigated the cost of poor adherence to anti-hypertensive therapy in five European countries (Italy, Germany, Spain, France and England) over a 10 year period. The study explored cardiovascular complications associated with hypertension (i.e. stroke, heart attack and heart failure). Improving patient adherence to anti-hypertensive therapy to 70% could reduce the cases of cardiovascular complications by 82,235 in the five European countries combined, with 6,553 fewer cases in England alone.

Fitzgerald et al. (2011) conducted a retrospective longitudinal study to understand the impact of non-adherence to medication on hospitalisations and mortality from heart failure. The study indicated that fewer than 80% adherence can lead to risk of mortality and hospitalisation for the entire population. The level of adherence that is associated with health complications varies according to the disease. For instance, in HIV patients, a level of adherence lower than 90%–95% is associated with viral replications and consequences may result from this (Martin et al., 2005).

6.2.3 Impact on Cost and Workforce

Poor adherence also results in financial and workforce burdens, such as increasing healthcare costs and a negative impact on healthcare workforce productivity (Bosworth et al., 2011; Conn et al., 2016). For chronic diseases, the financial cost to the EU healthcare systems was estimated to be Euro 110 billion in 2006, which represents around 10% of their total healthcare expenditure. In England, the drug cost is estimated to be around Euro 200–300 million. This cost includes the burden of non-adherence to the medical intervention. Improving adherence can reduce the cost by an estimated Euro 36.2 million in England (Mennini et al., 2015).

Cutler et al. (2018) assessed 79 individual studies which covered the cost of medical non-adherence in 14 diseases. In general, the cost related to all non-adherence causes ranged from \$5,271 to \$52,341 annually. Ho et al. (2016) conducted a systematic review of studies related to the clinical and economic impact of non-adherence in depressive disorders. The review categorised the costs into drug costs and medical costs, where the latter referred to the physician costs. The study concluded that the cost of non-adherence to the medication was significantly higher comparing to the adherence to the treatment.

Another example of the cost of non-adherence is located in Muduma et al. (2015), who found that improving the adherence in renal transplant recipients by adjusting the treatment of tacrolimus doses from twice- to once-daily could provide an estimated cost savings of £4,862 per patient over five years, based on the NHS reference reported costs in 2014. This cost savings extends to mental health diseases such as bipolar disorder. The cost of non-adhering patients with this disease is higher compared with adhering patients with the disease: £4,796 vs £2,150, respectively (Hong et al., 2011).

The failure to adhere to the medical intervention has direct and indirect impacts on the cost to the healthcare system. While the direct impact is the drug cost, indirect costs such as the complications associated with lack of adherence to the treatment can exceed the direct costs. For example, poor adherence to hypertension treatment may lead to a stroke, which requires hospitalisation and incurs rehabilitation costs (Baum et al., 2012).

6.2.4 Treatment Administration and Adherence

Hospitalised patients have more factors that lead to improving adherence to the prescribed treatment because the intervention is administered by clinicians. When the treatment is self-administered by the patients, the factors that improve adherence to the treatment regimen change, becoming more complex. In self-administered therapy, it is estimated that one-third of the patients adhere to physician directions while two-thirds do not adhere to the therapy (Becker, 1985).

The risk of poor adherence in self-administered treatment continues to be one of the biggest challenges in the process of medication intervention. Hall et al. (2016) emphasised that the level of adherence to the self-administered cancer treatments (e.g. haematological cancer) varied, ranging between 76%–100%, depending on the definitions and measurements used. The study concluded that, to achieve high adherence to the treatment, a multi-component intervention strategy is required. In another study of self-administered chemotherapy, 43% of the patients met the non-adherence criteria defined by the study (Lebovits et al., 1990). The latter studies highlighted another aspect of understanding adherence, which is the measurement of adherence. A clear measurement of adherence is required in order to identify the impact of adherence on the treatment intervention.

According to the above literature, the research scope from the perspective of the disease and its administration is as follows:

- The focus on chronic disease is determined because non-adherence magnifies the impact of chronic diseases as time progresses. This causes increasing clinical complications and financial costs.
- The focus on the self-administered treatment is determined because adherence decreases when patients administer interventions themselves.

The above two points determine an increased level of non-adherence and subsequently its complications.

6.3 Factors that Affect Treatment Adherence

There are many theories which explain the complex nature of adherence (Aldeer et al., 2018). Different approaches have been taken to patient adherence, and the theories these approaches have been based on have varied on their scope and how the phenomenon was addressed. An exploration of these theories reveals that they can be divided into two main categories: factor-based theories and stage-based theories. The first category focuses on the factors that affect adherence, such as the social learning theories (Martin & DiMatteo, 2013). The second category of theories focuses on the stages people move through in order to achieve the behaviour change or adhere to medical treatment, such as the transtheoretical model (Aldeer et al., 2018; Martin et al., 2010). An interesting observation from the investigated literature is that adherence theories do not consider the type of medical practice (e.g. treatment, monitor or diagnosis), nor the type of intervention (e.g. pharmaceutical drug or medical technology), nor the administration of the practice (e.g. clinically administered, self-administered or both). However, there is a clear appreciation of the idea that adherence factors impact patient behaviour differently depending on the disease (Bosworth et al., 2005).

The factor-based category of theories is most relevant to the aim of this research, which is to understand the factors behind adherence. The theories in the second category (stages theories) focus on the cognitive process of behaviour change. The focus of this study is on understanding the factors that influence adherence which should be considered during the design process of the treatment technology. Therefore, the discussion in this chapter will focus on the first category.

6.3.1 Factor-Based Theories

Some theories which aim to explain behaviour change focus on the factors which drive the change. Those theories present an opportunity to understand adherence factors, both individually and also in relation to each other. I will identify this set of theories as factor-based theories because they focus on the factors that affect adherence.

6.3.1.1 WHO Five Dimensions

The WHO defined five dimensions which affect patient adherence. These dimensions acknowledge the complex nature of adherence (Aldeer et al., 2018). These dimensions include the following (Sabaté, 2003):

- 1) Social and economic factors (e.g. economic level and poverty, education level, age, unemployment and high medication costs)
- 2) Healthcare team and system-related factors (e.g. poorly developed service and poor medication distribution)
- 3) Condition-related factors (e.g. illness-related demands and patient perception of risk)
- 4) Therapy-related factors (e.g. side-effects and the availability of medical support)
- 5) Patient-related factors (e.g. knowledge, attitude, beliefs, perceptions and expectations).

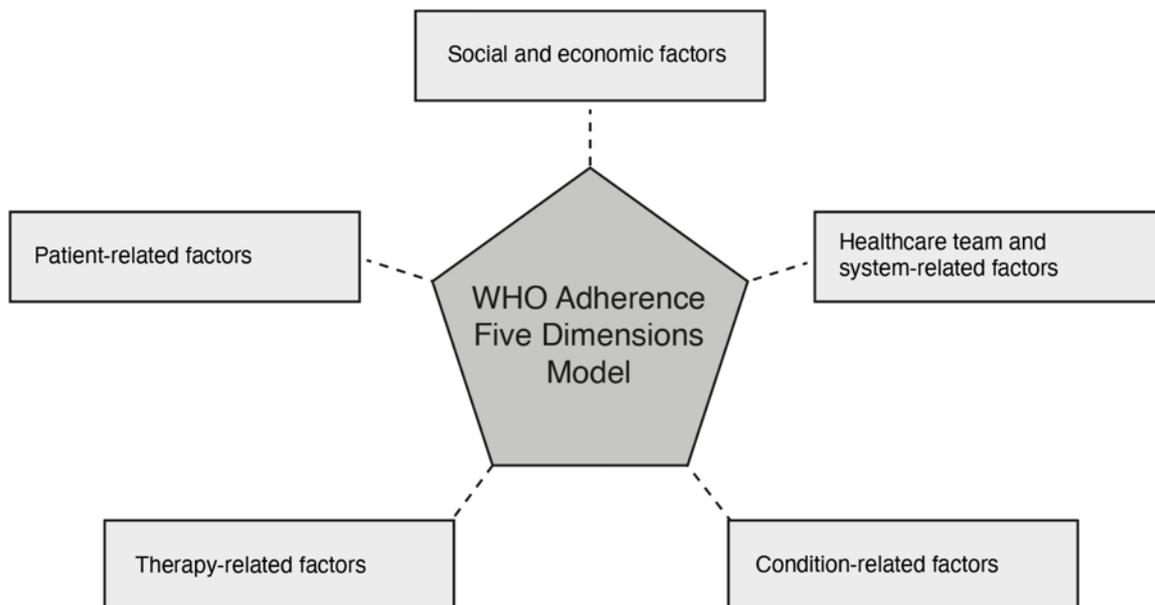


Figure 6.1 The WHO five dimensions model of adherence. Based on Sabaté (2003).

The WHO model (Figure 6.1) is supported by clear definitions of different factor which affect patient adherence. However, this classification is very broad and includes many factors,

such as economical levels and healthcare team factors, which cannot be controlled by the companies working in the field of medical treatment technology.

6.3.1.2 NICE Medical Adherence Guidelines

The fifth factor (Patient-related factors) of the WHO model aligned with adherence variables is indicated in the National Institute for Health and Clinical Excellence (NICE) Medical Adherence Guidelines. The guidelines suggest that the causes of patient non-adherence fall into two intersecting categories: intentional and unintentional. The latter factors can be either perceptual, which motivate patients to continue the treatment (e.g. beliefs and preferences), or practical, which influence their ability to adhere to the advised treatment (e.g. limitations in capabilities and resources) (Bosworth et al., 2011; Chapman et al., 2015; Nunes et al., 2009). The above guidelines present a simple yet broad model. The model is suitable for companies which have already developed a clear idea about the factors that affect patient adherence amongst their target patients.

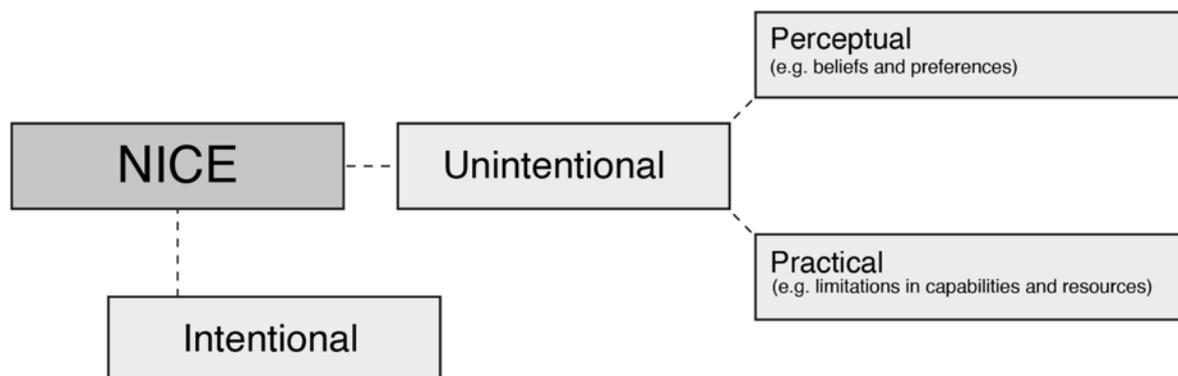


Figure 6.2 The NICE definition for adherence factors.

The psychology literature introduced theories targeting behaviour change and treatment adherence. Below, an overview of the literature theories related to adherence is presented in order to clearly identify the adherence factors.

6.4 Theoretical Adherence Frameworks

Different theories have been proposed to understand patient adherence to treatment or behaviour change. These theories are based on psychology research (Rosenstock et al.,

1988). As highlighted earlier, adherence theories can be categorised based on how the adherence is addressed as a number of intersecting factors, or as a sequence of stages that leads to the continuation of adherence to the medical treatment.

6.4.1 Stimulus Response Theory (SRT)

Stimulus response theory (SRT) focuses on the stimuli of the event rather than on the physiological drivers. SRT theory views learning as the result of events that provide ‘reinforcements’. For example, a person who is rewarded for a specific behaviour tends to repeat that behaviour in order to receive the reward. In contrast, a person who is punished for a specific behaviour learns the outcome and tends avoid that behaviour, as this reduces the tension incurred by the punishment (Rosenstock et al., 1988). Skinner and Champion (2015) explain SR theory by noting that the frequency of the behaviour is determined by its consequences. The immediate reward or punishment after the event is enough to drive the behaviour response without the need for mentalistic concepts. Based on this description, SR theory focuses on main two factors:

- Immediate reward reinforcement
- Immediate punishment reinforcement

6.4.2 Social Learning Theory (Social Cognitive Theory)

Bandura (1977) introduced social learning theory (SLT), which was later renamed social cognitive theory (SCT). According to SCT, behaviour results from external stimuli and can be explained by reinforcement (reward and punishment). In this theory, the behaviour is a result of mental processing activities (such as reasoning, decision making and problem solving). SCT points out that the drivers of behaviour reinforcements are social in nature (Bosworth et al., 2005) and behaviour is determined by two types of factor categories:

- **Expectations:** Three types of expectations can drive behaviour: 1) expectations about environmental cues such as beliefs about connected events and the surrounding environment during the action; 2) expectations about the consequences of the action (outcome expectancies); and 3) expectations about one’s ability to perform the behaviour (self-efficacy).

- **Incentives:** An incentive is the value of a particular object or outcome (reward and punishment). For example, relieving pain can be a reward of taking painkillers or being healthy can be a reward of physical exercise.

The above two theories highlight the social aspect of learning, as people learn by observing others perform the behaviour (observational learning). Practices informed by these theories can lead to higher adherence to the behaviour (for example, treatment intervention) (Bosworth et al., 2005). Furthermore, some shared factors can be noticed between SR theory and SCT, represented in the reinforcement of rewards and punishments, which are described more broadly in SCT as the expectations about the consequences of the action.

6.4.3 Locus of Control Theory

Rotter (1966) introduced the Locus of Control Theory, which suggests that in the presence of the same information people react differently either by learning different things or responding to reinforcement.

The expected varied behaviour is affected by number of variables known as the 'locus of control'. These variables can be categorised into two dimensions:

- **Internal locus of control:** the reinforcement of the behaviour is internal to the person. For example, physical exercise rewards the person with good health.
- **External locus of control:** external factors, such as luck, fate and chance, are the drivers of the reinforcements.

Wallston & Wallston (1978) suggested that the influence of other people can be considered an external reinforcement of behaviour. Those influencers (powerful others) can be clinicians, consultants, or families. Different studies have used the Locus of Control Theory to improve the adherence to treatments and therapeutic recommendations such as HIV, smoke cessation programmes, and hypertension medication (Bosworth et al., 2005; Martin et al., 2010).

There is a shared border between the reinforcement factors in SRT, incentives in SCT theory and the Locus of Control Theory factors. Each of these three theories address stimuli factors from different perspectives. SR theory addresses it from the reward/punishment/reinforcement perspective. SCT presents the incentive as a broad factor that can include any stimulus to drive the behaviour change. Locus of Control Theory presents a more detailed categorisation which focuses on the location of the locus of control factors which drive the behaviour change.

6.4.4 Self-Efficacy

Bandura (1977) suggested that social learning is not a strong enough factor to make a person behave or react to reinforcement; the person must also be confident in her ability to perform the behaviour. This aspect is known as self-efficacy. Different studies have shown self-efficacy to be a significant factor in treatment adherence in, for example, smoking cessation and the ability of women to perform breast self-examination (Bosworth et al., 2005). Four aspects affect self-efficacy: performance mastery, vicarious experience, social or verbal persuasion, and physiological cues perceived by the person. Self-efficacy focusses on the internal locus of control factors represented in the locus of control, which subsequently related to the incentive factor in social learning theory.

6.4.5 Continuum Theories

Several theories based on social learning theories have been produced. A subsection of these theories, known as continuum theories, assume that the variables which influence behaviour can be combined in one equation which can predict adherence behaviour. Below are some examples of continuum theories.

6.4.5.1 Health Belief Model (HBM)

The Health Belief Model (HBM) explains why some patients adhere to a specific regimen while the others do not. In this theory, the likelihood that a patient will adhere to a regimen is affected by the patient's personal beliefs about the: 1) perceived susceptibility; 2) perceived severity; 3) perceived benefits; and 4) perceived barriers of the disease and

treatment. The influence of these factors depends on the demographic variables and psychological characteristics of the patient. The health belief model presents a point of intersection between two theories: Stimulus Response, and social learning (Williams, 2014).

Different modifications were added to HBM. For example, Bandura (1977) introduced self-efficacy as one of the barriers in the model. Other factors, such as health motivation, relevant personal attributes, susceptibility to the condition, general orientation toward the treatment and the characteristics of the relationship between the patient and the doctor, were also added (Bosworth et al., 2005).

Factors from SR theory and SCT can be seen in HBM theory. For example, the punishment reinforcement in SR theory is represented in the HBM as perceived severity. The self-efficacy factor in the modified version represents both self-efficacy theory and the incentives in SCT. The incentives reinforcement in SCT is represented in HBM as perceived susceptibility.

6.4.5.2 Theory of Reasoned Action and Theory of Planned Behaviour

Unlike theories which depend on exploring the factors that affect how well a person adheres to a treatment regimen, this theory suggests that the strongest predictor of a behaviour is the intention to engage in that behaviour. This intention is determined by the attitude toward this behaviour—for example, the personal evaluation of the behaviour—and the subjective norm (the personal perception of how others feel about the behaviour). The theory of reasoned action was modified by Ajzen (1991) to include the perceived behaviour control. This third factor refers to the level to which the person feels in control when engaging in the behaviour. This last factor—perceived behavioural control—shares similar meaning with the previously discussed theories, such as the self-efficacy theory.

Various studies have attempted to understand the factors which drive people to adhere to specific behaviours and have approached this from different perspectives. For example, Social Learning Theory discussed above tends to address adherence from the perspective of social learning and seeks to observe the change in behaviour based on internal and external

factors. Additionally, this perspective considers the predictors of adherence and what the factors are that drive the behaviour. The second type of theories address adherence from the perspective of the stages that one moves through in order to react to the threat and how the behaviour is addressed. An example of this is the Self-Regulatory Model of Illness, which describes how the patient's behaviour change starts with situation stimuli (internal or external) which lead the patient to representation of danger or fear. The patient then tries to cope with the new changes and appraisal to evaluate the impact of the coping procedures. Another example are the Stages theories, which include Transtheoretical and Precaution Adoption Process Models, describe behavioural change as a process that occurs via progression through different stages.

6.5 Communication and Adherence

A wide range of literature studies have highlighted the positive correlation between communication with the patient and adherence to treatment regimen (e.g. Haskard-Zolnieriek & DiMatteo, 2009; Martin et al., 2010; Martin & DiMatteo, 2013). Effective communication between the clinician and patient can improve adherence by 19% (DiMatteo et al., 2012; Haskard-Zolnieriek & Dimatteo, 2009). Although the importance of the patient-physician relationship has long been understood, it was not until the 1960s and 1970s that studies explored the factors that affect the communication between patient and physician, and subsequently affect the adherence to the medication. Literature studies have addressed patient-physician communication from five perspectives: 1) the physician's interpersonal skills; 2) the physician's teaching skills; 3) the patient's satisfaction; 4) the patient's recall of instruction; and 5) the patient's satisfaction with and adherence to the regimen. Studies that focused on the fifth perspective have indicated that the relationship between the patient and physician is significant. Korsch et al.(1968) highlighted number of elements related to communication between the patient and physician, including how friendly the physician is, how well the physician understands the patient's concerns and the patient's satisfaction (Bartlett et al., 1984).

Haskard-Zolnieriek and Dimatteo (2009) presented a meta-analysis based 127 studies of patient-physician communication. A number of factors were found to affect patient adherence, including:

- 1) Physician communication skills: physicians with good communication skills can improve patient adherence.
- 2) Patient involvement in decision making.
- 3) Discussing with the patient information about the treatment benefits and risks, as well as the barriers that may affect adherence to the treatment regimen.
- 4) Building a rapport and trust with the patient, and providing support and encouragement for the patient.

The third and fourth factors above align with the patient's knowledge, which can be mapped onto different adherence theories, such as the patient-related factors in the WHO five dimensions of adherence (Sabaté, 2003) and the consequences in Social Learning Theory (Bosworth et al., 2005). Furthermore, those four factors are linked to the perceived susceptibility, barriers, benefits and severity in the HBM (Bosworth et al., 2005; Williams, 2014). This involvement can extend to broader patient empowerment, a concept that aims to widen the patient experience to involve decision making, self-management and patient education (Anderson & Funnell, 2010). Various of studies have shown a positive relationship between patient empowerment and adherence (Delamater, 2006; Náfrádi et al., 2017).

'Communication' refers to the adherence factors related to the patient's communication with the outer world, including clinicians and friends, and how the patient perceives others' opinions about the practice. According to the reviewed studies above, the following factors can be part of the communication section.

6.6 Patient Empowerment

Another benefit of the communication between the patient and the clinician is patient empowerment. A close connection can be found between patient communication and patient empowerment. The term 'patient empowerment' refers to the patient's extended

capacity to make decisions and take responsibility for the consequences of these events (Aujoulat et al., 2007; Feste & Anderson, 1995; Funnell & Anderson, 2003; McAllister et al., 2012). It is an educational process which encourages patients to self-manage their treatment regimens and achieve behaviour change (Anderson & Funnell, 2010; Feste & Anderson, 1995).

Studies which have covered patient empowerment have highlighted the role of the healthcare system and tried to define the boundaries between patients and clinicians (McAllister & et al., 2012). These boundaries should be negotiated between both the patient and the clinician to ensure an effective outcome (Funnell & Anderson, 2003). The successful application of the patient empowerment concept can have a positive impact on patient adherence and participation in planning the treatment regimen (Powers & Bendall, 2003). In self-administered treatment devices, patient empowerment plays an essential role, as patients are responsible for the administration of the treatment. However, the communication factor between the patient and the clinician is one of the most challenging factors, as it may be hard to maintain the self-administered treatment even though it is crucial to improve adherence.

Gamble et al. (2011) have indicated that poor adherence increases the burden of controlling asthma. However, adherence improves after involving the patients in concordance meetings with the clinicians.

6.7 Patient Monitoring

As highlighted earlier, a number of external factors impact patient adherence and behaviour change, such as the external locus of control in the Locus of Control theory (Rotter, 1966), the environmental cue in SCT (Bandura, 1986) and the subjective norm in perceived action and planned behaviour (Ajzen & Madden, 1986).

Health technology provides an opportunity for the clinician to monitor a patient's data without the need for the patient to be in a hospital or a clinic during the monitoring. This

helps clinicians gain a better understanding of the patient's disease and provide effective treatment (Car et al., 2017).

6.7.1 Follow up and reminders in adherence

Fenerty et al. (2012) conducted a meta-analysis study that systematically reviewed four randomised controlled trials (between 1999 and 2009) related to reminded intervention and how it may improve patient adherence. The study concluded that reminders may improve patient adherence to medication. However, this application cannot be generalised to different types of diseases and needs to be adapted for 'alternative adherence-modifying strategies' (Fenerty et al., 2012. p.127).

Another meta-analysis conducted by Vervloet et al. (2012) explored the role of electronic reminders in improving adherence in the treatment of chronic diseases. In this study, a varied number of electronic methods were used to remind chronic disease patients to take their daily medications. The study concluded that electronic reminders can improve adherence in the short-term. However, the long-term impact of electronic reminders is not clear.

6.7.2 Adherence and technology

Medical technology can provide an opportunity for the clinician to better observe patient adherence and improve it using different types of technologies. For instance, using the short message system (SMS) on a daily basis for a short period has been shown to improve patient adherence to anti-asthma medications (Strandbygaard et al., 2010).

Using monitoring devices and strategies such as the Self-Reporting Adherence Questionnaires (SRAQ) can play a crucial role in improving patient adherence, especially for self-administered treatments (Bus et al., 2012; Shi et al., 2010).

6.8 Information, Motivation, Strategy

The theoretical factors of adherence present challenges when identifying the factors underpinning adherence behaviour. This is because: 1) some factors are shared between theories or hold similar meanings, such as consequences (social learning theory), perceived barriers and benefits (health belief model), and threat appraisal (protection motivation theory); and 2) some factors are addressed from different perspectives in each theory. For example, the environmental cue in social learning theory refers to the external environment in which the patient is located while doing the behaviour. In the theory of reasoned action/planned behaviour, the concept of subjective norm holds similar characteristics compared with the environmental cue concept.

A general classification of the nature of adherence factors is required if companies are to easily consider them. One of the most interesting classifications of adherence factors is the three-factor model presented by Martin and DeMattio (2013). In this model, the adherence drivers are classified into three main factors: information, motivation and strategy (I-M-S). The main aim of the model is to provide a practical guide for clinical action. Towards this end, the model addresses three main aims:

- Ensure the patient has the right information related to how to adhere to the treatment, which includes listening to the patient's concerns, encouraging patient's partnership in decision making, building trust and empathy and enhancing recall.
- Help the patient to believe in the treatment and commit to it by addressing different cognitive, cultural, social and normative factors.
- Help the patient to overcome the barriers to treatment adherence and develop strategies for chronic disease management (DiMatteo et al. 2012).

The above model presents a practical guide for clinicians to build a strategy to improve patient adherence by focusing on the general factors that affect adherence in the majority of diseases. This model was developed based on a meta-analysis study of the literature from 1948 to 2001 (DiMatteo, 2004). The simplicity and adoptability of the model make it more efficient than following the theoretical factors of adherence. However, in the interest of this research, two observations should be noted:

- The model can work effectively with physicians, as they have experience with the diseases they specialise in and how patients adhere to the prescribed medication. However, for new companies working on delivering medical technologies, this model becomes challenging to adopt when manufacturing treatment devices and measuring the efficiency of adherence factors.
- The I-M-S model considers the general factors that affect patient adherence in controlled non-technological treatment interventions. When the treatment is a self-administered device, the adherence involves other factors, such as how the adherence will be monitored and measured. Furthermore, the model considers how the design and function of the medical device contributes to adherence to the treatment regimen.

According to the above, in order to guide and measure how adherence is considered in self-administered treatment devices, a more inclusive and achievable Adherence Canvas is required. This model should consider the nature of self-administered treatment devices and the contexts of their use.

Figure 6.3 presents a visualisation of examples of 1) the theoretical frameworks of adherence, 2) the factors in each theory, 3) communication-related factors, and 4) design-related factors. Furthermore, the figure links and re-orders the factors into categories as described below:

- Examples of the adherence theoretical frameworks (blue) are presented on the right side. Some theories are linked to each other (grey lines). In some instances, the Social Learning theory overlaps with other theories, such as the Health Belief Model. For example, in the Social Learning theory, the expectancies factor refers to the expected outcome of the intervention, which aligns with the Health Belief Model factors of perceived barriers, benefits and severity. The expectancies factor in the Social Learning theory includes the environmental cue (sub-factor) that refers to the patient's environment and its social and cultural impact on adherence. The environmental cue is described in Researched Action/Planned Behaviour theory as the subjective norm.

- In linking different factors and their relationship to each other, three main categories can be identified: Motivation, Knowledge and Communications. The latter category can map onto other factors that are not listed in the adherence theories but can affect patient adherence. The communication between patient and clinician can lead to a higher level of adherence as highlighted in the literature (Chapter 6: Theoretical Factors of Adherence) and case studies interviews (Chapter 9: Case Studies Interviews). Factors such as the environmental cue (Social Learning) and subjective norms (Reasoned Action/Planned Behaviour) have communication aspects as they involve social interaction.
- In medical technologies, the patient experience extends beyond behaviour change factors to involve design aspects, as highlighted by the five case studies interviews (Chapter 9: Case Studies Interviews). The lack of linkage (grey lines) between the Experience category and the adherence theories confirms the design aspects' lack of consideration in physical and digital treatments.

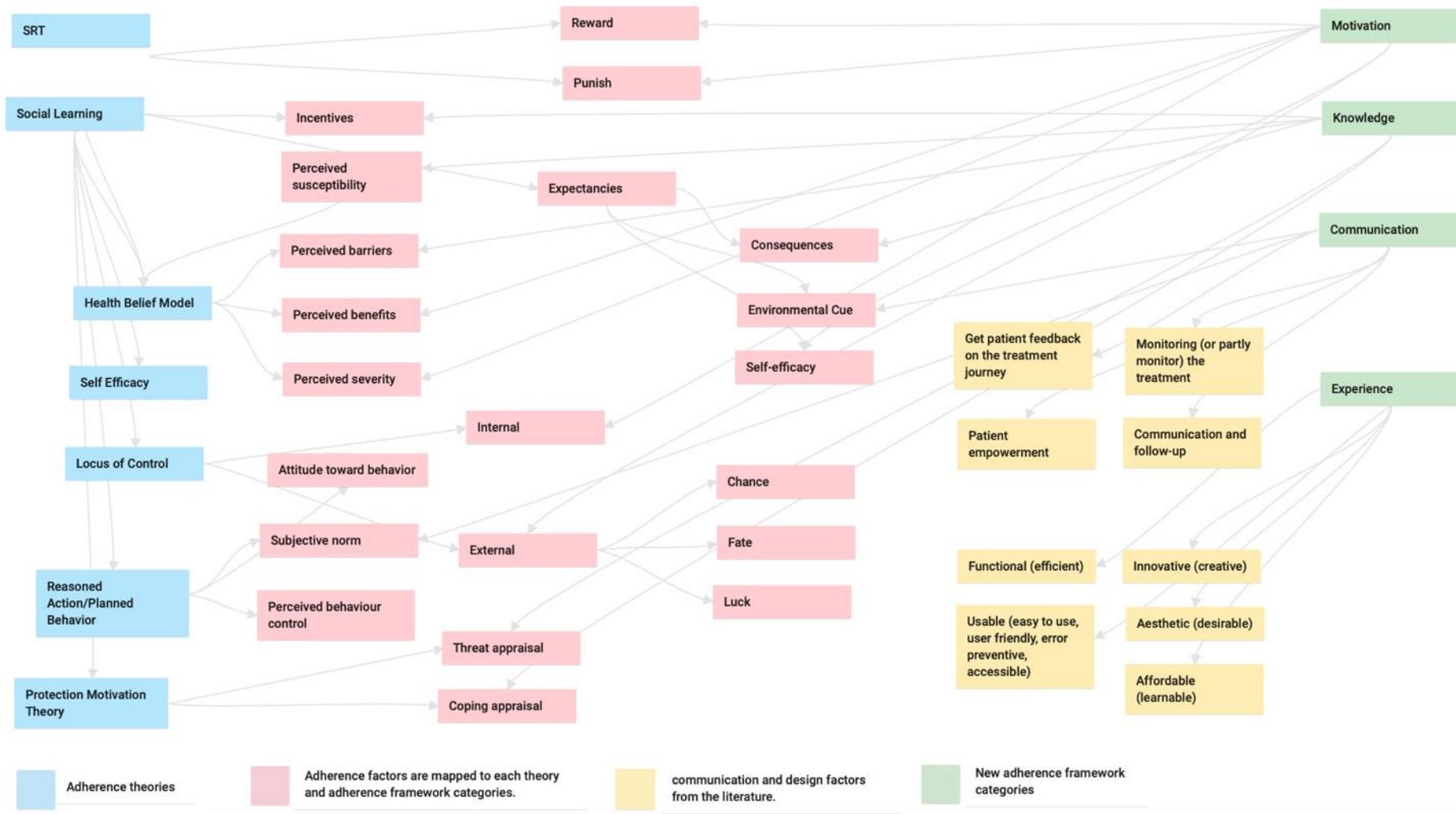


Figure 6.3 Adherence factors linked to the theories on the left and the categories on the top right.

The theories cover adherence factors in general without considering that the factors that affect adherence may vary depending on the disease (Bosworth, Weinberger, & Oddone, 2005). Other aspects can determine the factors which affect adherence, such as the nature of the treatment, patient demographics and the circumstances associated with the treatment regimen. Thus, while common factors can be used in general consideration, these factors may need to be refined as a clear understanding of the patients, treatment and disease becomes available.

6.9 Adherence Factors in Different Diseases

Theoretical Adherence factors aim to understand the factors that affect how patients adhere to a treatment regimen. However, the impact of adherence factors may vary depending on the disease. For example, a number of factors stand as barriers to adherence to weight loss and diet recommendations. The barriers affect patient adherence and therefore the patient's ability to achieve the recommended goal, as well as to continue adhering to clinical recommendations after reaching the targeted weight. These factors include lack of income or resources, cultural factors, lack of motivation and especially patient knowledge, which may involve complex dietary information (Bosworth et al., 2005).

The frequency of the doses is a significant factor that affects adherence in the treatment of chronic disease. This being the case, the likelihood of adherence to one dose per day is higher than the likelihood of adherence to an intervention that involves two or more doses per day (Saini et al., 2009). Another example is the statin therapy used for the prevention of cardiovascular disease. A number of factors affect patient adherence to the statin therapy, including:

- Patient factors, such as comorbidities, financial issues, the constraints of adhering to the therapy and psychological issues.
- Practitioner factors, such as knowledge and education, time limitations and poor communication skills.
- System factors, such as lack of monitoring, financial barriers, and medication side effects (Bates et al., 2009).

6.10 Behaviour Change

The desk search used design-related keywords such as “Behaviour Change” in place of the keyword “Adherence”, which are used more frequently in healthcare, medical, and psychological knowledge. Behaviour change was used along with “Design” and “Patient” keywords in the search query (Behaviour change, design and patient) to identify the literature related to the usage of design to drive patients’ behaviour change. Using the last query, the results reflected research about using factors such as motivation and gamification to drive behaviour change in patients with diseases such as cardiovascular diseases (Gallagher et al., 2019; Pfaeffli, 2016). The research results retrieved several applications, including the Behaviour Change Wheel (Michie, Van Stralen, & West, 2011). The Behaviour Change Wheel includes more details about the wheel and the COM-B model. The model has been used to develop interventions for cancer patients (Webb, Foster, & Poulter, 2016). The Behaviour Change wheel presented an interesting approach that presents a practical tool to consider behaviour change factors based on a COM (Capabilities, Opportunities, and Motivations) model. However, the following can be observed:

1. It does not focus on self-administered health technology. So, several elements were not considered, such as usability, user experience, and product characteristics.
2. While it provides a guide to different behaviour change factors, it does not provide a practical guide to evaluate these factors during the development process.
3. It does not provide levelling feature that can be used to rate the importance of behaviour change factors. The feature is needed, especially with building a behaviour change strategy that involves more than one factor.

Another type of literature addressed the outcome of behaviour change solutions rather than considering it, such as implementing mobile-health behaviour change interventions in cardiovascular disease self-management and using the behaviour change to encourage physical activities for cancer patients. In another study, The COM-B model improved self-care adherence in heart failure patients (Herber et al., 2018).

6.10.1 Persuasive Design and Behaviour Change

“Persuasive Design” is a design-related term that aims to use design as a persuasive tool to change behaviour. When searching using Google Scholar using the search query (persuasive design and patients adherence), the results mainly came from the medical and psychological publications similar to using the term “Behaviour Change”.

The search for persuasive design showed results related to the usage of persuasive technology design to encourage patients to behaviour change. The observation shows a close connection in the search results related to using persuasive design to influence behaviour change (or adherence) to technology such as web-based intervention (Kelders et al., 2012), e-health design (Baumeister et al., 2019) and home health-monitoring systems (Rezai, Torenvliet, & Burns, 2014).

Fogg (2009) presented the FBM, which connects both persuasive design and behaviour change. The model is built on three main elements: motivation, ability and behaviour trigger. The trigger to behaviour change occurs when the person receives a sufficient level of motivation and simplicity. In FBM (Figure 6.3), the motivators are factors that can drive a person to change behaviour, and these motivators include three factors that vary from high motivation to low motivation:

- Pleasure/pain
- Hope/fear
- Acceptance/rejection

The factors above present the scale of motivation. For example, pleasure is linked to high motivation, whereas the pain is linked to low motivation. The scale of the ability (simplicity) refers to how simple is the change from the perspective of six factors:

- Time
- Money
- Physical effort
- Brain cycles
- Social deviance

- Non-routine

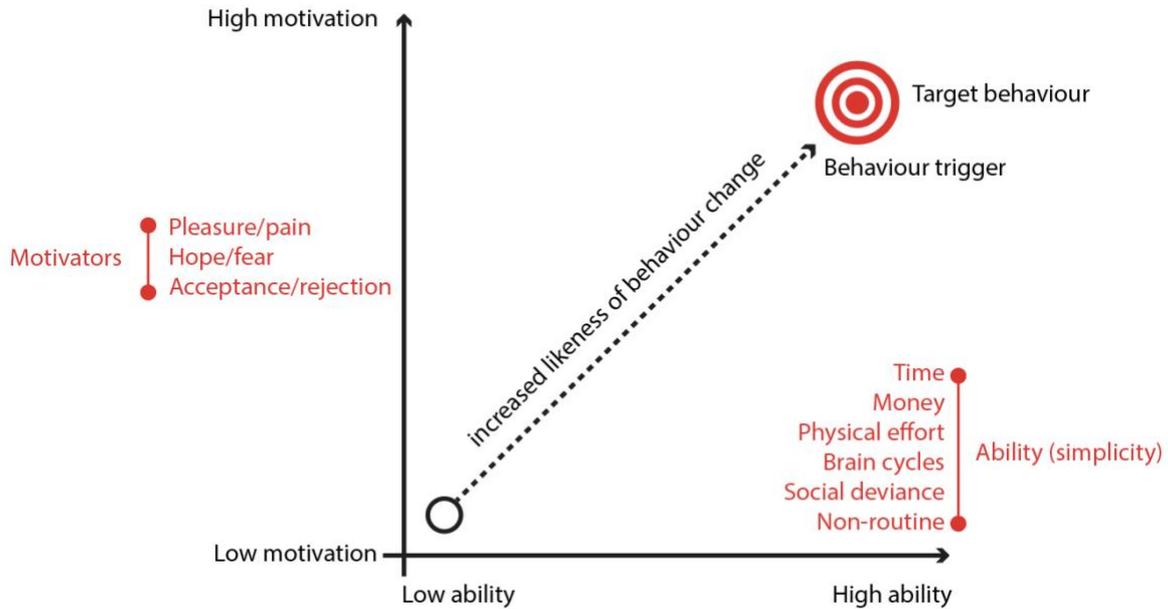


Figure 6.3 Fogg Behaviour Model (Fogg, 2009)

Fogg's model appreciates the complex nature of behaviour change and relevant factors in driving behaviour change. Many attempts at persuasive design fail because of the lack of understanding of the factors that lead the behaviour change (Fogg, 2009).

Another search query used as a synonym for "Persuasive design" is "Captology", which refers to using computer technology as a persuasive tool. Both terms are used in design and technology domains. The results were not sufficient when a combination of keywords "Persuasive design", "Captology", "Adherence", and "Behaviour change" were used.

The search for the terms above has revealed that most of the literature is presented from the psychology, medical and healthcare perspectives. A lack of studies from the design scholars in this area, especially how the mechanisms that drive adherence are defined and considered during the PDP. This finding presented a sub-claim as highlighted in Chapter 14 (14.2 Research Claims and Contribution to Knowledge).

6.11 Findings and Summary

Adherence presents one of the major challenges that face healthcare systems, as it has direct impact on 1) the efficacy of the treatment results (or other clinical testing procedures, including focus groups and advisory groups) (Viswanathan et al., 2012); 2) the difference between efficacious and effectiveness trials results; and 3) the real-world results of using the product (Car et al., 2017). The scope of the adherence literature investigation in this chapter involves non-adherence in the treatment of chronic diseases (Barnett, 2014; Bourbeau & Bartlett, 2008; Nunes et al., 2009; Sabaté, 2003) and self-administered treatments (Becker, 1985; Hall et al., 2016; Lebovits et al., 1990) as they present a high risk of non-adherence occurrence, as discussed in detail in 6.2.1 Non-adherence in the Treatment of Chronic Diseases and 6.2.4 Treatment Administration and Adherence.

A clear understanding of the theoretical models of adherence is required in order to explore its potential during the design process. Adherence theories have focused on either the factors that affect adherence or the steps that are taken toward the behaviour change. Factor-based theoretical models were overviewed to understand the factors that drive adherence and subsequently consider these factors in the design of the treatment technology. The other factors that affect adherence were discussed, especially the communication between patients and clinicians and the role of technology in improving adherence.

Four main observations can be found from the literature overview of the theoretical frameworks related to adherence:

1. The adherence theoretical frameworks did not consider providing, nor provided, a practical solution to consider adherence in the design and development of the medical intervention.
2. The theoretical frameworks did not consider the special characteristics that make medical technology different from pharmaceutical treatments. As a result, factors such as user experience, aesthetic look of the treatment and functionality of the treatment were not considered to be part of the factors.

3. The adherence theoretical frameworks did not consider patient-administered treatment in proposing that adherence behaviour is affected by whether the treatment is clinically administered or self-administered by the patients.
4. Communication-related factors were either not considered or not sufficiently considered. The theoretical frameworks overviewed did not consider the importance in communication and its role in patient empowerment.
5. There is a significant lack of the design literature about patient adherence especially in relation to providing solutions for companies to consider it in the development of the healthcare technology.

Understanding the theoretical factors of adherence provides an essential cornerstone in the design process for medical technology. Overlooking the literature about design thinking can lead to a better understanding of how adherence factors can be considered in the design process to develop patient-centred medical technology.

Chapter 7: Design Thinking

This chapter explores the literature on the design thinking process, focussing on the characteristics which can add value to the design of self-administered treatment technology. Furthermore, the value and the challenges of applying design thinking will be discussed from the perspective of its benefits for medical technology innovation.

Key Topics:

- 7.1 The Nature of Design Thinking
- 7.2 Design and Creativity
- 7.3 Design Thinking as a Process
- 7.4 Voting in Design Process
- 7.5 Design as a Driver for Innovation
- 7.6 The Multi-Perspective Problem Framing (MPPF)
- 7.7 Innovation in Small and Medium Enterprises SMEs
- 7.8 Evidence-Based Design
- 7.9 Summary and Findings

The term 'design thinking' has been commonly used over the last two decades to refer to a tool that companies use to achieve innovation. However, the philosophical approach behind design thinking has been blurred due to the over-commercialisation of the term by those who lack a clear understanding of the core value behind it (Kimbell, 2011). This chapter will clarify the core value of design thinking. It will furthermore discuss why design thinking has been used as a framework to design and develop medical technology treatments.

This chapter will explore design characteristics to identify the potential role of design thinking in driving innovation in medical technology SMEs. Over the course of this literature review, this chapter aims to answer the following two questions:

- What are the characteristics of the design thinking process?
- What are the barriers to and opportunities for adopting design thinking?

Over the course of answering the above two questions, the main reasons behind focuses on design thinking as a process used to design and develop medical treatment technologies will be addressed.

7.1 The Nature of Design Thinking

Scholars have been interested in the nature of design thinking since the early 20th century, and especially in the rise of craftsmanship and initiatives that have sought to define design practice as either a science or an art. The philosophical approaches that inform design thinking contribute to the nature of the design process, especially in how it addresses problems.

Simon (1968) defined design thinking, stating that: 'the proper study of mankind is the science of design, not only as the professional component of a technical education but as a core discipline for every liberally educated man' (Simon, 1968, p.83). Buchanan (1992) discussed John Dewey's view on design as a liberal art, which Dewey described in his *The Quest of Certainty*:

‘The old centre of the universe was the mind knowing by means of an equipment of powers complete within itself, and merely exercised upon an antecedent external material equally complete within itself. In this new centre is indefinite interactions taking place within a course of nature which is not fixed and complete, but which is capable of direction to new and different results through the mediation of intentional operations.’ (Dewey, 1960, p.91).

Dewey defined design thinking as a new liberal art, different from the traditional arts. This new definition, acknowledged by Buchanan, gave it an adaptive progressive nature.

Buchanan described this ‘liberal art’ as an ability that exists in all people, but some are more talented in utilising it in professional practice. Furthermore, Buchanan described the term ‘design thinking’ as expandable (Buchnan, 1992). Dewey’s and Buchanan’s descriptions of design thinking gives it a constructive pragmatic perspective which is a different view from Simon’s.

Cross (2011) supported Buchanan’s and Dewey’s understanding of design in his description of design ability. Cross highlighted Rowe’s observations of architecture design case studies. Rowe observed architecture case studies of large buildings in major American cities. In Rowe’s observations, designers were found to regularly switch between solution concepts and problem exploration in the design process (Rowe, 1987). This nature of design is addressed by Schön (1938), who describes the process through which designers address the problem as ‘a reflective process’ or ‘a reflective conversation with the situation’ (Cross, 2011. p.56).

Dorst (2010) developed his definition of the nature of design thinking around the abductive nature of design. For Dorst, abductive reasoning is one of the reasoning patterns used to solve problems based on what we know and do not know. He highlighted three main patterns:

- **Deductive:** Both ‘What’ (the elements of the system) and ‘How’ (how the elements work together) are known. Accordingly, the ‘Result’ can be accurately defined.
- **Inductive:** The ‘What’ and ‘Result’ are known. Accordingly, the working principle or the process ‘How’ can be predicted.

- **Abductive:** Dorst defined two forms of abductive reasoning. In the first form (problem-solving), both 'How' (the working process) and the 'Value' that needs to be achieved are known. Next, the system element 'What' needs to be figured out. In this case, the missing part is the designed product or service. In the second form, we do not know 'What' or 'How' but we do know what we need to achieve (Result). Therefore, we need to find out (or create) working principles and the elements or systems needed to achieve the value.

This nature emphasised the importance of testing in the design process, as designers need to test the different ideas (what) in the specific scenario (how) in order to achieve value.

This process moves from the problem space to the solution space and back again. It builds an intuition within the designers, which shifts the creative nature in design toward creative solutions and testing and improving those solutions.

7.2 Design and Creativity

The literature studies discussed earlier (7.1 The Nature of Design Thinking) presented evidence that design thinking is a driver of creativity and supports creativity in the design practice (Buchnan, 1992; Cross, 2011; Dewey, 1960; Rowe, 1987). This aligns with the International Council Societies of Industrial Design (ICSID)'s definition of design. The ICSID highlighted two main characteristics of design:

1. Aim: Design is a creative practice that aims to create an object, process or service, among others, and
2. Task: Design seeks to discover and assess the current situation to reach an improved state, such as enhancing global sustainability, giving benefits and freedom to people, supporting cultural diversity and giving products an aesthetic form and appreciating the complexity (De Mozota, 2003; Manzini, 2006).

The latter two definitions appreciate two main characteristics of design: 1) the creativity, form and aesthetics of the product or service; and 2) the move from one status to an improved one (addressing needs). These characteristics align with Tim Brown's definition of

design thinking as 1) a human-centred approach; 2) innovative; 3) targeted to address people's needs; 4) making the product desirable aesthetically; 5) technologically viable; and 6) feasible from the business perspective (2011). Other definitions for design thinking indirectly highlighted its support for creative practice, such as Dorst's (2012) definition of design thinking as a practice which can resolve issues with a broad approach and can be implemented to address both business and social problems. English et al. (2010) indicated that professional design practice resolves issues with a broad approach which reflects the multi-perspective approach to solving the problem. The unique opportunity to focus on the problem frame and understand the relationship between the problem frame and solution frame allows companies to leverage creative thinking and brainstorming in order to explore the problem space (Dorst, 2015). Keeping in mind the nature of medical technology, and how it originates from a clinician-administrated approach, the shift toward a patient-administered treatment may present a challenge, especially when considering patients' behaviours and experiences. The characteristics highlighted above can contribute to addressing this challenge in self-administered treatment devices, especially by addressing patient needs with creative solutions.

7.3 Design Thinking as a Process

Design thinking is a process that aims to identify innovative solutions through deep exploration of the problem space (Brown, 2011; Dorst, 2015) and move decisively to define the problem and evaluate prototypes in order to reach the final deliverable product (Cox, 2005). This early definition of the problem doesn't apply to wicked problems when the problem cannot be clearly defined until the end of the process (Coyne, 2005; Roberts, 2000). Several design thinking models have been presented which reflect the nature of the design as a process (Cox, 2005; Dorst, 2012) such as the Double Diamond (Design Council, 2015), IDEO D.School and IBM Design Thinking. While design thinking process models vary in the number of stages and how the process works, they follow similar sequential steps from exploring the problem, defining it, and move to developing of the solution such as the

Double Diamond (Figure 7.1).

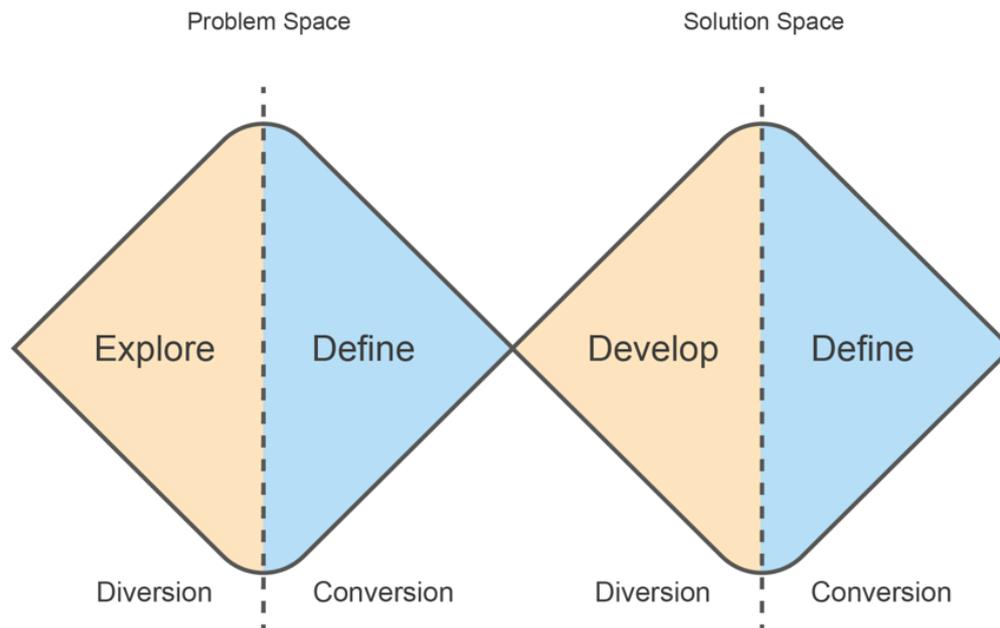


Figure 7.1 The diversion and conversion stages in the Double Diamond (Design Council, 2015). Adopted from Dorst (2015).

- The Diversion stage is where the ideas are explored in an inclusive environment. The nature of this stage remains the same in both the problem and the solution spaces, while the application differs. In the problem space, the diversion stage explores the problem from multiple perspective. In the solution space, the diversion stage aims to develop different prototypes and test them in order to reach a solution that is human-centric, viable from the business perspective and technologically feasible (Brown, 2011).
- The Conversion stage aims to filter ideas, excluding the ones that do not contribute to achieving the business target. In the problem space, the conversion stage aims to refine the problem for the subsequent prototyping stage. The second conversion stage is delivery, where the prototypes are refined, and one design is selected to be processed.

The Double Diamond in Figure 7.1 presents another characteristic of the design process, which is the iteration and prototype improvement (Design Council, 2015). Pugh (1990) presented the concept of ‘total design’, an iterative model in which the information is

shared with all the departments and from the early stage (Figure 7.2). The user is placed at the heart of this model in order to develop a product that meets consumer needs. In addition to the above benefits that design can add to the development of medical technology, challenges related to the adoption of the process need to be highlighted below: 'The design process is less scientific, and this may present a challenge to adopt the process in the current system as design process considers both user, technology, and business equally.' (Design Council, 2007, p.8)

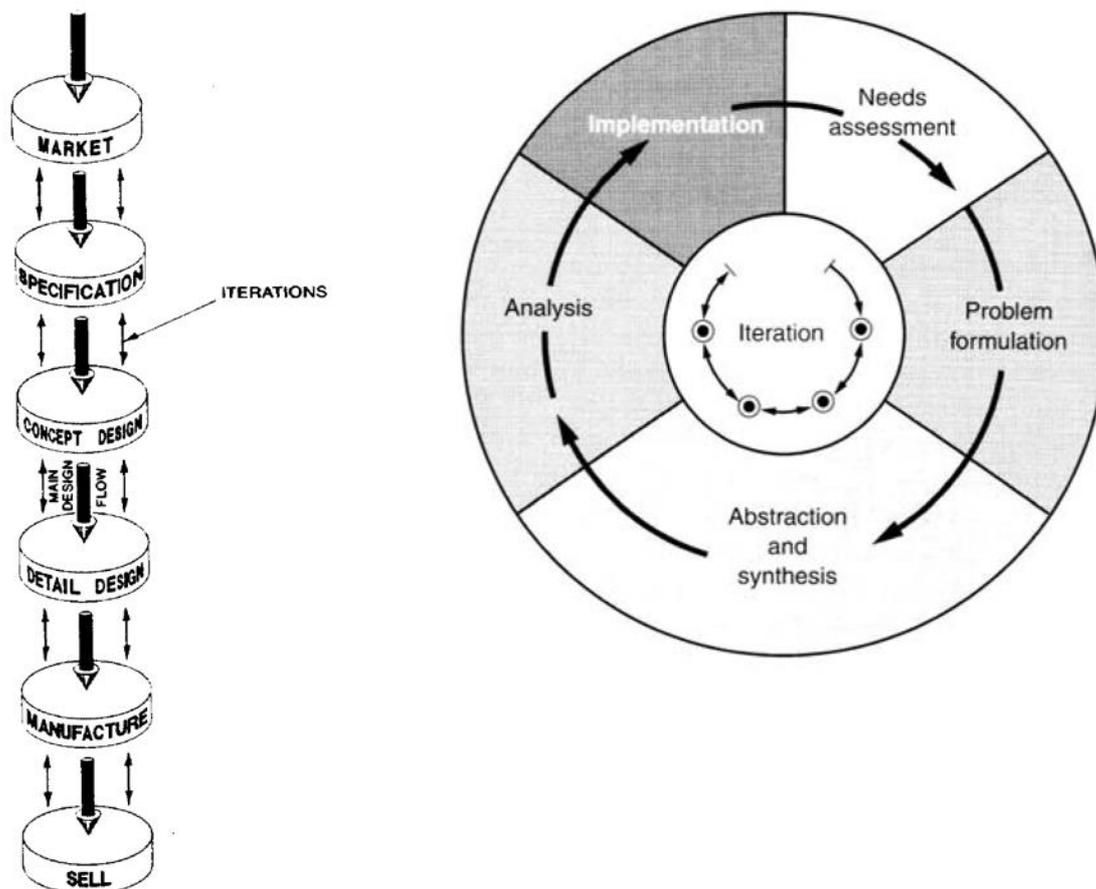


Figure 7.2 An iterative model (total design) by Pugh (1990). Source: (Council, 2007).

The world is evolving quickly, which makes it unrealistic to dictate a fixed methodology or a process. To this end, Cross (1994) was one of the first to look at this challenge from the engineering perspective. In *Engineering Design Methods*, he provided tools that help designers and engineers work together (Figure 7.3). While his model is related to engineering, his approach opens the door for further investigation into the integration between the design process and medical science.

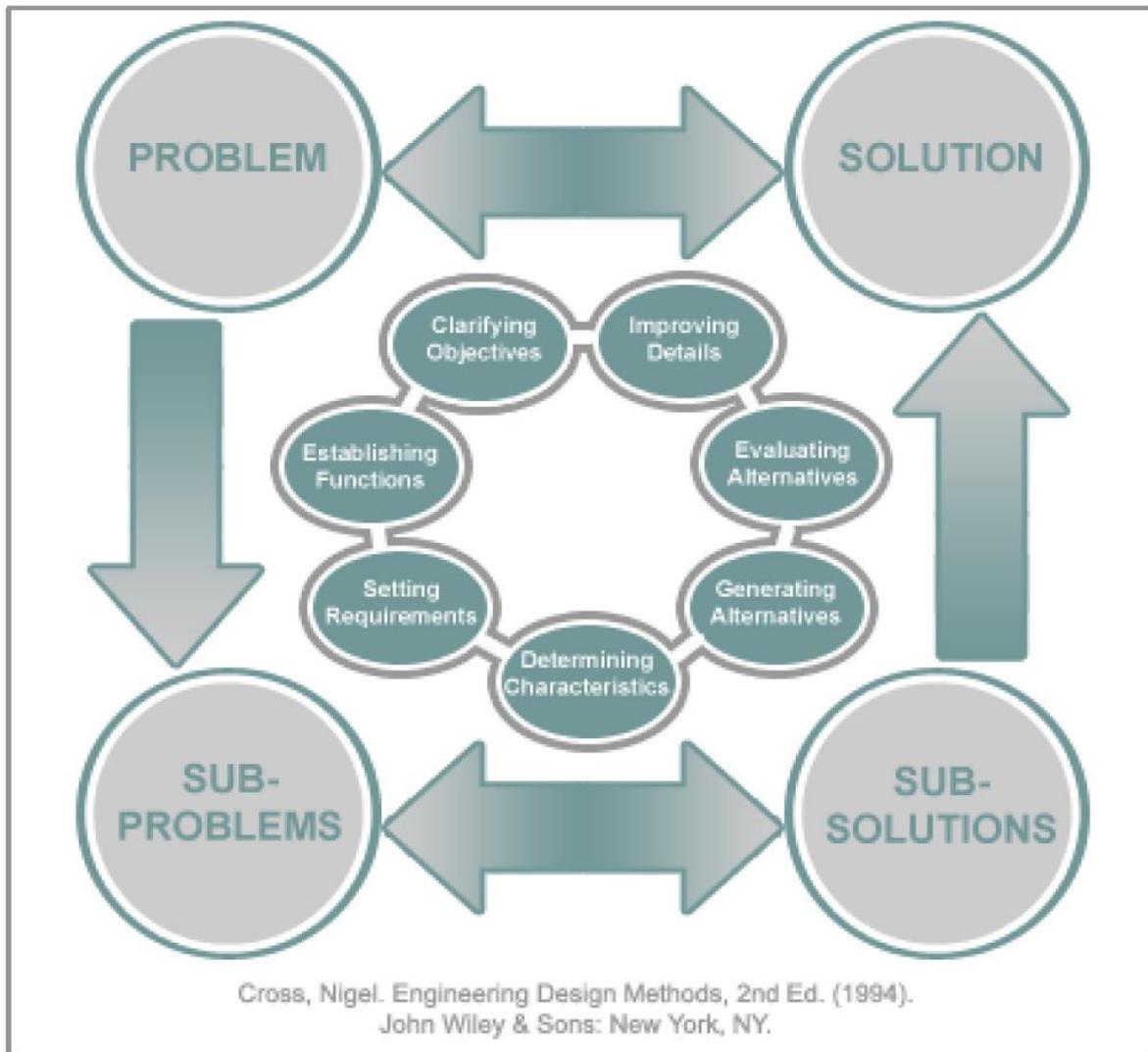


Figure 7.3 Cross (1994) for integrating both design and engineering. Source: (Council, 2007). This realistic look at the design process and how it works in real life companies is supported by Clarkson and Eckert's (2005) model (Figure 7.4). In this model, the design process does not move rigorously toward product development and delivery. However, it faces 'constraints' and 'drivers'. Therefore, the process needs to be generic and adaptable in order to face development challenges (Council, 2007). Best (2006, p.114) indicated: 'Design processes are difficult to standardise, in part because of their iterative, non-linear nature, and also because the needs of clients and users are so different.'

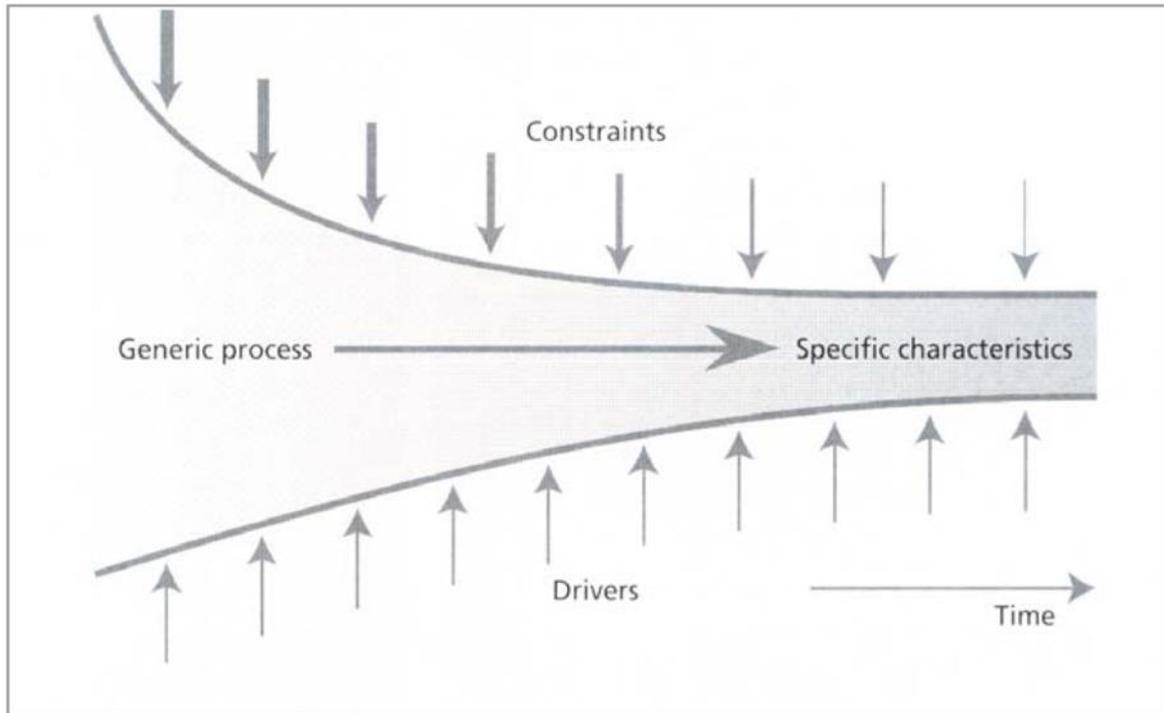


Figure 7.4 Clarkson and Eckert's (2005) model of adaptive design process.

According to the above exploration of the design process, a number of values can be realised through adopting the design thinking process including:

- **Creativity:** Several studies support the creative nature of the design process (Brown & Katz, 2011; Cross, 2011; Dorst, 2015; Kimbell, 2011; 2012). The divergent nature of the design process, especially in the Explore and Develop stages (based on the Double Diamond), encourages creative thinking and idea generation (Design Council, 2015). According to Benkenstein's (1998) innovation funnel model (Figure 7.5), the larger the mouth of the funnel, the more ideas are driven toward the R&D stage (Acklin, 2010).
- **Human-centric approach:** Similar to creativity, several studies have highlighted the focus on human needs and on solving problems associated with those needs' (Brown, & Katz, 2011; Giacomini, 2014; IDEO, 2015; Zhang & Dong, 2009). Design thinking focuses on the problem from three main perspectives: business, technology and human needs (IDEO, 2015).
- **Iterative process:** The design thinking process is distinguished from many other approaches with the appreciation of iteration through prototyping and testing

(Ballard, 2000). The design process shares some of these characteristics with the lean process (Motwani, 2003). These characteristics contribute to building human-centred products and services.

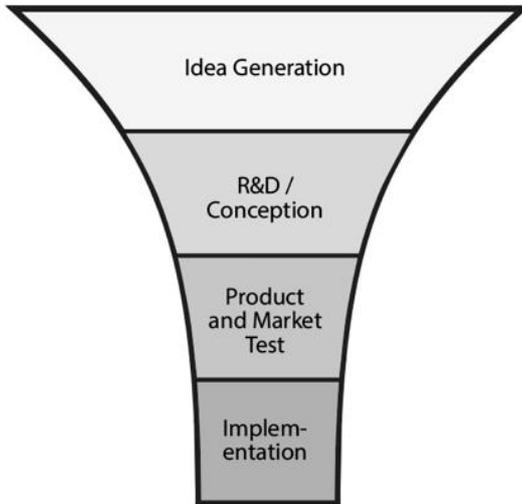


Figure 7.5 Benkenstein's innovation funnel model (Benkenstein, 1998).

7.4 Voting in Design Process

Voting is used by participants (i.e. design team) to determine the priority between a number of choices. Voting is utilised in a number of tools such as the affinity diagram, where participants vote for the priority of multiple elements or severity level of a number of problems such as software problems. (Alänge, 2009; Elmansy, 2016a). Design sprinting is another method that utilises voting to select between a number of layout design options (Banfield, Lombardo, & Wax, 2015; Elmansy, 2016b). Design sprinting is an iterative lean practice (Knapp et al., 2016) that drives innovation through an experimental process, where participants create wireframes for the applications' UI. A voting session is then applied to collect an agreement on which is the wireframe that is selected and processed to create the final design (Magistretti, Dell'Era, & Doppio, 2020). Design sprinting is used to develop prototypes into products during action design research (Keijzer-Broers, & de Reuver, 2016) and design thinking (Magistretti, Dell'Era, & Doppio, 2020).

7.5 Design as a Driver for Innovation

Cox (2005) defined the relationship between design and innovation. Cox indicated that design works as a process and catalyst to transform creative ideas into innovative products. This relationship works as an equation in which design describes the core process:

Creative ideas — Design —> Innovative products

Based on the above equation, design is the core tool (process) with which to achieve innovation regardless of the creative idea or the target market. Carpenter & Nakamoto (1990) defined design as an innovation that can add value, achieve profits and influence consumer preferences (de Mozota, 2003).

Battistella et al. (2012) explored the theoretical relation between innovation management and design from the innovation management perspective, highlighting that innovation management no longer focuses on technology and innovation alone (Chandy & Tellis, 2000). Instead, value is driven by building human-centric products, services and experiences. This shift toward design-driven culture represents the new boundary of business innovation (Geels, 2004; McCracken, 1986; Verganti, 2008). It presents an approach which focuses on the subjective meanings people ascribe to the product (Krippendorff, 1989). Verganti (2008) highlighted that every product has a meaning that reflects why people need the product and what they need from the product.

7.6 The Multi-Perspective Problem Framing (MPPF)

Multi-Perspective Problem Framing (MPPF) is a theoretical approach introduced by English (2008) to address complex problems. It is based on De-Bono's (1996) idea of breaking out of established ways of seeing in order to visualise new patterns that allow new design opportunities. The MPPF approach builds on radiant mind mapping techniques (Buzan,

1996) to create conceptual networks where new patterns and ideas can evolve. These patterns contribute to a new understanding of the problem, which leads to innovative solutions (Figure 7.3).

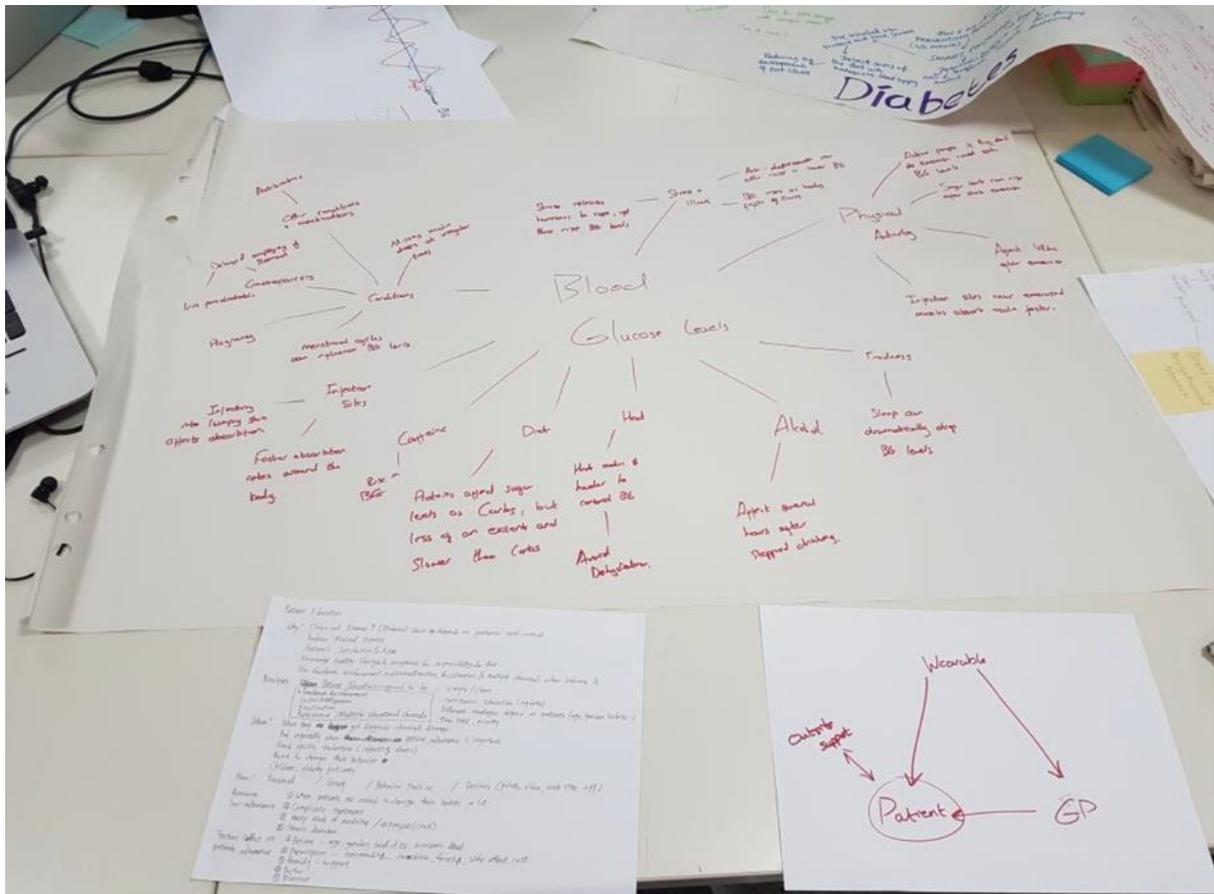


Figure 7.6 Example of a radiant map from the WearCare II project (Source: team 2 final presentation).

Radiant mind maps are utilised to build single perspective problem framing. Buzan (1996) introduced the radiant mind map as a diagram that includes a centre concept, such as an idea or a problem. Radiant mind maps start with a single centre of enquiry in the middle of the map and lead to single perspective problem framing. (Figure 7.4).



Figure 7.4 Team 2's integrated mind map from WearCare II project (Source: team 2 final presentation).

7.6.1 Cornerstones and Utilisation of integrated mind maps

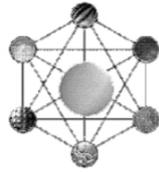
Integrated mind maps simulate the brain's ability to build connections. They have multiple centres of enquiry and branched ideas connect to develop complex patterns (Taylor, 2007).

Integrated mind maps are used to frame value through the definition of Cornerstones of Innovation (English, 2007). This can be seen in Figure 7.5.

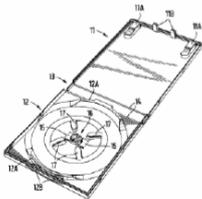


Figure 7.5 The key cornerstones defined by the WearCare II project (Source: team 1 final presentation).

Links that connect integrated mind maps help to define key cornerstones that can be used to identify potential value innovations. The cornerstones of innovation are used to frame design solution as highlighted in the value innovation case studies in Figure (7.6).

Design**Cornerstones
of Innovation****1. IR Lighting**

Low tooling budget
 Patented lens / reflector technology
 Sealed to IP 66 minimum
 Fast assembly
 Heat dispersal

**2. DVD Case**

Design for a VHS Video case manufacturer
 Springy Polypropylene material
 Nested cosseted treasured
 Push-button release
 Developing DVD Technology
 Very high volume

Figure 7.6 Examples of the cornerstones of innovation and the application to a product (English, 2007, p.4).

7.7 Innovation in Small and Medium Enterprises SMEs

Two main reasons behind the decision to focus in this thesis on SMEs working in medical technology innovation are:

1. SMEs make a key contribution to the world economy (Birch, 1989; Bommer and Jalajas, 2002; Lukács, 2005; Oke et al., 2007; Nauwelaerts et al., 2012). In the EU, SMEs represent 98% of the economy of member states combined. 93.2% (19.3 million enterprises) are considered small companies with less than 10 people (Lukács, 2005). In the UK, SMEs contribute up to 50% of the national GDP, which motivates the UK government to support this sector and encourage its growth (Cox, 2007; Oke et al., 2007).

2. SMEs are creative in nature. In these firms, creativity is transformed into innovation through design (Cox, 2007). As part of this, SMEs contribute to the economy because the technical nature of the companies supports innovation on both the organisational level and national level. This means that the jobs these companies create are related to innovative discoveries and ideas (Savlovschi and Robu, 2011). In addition, SMEs play an essential and unique role in inventing new technologies and improving existing ones (Almeida, 2004). Henderson (2002) highlighted that enter- returners contribute to the economy on multiple levels, including creating new jobs, increasing local income and wealth and connecting communities with the larger global economy. In order to further understand the role of innovation in SMEs, both the benefits of and the barriers to innovation were examined.

7.7.1 Benefits of Innovation in SMEs

Several studies have shown the positive benefits of focusing on innovation in SMEs. These include administrative benefits, competitive advantages and increased profitability. A brief discussion of these benefits is presented below:

- Profitability

There exists a positive relationship between adopting innovation and achieving success in SMEs (Heunks, 1998). Studies have shown this correlation from the profitability perspective. Innovative companies have higher profitability, growth and market value than non-innovative companies (Cefis & Ciccarelli, 2005; Geroski et al., 1993; Leiponen, 2000; Oksanen & Rilla, 2009). However, studies have highlighted that superior quality is essential for SMEs to maintain their success in the market (Cooper, 1990; Cooper and Brentani, 1991). Therefore, Cho and Pucik (2005) introduced the innovativeness-quality-performance model, which presented three factors that should be balanced in order to achieve profitability and growth (Cho, & Pucik, 2005).

- Market competitiveness

Cho and Pucik (2005) indicated that a firm's ability to innovate and create high-quality products can lead to it achieving high market value and sustained

competitiveness ability. In their report, Proter et al. (1999) showed that many CEOs agree that new ideas and innovation should be at the top of a company's priorities if it is to achieve success in the market. Lawson and Samson (2001) indicated that putting innovation at the centre of organisational competitiveness can drive global competition and technological advancement.

- SMEs and economic growth

As highlighted earlier, SMEs play an essential role in economic growth. A large percentage of SMEs focus on innovative products, and this results in market competitiveness and contributes to economic growth. Additionally, SMEs face continuous pressures, such as competition from large companies and rapid technological change. As a result of these pressures, SMEs focus on improving their innovative capabilities (McAdam et al., 2004) and adopting strategic approaches and effective innovation management skills. These pressures and the competitive environment led to economic growth.

7.7.2 Innovation Barriers in SMEs

As highlighted above, SMEs can escape the market challenges especially the high competency through innovating (i.e. new products, services, or business models). However, Barriers cannot be ignored as it can stand the company and its goals. In, Figure 7.8, organisational barriers can be categorised into two types: internal and external barriers. Some barriers such as the financial barriers and unpredictable success are affected by both internal and external factors.

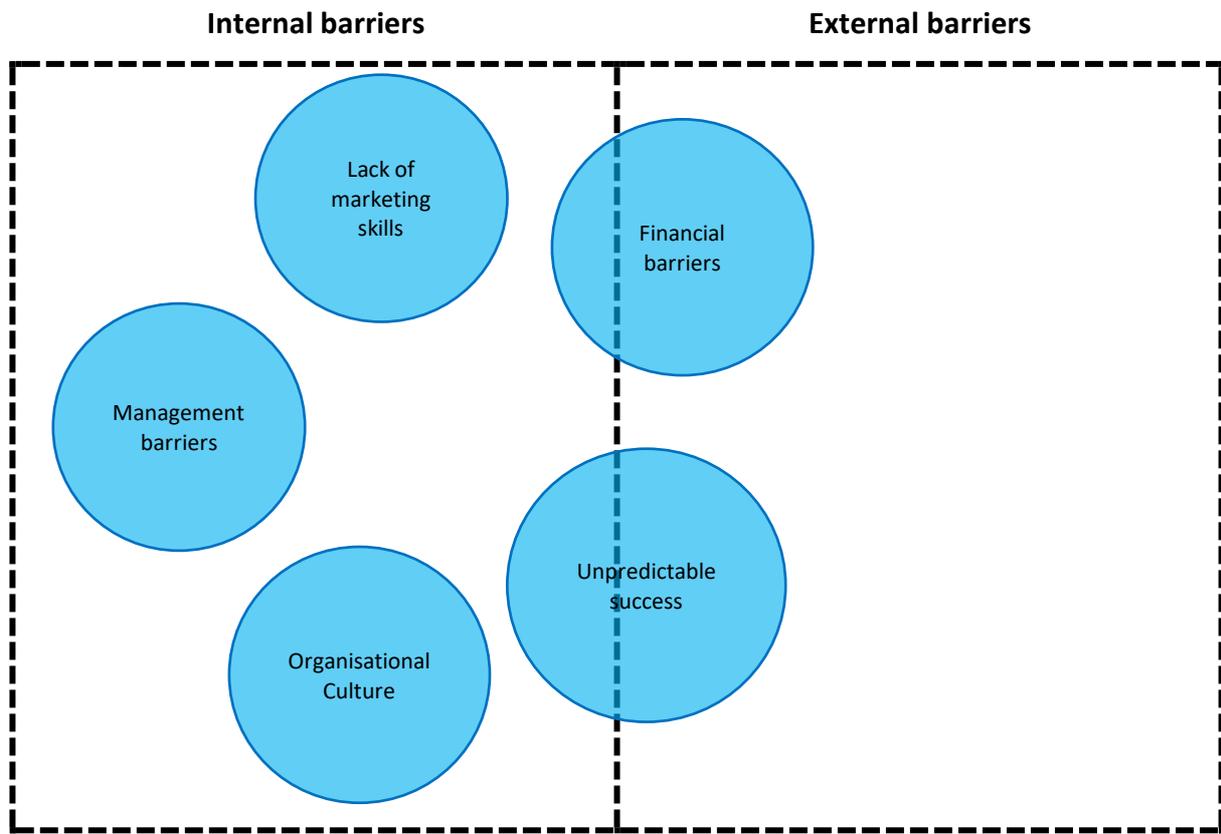


Figure 7.8 Internal vs external barriers (Larsen and Lewis, 2007; Nauwelaerts et al., 2012).

- **Financial barriers**

Financial barriers are among the top reasons behind SME failure and inability to achieve innovation (Larsen and Lewis, 2007; Madrid-Guijarro et al., 2009; Nauwelaerts et al., 2012). This is because financial barriers are complex and include elements such as short-term liquidity problems, insufficient working capital, insufficient funding, under capitalisation and poor financial management.

- **Marketing barriers**

Marketing skills are essential if innovative products are to be successful on the market (Foley and Green, 1995). Freel (2000) listed a number of factors that affect an organisation's marketing: poor planning, lack of expertise, insufficient marketing endeavours and discontinuity of management staff.

- **Management barriers**

Larsen and Lewis (2007) highlighted some factors related to poor management, including management experience, skills, determination to carry out innovation plans and the ability to judge situations and make decisions.

- **Organisational Culture Barriers**

Changing a company's culture to a design-driven one can stand as a barrier to adopting design thinking in the company's process. Trompenaars & Pru'hommer van Reine (2004) call this phenomenon an 'organisational culture dilemma'. In this state, there is tension between the design thinking innovation drive and the organisational drive. Table 7.1 visualises the relationship between organisational culture dilemmas (Trompenaars & Prud'homme van Reine, 2004) on the top row and the expected tension in design thinking for innovation (Prud'homme van Reine, 2015; Prud'homme van Reine & Dankbaar, 2009) on the bottom row. The organisation culture dilemma here is specific vs diffuse culture.

Organisation thinking	Analytic thinking	Product push	Focus on functional aspects	Closed innovation	Innovation as a structured process	Linear thinking	Individual creativity	Hierarchical leadership	Short term innovation
	↓	↓	↓	↓	↓	↓	↓	↓	↓
Organizational culture dilemmas	Specific (segmented thinking) vs Diffuse (holistic thinking)	Internal drive versus Responsiveness	Internal drive versus Responsiveness	Competing versus Partnership orientation	Consistency versus Pragmatism	Stable continuity versus Dynamic change	Individualism versus Group orientation.	Egalitarian versus Hierarchical cultures	Short term versus Long term orientation
	↑	↑	↑	↑	↑	↑	↑	↑	↑
Design thinking	Intuitive and creative thinking	User empathy	Focus on aesthetics and emotional aspects	Open innovation	Bricolage innovation	Non-linear, iterative processes	Group collaboration	Leadership in design thinking: Egalitarian	Long term innovation

Table 7.1 The organisational culture dilemmas. Modified from (Prud'homme van Reine, 2

7.8 Evidence-Based Design

Evidence-based design is a relatively recent trend, as it has developed in the last 25 years and is inspired by the evidence-based approach to decision making adopted in healthcare system (Ulrich et al., 2011). The term 'evidence-based' refers to the use of research evidence to both inform and validate design decisions. Sackett et al. (1996) defined evidence-based design as 'the conscientious, explicit, and judicious use of current best evidence in making decisions' (p.71). Evidence-based design is a growing trend in the healthcare system, especially in the field of space design and hospitals design (McCullough, 2010). As this trend is relatively new, it has recently evolved to include consideration of design elements such as environment, visual design, safety and sustainability.

Various methods have been introduced with which to measure the evidence in the evidence-based design. These include the Oxford Evidence-Based Medicine Levels method and the American Institute of Architects Guidelines for Healthcare Design method. While the former method is concerned with medicine interventions, the latter focuses on architecture and space design. The general factors that affect patient adherence from the Healthcare Design Center suggests a level-based measurement system. These measurements aim to evaluate the credibility of the research evidence used to guide the design process. Table 7.2 shows the Health Environments Research & Design Journal (HERD) model, which consists of six levels which classify the rigorousness of the research conducted to dictate the design process (Stichler, 2010).

High credible evidence		Level 1	Systematic reviews of multiple randomized controlled trials (RCTs) or nonrandomized studies; meta-analysis analysis of multiple experimental or quasi-experimental studies; meta-synthesis of multiple qualitative studies leading to an integrative interpretation.
		Level 2	Well-designed experimental (randomized) and quasi-experimental (nonrandomized) studies with consistent results compared to other, similar studies.
		Level 3	Descriptive correlational studies, qualitative studies, integrative or systematic reviews of correlational or qualitative studies, or RCT or quasi-experimental studies with inconsistent results compared to other, similar studies.
		Level 4	Peer-reviewed professional standards or guidelines with studies to support recommendations.
Low credible evidence		Level 5	Opinions of recognized experts multiple case studies.
		Level 6	Recommendations from manufacturers or consultants who may have a financial interest or bias.

Table 7.2 The HERD Evidence Based Levels (Stichler, 2010).

7.9 Summary and Findings

This chapter provided an overview of the literature studies linked to the research scope, including the decision to focus on design thinking as a process which can add value to the design of self-administered treatment technology. Furthermore, the focus on SMEs was discussed as part of a focus on the size of the companies working in developing treatment technology. The characteristics of design thinking were discussed and how these characteristics provide benefits to the organisation. These benefits include creative problem solving as the driving force behind creativity as the company explores the problem from different perspectives. This approach helps drive innovation in the company culture, as highlighted by various literature studies. Another benefit of the process is the focus on human needs when considering the business viability and technological feasibility. In addition to the above benefits, several barriers which can hinder the benefits of the design process were identified. These barriers are either internal or external. Internal barriers include lack of skills, management structure and cultural barriers. External barriers include financial barriers and the unpredictability of success. These external factors can affect

internal linkages. For example, the unpredictability of success can hinder a company's expansion if the internal team is not ready for the expansion or lack the experience to manage the company on a larger scale. Prud'homme van Reine (2017) introduced organisational culture dilemmas, which map onto the current organisational culture and how it hinders change opportunities. The organisation's cultural dilemmas reveal the internal culture as another possible barrier to the company's intention to change.

The above findings highlight several challenges that face the companies seeking to exploit the benefits of the design thinking process. This complex process happens to the company from the exploration stage to the final delivery. In relation to the adherence, the consideration of adherence factors is a complex and challenging practice because several factors affect patient adherence to the treatment regimen. As a result of this complexity, the consideration of adherence factors may change over the course of designing and developing the medical treatment. A mechanism is needed to ensure the consideration of the factors that affect patient adherence to the treatment regimen.

Chapter 8: Medical Technology Innovation

This chapter explores the medical technology innovation and its role in empowering patients. Also, the role of technology in addressing patients' unmet and unrealised needs. The challenges that face innovation in medical innovation are also discussed.

Key Topics:

- 8.1 Medical Technology Innovation: Opportunity and Benefits
- 8.2 Barriers of Innovation in Healthcare
- 8.3 Medical Technology as a Driver of Patient Empowerment
- 8.4 Summary and Findings

This chapter explores medical technology innovation in the UK healthcare system. Over the course of this exploration, the following questions reformed the objectives of this chapter and the main research questions:

- What is the current state of innovation and medical technology?
 - What are the hindlers and opportunities for innovation in medical technology?
 - What is the role of medical technology in driving patient empowerment?

8.1 Medical Technology Innovation: Opportunity and Benefits

Since the inception of the NHS in 1948 until today, it faces continuous challenges, not only because of the lethal diseases such as tuberculosis, diphtheria, and currently the COVID-19, but also the chronic diseases such as dementia, cancer, diabetes, and cardiovascular diseases. These events triggered the question how the healthcare system can be changed to address future challenges (Shapiro, 2010). While medical technology innovation can provide an opportunity for such a change (Wamble et al., 2019), the NHS is taking insufficient (Mayor, 2005) and slow (Kyratsis, Ahmad, & Holmes, 2010) steps toward the adoption of medical technology.

Medical technology innovation is widely implementing in a large spectrum of healthcare sectors including but not limited to treatment, monitor, diagnosis, procedures, and drug prescriptions. Innovative technology has contributed to increasing the life expectancy and QALYs. Various studies have highlighted the positive impact of investing in medical innovation in increasing the health outcomes and Return of Investment (ROI) (Wamble et al., 2019). The benefits of adopting the medical technology vary based on the technology, its implementation, and administration. For example, telehealth is a technology which enable patients to meet virtually either through phone calls or video calls with their GP or physician. The technology has different advantages including (Eaton, 2019):

- Provides access to consultation for patients in rural areas or have medical conditions that prevent them from visiting the GP or admit to a hospital
- More flexibility in time of appointment which reduces patients' waiting time
- Reduces the missing appointment problem as clinicians contact patients

Edwards et al. (2014) conducted a survey to evaluate the telehealth intervention with patients with chronic diseases. The results have shown general interest in the telehealth service amongst the research sample regardless their age, chronic health condition, and access difficulties. During the widespread of the COVID-19, remote consultations (such as phone and video appointments) have presented an opportunity for patients to get consultation and reduce the risk of visiting the clinicians. Greenhalgh et al. (2020) highlighted that the result of a randomised trials has shown high level of satisfaction among patients and clinicians regardless the disease progression and difference of the service.

Another example is the self-administered app-based psychological interventions. Leigh and Flatt (2015) indicated that there is an increasing demand for the psychological appointments and services which is faced with decreased in resources, funding, and clinicians. 1 in 10 patients has experienced a wait of over a year, and 1 in 2 has a wait of over 3 months. 1 in 6 from the waiting list are expected to attempt suicide, and 4 in 10 patients are expected to self-harm. Self-administered psychological app therapy can provide an opportunity for patients to access treatment programs by simply download the mobile app. However, patient adherence and engagement to the treatment is a key to achieve successful outcome.

Grist, Porter, and Stallard (2017) highlighted that there is a lack of research evidence to support the effectiveness of the mental health apps for children considering its safety, efficacy, and effectiveness.

8.1.1 Unmet Needs

Medical technology innovation contributes to addressing the so-called ‘unmet needs’, which is core strategy of Devices for Dignity’s (D4D) technology development process. D4D is part of the Health Technology Cooperative (HTC) that aims to ‘to deliver innovative medical devices to support patients with long term conditions, which preserve their dignity and independence’ (Robertson et al., p.72). The clinical unmet needs refer to the lack of specific human functionality or aspects that require technological assistance. These needs aim to serve the roles below (McCarthy et al., 2015):

- Unmet needs are a driver of innovation as companies find it an opportunity to address an unmet patients’ needs
- The solution can start by identifying the problem in an existing technology
- It focuses on potential technology ideas that can present a future solution
- The unmet needs vary from being focused on one-person health issue or a need of large group of people

The role of D4D in driving medical technology has been highlighted in this study during the interview with one of the case studies (ESA) covered in the Chapter 9: Case Studies Interviews. Figure 8.1 shows the D4D PDP.

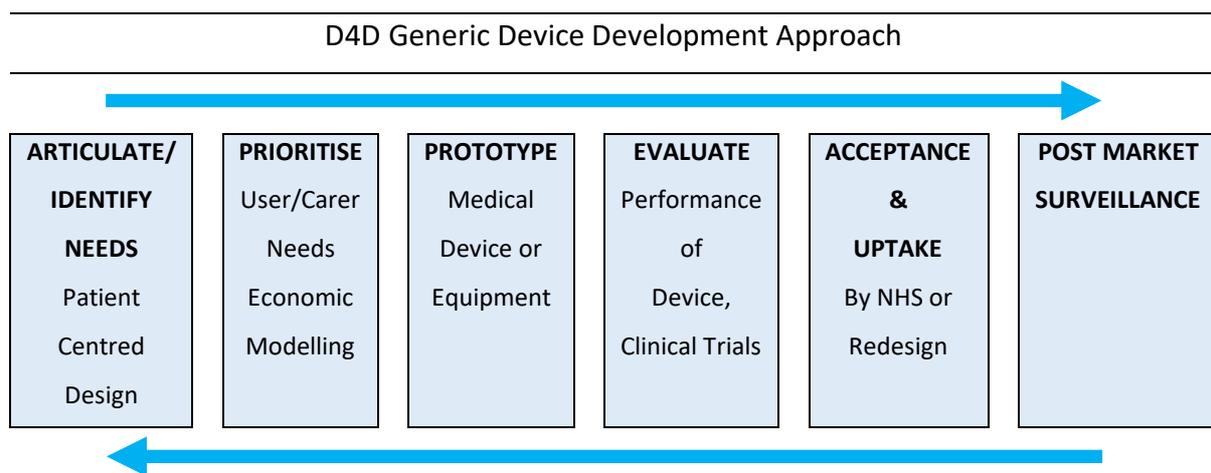


Figure 8.1 D4D generic device development approach. Source (Robertson, Hawley, & Herons, 2010)

The D4D Generic Device Development Approach is a practical example of the application of user-centred design in medical technology innovation in a number of specialised areas (renal technology, urinary continence management, paediatrics and assistive and rehabilitation technology). The focus on patient needs is part of the identification of unmet needs, which is the first step in the development process (Moody, 2015).

As part of the focus on patients' unmet needs, the process highlights the presence of the consideration of patients in four out of six stages of the process: Articulate/Identify Needs, Prioritise, Prototype and Evaluate (Heron, Tindale, & Hawley, 2010).

8.1.2 Unmet vs Unrealised Needs

The unmet needs model provides an opportunity for companies to establish their position in the market by addressing patients' unmet problems on the one hand and by integrating with the healthcare system which is expected to provide support in terms of funding, experience, and partnership opportunities on the other. The opportunities that the model present is the unrealised needs. Unlike unmet needs, unrealised needs are solutions (or improvement) of situations that clinicians and patients don't release it as a problem (McCarthy et al., 2015). They tend to see the problem only when they experience the solution of the current situation. While the unmet needs are obvious and required by patients and clinicians (pull), the unrealised solutions as not and usually pushed (or presented) to patients and clinicians through new technologies (push) as see in figure 8.2.. An example for the unrealised needs is the self-administered chemotherapy pump (infusion pump). While there was a general acceptance for the clinician-controlled hospitalised chemotherapy sessions, the patient-administered pumps let patients get chemotherapy at home based on the type of the infusion pump (ambulatory or CADD pumps).

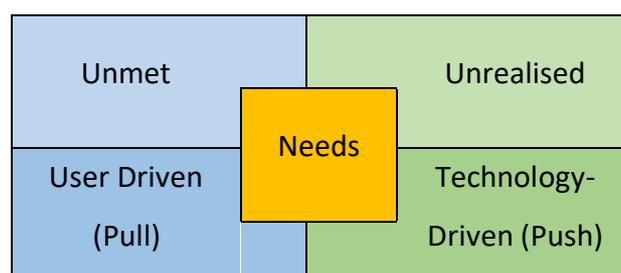


Figure 8.2 The unmet and unrealised needs. Source (McCarthy et al., 2015)

8.2 Barriers of Innovation in Healthcare

The NHS is blamed for insufficient (Mayor, 2005) and slow (Kyratsis, Ahmad, & Holmes, 2010) adoption of medical technology. A criticism that has backed by the House of Commons Health Committee. The British Healthcare system spends only 0.36 per cent of its GDP on medical technology, while the average of the European average is 0.55%. Furthermore, NHS trusts (around time 700 trusts) have inconsistent policies and practices in relation to the development of medical technologies (Mayor, 2005).

Another barrier is the complex national policies either domestically or internationally. These complex regulations stand as a barrier for SMEs working in designing and developing medical technologies especially new companies who have no prior experience with the NHS regulatory process. The World Health Organisation (2003) advised to harmonise the regulation systems in order to reduce the cost and complexity for the companies working in medical technology development (Faulkner, 2008). For example, Grist, Porter, and Stallard (2017) highlighted that there is a lack of research evidence to support the effectiveness of the mental health apps for children considering its safety, efficacy, and effectiveness.

Asthana, Jones, and Sheaff (2019) ran a study that examine the macro, Meso, and micro factors that affect eHealth innovation the NHS. The study concluded that barriers exists at all scales, yet at the top of the factors is the fragmentation of the healthcare system, which plays a significant factor in limiting the adoption and diffusion of the technology.

Castle-Clarke, Edwards, & Buckingham (2017) highlighted a number of structural factors that obstruct the NHS making the most of the new innovations. These factors include the structure of the system which is based on a supply-driven and top-down approach to innovation. The model needs to be shifted toward co-production where clinicians and industry work together to find solutions. Other factors are related to the strategic planning of organisations such as the focus on the short funding rounds rather than the innovation impact.

Herzlinger (2006) introduced three types of innovations that are convenient to the healthcare system and target to improve it and make it cheaper:

- **Consumer Focused:** The aim of this innovation model is to focus on addressing patients' needs by creating effective, convenient, and cost-effective interventions.
- **Technology:** This type of innovation focuses on the offering such as new treatment technology, drug system, and monitoring.
- **Business Model:** The business model can involve patient or focus on the healthcare system such as supporting SMEs in developing medical technology, supporting telehealth systems, and helping SMEs to access evaluation mechanisms such as clinical trials.

While the above types of innovation focused on the United States (US) healthcare systems, it provides generic types that can actually implemented in other systems such as the NHS. Additionally, he highlighted six factors (forces) that can improve or kill the innovation in the healthcare system. These factors include (Herzlinger, 2006):

- **Players** – The stakeholders inside the healthcare system (e.g. patients, nurses, clinicians, managers, and decisionmakers)
- **Funding** – The funding that can facilitate the innovation process or kill it as one of the big hinders
- **Policy** – The current regulations and legislations required from companies to push their innovative technology to the medical use
- **Technology** – The required technology to utilise the innovative solutions such as patients' access to smart phones and suitable Internet connection
- **Customers** – The level patient empowerment and concordance between patients and clinicians
- **Accountability** – The cost-effective, safety, and effectiveness of the innovative product comparing with the other competitors in the market.

8.3 Medical Technology as a Driver of Patient Empowerment

Medical technology plays an essential role in patient empowerment as it provides patients the opportunity to take part or self-administer the treatment intervention and educate patients about their condition and how to take control of their lives. The type of the technology intervention reflects how the intervention is empowering patients. For example, BabyCareLink is an online collaborative secured platform that supports infant families especially who are living in rural areas. Safran (2003) highlighted that 300 parents have used the platform more than 11,000 times in a period of 1 year. 85% of the platform visitors accessed it from home, work, library, or public places (Gray, et al., 1998).

Ziefle, and Schaar (2014) indicated that the usage of technology can help older patients to be independent through self-administered technology. However, the research highlighted that human factors need to be considered in order to build a successful technology design. The intervention technology should consider a multidisciplinary implementation in order to consider the different aspects of the intervention. Additionally, solutions should consider the special needs of patients and provide tailored solution to fit with their needs. From a holistic perspective so the technology should be patient-centred and inclusive.

8.4 Summary and Findings

Medical technology innovation presents an opportunity for the healthcare system to overcome many of its current challenges not only in treatment but also other healthcare systems. From the patient's aspect, medical technology can help patients to access to services much easier and faster such as the telehealth used in GP appointments. Additionally, it can help patients to self-administer their treatments. Medical technology can provide cost-effective solutions that help patients to avoid surgical interventions.

Innovation in medical technology should address both unmet and unrealised needs. While the unmet needs are already known by patients and the design process focuses on these needs, the unrealised needs cannot be seen as a problem until the design process investigate the problem space and provide a solution. The abductive nature of design thinking (7.1 The Nature of Design Thinking) can provide an opportunity to address both unmet and unrealised needs (Dorst, 2010).

Having that said, the medical technology innovation faces challenges and barriers that standing against it and achieving innovation. Herzlinger (2006) introduced six factors that can drive the medical technology innovation or kill it. These factors are players, funding, policy, technology, customer, and accountability.

A further benefit for the medical technology, especially the self-administered interventions is the patient empowerment, as it provides the opportunity for patients to take part in the treatment or diagnosis practice. Further discussion about the patient empowerment is covered in Chapter 6: Theoretical Frameworks of Adherence.

Chapter 9: Case Studies Interviews

This chapter reviews the second step in the Investigate phase (Case Studies). In this step five SMEs were interviewed to explore the design process and how adherence is considered at this stage of the design process. This step involves a triangulation of the desk research data.

Key Topics:

- 9.1 SMEs Characteristics
- 9.2 Employees' Experience
- 9.3 Integration with the Healthcare System
- 9.4 Design Thinking Process
- 9.5 Barriers of Product Design and Innovation
- 9.6 Treatment Adherence
- 9.7 Patient Communication and Adherence
- 9.8 Findings and Summary

The second step in the Investigate stage involves interviews with five SMEs working in developing treatment devices to build a clear understanding of the design process implemented in the case studies to develop self-administered treatment (or treatment support) technologies and how adherence is considered during this process. Semi-structured interviews were conducted with the case studies. The interviews included pre-prepared questions that were altered, skipped, or expanded based on the discussion and information shared by the interviewees (Gubrium, and Holstein, 2012). The questions in the interview can be mapped to the main research questions, as highlighted in Chapter 2: Methodology Introduction. Part of the aim of these interviews to understand the design process used on developing treatment devices and how adherence factors are considered during the development of the treatment or during patient's usage. A detailed description of the research methodology is covered in Chapter 3: Case Studies Methodology.

This chapter provides an overview of all the five interviews based on the topics related to the research aims. Full details of answers for each case can be found in the transcript listed in Appendix 9.1. Sections in this chapter focus on the themes across the interview data, map interview answers to the main research questions, and summarise how the main findings here will support later research stages (explore and assess). An italic font will mark the factors that have an impact on adherence. All the interviews were conducted with the companies' representatives who are usually the founders of the business. One interview with YMX company included two of the team members, one with an speciality in the technology and the other with speciality in the business side. When talking about YMX answers, they will be referred as interviewee 1 and interviewee 2.

The next section summarises the SMEs' characteristics. After that, sections focus on the key findings will be triangulation with insights from the literature (Chapters 6 to 8) to plan the remaining stages: Explore (WearCare project observation) and Assess (Delphi Method).

9.1 SMEs Characteristics

This group of questions aims to identify the status of the companies based on their size, integration with the healthcare system, and information about the product. This group includes the following questions:

- Tell me more about your company: date of establishment, size, number of employees, branches, and capital.
- How is your company integrated with the healthcare system in the U.K.?
- Explain to me your product and its current state. And how patients self-administer the treatment?

Five companies participated in this research. Due to the anonymisation procedure, the names of the companies were removed and replaced with a coded name. More information about the anonymity of the case studies can be found in Chapter 3: Case Study Methodology. Below is a brief description of each company's and targeted product in the study:

3AB

The company is a SME run by one person who is the founder. The company was established in 2015 with a capital of £35,000. Company size varied from one to three members during the four years. Currently, there is only one member who is the founder of the company. The company funding was based on loans (£25,000) and other funding sources (£10,000). Most of the funding was spent on evaluation research and building multiple prototypes of the product.

The company faced several barriers which affected the progress in the product development. These barriers include lack of funding, experience, and team dedication. The product is wearable that provides a sensory experience for patients who have long-term treatment goals. It helps them to break their big goals to small achievable ones with little reward once any of the goals are. The wearable product is very generic as it can be used with any disease especially the chronic ones, to motivate patients to adhere to long term treatment such as weight loss.

DE7

The company established in 2018 and currently it has four employees in the USA and UK. The main product is a device to support sleeping quality. It is used to avoid pharmaceutical drugs while patients are sleeping. The treatment device sends electromagnetic signals that can improve the sleep quality. The technology that can help patients and people who are in a risk of Alzheimer's or insomnia. The product is in the prototyping and testing stage, and it is part of research in a USA-based university.

LW7

The company was established in January 2017 as a pre-revenue medical technology start-up. The founder is the only full-time employee. However, there are 18 sub-contracts and an advisory team working with the company. The capital is £196,000 raised by charitable sources.

-

“the difference between us and a limited company is we have an asset lock and the mission lock, which dictates how we may use our profits” LW7 Interviewee

The description of the company puts it on the micro or small company. The company's status as a community interest reflected on the funding channels and opportunities. The differences between this company type and limited liability companies include assets lock and mission lock, which dictates how the company uses the profit.

-

The product is a device that integrate with cystic fibrosis physiotherapy to encourage children to follow their physiotherapy intervention. The product aims to improve young patients' adherence to self-administered therapy and help parents to ensure that they do the therapy correctly. The device is connected to a mobile game that rewards children when doing daily therapy.

YMX

The company was established in 2009 (around 11 years old). The current number of employees is 9 and starting capital is £500,000. The number of employees has changed over the years based on the company status. The company provides a non-invasive treatment device for Diabetic Retinopathy (DR) and Diabetic Macular Oedema (DME). The treatment device replaces or reduce dependency on painful surgical intervention. However, adherence to a minimum usage time over the treatment regimen is required. While the company's product is self-administered, current surgical intervention is clinically administered and requires admission to the hospital.

The treatment is a wearable device that is fully administered by the patients themselves. In some cases, such as first-time use, the product can be partially be administered so clinicians can follow-up the usage of the device, replacing it, or transferring the data from the device into the clinician computer to analyse it.

The product can be considered patient-centric as it uses technology to address the patient problem, which is reducing or eliminating the need for invasive intervention. A second benefit is reducing the times that the patient needs to be in hospital. The third benefit is reducing the cost of traditional treatments and saves patients the burden of many unnecessary hospital visits.

The treatment device has an educational aspect. It requires behaviour change as patients need to wear it for a long-term regimen. Table 3.1 in Chapter 3: Case Studies Methodology shows that behaviour change is a common feature between all the SMEs. Patient education affects adherence based on two perspectives:

- Literature studies highlighted the importance of patient education such as the Social Learning and Health Belief Model theories. These theories highlight factors that can affect patient adherence such as expectancies and incentives in Social Learning theory, and perceived susceptibility, barriers, benefits, and severity (Bosworth, Weinberger, & Oddone, 2005).

- The other perspective is patient empowerment. Educating patients take them from the position of obeyers to an active partner in the decision-making process (Powers, & Bendall, 2003; Funnell, & Anderson, 2003; McAllister *et al.*, 2012).

As a result, the type of patient education, and the quality of the shared information plays an essential role in influencing patient adherence to the treatment regimen.

ESA

The company was established in 2015, the company includes two directors (founders) and a secretary. Until the time of the interview, the funds invested in the company was over £700,000. The company portfolio includes a number of tailored products for patients who require external catheter line such as young patients with renal and peritoneal dialysis. The product main aim is to fasten the catheter line to the patient's body to avoid movement, which can lead to bleeding or infection. As a result, patients can live their normal life. So, patients, especially young patients, can play, exercise, and do other daily activities that require body movements without worrying about the catheter attached to their bodies to move or disattached.

9.1.1 Contrasting the SMEs

Companies vary in terms of their size, structure, funding, management, location, and integration with the healthcare system. The characteristics of four companies are those of micro- or small-size enterprises (ESA, LW7, 3AB, and DE7). While in the UK definition these companies can be considered a small company, other definitions put it in the micro-size category. This variation in definition will not affect the interviews nor the analysis of the data.

One company (YMX) falls in the small- or medium-sized enterprise, yet its employees and capital changed over time, which makes its nature swing between both small and medium nature due to the change in the number of employees and turnover.

All companies are registered in the U.K. Companies House. DE7 was registered in the U.S. before moving and getting registered in the U.K. as highlighted by the company founder. In terms of the establishment date, the establishment date for all companies ranges between 2009 and 2018. The oldest is YMX, and the newest is DE7 (table 9.1).

Company name	Establishment date	Type
3AB	2015	Limited liability
DE7	2018	Limited liability
LW7	2017	Pre-revenue charity
YMX	2009	Limited liability
ESA	2015	Limited liability

Table 9.1 Companies establishment date and type

Companies' ages do not necessarily relate to the maturity of their products because the developing rate of the product varies from one company to another. Product maturity varies based on different factors, including availability and funding.

9.2 Employees' Experience

The above overview shows that companies share similar characteristics. Some of these characteristics may have an impact on the design process and adherence such as experience. Therefore, companies who already have background experience in patients' needs and behaviour are more likely to target adherence factors during the design process. This was observed in the interviews with case studies such as LW7 and ESA, which will be covered in this chapter. Observing the interviewees' background and the general information about the company highlights a possible correlation between the founder background and target product. For example, LW7's founder had a background in software and game development, which inspired the company solution that uses gamification to improve children adherence for daily therapy. This influence was observed during the conversation, especially related to the inspiration behind the device. In another interview, ESA's co-founder had no design background. However, his experience journey through the

AHSN innovation pathway (Figure 9.1) required to get funding and access the NHS trusts helped him to build a good understanding of patients' needs and product characteristics (catheter support wearable device) to tailor the wearable product based on the patient's case, for example, the location of the catheter. In YMX, the consideration of adherence was driven by testing and clinical trials about patients' feedback about product usage. The AHSN pathway aims to guide companies through the steps needed to get their products adopted by the NHS trusts, and it has a human-centric aspect which focuses on patients' needs during the pathway steps. For example, evaluation steps allow SMEs to test their products with patients through clinical trials or the patient advisory group, as discussed later in the ESA case study interview.



Figure 9.1 AHSN Innovation Pathway guide for SMEs (Source: Eastern AHSN)

There is no fixed answer to the question of why some companies consider adherence better than others. Varied factors are involved in considering adherence before and during the development process. Based on the adherence factors discussed in the theoretical frameworks, one thing in common between companies, there is either a lack of consideration or partial consideration of adherence factors.

In terms of the products offered by companies, SMEs can have one or more products. In order to maintain the scope of this research and ensure clarity of the collected data. The scope of the study is self-administered patient-centric treatment and treatment support technology. The characteristics of each product are shown in Table 3.1 highlighted earlier in Chapter 3: Case Studies Methodology.

9.3 Integration with the Healthcare System

The integration with the healthcare system provides an opportunity for companies to build a partnership with hospitals and navigate the regulations and legislation that can help companies to sell their products nationally. Additionally, it can help companies to receive funding, experience, and access to patients' evaluation and testing (e.g. patient advisory groups and clinical trials). The level of involvement is also associated with the type of product and the level of communication between the company and different healthcare organisations.

From the perspective of adherence, the integration with healthcare system helps companies to clearly understand their patients' needs, test the treatment device on patients, and get feedback to improve the product. Hence, the experience gained from this integration with healthcare system can help companies to consider factors that improve patients' adherence, especially for chronic diseases. In the same time, funding, experience, and type of the product may stand as barriers for companies to test and evaluate the impact of their products. YMX highlighted two factors related to the integration with the healthcare system:

- Expanding the collaboration between companies and the healthcare system to involve consultation and mentorship can help companies to consider the different factors in the treatment device design process including patient adherence to the regimen
- Lack of access to patient data impedes companies' ability to build a strategy to improve patients' adherence
- SMEs working in medical products face a complex range of legislation, as they register their products in different countries. Complex legislation can vary from one country to another, which may be a barrier for companies to expand their offering to other countries.

The above challenges that face companies in order to design health device by considering the adherence can be categorised as *clinical-side factors*. These factors are not related to patient-device communication. It is the communication between the company and the healthcare system. Other adherence factors can be related or affected by the relation between the treatment and healthcare system include:

- Patient information
- Patient-centred shared knowledge
- Effective communication
- Understanding of patient behaviour

In terms of the integration with the healthcare system, three main stakeholders can be identified: the healthcare system, SMEs, and patients as shown in figure 9.1. The interviewees described their relations with the healthcare system, which should include the relation between patients and the healthcare system and how this impact adherence to the treatment.

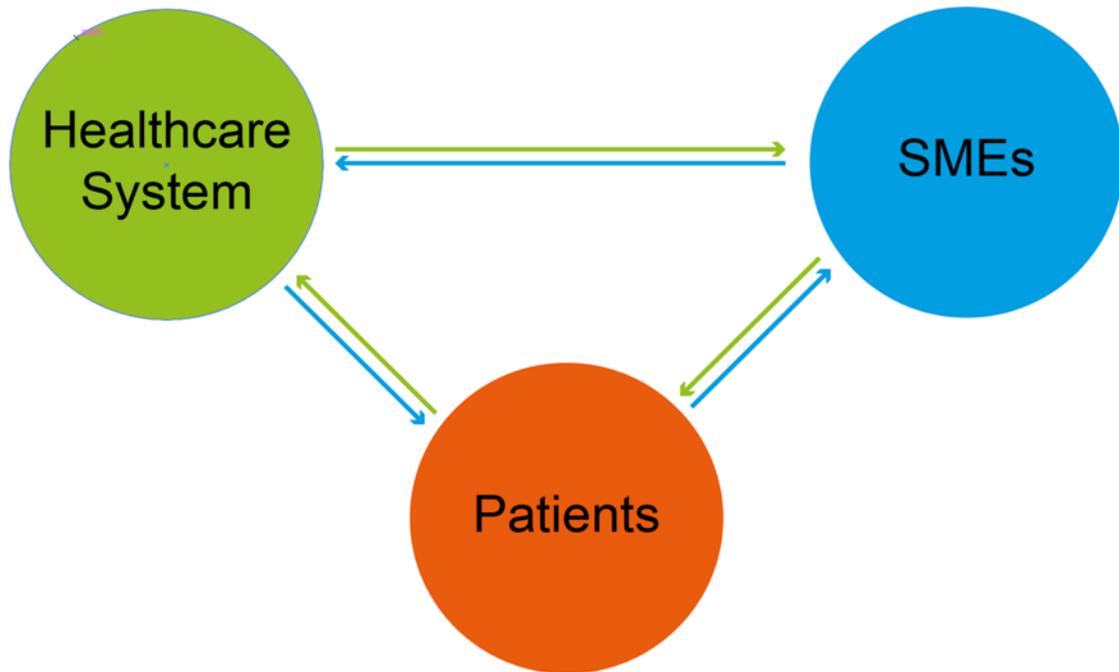


Figure 9.1 The relation between the Healthcare system, SMEs, and patients.

Figure 9.2 shows SMEs' activities and maturity from the perspective of integration with the healthcare system and direct market sales. Each circle represents a company. Each circle is divided into top and bottom halves. The top half reflects NHS integration, and the bottom one refers to direct market sales. The maturity levels are divided into four levels:

- No integration: the company does not have any integration with the healthcare system or has any activities to sell the device in the market
- Early stage (research): The company is on the early stage of the collaboration with the healthcare system or the market access
- Partial integration: The company is integrating with the healthcare system. In the market, companies can sell their products with a specific arrangement such as limited sales units.
- Full integration (market sale): The company's product is fully sold and implemented in national hospitals. In terms of the market, the product is sold on shelves without limitations.

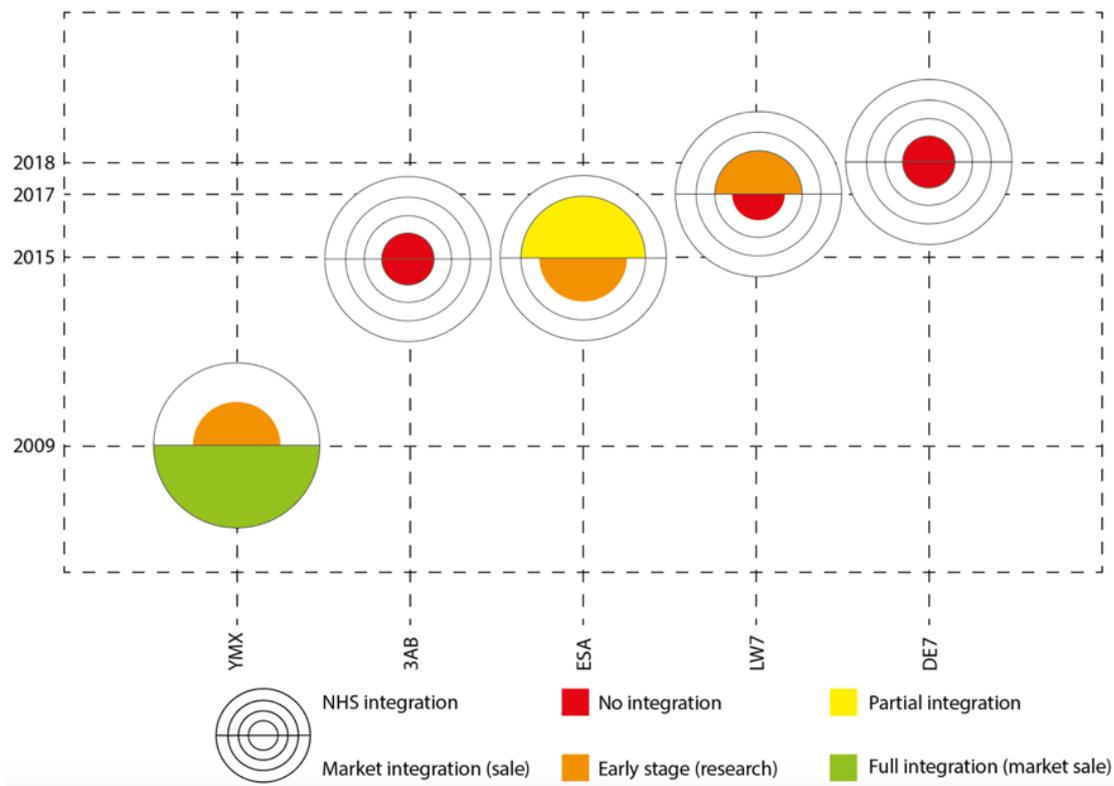


Figure 9.2 Visualisation for the companies' maturity based on its integration with the healthcare system

The above figure presents an interesting status for 3AB company. The company started earlier than other start-ups such as ESA. As the founder highlighted, the development of the treatment device moved slower than other companies because of financial, experience, and team commitment barriers. Because of the lack of funding, previous company founders and stakeholders could not maintain their duty toward the company, which affects its progress in the device development. Financial barriers are shared between the company and other SMEs, regardless of their industry. In response to these barriers, founders may be able to sustain for a limited time because hindrances increase and lead to other problems. As the financial limitation stands on the top of the SMEs barriers, this affects their ability to do any evaluation or testing their product (e.g. clinical trials, evaluation studies, or patient advisory group).

While YMX is the oldest case study company, there is not significant development of the relationship between them and the NHS. Interviewee one indicated that there is no formal

integration with the healthcare system in the UK (NHS). While the NHS was enthusiastic about the company's solution, the collaboration was limited in the form of financial funding and a grant. These funds were granted to the company through NHS research and funding bodies such as the 'National Institute of Health Research' (NIHR). This answer may highlight one of the barriers that face SMEs, which is the lack of support in terms of skills and experience. While financial support presents one of the barriers that faces SMEs, other barriers need to be considered, such as marketing experience and management experience (Larsen and Lewis, 2007). Based on this, providing only funding for SMEs may not be a sufficient support scheme.

“So in the past we work with patients through less or less the NHS because there's an issue there that they see themselves very much of holding patient medical records.”

YMX interviewee

Interviewee one indicated that there was work done with patients. However, it faced difficulties due to the obstacles related to accessing medical records for patients. The arrangements related to clinical trials held inside NHS hospitals involved the Clinical Research Network (CRN), which was responsible for the usage of NHS facilities for clinical trials and the company paid for this utilisation. Another group involved in collaboration with the company is the Academy of AHSN.

The description of the relation between the company and the NHS is limited to funding and usage of facilities. The limited ability to access patients' data presents a barrier for companies to understand patient adherence and consider it. A broad collaboration between SMEs and the NHS may contribute to building effective health and medical technologies.

ESA is having good collaboration and integration with the healthcare system. The company follows the AHSN innovation process, which demonstrated success. The company has another partnership with the NIHR. These connections help the company to access the NHS trust hospitals and Young Patients Advisory Groups (YPAG), which allows the company to get feedback, address individual patient cases, and understand the patients' needs related

to their attached catheter line. Another company who is having an integration with the NHS is LW7.

Because the founder has a family condition that inspired him with the solution device, he built a good connection with the NHS trust for this particular disease (cystic fibrosis). So, although the company is small and relatively new, it could build a good relationship with the NHS trust and other healthcare bodies. Probably this is the reason behind their ability to go through clinical trials early. The interviewee highlighted that a second clinical trial is underway. The first clinical trial was over 24 weeks period, then it was extended to another 24 weeks. The initial feedback from the sample was positive in terms usage of the solution.

9.4 Design Thinking Process

Most of the companies are on at early stage of development. The development of the product presents an early prototype (e.g. 3AB and DE7), while others have a more developed product status (e.g. ESA, and LW7, and YMX).

9.4.1 Idea Inspiration

One of the characteristics that mark out a creative design process is the developing of ideas and how the early process of problem framing is conducted to diverge different ideas that may evolve to become the product idea.

“the starting point is what the health care industry called the unmet needs. The unmet need really identifies that there is a problem. And it is noticing or seeing identifying that patients that are fitted with lines wherever they are in their body, there are no robust, clinically approved, regulatory approved products to meet that unmet need.” ESA interviewee

Table 9.2 highlights the source of the product idea or how the product idea developed from each company. Some interviewees were able to describe the inspiration process better than

others similar to how Cross (2005) described that some designers are more able to describe the final idea rather than the cognitive process of how they reached it.

Company	Source of idea (inspirational source)
3AB	Student project on quit cessation
DE7	Professional experience + education + previous product
LW7	Personal family case + professional experience + education
YMX	Previous published research + apply Multi-Perspective Problem Framing (MPPF)
ESA	The unmet needs in healthcare

Table 9.2 The inspirational source behind the treatment (or treatment support) of each company

9.4.2 Design Thinking Characteristics

While some companies did not follow a design thinking process such as the Double Diamond (Design Council, 2015), the core value of the process lays in the characteristics that add value for the design of the product. Table 9.3 shows the design characteristics that emerged during the content analysis by each case study. Also, the last column shows the reference to the literature studies.

Design characteristic	SMEs applying it					Reference to literature
	3AB	DE7	LW7	YMX	ESA	
Focus on patients' needs						(Cross, 1994; Brown, 2011) (Brown, 2011) (Cross, 1994; Brown, 2011; Dorst, 2012) (Buchanan, 2001; De Mozota, 2003; Mozota, 2003 Dorst, 2012)
Inclusive ¹						
Iterative and prototyping ²						
Problem solving						
Creative and inspiration ³						

Table 9.3 Design thinking characteristics, the companies applying it, and the literature highlighted each factor

¹ **The inclusive factor** involves a co-creation and working with different parties (e.g. patients, clinicians, and carers) to reach a testable product. While all the companies got the

chance to conduct an evaluation practice (e.g. clinical trials, evaluation study), this practice involves evaluating the medical product effectiveness rather than its commercialisation.

² **Iteration and prototyping** refer to building various prototypes for the product test and share it to get feedback and subsequently improve the future version. While all the companies created different prototypes of its products, few were able to make an advantage of the co-create practice. For example, ESA meet with patients, carers, and clinicians to share ideas about the medical device, then the professional stakeholder meets to review and provide feedback on each prototype especially when the patient requires a tailored solution.

³ **The creative and inspiration** characteristics, in the table above, refers to the how the idea of the treatment device is inspired or originated. It doesn't consider the product design characteristics, which will be overview later in this chapter.

9.4.3 Product Development

During the conversation with companies' representatives such as 3AB and DE7, new companies are more able to address feedback than established firms, including shifting the product scope to a different type of patients (e.g. focusing on Alzheimer patients in DE7, and expanding beyond weight loss in 3AB). For example, 3AB expanded the scope of the product to any conditions that require behaviour change. Larger companies such as YMX may not be able to consider radical feedback especially when the cost is high with limited resources. Accordingly, radical changes are postponed even it may be important changes.

“Yes, well, the steps of how the process works in reality is we start with a an initial meeting with interested parties, with the clinicians, that will be the clinical champion will invariably be a consultant specialist on the field wants the specialist in the field, the champion, if you like endorses the go ahead to collaborate, and then the infrastructure will be built around them. So the specialist nurses is a national institute of health research, clinical researchers,” ESA interviewee

Although companies didn't show a clear application of any design process stages, creative design practices have been followed during the product development. For example, ESA distinguished between problem definition and the solution. For example, ESA highlighted that co-working with patients, clinicians and consultants to understand the problem and then transform the basic ideas into prototype. Since the product is tailored based on each patient case such as the position of the catheter line, the company representative considers information related to the catheter position and patient's measurements. Then, the all the stakeholders meet again to provide feedback on the prototype. The iteration process continues until reaching a prototype that can be tested on patients.

"the patients will tell you exactly what they want." ESA interviewee

9.4.4 Design Factors

3AB interviewee highlighted human factors as a group of factors that the designer of the product considered. These factors include how it fits the human body, so its parts do not detach from the main device. The latter factor can be considered part of the user experience and product usability.

When trying out the wearable device some people adhered to the regimen and others stopped using the product because they did not adhere to the regimen from the first place. This reveals another impact of weak adherence to the treatment regimen. Patients who do not follow the recommended regimen of treatment end up by stopping using the treatment, which will have a negative impact on patient health and waste of the treatment cost.

Another point highlighted by the interviewee is the importance of patients' feedback. While the designer builds the device with specifications in mind, patients' feedback can provide information about improving the product that addresses patients' needs.

The above answer from ESA reveals a factor related to the development of the treatment device. While there is an appreciation of patient adherence, there is not any evidence to

consider the importance of adherence at the early stage of the device development, which may be because there is no instrument to measure companies' transfer of theoretical adherence frameworks into an action plan or a tool to identify consideration of adherence during the development. Accordingly, companies do not or "partly" consider adherence. This unclear picture of adherence drives companies to push their products to the market seeking consumer opinions. While firms can apply some of the consumer feedback, some feedback requires significant changes which increase the device production cost. Therefore, this feedback may be ignored due to its inapplicability.

Based on the findings from the content analysis, table 9.2 below tries to map design factors identified from the content analysis to the SMEs who mentioned it during the five interviews. For example, two companies (3AB and DE7) have considered the "patient friendly" factor in designing the product. Both "patient experience" and "considering patient feedback" factors were considered by all the five companies.

Design factor \ Companies	3AB	DE7	LW7	YMX	ESA
Patient friendly	Light Green	Blue	Yellow	Light Grey	Light Orange
Patient needs ¹	Green	Blue	Yellow	Light Grey	Light Orange
Patient experience (positive & negative)	Green	Blue	Yellow	Grey	Orange
Considering Patient feedback	Green	Blue	Yellow	Grey	Orange
Patient expectations	Light Green	Light Blue	Yellow	Grey	Light Orange
Considering risk factors ²	Light Green	Light Blue	Yellow	Grey	Light Orange
Sociability	Green	Light Blue	Yellow	Light Grey	Light Orange

Table 9.4 Design factors highlighted during the content analysis for the interviews

¹ **Patient needs** in this table refers to considering the needs in the designing the form and function of the product.

² **Considering risk factors** in designing the product itself to avoid patient harm and improper use of the treatment.

9.4.5 Design Value

3AB interviewee highlighted the importance of design to add value to the business, identify consumer needs, and other requirements (usability and materials). The interviewee focused on the role of designers rather than the design practice itself, which may be related to the interviewee's background as a designer. This observation aligns with Cross (2005) as designers tend to describe design from their practical perspective. Then, the interviewee moved to talk about the branding and packaging role in enhancing the communication between the device and patients. However, the financial barriers can hinder design from achieving its target aims.

The role of design as a driver for behaviour change was discussed. The interviewee mentioned that the first intention of the product was not a behaviour change, yet the initial focus was smoking cessation. The journey through the device design process and user group feedback can lead to changing the product target toward another disease or type of patients. In DE7, the interviewee described the current state of the product as a prototype. He appreciates the role of design in the look of the product. The treatment device is used at bedrooms; therefore, their design needs to be acceptable in this context.

"Okay, so what I have worked today, it is repeatable, but I would still say it is a prototype," DE7 interviewee

For examples, how it will be added as part of the mattress and how specific parts of the device will appear for patients while using the device.

"priceless?" ESA interviewee commenting on the value of design

The interviewee described the role of design based on its value as priceless. Its value can't be just added a budget, it extended this limit to add wide range of benefits for the product development. The above overview of the design value and how companies perceive it indicate two points:

- There is an agreement that design can add a value for the PDP.
- There is no or insufficient knowledge of the exact design value toward the business. Some views limit the value of design to only the ethical aspects ignoring the impact of design in business innovation and competitiveness in the market.

9.5 Barriers of Product Design and Innovation

SMEs face varied types of internal and external barriers (Nauwelaerts, Antwerp and Hollaender, 2012; Larsen and Lewis, 2007). In 3AB, the interviewee highlighted two barriers that faced the company, which are time dedication and financial funding. The company partners kept getting in and out from the company for different reasons, such as getting a full-time job. The barriers reflect the team-related challenge. At this early stage, companies depend on funding and may face limited financial support, which means that the company's founders usually dedicate a long time for none or very little financial support. If this stage went longer than expected, some team members find it hard to continue with their dedication, so they try to find other financial support and leave the team. Financial barriers are pervasive in micro and small firms, and they run on limited funding and financial support.

While barriers may have a direct and indirect impact on considering adherence, the financial barriers come at the top of barriers to considering adherence. Companies find it hard to apply any evaluation studies or clinical trials due to the cost of these procedures, and subsequently, they do not have a clear idea about patient's adherence to the treatment.

Table 9.5 shows the innovation barriers highlighted in the content analysis and its occurrence in the case studies.

Innovation barrier \ Companies	3AB	DE7	LW7	YMX	ESA
Access to information					
Experience					
Access to expertise					
Financial					
HR					
Operational					
Production					
Regulatory					
Teamwork					
Technological					
Time limitations					
Understanding the business					
Process					

Table 9.5 The innovation barriers highlighted by companies in the content analysis

Financial barriers are the most important obstacles facing SMEs, as agreed by all five companies. The inability of SMEs to secure funding is why they fail to achieve their strategic goals (Larsen and Lewis, 2007; Madrid-Guijarro et al., 2009; Nauwelaerts et al., 2012). Lack of experience and skills was considered the second highest barrier to success in the market by four out of the five companies. The literature indicated that this lack of skills can be marketing skills (Foley and Green, 1995; Freel, 2000) and management skills (Larsen & Lewis, 2007). Other barriers, which were reported by a single company, include access to information (YMX), teamwork barriers (LW7) and process barriers (ESA). More details about key barriers are discussed later in this chapter.

YMX interviewee one saw barriers from the perspective of offering a number tailored product. The diversity of conflicting needs presents an obstacle to the design of the treatment device. For example, designing treatment devices that are wearable or attached to the patient's body needs to consider the different measurements of the patient's body.

YMX Interviewee two highlighted that being a small company; it makes it hard to have multiple products. The company size and resources only able to focus on one product. This reason indirectly linked to one of the barriers that face SMEs, such as limited resources, which affects the decision to develop new products.

"I think the biggest barrier to development is a conflicting need for us to have a single one size fits all product." YMX Interviewee one

The above issue extends its impact to affect the clinical trials and choice of the trial population. When the device is tested, the aim is to address 80-90% of the population. If the study did not clearly define the population sample to meet with the product's target patients, problems might raise from patients' who do not have the product fit them.

"Do not take to everyone you know if you have got someone who is you know got gigantism or someone who has got dwarfism or something they are not going to, you know, you are not going to be able to say this patient is 45 years old they need, you know, three milligrammes of this drug because it is just that that is just based on an average based on averages doors are based on averages, so you know any anything that has any kind of physical interaction with a human being is always going to face that kind of problem." YMX Interviewee two

While the population selection mechanism is based on the average person, this mechanism may not suitable for medical technology as the nature of the usage of the device is different from the traditional drugs.

Interviewee one described the barriers that faced when developing the product. For this treatment device, one of the barriers to overcome was people's different physical measurements. The description of the different modifications to the design indicates the

importance of the iteration in the design process. While there are some elements of the device that cannot be modified such as the technology itself, the ability to modify the wearable parts to fit with the patient's needs can be modified based on patient's needs. The iteration and modifications of the device are continuous because of different reasons such as 1) improving the product, 2) address Patient's comments, and 3) changes in the technology.

"We have also got so much learning." YMX

Interviewee two

The process that interviewee two described is a learning curve. The team uses one material and then need to change it for a specific reason. Some design issues cannot be anticipated, and they require practical, real-life patient usage in order to figure out these issues. The nature of a design process here is not only iterative but also learning curve that is guided by patient's feedback about the device usage. Another element that affects product development over the timeline is the evolution of technology. Products that are developed at a specific point of time used the available technology at this time. After developing the product, new technologies are introduced that can provide opportunities and improvements. The longitudinal observation for the product over its lifetime raised another design challenge, which is what is the company's decision to face this challenge? Usually, SMEs run in a tight budget and limited resources, which may present one of the company's barriers to innovate.

DE7 interviewee discussed the experience barriers that faced the company, and one of the barriers is his own experience himself. So, he discussed how his engineering background helped to create a complicated solution to how the target design needed to be simple.

"But in terms of look and feel. But for me, as an engineer, I make it a lot more complicated than needs to be. So, I would say that the barrier focus groups were not being open enough myself in mind to consider a simplistic design. I made it too complicated, but it is not. It is not that way. Now it has all been changed." DE7 interviewee

Other barriers are related to intellectual property (IP). The interviewee highlighted that he did not want to provide details about the product. Therefore, he could not file an IP patent for the product as he did not want to provide details about it. The interviewee filed a trade secret instead.

In LW7 case study, medical regulations and funding presented two of the main factors that were considered and presented barriers during the development process.

“Finding the right people is challenging.” LW7 interviewee

Another issue that was considered during the development is the expertise of the working team. As the device presents a new idea of the treatment technology, the team is required to be able to understand the problem and the possible solution in order to visualise the solution and understand the founder’s description of the solution.

9.6 Treatment Adherence

Part of the aim of this stage is to understand how companies consider adherence in the treatment design and how adherence is considered in clinical trials or other evaluation procedures.

9.6.1 Self-Administration of the Treatment

The administration of the treatment plays a critical role in determining the level of adherence to the treatment regimen. A treatment device can be either fully patient-administered, partially patient-administered, and fully clinical-administration. The more the treatment is patient-administered, the more likely that adherence level decreases (figure 9.3)



Figure 9.3 The level of adherence in both patient- and clinical- administered devices

This study aims to explore self-administered treatment technology, which involves both fully and partly self-administered solutions. For example, YMX's and LW7's devices require support at the beginning of the treatment to educate patients on how to use the device before they fully administer it at home. In one of the clinical trials for YMX, communication with the sample was held every month. In contrast, in another trial, the communication with the patient was every six months, and was limited to collecting the usage data from the device. In the later trial, patient adherence was 70%, which is higher than the earlier trials that showed less than 20% adherence to the regimen. As a result, we may identify the *communication factors* as motivators of patients to adhere to the treatment regimen.

"Yeah, it is very, very simple. It is designed for simplicity." DE7 interviewee

Three companies (YMX, LW7, and ESA) out of the five have highlighted the importance of *communication* with patients to improve adherence.

9.6.2 Patient-centric Treatment

LW7 interviewee highlighted the way feedback is taken from patients. The interviewee indicated the importance of prototypes in getting patients' feedback. Without the prototype their feedback is not effective.

"And that feedback would be so undirected and so loose, to be really have no value at all. But when you give somebody a prototype, for example, you know, then they frame their feedback based upon that prototype," LW7 interviewee

For ESA, as highlighted earlier, the process of designing the treatment medical solution involves patients' needs and tailor the solution toward them. As highlighted by the interviewee, the design aims to meet requirements from patients, families, carers, and clinicians.

While the founder does not have a design background, the design process practice presented a good example of patient-centred design. Although, the initial pathway is guided by the AHSN, the meetings with patients (or their representatives such as carers, nurses, and clinicians) and working with patient advisory groups presented a good application for the patient-centred design.

The above model of patient and stakeholders' involvement in the design and development of the product reflects an interesting observation that the patient-centric principle is very crucial in building a successful project. However, it needs to be practiced properly in order to achieve the intended goal. Part of the company practice is to follow the AHSN innovation pathway to integrate with the healthcare system.

In DE7, the design of the product was influenced by varied expertise, including that of a clinical advisor, a business advisor, and a statistician. The results of clinical testing used to develop the product as well in one of the studies that included 50% men and 50% women. The study used several variables to determine the level of sleep quality; these variables included patient rating and examining the physiological and physiological status of the patient. The results showed that the product helped 50% of the women, and 40% of men to sleep deeper. Evaluation studies can provide useful tools to improve device design. However, the study aims, design, and expected outcome should be considered to ensure a valid outcome that can be used to improve the treatment device.

9.6.3 Patient Adherence and Product Design

While DE7 interviewee did not provide proof related to patient adherence to the device therapy, he provided two main points that make him believe that adherence to the therapy will be high:

- The device has a direct impact on improving sleeping. Therefore, the patient will most likely adhere to it in order to maintain a positive experience
- The results of using device therapy are quick and do not need to depend on drugs. This advantage can be a factor to influence adherence, especially with diseases like insomnia and depression.

"People have tried to come off the sleep system, after they have been familiar with it and improve their sleep and realise, they do not sleep as well when they turn off. So, in terms of adherence is an easy one, they want to go, they want the extra bed asleep. So, they go back on it, right? They, they, they get bruised when they turn it off, they realise that they need it." DE7 interviewee

YMX's Interviewee one and two talked about the pattern of use as a source of information about patients' behaviour when wearing the treatment device and when not wearing it. In terms of the factors that affect adherence, Interviewee one highlighted the fear of deterioration of the patient's health condition as one of the motivators to adherents to the regimen. Another factor is the follow-up communication between the company and the patient. If patients know there is someone who is going to call to follow-up their treatment progress, they would adhere to the treatment regimen.

"So I do not want that to be the only message. The biggest message for compliance is about finding ways of motivating a patient and finding multiple ways. Trying to press on all of those buttons, but it cannot be denied that there is one motivation." YMX Interviewee one

Patient motivation is the top factor to improve adherence as interviewee one highlighted. However, this factor includes different factors. The company should explore the best

motivation factor or group of factors that can affect patient adherence. Another factor that can influence patient adherence is reasoning. For example, some patients do not adhere to the treatment; then later, they change after facing a specific experience like a shock. Some patients rationalise their actions related to adhering or not to adhering to the treatment. This factor aligns with the theory of reasoned actions (Bosworth, Weinberger, & Oddone, 2005).

In 3AB, while the product is in an early stage, it was evaluated through patient user groups where some information regarding the usage adherence can be explored. The interviewee highlighted that user group member had feedback regarding the physicality of the product in terms of efficacy (this may actually be effectiveness, see Section 9.5.3).

"Yes, 78%-82% of respondents reported that using the device had helped them achieve their goal, that is, I mean that is a big number for such a specific question." 3AB Interviewee

Thus with respect to confidence in the device to achieve its target within the user group sample, the results showed that 78% to 82% of the respondents reported that the device helped them to achieve their goal. The interviewee mentioned this percentage in the context of discussing adherence, which is high comparing with the literature (Bosworth, Weinberger, & Oddone, 2005; Martin, Haskard-Zolnierrek & DiMatteo, 2010; Williams, 2014). However, this percentage may indicate patients' opinion about the product rather than adherence percentage. A long-term study with clear population sample is required to determine the accurate level of adherence to 3AB product.

Table 9.6 below lists the adherence factors and the companies who considered it during the design of the treatment device. While all the interviewees acknowledged the important role of adherence, the below table shows that only few factors were considered, and few companies considered these factors in designing the product.

Adherence factor	Companies	3AB	DE7	LW7	YMX	ESA
Communication with patients						
Health belief (patients believes about their own health)						
Knowledge and education						
Patient empowerment						
Protective motivation						
Self-motivation						
Reasoned action						
Behaviour change						

Table 9.6 List of adherence factors considered by the companies

9.6.4 Adherence Considerations and Involvement in Clinical trials

3AB sees adherence from the perspective of two parts:

- The first part is based on how patients use the product in the way intended and clearly defined to patients
- The second part is how the product is used in terms of the target challenge.

While the interviewee may not come to a cross literature definitions of adherence, the practice and the experience acquired while developing the device may help to build a clear, realistic idea about adherence.

"There are two levels on there; the first level is using actually using the product. Yes. So, using the product in the way you intend to use the product. And the other level is how the product is used in relation to the challenge." 3AB interviewee

Although there is a clear idea about adherence and how to measure patients' adherence to the treatment, there is a lack of a tool to evaluate how adherence is considered for a

product (adherence-friendly) during the development stages before moving toward any clinical trials or any other patient evaluation procedure.

"Okay, so, in the old clinical trials. No, I do not think it was taken into account as we go forward. We have refined how we look at compliance." YMX interviewee one

YMX Interviewee one talked about compliance and how it is considered in the clinical trials. At the early clinical trials, patient compliance was not considered and then added into account in later clinical trials. Clinical trials were expanded to consider patient compliance with the treatment. While the treatment has a minimum and maximum usage hour to achieve the target goal of usage, the compliance target in the clinical trials had been set to the maximum number of hours, which may contribute to unrealistic outcomes. For example, the patient may use the product for five hours which is sufficient for the treatment; his would still be considered as non-compliance.

Another factor is the surrounding environment. So, if the surrounding environment during usage device is supportive for the patient, this can improve adherence. However, clinical trials did not consider this factor. In terms of consideration of environmental factors, there are two types of clinical trials: efficacy and effectiveness in clinical trials. While the first applies the trials in a controlled environment, the second applies the trials in the real-life environment (Flay, 1986). The clinical trial setup for the treatment device did not take into consideration the environmental factor surrounding patients while they use the treatment. As a result of the above consideration for compliance measurements, the results of the clinical trials can lead to misleading compliance data.

Another challenge that faces the company in terms of compliance is the accuracy and realistic data about compliance reported by patients themselves. For example, patients can say they used the treatment for six hours while they only used it for four hours. This does not necessarily relate to patient honesty; it is sometimes related to wrong perception, especially when the patient is not keeping record of the usage hours.

The accuracy of patient feedback can be affected by when and how the question is asked. If the question is at an early stage of the trial, the probability of getting an accurate answer is higher comparing with late stages. Another factor is how the question is asked. For example, if the question about the usage hours was asked by a threatening style, there is a high chance of a less honest answer. Sometimes, patients tend to give the clinical trial administrators the answers they want to hear, which can also lead to misleading information.

“But the way we ask the questions is really important to get to the truth, not the answer they think you want to hear.”

Interviewee one highlighted an interesting observation regarding asking patients about their actual compliance for the treatment regimen. The format of the questions is used, and the way clinicians ask their patient plays an essential role in getting an accurate (true) answer about the patient level of adherence. Turner III (2010) and Jacob and Furgerson (2012) highlighted the influence of the question format on the outcome answer. While in clinically administered trials, the truth (or honesty) factor does not exist, and it plays an essential role in patient-administered treatment as it may be the only way to track patient adherence in some treatments.

In YMX, Interviewees one and two talked about the pattern of use as a source of information about patients' behaviour when wearing the treatment device and when not wearing it. In terms of the factors that affect adherence, Interviewee one highlighted the fear of deterioration of the patient's own case as one of the motivators to adherents to the regimen. Another factor is the follow-up communication between the company and the patient. If patients know there is someone who is going to call to follow-up the treatment progress.

“So I do not want that to be the only message biggest message for compliance is about finding ways of motivating a patient and finding multiple ways. Trying to press on all of those buttons, but it cannot be denied that there is one motivation.”

Interviewee one

9.7 Patient Communication and Adherence

Patients who take home a self-administered treatment start can using it without administration from the clinicians. However, interviewee one highlighted that they do not want this to happen and prefer providing partial clinical consultation or control over the treatment due to the following:

- There is no control over who is taking the treatment and their underlying conditions which may add responsibility to the company
- Approved providers can sell the device and provide consultation services to their patients to test and prescribe the treatment accordingly.

As communication is one of the crucial factors that impact patients' adherence to the treatment, I found this is an excellent opportunity to get an insight about the company communication with patient before and during the intervention.

YMX company and clinicians communicated with patients during clinical visits to set up the clinical trials, check patients' health status, provide the patients with a device replacement, get feedback about the treatment, and collect usage data from the device. The other form of communication was through phone calls, which aimed to follow-up with patients their usage to the treatment device and any feedback they had. The later involvement of communication between patients and clinicians show the importance of *communication-related* factors to drive adherence.

The way these communication channels were conducted reveals the following about adherence as below:

- The clinical sessions that included a discussion between patients and clinicians regarding their experience with the device and their usage regimen may help improving patient adherence. Clinical trials which involve Follow-up phone calls showed higher adherence percentage.
- The interval time between the communication session presented an important especially. Shorter communication interval (monthly) has shown higher adherence level.

As the communication is one of the crucial factors that impact patients' adherence to the treatment, further discussion aimed to elaborate this opportunity to get an insight about the company communication with patient before and during the intervention, and during the clinical trials. The aim of this part of the conversation was also to explore how the clinical trials were set up and the impact of this set up on patient adherence.

YMX's product was a subject of two clinical trials. In order to maintain the anonymity of the company, the names of the trials were removed from the context here. The first one used an early version of the product; which patients need a new mask every 3 months (due to memory and battery capacity). So, patients needed to see clinicians every 3 months. During these visits, they were given a new device, got clinician checks, and the data was collected from the device. While using the mask, patients were followed-up by a monthly phone call to record their experience. The patient adherence to this clinical trial was high and reached around 70%. The result of this clinical trial was very supportive as the mask was able to prevent (or cure) the degradation of the retina's thickness, which has a direct impact on the RT and DR (Kuchynyka, Grierson, & Veith, 2017).

"So, the classic example, everyone gives is the eyedrops for glaucoma, of which the adherence rate is 4%. Generally, and because it is eyedrops, you cannot check whether a patient is using it or not." YMX interviewees.

The second clinician trial was not set up by the company itself, which had limited involvement in writing the protocol of the study. In this trial, patients were given the device without much interference nor support. The patients were using the intervention for two months. Every month, patients visit the clinician for a regular check and not to get information regarding the device usage information or to collect patients' feedback regarding the treatment device. The outcome of the trials showed an adherence level less than 20%. One of the interviewees highlighted that in self-administered treatment, the adherence might drop to 15% even in severe heart conditions. He highlighted that if patients are sent home to use the treatment, they will unlikely adhere to it even in chronic conditions.

"even for relatively short things, so you know things like antibiotics, for example, you know, the doctor will give them a 20-day course of antibiotics, they will feel better after a week now stop taking them." YMX interviewees.

YMX Interviewee indicated that there are issues related to considering adherence during the clinical trials. These issues can be summarised in the following points:

- The company knew ahead that low adherence would have a negative impact on the outcome related to the abilities of the device. When sharing this information with the clinician trial administration, they indicated that clinical trials do not check the adherence level without providing a clear rationale for testing it.
- The time allocated to each patient during the clinician session was insufficient to ask questions related to patients' adherence and usage of the device.
- The clinical trial was a single-blind randomised controlled trial. Part of the sample was using a placebo device (sham). However, the sample who received the sham device was able to identify it which affect their adherence to the intervention.

"They knew full well that you could check the patient compliance and feedback. Furthermore, you know, we even had informed them that they had relatively low patient compliance, and they just said we are not checking.

They refused to do it exactly why they never really gave us a reason so ultimately; it is just going to be speculation. One is you know that if they were checking it, they would end up treating patients differently based on whether they were behaving or not and." YMX interviewees.

The above statement from interviewee two highlighted another dimension of the barriers that face considering adherence factors in clinical trials. Although it could be, the adherence factors were not considered during the clinical trials. As a result, the outcome and recommendations from the clinical trials can dramatically be affected by eliminating the opportunity to consider measuring patient adherence. For example, if a company did not consider adherence's factors during the development process, the evaluation of the effectiveness of the intervention would be blinded by the low adherence to the prescribed regimen.

While the benefits of self-administration were highlighted, the communication between patients is required to empower patients which has positive impact on adherence (Feste, & Anderson, 1995; Funnell, & Anderson, 2003; Aujoulat, d'Hoore, & Deccache, 2007; McAllister *et al.*, 2012). Adding clinical communication with patients as part of the factors that encourage adherence suggests that self-administered health tech does not require full disconnection between the patient and the clinicians. So, the dependability on the clinicians is reduced to only regular follow-ups (e.g. phone calls or virtual appointments) can help to reduce the hospital admission, clinical appointments, surgical intervention cost, and both the physical and psychological impact on patients.

9.7.1 Treatment Usage Regimen

There is a mutual correlation between adherence to regimen and treatment continuation. 3AB highlighted that patients' proper adherence to the regimen leads to positive outcomes (improvement in the patient's condition), which encourages patients to continue with the treatment. In YMX company, patients need to wear the treatment device for a specific number of hours daily for 24 months. DE7 treatment device needs to be used daily at the beginning in order to see an outcome. In contrast, lack of adherence leads to insufficient or no improvement, which subsequently leads to discontinuation of the treatment regimen. Another aspect affects patient adherence highlighted by DE7, which is the cost of the treatment. When patients pay for the treatment, they are more likely to adhere to it compared with the free offered treatment.

9.7.2 Patient feedback

YMX highlighted the importance of patient feedback in improving the product and subsequently, the adherence for the treatment regimen. For example, patients did not feel comfortable wearing the device as it causes skin issues. It was interesting that some of the patients' feedback faded away after a short time of usage, and patients get used to the device. Therefore, clear analysis for patients' feedback can help companies to plan a strategy to improve the product for both short and long term.

In ESA, feedback is collected from patients, parents, and clinicians during the meeting with the YPAG to modify the product prototypes to meet both patient's comfortability and treatment goals. DE7's device aims to provide a comfortable sleeping experience for patients, especially by using the device for the long term. The patient's feedback was used to improve the device, so it does not interrupt patients' sleep experience.

9.8 Findings and Summary

Five SMEs have been interviewed as part of Phase One: Investigate of this study. The aim of the interviews is to investigate the state of medical technology innovation, explore the role of design in developing innovative treatment technology, and how adherence is considered during this development. To this goal, a number of objectives have been set:

- Explore the current state of SMEs working in the medical technology innovation including building understanding of the barriers and opportunities they face
- Explore how design thinking characteristics are adopted during the design and developing of the treatment technology (including the hinders and opportunities of its application)
- Explore how adherence is considered during the design and development of the treatment solution
- Explore how the treatment products are considered in the clinical trials including how adherence is considered during the evaluation procedures

This chapter provided a summary analysis of the five semi-structured interviews. The transcripts of the interviews are available as a confidential Appendix 9.1. Four of the interviews were held based on face-to-face meetings, and one via the Internet. Details about the interview methodology were discussed in Chapter 3: Case Study Methodology.

The profile of each company was reviewed and its integration with the healthcare system was discussed with the company interviewee. Also, details about each product was covered. Some information was eliminated from the discussion here due to anonymity agreement with the company.

Four companies did not follow any design thinking process. One company (YMX) applied the double diamond process in designing the treatment device (Design Council, 2015). While there is an acknowledgement of creative design practices and their benefits, companies vary in providing evidence related to making use of these practices. There is no strategic-led process that can help companies to improve their implementation for design characteristics. Most companies run based on the expertise or the professional background of the founder. While there is an agreement on the value of design to business, companies did not provide sufficient details about this value and how it is considered by the company. In addition to the literature studies related to the medical technology innovation. These findings contribute to understanding the design process used in the medical technology industry, which is one of the study questions (what are the current development processes applied in medical technology?).

In terms of the obstacles faced by companies when trying to innovate, all the companies have shared barriers that including experience, financial, regulatory, and technological barriers. This finding is supported by the literature studies covering the barriers of innovation in SMEs, and answers the study question (what are the barriers to and opportunities for adopting design thinking?)

The fourth group of questions addressed adherence, its consideration in the design process, and its consideration in the clinical trials. A close look at the adherence literature shows a lack of studies related to medical technology in general and particularly self-administered treatments. The current theoretical models that help understanding adherence (Bosworth et al., 2006; Nunes et al., 2009; Sabaté, 2003) do not provide practical guide for companies to follow to overview and measure the consideration of adherence factors in the design process. Practical considerations when considering adherence extends to the clinical trials, where adherence is poorly considered. The journey of YMX case study provides an insight to how inadequate consideration of adherence in clinical trials setup can dramatically affect the outcome of the trials.

The companies are working in a challenging industry. While self-administered treatment technology can provide solutions to many of the challenges that face the healthcare system,

there is a gap between the theoretical knowledge, industry application, and evaluation (clinical trials). There is a lack of literature studies related to self-administered treatment technology. The current theoretical models of adherence do not provide a practical mechanism for companies to consider adherence factors in the design of the medical intervention. Additionally, these frameworks do not have a sufficient focus on self-administered medical technology. Regardless of the companies' appreciation of the importance of adherence, the lack of an effective practical approach to understanding adherence and consider it stands as a barrier for SMEs to effectively consider it in the design of technology treatments.

Part 4

Explore

Chapter 10: WearCare II Project

This chapter reports on the second stage of this study (Explore). In this stage, the WearCare II project was observed in order to explore how adherence factors are considered in an early stage of the design process. The WearCare II project was a collaboration between post-graduate design students at Northumbria University, CPI and AHSN.

Key Topics:

- 10.1 WearCare II Role in the Study**
- 10.2 Observation Time and Location**
- 10.3 The WearCare II Project**
- 10.4 Workshop Progress and Reflection**
- 10.5 Reflection and Discussion**
- 10.6 Summary and Findings**

The second phase of the research involved observing the post-graduate project of the taught Master of Design's (MA Design) students, WearCare II. It aimed to explore how to use design thinking to develop a patient-centred self-administered wearable to monitor vital health information. The project was a collaboration between Northumbria University, CPI and AHSN. The research aimed to explore how adherence is considered at an early stage of the design process.

Two main limitations in the SME interviews indicated a need, and directed the study design, for this phase:

1. Early consideration of adherence in design work could not be observed as the companies had already developed the product or a high-fidelity prototype of the product, and
2. The interviews' limited timeframe prevented observation of new product development, especially considering the long-term medical technology development process.

Accordingly, the WearCare II project provided an opportunity to observe how adherence is considered early in the design thinking process in a similar (or nearly similar) setup to that of SMEs. The project environment was similar to that of SMEs: it required teamwork, involved team members with a variety of backgrounds and skills and focused on the design process. However, there were also differences, such as the financial setup, legislation and company setup. This research stage aims to provide a complementary perspective on how adherence consideration progresses when exploring the problem and formulating the idea for the solution.

10.1 WearCare II Role in the Study

The WearCare II project presented an opportunity to observe the design practice at an early stage of the Double Diamond (Design Council, 2015) process and observe how the consideration of adherence progresses from one step to another. A number of limitations lie within the WearCare II project itself, such as its practice which varies from real SMEs setup. Also, the target of the academic project is different from a commercial company which

reflect on the students' practice. Having said that, both opportunities and limitations in this stage were acknowledged. WearCare II project presented one perspective to observe the design practice as highlighted regarding the SMEs observation limitations highlighted earlier in this chapter. In addition to the WearCare II project, other perspectives were used to strengthen the understanding of the design practice. These perspectives include:

1. The interviews with the five case studies' descriptions for the design process of the healthcare product
2. The literature related to the design process and the nature of each stage
3. The researcher's perspective as a designer with 15 years of experience in various design projects

In the WearCare project, the teams were observed doing design practice, while the Delphi stage aimed to observe the panel assessing the practice. Accordingly, the WearCare project has importance from a design practice perspective.

Additionally, WearCare project presented a core role in developing the 2nd claim of the study highlighted in Chapter 14 (14.2 Research Claims and Contribution to Knowledge).

10.2 Observation Time and Location

The project ran as part of the Design Thinking DE7001 module, which was part of the MA Design post-graduate degree and was conducted between September and December 2019. It took place on the university campus in Newcastle upon Tyne. This module investigated the design process based on three main components: 1) reflective practice; 2) enterprise; and 3) intercultural communication. The first component involved using the reflective practice process (explore, act, observe and reflect) to explore the problem space and solution space related to the project.

10.1.1 Participants

The project included eight groups with three to four students in each group. All the groups worked on the same project, and the students had different educational backgrounds and

experience. This group setup is similar to the structure of real-life micro-size companies and start-ups, which are usually a group of partners trying to create a new product to introduce to the market. The environment simulated a very early stage in common SMEs' lives, when they consider an innovative product. This setup provided an opportunity to observe how this early stage works, and especially the consideration of adherence factors. Below is a list of the student groups, the number of students in each group and the solution project's name presented at the end of the semester.

Team No.	Number of students	Solution name
1	4	Don't Sweat the Small Stuff
2	4	Insulin Pump
3	3	Chronic Stress: Discover Recover
4	4	Push Pal Stress Relief (Osteoarthritis Pain Tracking)
5	4	Anxiety Disorder
6	5	Loneliness and Isolation
7	4	Rehabilitation of Elderly People
8	2	Food Allergy Detection

Table 10.1 List of the teams working on the WearCare II project, the number of students in each team and the solution name.

10.1.2 Data Collection and Management

The groups' work was observed, and the progress of each group was documented as follows:

1. Notes were taken of observations and interpretations of each teams' practice.
2. Students were asked about their progress, which was documented through written notes. During the two weeks when direct observations could not be performed because I could not attend the class, updates were collected through an online survey page (the survey was created using SurveyMonkey.com).
3. The final presentation of the groups' work was recorded, and a transcript was created using Otter. The final presentation was documented in photos.

I attended the classes on a weekly basis with prior coordination with the course lecturers to avoid disrupting the teaching process. In each class, teams were observed for around 5-10 minutes, and notes were taken to document their practice. I then summarised these notes to document the weekly progression of all the teams.

10.3 The WearCare II Project

CPI and AHSN introduced the WearCare II project. The project's main theme was 'How can design thinking reposition healthcare towards patient-centred and self-administered services?'. The students followed the MPPF method (English, 2007) to explore the current situation from different perspectives. According to the MPPF (refer to Chapter 1: Introduction, 1.5 Definition of Terms), six centres of inquiry are used to drive push questions, which are used to explore the problem. Whitehead (2007) highlighted that in order to build a space for innovation 'fuzzy situation', six to seven key areas (cornerstones) need to be defined to establish a starting point for designers to explore the problem space (English, 2007). In the WearCare II project, students were asked to investigate the following key areas:

- **Patient needs:** Both physiological and psychological factors related to patient needs within the context of using the treatment.
- **Patient adherence:** The drivers of patient adherence and the factors which affect a patient's compliance with the treatment regimen.
- **The NHS:** The healthcare system's strategic elements, such as function, structure, assets and funding mechanisms .
- **Technologies:** The products, systems, services and future opportunities for diagnosis and treatment.
- **Value networks around about the patient:** The stakeholders involved in the environment around the treatment.
- **Change factors:** The threats and opportunities related to patient behaviour change.

The students created push questions to explore each of the six inquiries and represented each answer with a keyword written on a sticky note. They then arranged their findings and

investigated the connection between the results related to each centre of inquiry. At the end of this process, they defined cornerstones which represented the solution. The representatives from both CPI and AHSN introduced the students' projects at the beginning of the semester. They attended a follow-up presentation to review the students' practice and a final presentation at the end of the semester. The representatives provided feedback to all the teams and awarded a prize to the winning team.

10.3.1 Progress and Documenting Observation

As discussed above, I attended and observed most of the classes. The progress of teams was documented weekly through the following methods:

1. Taking written notes about and interpreting student practice.
2. Asking students about their progress and documenting their practice.
3. Using an online questionnaire to document their practice during the classes that I could not attend.

Various media were used to take notes, including paper, mobile phone and iPad. The notes were then collected, firmed up, and summarised, as highlighted in Table 10.2 before highlighting the team practice. During this practice, I shared thoughts and insights with the students from the literature studies about their topics in order to highlight useful resources without interfering with the course.

Below are general notes regarding the teams' progress, attending the classes and other observations:

- Some observational data was not available due to two the team was absent or came late to the class.
- The team members had different experience and study backgrounds. While a majority of them were from design education, the teams had a multi-disciplinary structure.
- The teams were very similar to early stage start-ups. At this point, the start-up team may not know much about the product and therefore will build on their expertise.
- At the beginning of the project, adherence was presented to the students in one lecture at the first week in the semester, so that they would consider adherence

factors in the project. This introduction presentation was brief so as not to shift the team's focus entirely to adherence and also so I could gain an overview of their practice and how they dug deeper to understand adherence.

- Team 8 faced some communication and teamwork issues. Therefore, they were split into two teams. For this reason, some data for team 8 and team 9 are incomplete.

10.3.2 Documenting Each Team's Progress

In each class, around 5-10 minutes were spent with each team so that I could take notes on their progress. I then summarised these notes in order to document the weekly progression of all the teams. Generally, groups moved through three stages (Figure 10.1):

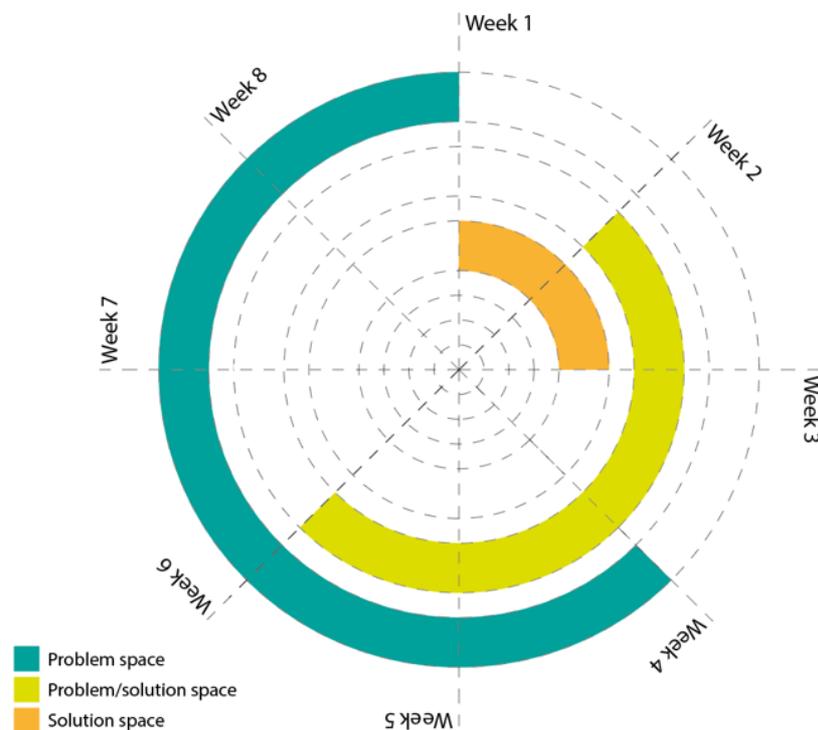


Figure 10.1: The progress timeline for the WearCare II project.

- The problem space, where they explored the design challenge
- The problem/solution space, where they explored the possible solutions, and
- The solution space, where they defined their proposed solution and drafted ideas

These three stages defined each group's state in terms of the findings or identifying the possible solution and did not reflect the application of the MPPF itself.

Based on the progress highlighted in Figure 10.1 above, written field notes about teams' progress were documented weekly. I then reflected on the field notes (Baarts et al., 2000; Mills et al., 2010) and summarised those observations (Table 10.2). A detailed table, including field notes and associated reflections about each team, is available in Appendix 10.1.

Weeks	Observation
Week 1	<ul style="list-style-type: none"> • The AHSN speakers and the CPI speaker presented the project brief and specifications. • Students started to organise themselves into groups. Each group works together throughout the semester. • I presented the problem of poor adherence to the students and why it is important to address.
Week 2	<ul style="list-style-type: none"> • Groups were uncertain about choosing a problem to solve. So, they shared their own experiences to reach an agreement about the problem. • Teams overviewed the project requirements and critical aspects that may help them define the health challenge they would like to focus on. • Groups explored the different problem perspectives using the MPPF, which helped them find key areas of interest (cornerstone). So, they explored their own experience, knowledge and their observed relatives and friends. • Some of the group discussed adherence together to consider it in their project.
Week 3	<ul style="list-style-type: none"> • Some teams were still uncertain about the problem they want to address. So, they continued to explore the problem space. • Some teams defined the problem and started to think about solutions. • Some groups started desk and field research to learn more about the problem as well as exploring possible solutions. • Teams used mind maps related to cornerstones they identified through the MPPF. • Few groups advanced in considering adherence. I reminded the groups with adherence as they dropped it from their discussion

Week 4	<ul style="list-style-type: none"> • The students continued to learn about the areas of knowledge related to their defined problem. • Their ideas become a bit clearer than before. Many of the groups started to either do primary research or develop the solution idea. • There is evidence in the solution space of low consideration of adherence as an influencer of patient behaviour during teams' investigation.
Week 5	<ul style="list-style-type: none"> • Students presented their progress to the AHSN and CPI representatives, who provided feedback and comments about their work. • Groups have a clear definition of the problem they intend to solve. • Group presentations included their progress in the solution space and the research done toward this goal.
Week 6	<ul style="list-style-type: none"> • Groups continued to work on their solutions based on their investigations, brainstorming and feedback received from the presentation. • Students used tools to help them build the solution and understand the business associated with it such as PESTLE analysis and personas. • Groups worked on the product design with a focus on the aesthetics and function of the product. • Some of the groups continued to do primary research through interviews and questionnaires.
Week 7	<ul style="list-style-type: none"> • Students continued to develop their wearable devices and prepared for the final presentation to AHSN and CPI.
Week 8	<ul style="list-style-type: none"> • Tuesday is the final presentation for the students in front of AHSN and CPI. • Students presented their wearable device solutions during the presentation. • Their products showed a focus on the psychological needs and behaviour change of patients. This provides an interesting insight: while the teams indicated they considered adherence, observing the team practice showed insufficient consideration for the adherence factors. • They built the early-stage product prototype through sketching and 3D modelling.

Table 10.2 Brief reflections on the teams' activities during their work on WearCare II.

The above table shows a summary of the students' progress throughout the semester. During these weeks, the groups' practice was recorded into written and audio notes in order to explore how the findings can contribute to answering the main research questions highlighted in Chapter 1: Introduction. An interesting observation from the teams' progress is the adherence consideration which faded as the team progressed in their projects. This insufficient consideration of adherence factors was clearly observed in the teams' final presentations.

10.4 Workshop Progress and Reflection

Each of the teams took one of two routes: they either started with a health problem in mind (team 2, team 3, team 4, team 5, team 6, team 7, and team 8) or started with no idea about the problem they wanted to address (team 1). Choosing which route to take was linked to discussions between team members and if they had previous experience with a specific health condition. The majority of the teams decided to address problems they had personally experienced, representing the reflective practice nature of design (Schön, 1983). While there were eight teams in this class; the three teams shown in Table 10.3 below were selected based on the following four criteria:

- The team started with a problem in mind or explored the problem as they moved in the process.
- How adherence was considered during the design process.
- The design process which was used by the team.
- The clarity in describing the process.

Of the eight teams, three teams were selected to be overviewed in this chapter (Table 10.3). The rest of the teams followed the same process flow of the three selected teams. A table with the remaining five teams' progress is available in Appendix 10.1.

Team	Selected problem	Reason for selection
One	Don't Sweat the Small Stuff (measurement and monitoring health vitals via sweat sweat) – Health monitoring	The team started with no clear idea about the problem to address.
Two	Insulin Pump (reinventing the Insulin pump) – Treatment and monitoring of chronic condition	The team demonstrated partial consideration of adherence from the diabetic patients' perspective.
Four	Push Pal (pain-tracking device and app for patients with Osteoarthritis) – Monitoring of chronic condition	The team demonstrated partial consideration of adherence from the chronic osteoarthritis patients' perspective.

Table 10.3 The overviewed three teams, their solutions and why they were selected.

Below is an overview of the teams' progress through the design process stages and some key findings based on observing the teams. A complete list of the teams' progress is available in Appendix 10.1.

10.4.1 Problem Exploration

The teams started to explore the problem using the MPPF method to explore the problem frame by identifying the cornerstone keywords representing the problem's definition.

Teams varied in their search for the knowledge related to the problem. As highlighted above, team 1 started without a prior idea about the problem they want to solve, which is a key difference between them and the rest of the teams (Figure 10.2). This being the case, they started by exploring the centres of inquiry: measurable factors, medical and wearable tech trends, ailments, existing wearable med-tech, research opportunity, wearables and why a wearable?

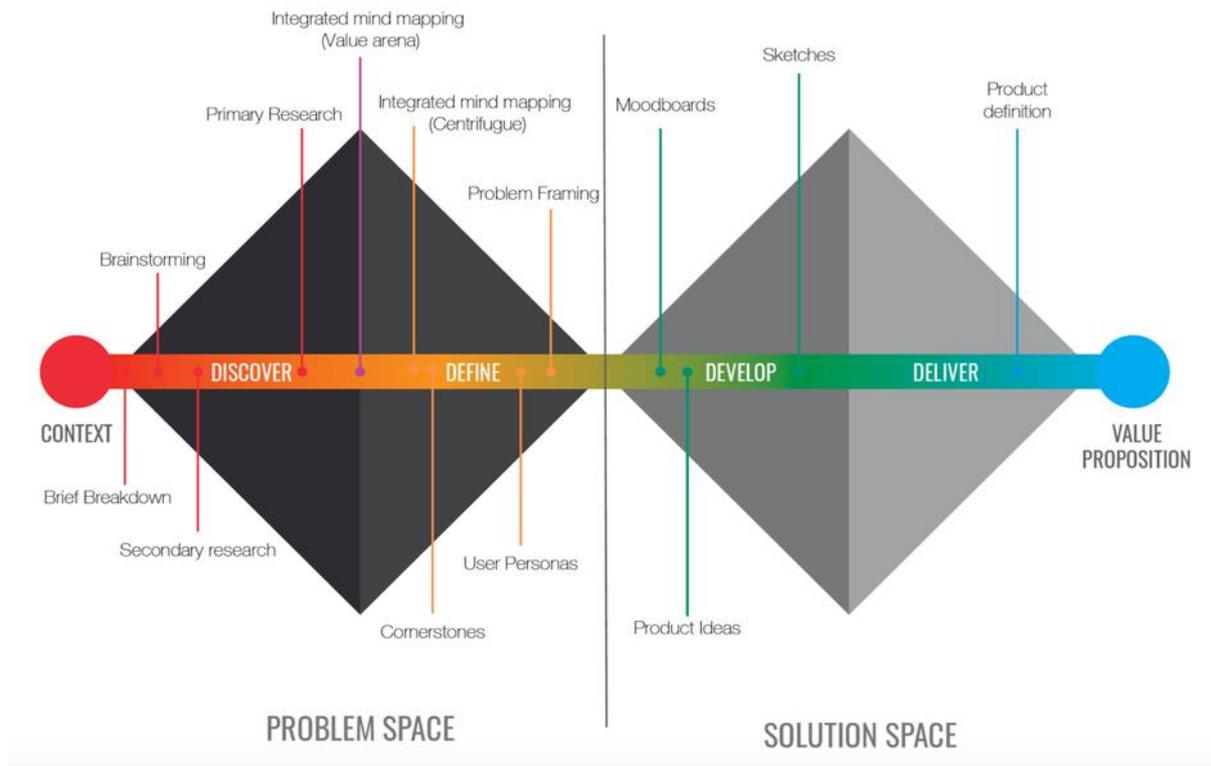


Figure 10.2 Team 1's activities mapped onto the Double Diamond (Source: team 1 final presentation).

Along with the above, team 1 presented a clear map for all of their activities to provide a design solution for the medical problem they selected (Figure 10.1).

10.4.1.1 Team 1

Team 1's cornerstones were different from what was described in the project brief. The cornerstones were based on the team discussion and the team's decision concerning the key areas that they were using to explore the problem. Each team used the centre of inquiry related to the targeted disease and this may be a reason behind the neglect or poor consideration of the adherence factor. This observation shows that a gap can occur between the initial requirements and the team's selected centre of inquiry. Team 1's defined inquiry neglected adherence and its related factors.

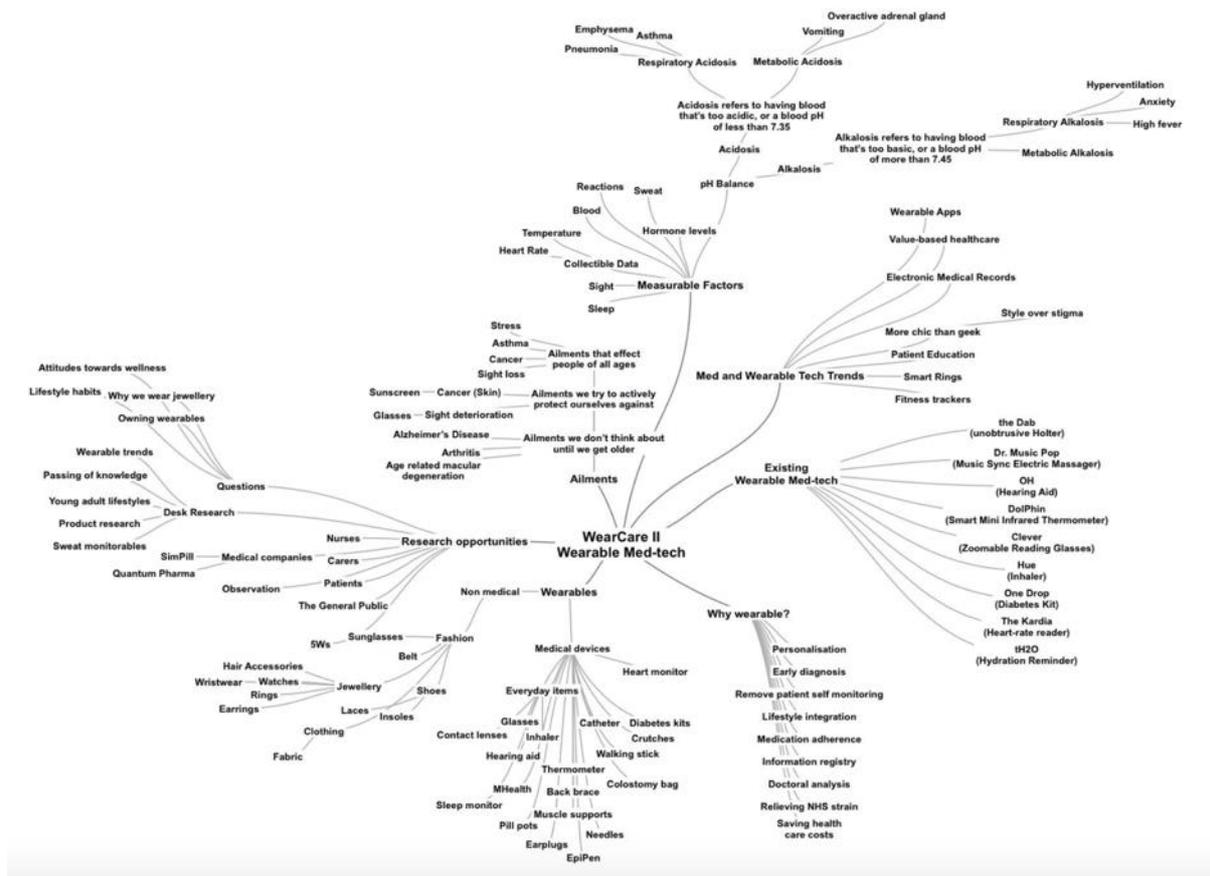


Figure 10.2 Team 1’s exploration of the centre of inquiry in the value arena (Source: team 1 final presentation).

Figure 10.2 shows team 1 exploration of the centre of inquiry. Without a clear idea of the target disease, the team explored a broader scope of medical technology applications.

10.4.1.2 Team 2

Team 2 started with a clear idea of the health condition to address (Diabetes). They considered adherence in three areas of investigation: Adherence, Patient Education and Prediction Model (Figure 10.3). These areas presented a limited consideration of adherence factors with no clear idea of why and how the above adherence factors were selected. However, the team’s consideration of adherence is interesting. While the team did not consider the broader scope of adherence factors, their centre of inquiry keywords show they considered adherence within their initial investigations. For example, the above areas of investigation are closely related to the adherence factors related to diabetes (Wu et al., 2020).

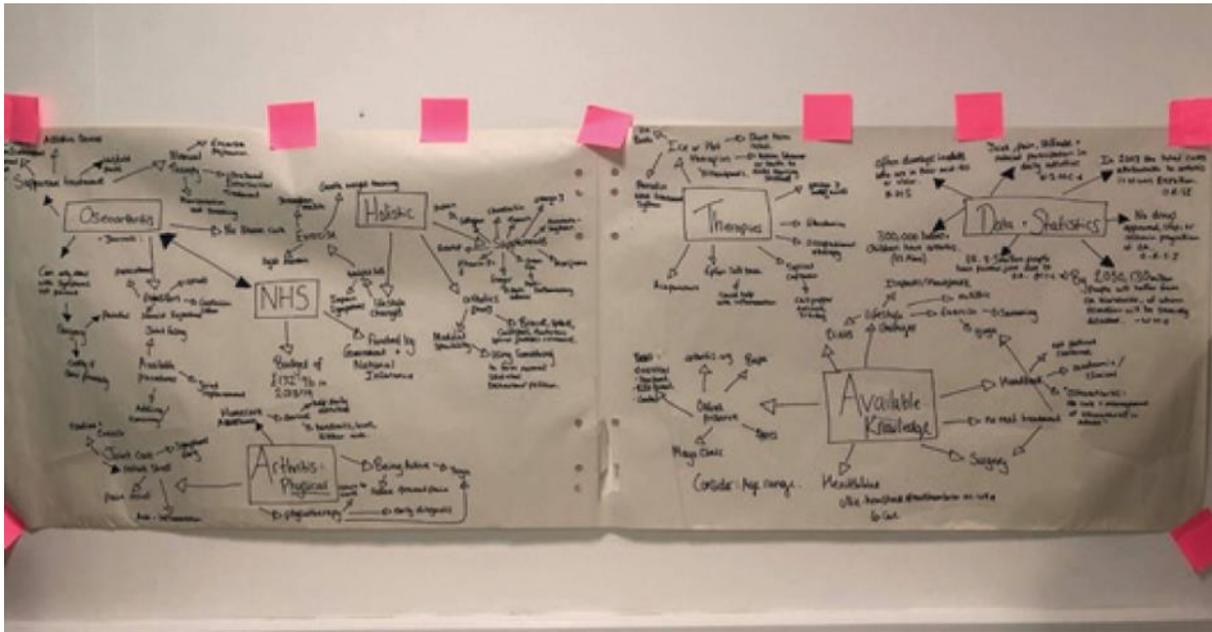


Figure 10.4 The radial mind map for the centres of inquiry investigated by team 4 (Source: team 4 final presentation).

10.4.2 Problem Definition

In the second stage of the Double Diamond (Design Council, 2015), the teams converged their findings to define the problem in hand. As the teams applied the MPPF method to identify the cornerstone keywords related to the problem, they used a centrifuge process to progress toward this goal.

10.4.2.1 Team 1

Team 1 used an integrated mind map to identify the cornerstone keywords that could set the problem frame that could then be used to define the target problem in the subsequent stages (Figure 10.5). The team defined seven cornerstones: Research opportunities, ailments, wearable, why wearable, measurable factors, med and wearable tech trends and existing wearable med-tech.



Figure 10.5 The centrifuge process used to identify the key cornerstones (Source: team 1 final presentation).

The team identified the context of the problem and move to the solution space. The questions they asked are:

- Why is it needed?
- How will it work?
- When will it be used?
- How will it be used?
- Who will use it?
- How long will it be used?
- Where will it be used?

To answer these questions, the team conducted primary and secondary research based on many personas. According to the findings, the number of personas was reduced to two (Figure 10.6).

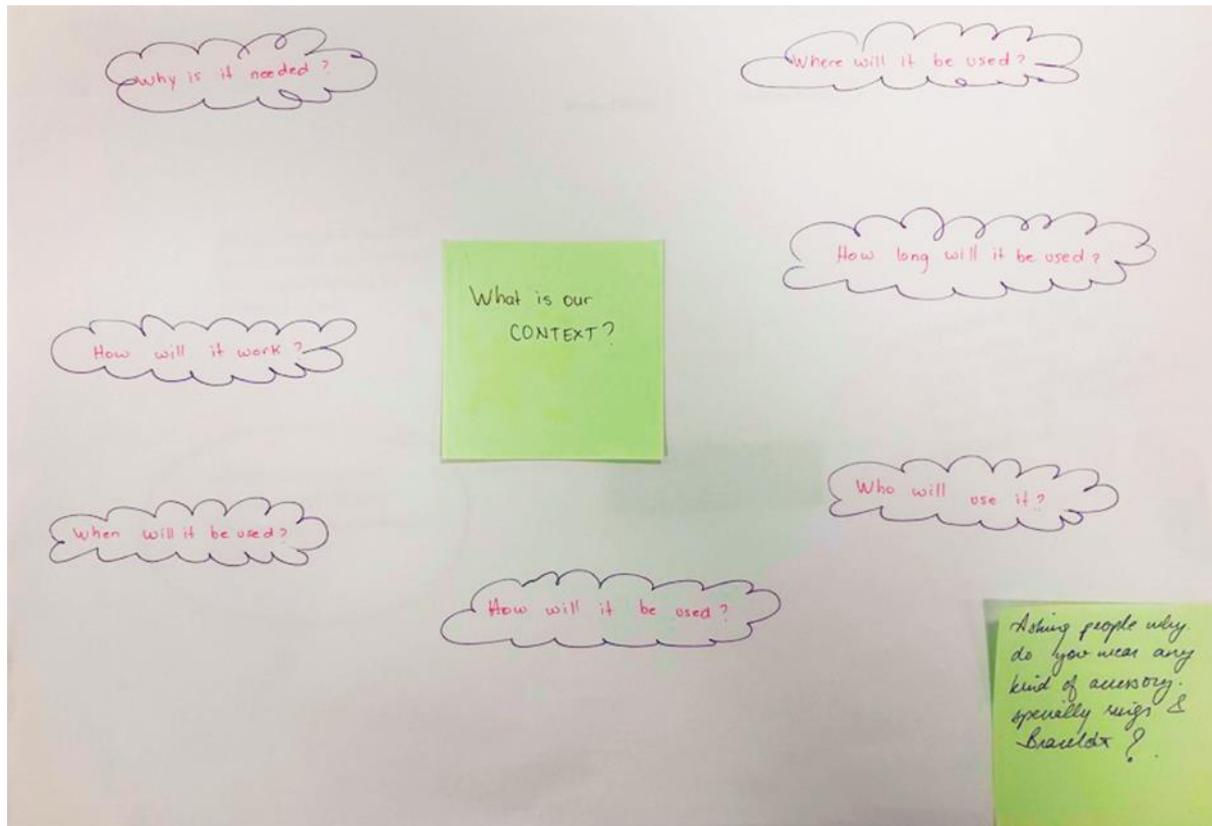


Figure 10.6 The application of '5Ws' method to identify the characteristics of team 1's solution (Source: team 1 final presentation).

Patient adherence was absent from team 1's initial mind maps. This neglect or insufficient consideration of adherence subsequently continued until the stage where the target solution's characteristics began to form. Therefore, adherence was outside of the scope of the team progress.

10.4.2.2 Team 2

Team 2 continued to build an integrated mind map (Figure 10.7) to define the key cornerstone. They used the universals (English, 2007) to break the idea down to its fundamentals in order to address the solution space. The solution universals are:

- Removal of medical design language to counteract insecurities and stigmas whilst wearing the devices.
- Accessible to all ages through the NHS.
- A system to educate users about how to better manage all the factors which affect their diabetes.

- Utilise multiple pre-existing wearable media technologies for broader data collection.
- Improve GP-patient relationships for better understanding and tailored medication.

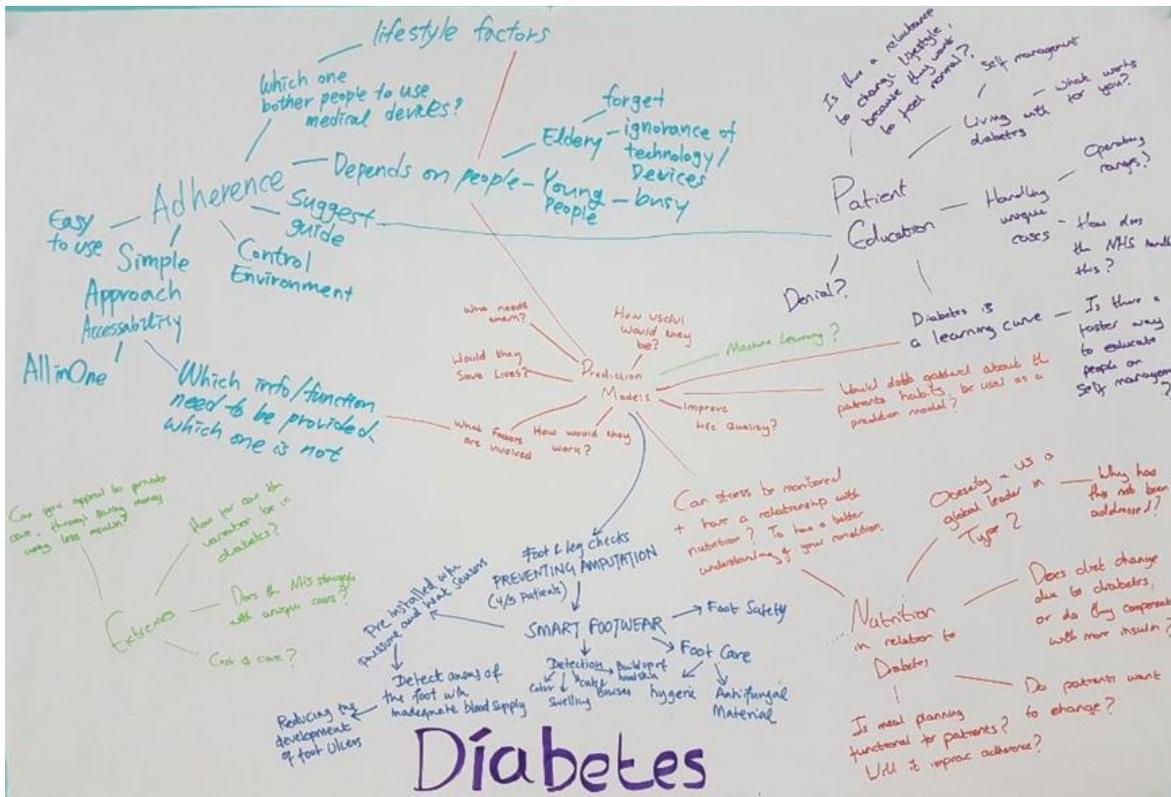


Figure 10.7 Team 2's integrated mind map using the centre of inquiries (Source: team 2 final presentation).

Team 2 showed early consideration of some adherence factors. The consideration was reflected in the following stage (problem definition). For example, the universals reflected the consideration of adherence, as highlighted in Table 10.4.

While team 2 considered some adherence factors, others were not considered. The reason why some factors were considered and other factors were not is unclear; however, a review of other companies who target diabetes reveals that they focus on adherence factors such as patient education, communication and self-administration of the treatment over a long-term period.

Universals	Adherence factors	References
Removal of medical design language to counteract insecurities and stigmas whilst wearing the devices.	Environmental cue, Subjective norm, Coping appraisal	Bosworth et al., 2005; Martin et al., 2010; Williams, 2014)
Accessible to all ages through the NHS. A system to educate users about how to better manage all the factors that affect their diabetes.	Affordability, accessibility, inclusiveness	(Nunes et al., 2009; Sabaté, 2003)
Improve GP-patient relationships for better understanding and tailored medication.	Patient empowerment, patient-clinician communication, monitoring	DiMatte et al., 2012; Henson, 1997; Horne et al., 2005; Williams, 2014)

Table 10.4 Mapping team 2's universals and adherence factors.

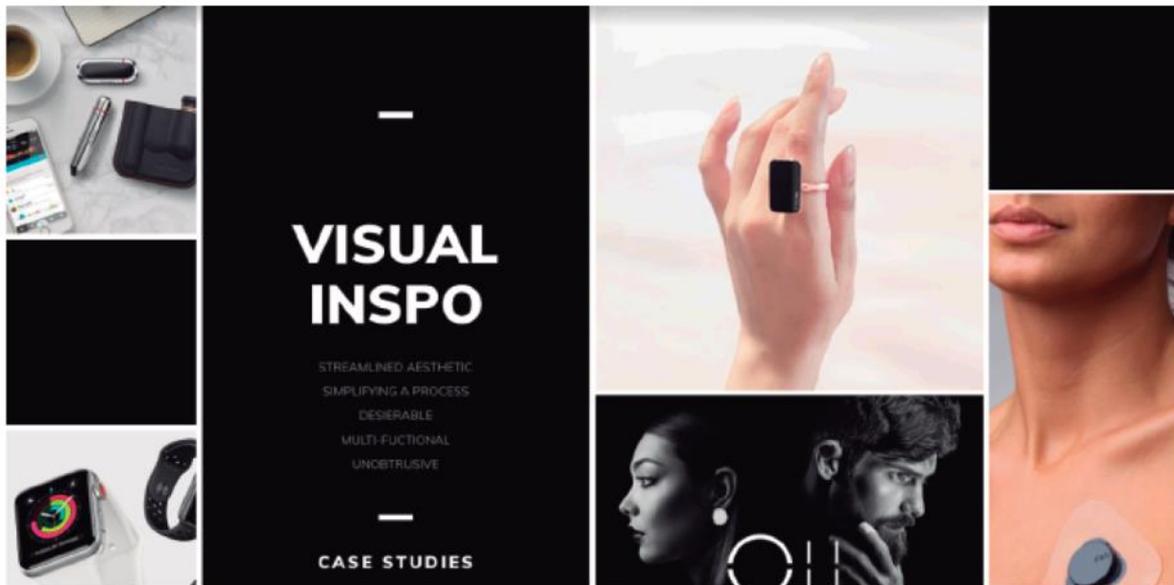
10.4.2.3 Team 4

Team 4 continued to work on the radial maps (refer to Chapter 1: Introduction, Section 1.5 Definition of Terms) and then used them to build the integrated maps used to define their cornerstone keywords which contributed to the solution frame. Figure 10.8 shows the main cornerstone keywords: Wearable technology, physical, holistic, inclusivity, available information, psychological and physical. As the team moved to the integrated map, the keywords related to adherence factors influenced the consideration of adherence (i.e. available information, self efficacy and impact). The rest of the teams followed the same process as above, focusing on the medical condition that they wanted to address.

10.4.3.1 Team 1

Team 1 began by defining personas for possible patients, which were reduced and filtered after their research. Part of their research was to identify the aesthetics of the solution. At this point, the team had an idea of their solution frame. To understand the solution's possible aesthetics, they built a mood board to reflect the expected visuals and styles (Figure 10.9).

Initial Moodboard



Final Moodboard



Figure 10.9 Mood boards created by team 1 (Source: team 1 final presentation).

During the 'Develop' stage, team one explored different tech wearables and how they are used as fashion accessories, especially where and how they are worn on the patient's body (Figure 10.10).



Figure 10.10 Team 1 explores the different wearable options for the medical device.

The product's final design was based on primary research to discover where patients in the sample preferred to wear the device. Accordingly, they decided to design the product to be wearable on the wrist. This provided the benefits of easy control and customisation and also had to do with many of the existing med-tech and smartwatches in the market (Figure 10.11).

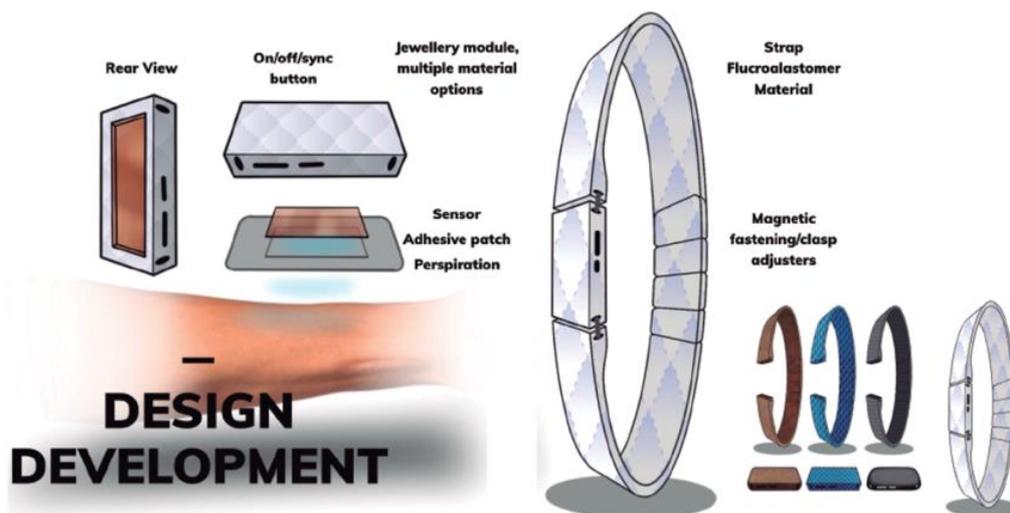


Figure 10.11 The final design for the product designed by team one (Source: team 1 final presentation).

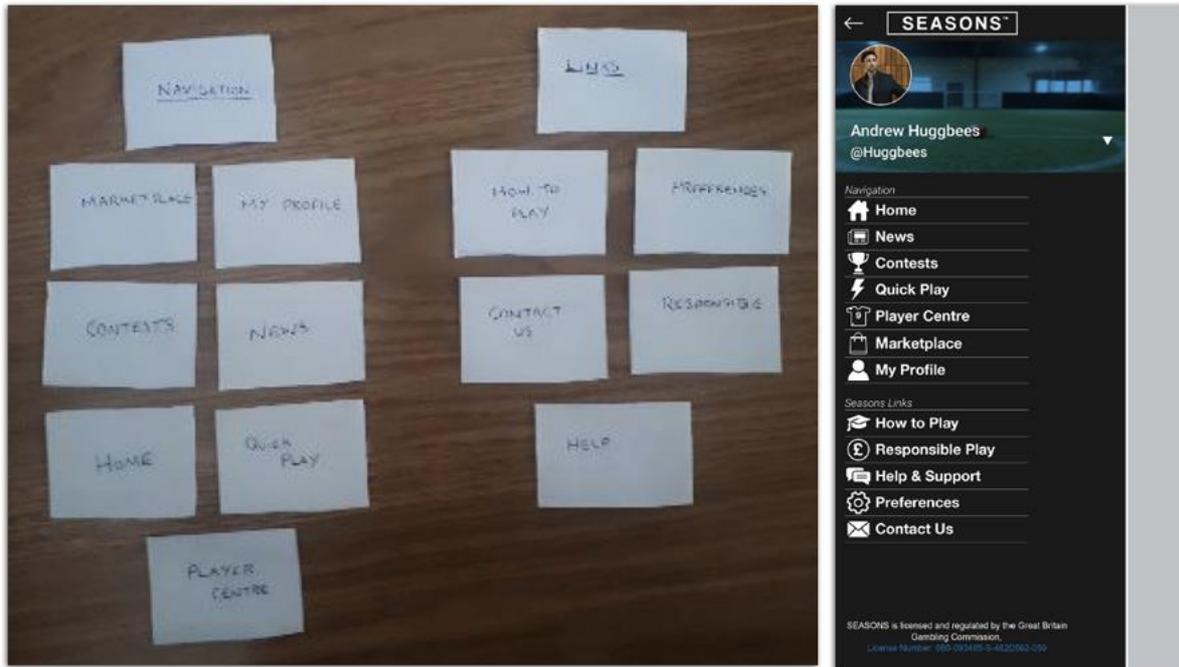


Figure 10.13 The features organised on the left. The features appear in the mobile app navigation (Source: team 1 final presentation).

10.4.3.2 Team 2

Team 2's solution was a device (Insulin pump) and software application. The application collects data from the patient's several wearables to build an accurate prediction of the patient's habits and provides alerts on bad habits. Also, the usage of data from multiple devices helps the app determine the amount of Insulin required to be injected using the Insulin pump (Figure 10.14). The team proposed designing the pump to look less like a medical device by using colours. As a result, patients would use the exact amount of Insulin required for their case, which would be cost-effective for the NHS due to the high cost of Insulin. This would result in more people benefit from the NHS service, especially when the treatment is self-administered.

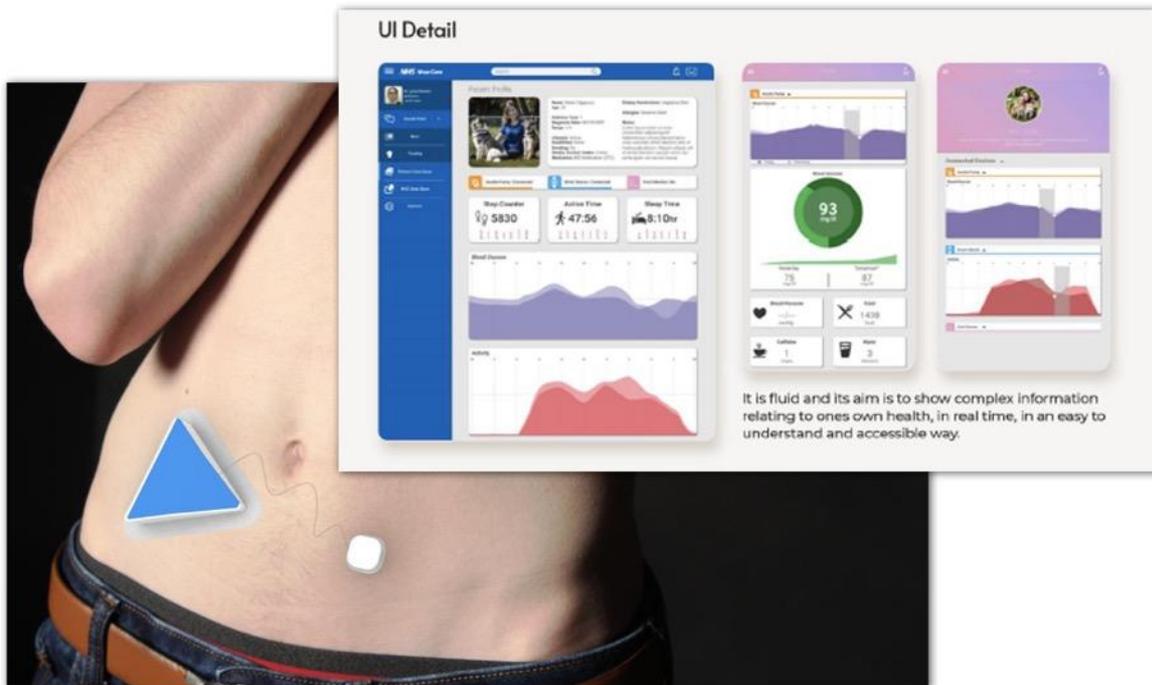


Figure 10.14 Team 2's design of the Insulin pump (left) and the associated application (right) (Source: team 2 final presentation).

The treatment has an educational component, as it can advise patients to follow a healthy diet and encourages habits that can drive a healthy lifestyle.

The final solution shows a level of consideration of adherence factors, including patient prediction models, patient education, alerting patients and encouraging a healthy lifestyle. These factors were reported during the case studies interviews (Chapter 9: Case Studies Interviews) and literature adherence theories (Chapter 6: Theoretical Frameworks of adherence). While there may be other factors to consider, the treatment solution's features show that the team was able to consider adherence factors during the design process, which contributed to reaching an adequate level of consideration in the final treatment solution.

10.4.3.3 Team 4

Team 4 went through possible solutions which could be used to record and track pain. These potential solutions had common criteria, such as being easy to understand, use, hold and difficult to forget (Figure 10.15). The device aimed to record the pain level through the

number of clicks of a button that the patient pushes. These clicks are saved and collected by an app that can provide detailed information about the pain and related data level.



Figure 10.15 Team 4’s draft prototypes of the PUSHPAL solution for osteoporosis pain tracking (Source: team 4 final presentation).

The final solution prototype (Figure 10.16) shows the device (PUSHPAL) in on and off mode, as well as its charging cable. The device can also be used with voice activation for patients who cannot use their hands due to osteoporosis pain. The device is connected to a mobile app that monitors and shows the pain patterns and records specific activities that may increase the pain level.

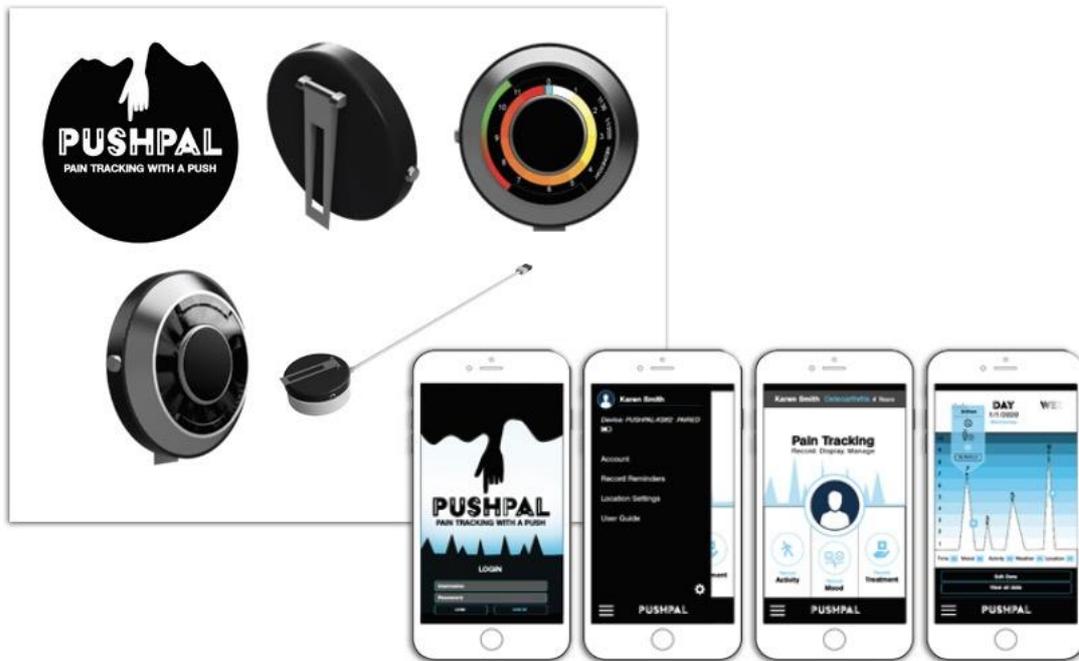


Figure 10.16 PUSHPAL device and mobile application (Source: team 4 final presentation).

Team 4 showed poor consideration of adherence factors, and the prototype reviewed above does not provide sufficient evidence of consideration of adherence in either the device or the mobile application. The only feature that can be linked to adherence is voice activation, which is related to usability (the application is user-friendly) and accessibility (the application considers patients with disabilities).

10.4.4 Product Delivering

At this stage, the teams should have a clear idea about the solution frame and have transformed the theory into a prototype which can be tested and evaluated. While the class was not designed to facilitate creating and testing a product in reality, students nevertheless used PESTLE to analyse the market compared to external competing factors (Jonathan, 2016). They also utilised the Value Proposition Canvas to define the product potential value (Figure 10.17). After identifying the value that a product can add to the market, teams could use these data to build their business strategy.

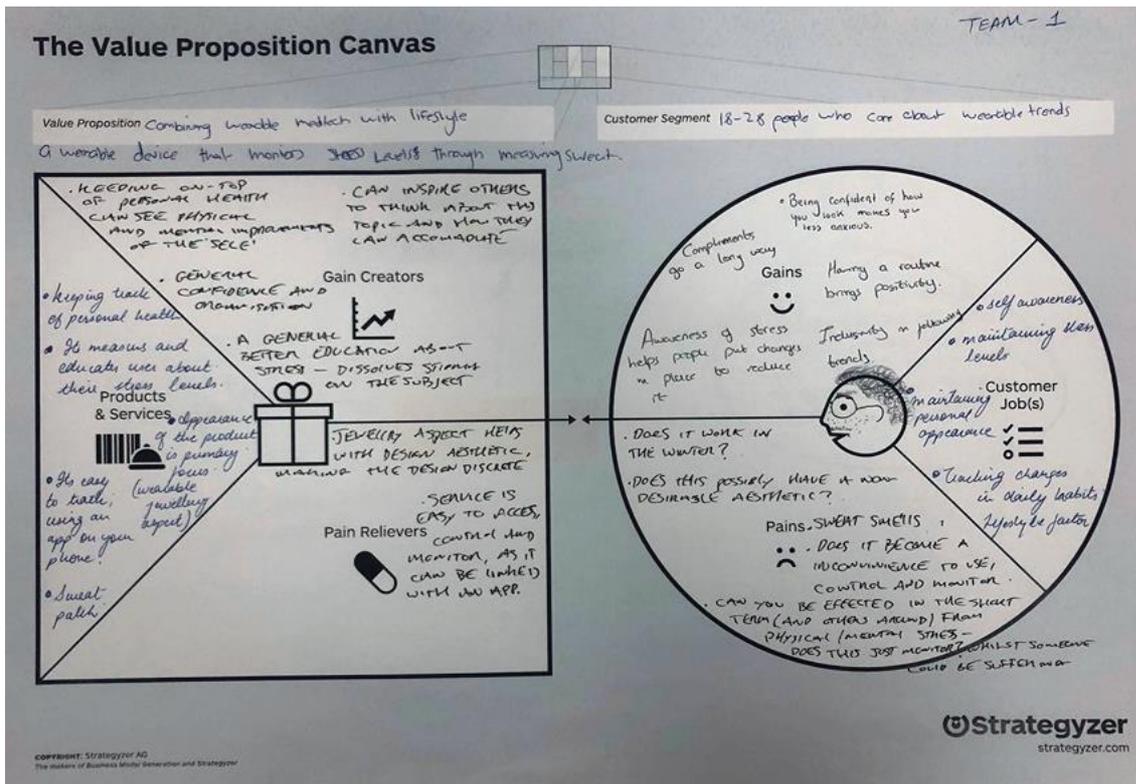


Figure 10.17 The Value Proposition Canvas of team 1 (Source: team 1 final presentation).

For example, team 1 defined their value proposition as follows:

‘Our product aim is to measure hormone levels as a form of preventative healthcare for young adults (18-28) by integrating an electronic sweat monitor into a wearable accessory. By doing this, we target to blur the line between medical tech and lifestyle.’

Each team asked the rest of the class to evaluate the final idea based on the PESTLE factors.

The teams could then use these data to improve the product idea. Figure 10.18 shows examples of the teams’ feedback to each other. Each team then visualised the PESTLE analysis findings using a radial map in order to identify the areas that needed to be improved (Figure 10.19).

Project Team: 1
Helping Team: 5

ELEVATOR PITCH

Our product aim is to measure hormones in a form of presentable healthcare for young adults (18-25) by utilizing obvious sweat sensors in a wearable device. By doing this, we aim to blur the line between medical tech and lifestyle.

INFLUENCES

Political → Current government can potentially cut funds of health care system and development, resulting shortage of financial resources.
Economic → Young adults usually have low income and might not be able to afford.
Social → Monitor health like helping to manage & habits, improving lifestyle.
Technological → Technical devices that can achieve the same with minimal amount of sweat.
Legal → Legislation from the UK might accept the patent of the device however other countries need to approve the device (initially the acceptance process automatically).
Environmental → Global warming can affect sweat levels and damage the device.

STRATEGY

Political - we will not be dependent on the NHS. Our product will be bought by consumers.
Economical - we will be using cost-effective materials for aesthetics.
Social - we will be using hormones to monitor stress through sweat as a more presentable measure (health care).
TECHNOLOGY - we will be focusing on the aesthetic appearance along with medical attributes of the product.
ENVIRONMENT - we will ensure the patch is replaceable.
LEGAL - we will begin the test in UK.

Project Team: 5
Helping Team: 7

ELEVATOR PITCH

Create a wearable medical device that helps to cope with and cure anxiety disorders in children. Through the concept of non-dependent / independent using over a period of time.
 To achieve this we have undertaken primary and secondary forms of research through communication with experts in the field of psychology and referring to books, articles & journals respectively, to understand the significance and application of the device.

INFLUENCES

P - EDUCATION - government can focus on mental problem in schools.
F - FINANCE - can support their needs of hospitals, using, education, etc.
S - ACCEPTANCE - to improve care, support, involvement in social to avoid negative thought about people - to develop future of children education.
T - APPLICATIONS - to make new friends & reduce pressure - games to improve mind & distance from anxiety.
L - PROTECTIVE GEAR - protect them from heat & injury, to preserve the future generation.
E - SCHOOLS - special space for children - private discussions with teachers & psychologists.

STRATEGY

- To address. Decision is important from a social perspective that the device is concealable and discrete for users.
- From an economical perspective, it is important that there is a budget from different government sectors including Education + Health care + Social welfare to support the development of the device. Additionally, using a sustainable material that keeps production and environmental expenses low.
- Encouraging health education and awareness of mental health issues from a post-act perspective since children are going through anxiety more and more.

Figure 10.18 PESTLE reflections of team 1 and team 5 (Source: team 1 and 5 final presentations).

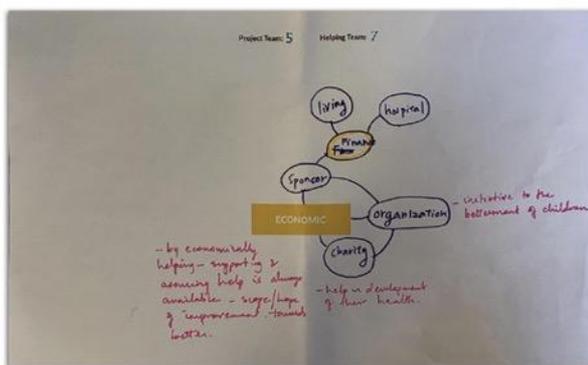
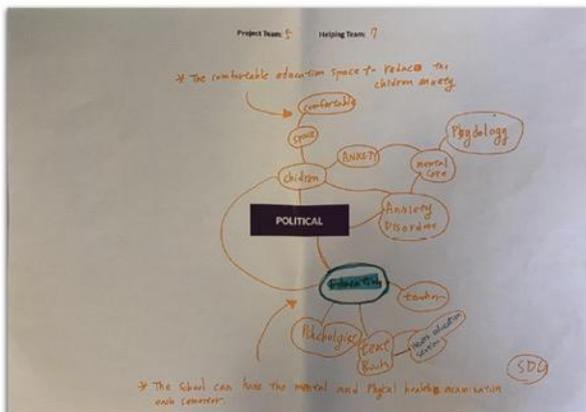


Figure 10.19 Team 5's reflection on the PESTLE feedback from team 1 (Source: team 5 final presentation).

At the end of the project, students presented their ideas for new products to representatives from AHSN and CPI. The presentation was an opportunity to explore how adherence was considered in the final concept. In Table 10.19, final ideas from the rest of the teams that were presented in the final presentation.

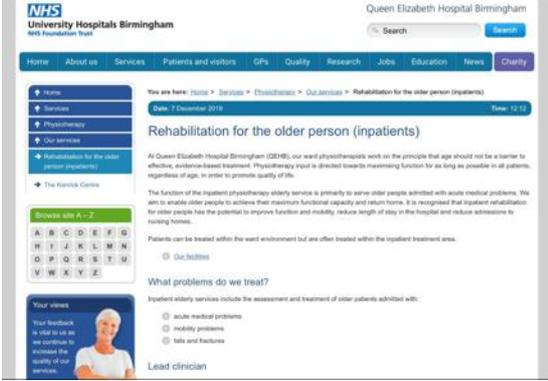
<p>Team 3: Discover Recover (chronic stress)</p>	<p>Team 5: COCUMON (anxiety disorder patch)</p>
	 <p>Figure 19. Product application on body</p>
<p>Team 6: Loneliness Lab (a website and installation of areas for lonely people to meet)</p>	<p>Team 7: Rehabilitation of the elderly website</p>
	
<p>Team 8: Allergies detection device and mobile application</p>	
	

Table 10.5. Each group presented the final ideas at the end of the semester. (Source: final team presentations).

10.5 Reflection and Discussion

The above examples provide an overview of the practice of the eight teams in this project. Three examples were selected based on the ideas they had at the beginning of the project, the consideration of adherence, the design process used and the clarity of describing this process. The rest of the teams worked via a route similar to the examples discussed in this chapter. Two teams (team 1 and team 3) did not start with an accurate definition of the health condition. One team (team 3) did not show any consideration of adherence-related factors. The following can be observed by the early-stage mind maps above:

- The observation of the above process shows the complexity of the design practice, which may present a challenge when considering a complex factor such as adherence and maintaining this consideration throughout the process.
- All the teams acknowledged the importance and impact of adherence on health or medical intervention. However, adherence factors were poorly considered during the design process of almost all teams.
- The teams who considered adherence factors did not fully consider the primary factors that affect patient adherence. For example, Team 5's consideration of adherence ignored other factors such as communication between patient and clinician, motivation, locus of control and social learning.
- Teams explored areas which are related to their target health condition. These areas are related to adherence as they can be mapped onto the theoretical frameworks of adherence. For example, team 2 targeted a disease (diabetes) where patients are more likely to adhere to the treatment than others.

10.6 Summary and Findings

The observation of the WearCare II project aimed to see how adherence is considered at an early stage of the design process. This perspective was not available in the case study interviews as the companies were established and had the product already developed in stages which varied from one company to the next. Observing the eight teams working on the WearCare II project revealed a number of insights that may help identify the research

contribution to knowledge. These observations include: 1) the complex nature of the design process, especially considering its iterative nature; 2) the poor consideration of adherence factors; and 3) the lack of a mechanism that maintains consideration of adherence factors during the iteration stages of the process. The findings from this stage contributed to the next stage by triangulating findings about the consideration of adherence at an early stage of the design process in the Assess stage).

The above final project ideas show that some teams could provide an adherence-friendly health solution, while others could not achieve this target. This observation mirrors real-life cases, as some companies can deliver a product based on their initial plan target, and others cannot. There may be many reasons for this, but the one which stands out is that there is no mechanism or a tool with which companies can measure their compliance with the adherence strategy during the product development.

Part 5

Assess

Chapter 11: Delphi Method Application

This chapter describes the assessment stage, which is the last stage in this PhD research. The Assess stage involved both triangulation of the previously collected data and developed consensus on the adherence factors. The assessment was conducted using the Delphi method, which will be covered in this chapter.

Key Topics:

11.1 Delphi Round One Questionnaire

11.2 Delphi Round Two

11.3 Delphi Round Three

11.4 Findings and Summary

Assess is the final stage of this research. Before this point, literature studies related to patient adherence, medical technology, and design thinking was reviewed and analysed in the Investigate stage. Then, interviews with five case studies were conducted to explore and understand the design process and the consideration of adherence during the design and development of treatment (and treatment-support) technology. The second stage, Explore, involved observation for the Wearcare II post-graduate students' projects. This stage assessed the findings from previous stages and collected a consensus from the panellists on a design-focused adherence canvas, a resource that could be used to guide and measure adherence consideration during the design thinking process. The primary aim of the stage is to find an agreement on an Adherence Canvas influenced by the design thinking process and improve adherence during the development of self-administered treatment technology.

Based on the research aim, three words were considered to describe this stage: 'assess', 'evaluate' and 'test'. Based on the Cambridge Dictionary entry for 'assess', the word means to judge or decide the value or importance of something (Cambridge Dictionary 2020, 'assess'). The term 'evaluate', in contrast, means to judge or calculate the quality, value or importance of something (Cambridge Dictionary 2020, 'evaluate'). This definition indicates the measurable nature of the evaluation process. The word 'test' varies from the above two as it suggests the questioning of or carrying out practical activities in order to understand a specific phenomenon (Cambridge Dictionary 2020, 'test').

The term 'assess' refers to documenting a specific knowledge or skill measurement in order to improve it in the future. The word 'evaluate' refers to making a judgement based on evidence. The last word, 'test', examines someone or something based on a measurable guide to identify the level of the skills or improvement reached (Penn University, 2020). According to these definitions, the aim of the research and the time limitations of the PhD study, the word 'assess' is used in this stage to describe the method used to obtain a consensus about the adherence framework, which is based on the findings from the previous stages. These findings were used to develop a framework that was assessed and refined through the Delphi process. This framework can support SMEs during their production of treatment devices (5.6 Implementation of Delphi methodology).

Two main factors dictated utilising the chosen research method at this stage: 1) the confidentiality of information shared by companies (Keeney et al., 2011); and 2) the target, namely assessing the proposed framework. Based on these two factors, the Delphi method was chosen to obtain a consensus about an Adherence Canvas (Linstone & Turoff, 1975).

Additionally, this study takes a phenomenological approach to understanding the phenomenon of adherence and the factors affecting it in relation to the social actor (the patient). To achieve this goal, the Delphi approach will be used to assess the factors which can be used to improve adherence during the design and development of self-administered treatment technology through collecting data from the panellist about what they consider are the adherence factors and how adherence can be considered. This approach will guide the process and selection of the panel if you mean Delphi, say so as well as its design.

During the Delphi method stage, the U.K. and the world were hit by the COVID-19 outbreak. It affected both the business and also the social lives of many people in the U.K., including the Delphi panellists and me. The government's strategy of asking people to stay home and work from home had a significant impact on this study. The outbreak's effect on the study is reflected in the panellists' time in responding to the questionnaire.

11.1 Round One Questionnaire

The aim of round one was to collect feedback from the Delphi panellists about adherence factors. The questions and their categorisation were influenced by the analysis of the data collected from the literature studies, case study interviews, and WearCare II study. This round's main aim was to benefit from the experts' points of view, focusing particularly on what they agreed and disagreed on. Therefore, the questions take an open-ended qualitative form (Keeney et al., 2011).

The first round ran from 10 February to 27 March 2020. This period included sharing the pilot round questionnaire with the sample panellists, analysing the pilot panellists'

comments and circulating the first-round questionnaire. The invitations to answer the first-round questionnaire were shared with the panellists through an email which contained a URL to the questionnaire on SurveyMonkey. Panellists were able to visit the URL and answer the questions. The answers were recorded and analysed through SurveyMonkey web tools. The above period included follow-up emails and messages to remind the panellists to answer the questionnaire.

The first round consisted of five questions. Each question presented a possible category of the adherence factors which was influenced by the literature studies. The panellists were asked to fill out the questionnaire and confirm answering it through email. Furthermore, SurveyMonkey.com sent me alerts of new answers. Below is a list the questions shared with the panellists. For a sample of the open-questions' answers, please check Appendix 11.1.

PhD Study: Explore the Role of Design Thinking in Improving Patient Adherence in Self-Administered Treatment Technology

- Information factors:

Information is a crucial part of patient treatments (e.g. patient education, usage information, and patient perception about the treatment). These factors become essential when the intervention is self-administered by the patient.

What are the information-related factors you would identify as impacting patient adherence in self-administered treatment? Please list these factors and add explanations where possible.

- Motivation factors

Different psychology-based theories highlight motivation as a driver of behaviour change and adherence improvement in self-administered treatment technology.

What motivation-related factors do you think can affect patient adherence in self-administered treatment technology? Please list these factors and add explanations where possible.

<ul style="list-style-type: none"> • Communication factors: <p>Communication between patients and clinicians can improve adherence (e.g. monitoring, phone follow-ups and regular checks). However, communication can present a challenge in self-administered treatment.</p> <p>Which communication-related factors would you identify as impacting patient adherence in self-administered treatment? Please list these factors and add explanations where possible.</p>
<ul style="list-style-type: none"> • Product design factors <p>In treatment devices, design factors (e.g. device look, usability and affordability) play an essential role in the patient's adherence to the treatment regimen.</p> <p>What are the design-related factors you think can affect patient adherence in self-administered treatment technology? Please list these factors and add explanations where possible.</p>
<ul style="list-style-type: none"> • Adherence consideration <p>During the development process of the treatment device, adherence can be considered in different ways (e.g. prototyping, testing and patient advisory groups).</p> <p>How can adherence be considered during the development of treatment devices? Please list how adherence can be considered during the design and production of self-administered treatment devices and add explanations where possible.</p>

Table 11.1 Round one open-ended questions.

The main questions' headings represent the categories for the adherence factors. The questions (highlighted in bold text) were then presented with a description which attempted to clarify each section for the panellists.

11.1.1 Round One Analysis

The time it took to answer this round was longer than expected due to the COVID-19 outbreak and government's instruction to work from home, which may have affected some of the panel members' plans to answer the questions. After 27 March, the results of round one's answers were analysed. The response rate was 100%, as all 15 panellists answered all the questions. The average time spent answering the questionnaire was 21 minutes.

As highlighted in Chapter 5: Delphi Method Methodology, the classic Delphi and eDelphi usually involve open-ended questions in the round one questionnaire, which may produce a large number of data to be analysed (Keeney et al., 2010). Therefore, content analysis for the collected data can provide an opportunity to categorise the data into themes which can be easily tracked and processed in the following rounds (Powell, 2003).

Content analysis is a widely accepted method of analysing qualitative data, especially in applied research which has been extended so as to be accessible to those who are not part of the academic community (Braun & Clarke, 2014). This makes it a suitable tool for the nature of this research. In particular, deductive content analysis was used, so the evolved codes documented from the panellists' answers informed the theme development. Another feature of the deduced content analysis is the ability to look behind the words for the meaning (Smith, 2003). However, a minimal level of interpretation to the content was used in order to avoid biased and inaccurate content.

11.1.2 Content Management

After collecting the answers to round one, the content was copied to NVivo in order to apply the thematic analysis. Each of the 15 panellists' answers were copied to NVivo in files. Each File included the responses of one panellist. The Files were named after each of the panellists, as no anonymity was needed at this stage.

Each file was reviewed, organised, and highlighted the questions so as to identify the questions and their answers. A minimal level of cleaning the content was conducted as the text collected was written by the panellists themselves. The responses were refined, and no further communication with the panellists was required to clarify any of their answers.

11.1.3 Content Analysis

An earlier expectation was that there would be many codes generated. This being the case, there was a plan to analyse the content to provide codes which represented the panellists' answers, categories and subcategories. This categorisation would make it easier to follow

the adherence factors while reviewing the analysed data and when conducting a reliability procedure.

The content was reviewed with more focus to analyse each sentence and identify the codes they reflected. Each sentence was selected and assigned a code using the Nodes feature in NVivo. Along with the code name, a description was assigned for each code to make sure its meaning was accurate and improve clarity and accuracy.

Once the coding stage was completed, The created codes overviewed, determined the relationship between them and created categories for similar codes. This process involved reviewing the codes and the connections between them. Once the categories had been set, I exported the content to Microsoft Excel so that I could easily discuss and share it with the inter-raters in the following reliability test stage.

The codes, the relevant text and the categories are reviewed and organised in a MS Excel document. The generated codes presented a large amount of data, which turned the theme identification into a challenging process. Therefore, other subcategories were created to define the several sub-sections of the adherence factors. Table 11.2 below shows the categories, subcategories and the codes associated with them. The Participants column indicates the number of panellists who mentioned each specific code or category. The Item Count column shows the number of text phrases coded under the below codes to identify the content themes. For a complete list of the codes, their descriptions and the answers associated with them, please refer to appendix 11.1.

11.1.4 Inter-rater Reliability

After finalising the code analysis of the Delphi round one, the inter-rater reliability procedure was applied to ensure that the codes were reflective by assigning two raters to code the content. The coding results from the researcher and two raters were then compared to evaluate the agreement on code names. The term 'reliability' itself has various definitions, yet these definitions have similarities with each other. Some definitions include an agreement between two people on how to interpret the same data using the same

methods (Campbell & Fish, 1959). Other definitions reflected the ability to have a consistency measurement (Black & Champion, 1976) and the ability to reproduce the same answer (Bernard, 2000) based on stable (Lehner, 1979) equivalent (Johnston & Pennypacker, 1980) measurements (Guest et al., 2012).

Categories	Subcategories	Codes	Participants	Item Count
1.0 Communication	Patient-clinician relationship	Acknowledge change in physician role	1	1
		Replace communication with monitoring tech	1	1
		Consistence communication	1	1
	Communication effectiveness	Effective communication and feedback	9	16
		Follow-up and reminders	3	4
		Language used suitability	1	3
		Right style of communication	1	1
		Promotional communications	1	1
	Clinician side implementation	Clinical implementation	1	1
		Clinical trials feedback	1	1
	Intervention usage	Intervention support	3	3
	Confidentiality and privacy	Reliability and trust	7	10

Table 11.2 Content analysis and categorisation for Delphi round one questionnaire.

Knowledge	Adequate shared information about intervention	Clear treatment information	7	12
		Simplicity of information	3	4
	Shared adherence consequences	Connecting personalised choices and consequences	1	1
		Measuring targets of health outcome	1	1
		Effective treatment testing	3	3
	Understand patient behaviour	Mismatch in perception of urgency	1	1
		Perceived susceptibility – Belief selection	5	6
		Actual patient behaviour	1	1
		Identify adherence moments	1	1
	Patient information	Patient demographic information	1	1
		Technology literacy	4	4
		Treatment literacy	3	7
	Patient-centred shared knowledge	Considering patient knowledge	9	16
		Tailored information	2	4
		Media used in sharing information	3	3
Motivation	Goals motivators	Achievable goal setting	3	4
	Risk motivations	Drawback – Punishment	4	4
		Perceived severity – Punishment	3	5
	Benefits motivators	Perceived benefits (reinforcement) – Reward	9	15
	Internal motivators	Self-efficacy	4	5
		Health condition	1	1
	Environmental motivators	Subjective norm – Environmental cue	5	5

Table 11.2 Continued.

Patient Experience	Product design characteristics	Aesthetic	5	5
		Packaging and usage process	1	1
	Patient-centred design (tailoring)	Considers patient characteristics	10	16
		Psychological factors	3	3
		Inclusive	1	1
		Usability	8	14
	Adherence consideration	Compliance measurement	2	2
		Concordance – Participation	5	8
		Considering adherence during development	3	7
		Guidance of factors influencing adherence	1	2
	Design research	Field research and testing	5	7
		Design prototyping iteration	3	5
	Device usage	Practicality	1	1
		Affordability	1	1
		Comfortability	3	3
		Self-administration to treatment	4	4
	Social support – Facilitation	8	13	

Table 11.2 Continued.

The intercoder (inter-rater) reliability is one of the methods used to measure the agreement between multiple coders about the code applied to content analysis—the level of agreement of coded data. As the researcher interprets the sample qualitative answers into useful codes, the role of the inter-rater reliability is to ensure that the codes are representative and agreed upon between multiple coders (Campbell et al., 2013; Kurasaki, 2000). Additionally, the intercoder reliability provides measurement of the preciseness of the codes and their definitions (MacPhail et al., 2016).

The nature of this reliability procedure was affected by its position as part of the Delphi study and the Assess stage in the research. Round one collected feedback from panellists about adherence factors, and the panellists' answers were interpreted and coded. Accordingly, the reliability procedure aimed to ensure that code names were representative by allowing two raters to independently analyse and code the content. Furthermore, at this point of the research, data from the literature, interviews and WearCare II observations were triangulated to formulate the knowledge which was then assessed during the Delphi method (round one and round two). Therefore, the reliability procedure was conducted at this point of the research.

11.1.4.1 Selecting and Preparing the Inter-rater

Two inter-raters were assigned to conduct the inter-rating reliability process. This decision was based on 1) the timeline limitations of the study; and 2) limited access to potential coders who could make voluntary contributions to the study. A job list was created to ask for inter-coders. Then, all the applicants were overviewed. Two were chosen based on the following factors:

- Professional experience: their experience needed to be in related fields, which could give them an understanding of the study but not necessarily of adherence. Therefore, the selected individuals had expertise in medical research and biomedical engineering.
- Experience in qualitative content analysis: they needed to have a good amount of experience in qualitative data analysis.

According to the above, rater 1 (R1) and rater 2 (R1) were selected to facilitate the reliability process. They were contacted and given, individually, a general overview of the study, what they needed to do and the timeframe for conducting the procedure. By the end of the induction discussion, they both understood what the research was about, their task and that they could not know the other's identity nor the other's work.

11.1.4.2 Inter-rater Content Analysis

Each of the coders received a copy of the open-answer questions and the answers given by the 15 panellists. They coded the entire content instead of a sample because—since the answers were not very long and varied in length from one panellist to the next—this would likely reduce the margin of error in the measurements (Jones, 2004). I asked them to code the content and organise the codes into categories and subcategories. There were 101 codes generated through analysis of the five interviews, which made the inter-rating process complex and time consuming. Accordingly, the raters were asked to generate representative categories and sub-categories for the related (or similar) adherence factors. This aimed to measure the agreement on the categories and subcategories of the content created by me (the researcher), R1 and R2. Both raters were given the same content to code. Table 11.3 below shows a comparison between code categories of the researcher, R1 and R1. The codes categories were mapped onto each other and the research codes. Complete versions of the two raters' content analysis, including codes, categories, subcategories and description of their inputs, are available in Appendix 11.3.2 and 11.3.3.

Researcher	R1	R2	R1	R1
Communication	Communication	Communication:	1	1
Patient-clinician relationship	Patient-clinician relationship	Facilitated physician-patient relationship	1	1
Communication effectiveness	Communication effectiveness	Adequate communication about device usage	1	1
Clinician-side implementation			0	0
Intervention usage		Communication about device credentials	0	1
Confidentiality and Privacy			0	0
Knowledge	Knowledge	Information:	1	1
Adequate shared information about intervention	Treatment information	Appropriate delivery of information	1	1
Shared adherence consequences	Adherence information	Comprehensive content of information	1	1
Patient-centred shared knowledge			0	0
Understand patient behaviour			0	0
Patient information	Patient information		1	0
Motivation	Motivation	Motivation factors for adherence	1	1
Goals motivators	Behaviour motivation	Motivating features of treatment	1	1
Risk motivations			0	0
Benefits motivators		Positive expectations from treatment	0	1
Environmental motivators			0	0
Internal motivators	Physiological Factors	Patient acceptance of condition and treatment	1	1
Patient Experience	Patient Experience	Product design considerations:	1	1

Product design characteristics	Product design characteristics	Product characteristics	1	1
Patient-centred design (tailoring)		Patient-centricity	0	1
Adherence consideration	Adherence consideration		1	0
Design research	Design research	Iterative design process	1	1
Device usage	Device usage		1	0

Table 11.3 Summary of the code categories and subcategories for the researcher and both raters.

The colouring of the table was used to clearly overview the agreement between the raters. This step was made to make the process of calculating each case individually easier. The colour code is as follows:

	Both raters disagreed with the initial code
	Both raters agreed with the initial code
	Only R1 agreed on the initial code
	Only R2 agreed on the initial code

11.1.4.3 Inter-rater Agreement Measurement

A number of instruments can be used to analyse the level of agreement between the raters on the suggested categories and subcategories. The goal of this measurement is to calculate the agreement between raters while eliminating the disagreement that may occur due to chance. Therefore, the percentage method of calculating the agreement was not considered (MacPhail et al., 2016). Other methods, such as Cohn's Kappa (Cohen, 1960) and Krippendorff's Alpha (Krippendorff, 2004), were considered. While Cohn's Kappa method measures the agreement by eliminating the agreement due to chance, Krippendorff's Alpha measures the observed and expected disagreement. Additionally, Krippendorff's method is computationally and conceptually complicated (MacPhail et al., 2016). According to the above, Cohen's Kappa was used to calculate the agreement between R1 and R2.

11.1.4.4 Calculation of Cohen's Kappa Agreement

The measurements were based on a binary system, with the number '1' referring to an agreement with the initial code, and '0' meaning disagreement with the initial code. Table 11.3 above shows the agreement of both the first and second raters with the initial code.

The below table 11.4 shows the analysis of the agreement data:

		Rater 2 (R2)				
		0	1	Sum	%	
Rater 1 (R1)	0	6	3	9	0.4	R1 ₀
	1	3	12	15	0.6	R1 ₁
	Sum	9	15	24		
	%	0.4	0.6			
		R2 ₀	R2 ₁			

Table 11.4 Calculation of Cohen's Kappa Agreement.

First, P_a was calculated which represents the observed agreement amongst the raters. This value may include the probability of agreement by chance.

$$P_a = (N_{00} + N_{11}) / 24$$

$$= (6 + 12) / 24 = 0.8$$

P_a : Relative observed agreement amongst raters

N : Total number of codes (categories and subcategories)

N_{00} : The raters agreed with each other but disagreed with the initial (researcher) codes

N_{11} : Both raters agreed with the initial (researcher) codes

As seen in the table above, there are two chances that the raters both agree. The first chance is that they agree on the initial code created by the researcher. In this instance, they would record the same code (or a code with a similar meaning) in their codebook document. The second chance is that they do not record the same code as the code created by the researcher in their codebook document. In this case, they agree with each other but disagree with the researcher. The second step is to calculate the probability of agreeing with each other by chance (P_e). The equation used to calculate this probability is as follows:

$$P_e = (R_{10}/N) * (R_{20}/N) + (R_{11}/N) * (R_{21}/N)$$

$$= 0.4 * 0.4 + 0.6 * 0.6 = 0.6$$

P_e : Hypothetical probability of chance agreement

R_{10} : Total disagreed codes by the first rater | R_{11} : Total agreed codes by the first rater

R_{20} : Total disagreed codes by the second rater. | R_{21} : Total agreed codes by the second rater

Based on the above equation, there is a 0.6 probability that two raters will agree with each other by chance alone. Therefore, the final Cohen's Kappa value is:

$$K = (P_a - P_e) / (1 - P_e)$$

$$= (0.8 - 0.6) / (1 - 0.6) = 0.5$$

Cohen's Kappa value ranges from 0 to 1, where 0 means no agreement occurs without chance and 1 means that there is a full agreement between the raters without any probability of chance. According to this rate, the results show the value of 0.5 (Table 11.5). This value means there is 50% of agreement between the raters due a chance. To evaluate the value of data reliability in Cohen's Kappa, Landis and Kock (1977) introduced a new method with which to measure the outcome of Kappa's equation. According to the right side of the below table, the value of 0.5 refers to a moderate level of reliability (Cohen, 1960; Holle & Rein, 2013; Hruschka et al., 2004).

Value of reliability	Strength of agreement
<0.00	Poor
0.00-0.20	Slight
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial
0.61-0.80	Almost perfect

Table 11.5 Value of reliability and strength of agreement in Cohen's Kappa reliability test (Landis & Kock, 1977). Based on this scale, the strength of this study's agreement is Moderate.

Another measurement used to identify the level of reliability is proposed by Shrout (1998). There is a controversy in the literature studies between the Landis and Kock (1977) measurements and the Shrout (1998) measurements in terms of the level of reliability. According to the latter, the outcome value of reliability shows Fair agreement (Holle & Rein, 2013) as shown in the table below (Table 11.6):

Value of reliability	Strength of agreement
0.00-0.10	Virtually none
0.11-0.40	Slight
0.41-0.60	Fair
0.61-0.80	Moderate
0.81-1.00	Substantial

Table 11.6 Value of reliability and strength of agreement in Cohen's Kappa reliability based on Shrout (1998). Based on this scale, the strength of this study's agreement is Fair.

In this study, only the Landis and Kock weighting system will be used to evaluate the outcome of the inter-rater reliability. Accordingly, the level of reliability is moderate.

11.1.5 Conclusion of Round One

As a result of the desk research, interviews with case studies and observation of the WearCare II project, some factors were identified which impact patient adherence to the treatment regimen (i.e. communication with patients, health belief, knowledge and education, patient empowerment, protective motivation, self-motivation, reasoned action, and behaviour change). However, many of the factors and literature studies were influenced by the nature of the clinician-administrated treatment, where patients had no control over the intervention regimen. The challenge was to identify the factors which may affect patient adherence to self-administered treatments, especially those which use technology, where there is minimal to no clinical administration of the therapeutic experience.

Several factors have been shown to affect patient adherence to the regimen. Some of these factors are generic and may apply to any disease or health condition, and some elements

have an influence only on specific diseases (Martin et al., 2010; Williams, 2014). During the interviews, each case study elicited opinions regarding the factors which affect adherence related to their products and how these factors are considered during the design process. In this study, the Delphi method provided a tool to assess and collect consensus on adherence factors that affect self-administered treatment technology. Furthermore, the data triangulated from the previous stages help to build an adherence framework and canvas. The level of triangulation reflected the open-ended questions in the first round of the Delphi study.

The aim of round one was to allow a panel of members, who had different areas of expertise related to the scope of the study, to identify and rate the various factors which can affect patient adherence to self-administered treatment technology. The open-ended questions in the first round allowed the panellists to share their experience and knowledge regarding the factors which affect adherence.

11.2 Delphi Round Two

In round one, adherence factors were categorised into categories and subcategories. These data were then triangulated to round two's quantitative questionnaire in order to assess panellists' agreement on the importance of these factors. The challenge was that a large set of factors was collected from round one.

11.2.1 Questionnaire Design

The aim of the Delphi round two was to identify the agreement of the panellists on the level of importance of the factors which affect adherence. These factors had been collected from the content analysis of the open-ended questions in round one. However, the factors highlighted by the panellists aligned with some factors collected during the interviews and secondary research on adherence factors. Accordingly, this round presented a triangulation of the adherence factors from the literature and interviews. The adherence factors included

in the Likert questions and the adherence factors collected from round one. The questionnaire was designed as follows:

- The questionnaire was based on the Likert Scale question type to afford the chance to measure the importance of every subcategory collected from round one.
- Each category identified in round one required one matching Likert scale question. Therefore, there are four questions.
- Each question presented a category from round one's content analysis for adherence factors. Each Likert scale item presents an adherence subcategory.
- Next to each subcategory, the adherence factors were listed between brackets to give the panellists an idea of the meaning of each subcategory. For example, the first question covers Collaboration and partnership-related factors. The first subcategory in this question is Patient-clinician relationship, which represents adherence factors: (e.g., monitoring tech, consistency, follow ups, feedback, confidentiality, adaptability).
- The rating scale included five levels, in ordinal scale, for the importance of the factors. The levels were: Very High (5), High (4), Moderate (3), Low (2), and Very Low (1). This scale was selected for two primary reasons:
 - The panellists suggested the factors highlighted in each subcategory, so the aim was to assess their importance rather than eliminating them, and
 - There was agreement between many of the factors highlighted in the round one analysis and the factors highlighted in the literature studies and the interviews with the companies. Therefore, the scale in the round two Likert focused on the adherence factors' level of importance rather than accepting or rejecting the factors as a driver of adherence during the development of treatment technology. Round two presented an opportunity to understand the panellists' consensus on the adherence factors and their importance.
- The N/A option was available for panellists who thought that the factor was not applicable.
- A comments section let panellists provide further thoughts about the rating system. While these comments may have contributed to guiding the third round, their main

purpose was to get the opportunity to collect further opinions from the panellists which could be used to build the final Adherence Canvas.

According to the above, the questionnaire was created and populated through SurveyMonkey.com and sent to the panellists through email. A copy of the invitation to the round two questionnaire is available in Appendix 11.4. At the top of the questionnaire, the panellists needed to fill in their first and last name for monitoring and follow-up purposes. A copy of the questionnaire is available in Appendix 11.4.

11.2.2 Questionnaire Management and Data

Collection

During the period when the questionnaire was being populated, the U.K. government announced the lockdown in response to the COVID-19 outbreak. An extension for the replies was considered while circulating the questionnaire's invitations, especially for the experts who worked for or closely with the NHS and NHS facilities. Below are the guidelines presented to the panellists about this round:

- The number of questions: Five Delphi questions
- Type: Likert questions
- Estimated time to complete: 10-20 minutes
- The anonymity of data: Anonymised between the panellists
- Answers deadline: Answers are required within one week from receiving the email. If you need more time (especially from NHS panellists, please let me know through email).

An invitation to complete the questionnaire was circulated on 15 April 2020. One week was the allotted time to fill the questionnaire. However, it took until 4 May 2020 for all the panellists to complete the questions. During this period, the panellists were contacted with reminders and follow-up messages through email and other communication channels, such as Skype and Twitter.

11.2.3 Addressing Missing Data

At this stage, the word 'addressing' was used to describe the missing data rather than dealing with it. The reason for this usage is that panellists still had the chance to complete the missing data or change their minds in the third round of the Delphi study. At this point, dealing with missing data was limited to identifying them and contacting the panellists to learn more about them.

One of the panellists answered with N/A to the majority to the questions (16 out of 20). Two panellists one missed one question each. Although the percentage of missing data was less than 5%, these panellists were contacted regarding the missing data to find out if the answers to these parts of the questionnaire were dropped intentionally or due to technical or unintentional reasons. The two panellists responsible for two of the missing questions replied that they missed those questions and that they would complete them in round three. One of panellists did not rate one factor because he was not clear about its impact on adherence.

The panellist with 16 N/A answers was contacted; the panellist explained that some of the questions were not clear to him, so the questions were clarified to the panellist, the aim of the questions and the plan for the use of the answers. He also explained that he could not modify the answers when he tried to have a second look over them. Therefore, the technical issue was fixed and gave him access to reply to the questions so that he would have the same opportunity to answer the questions as the rest of the panellists.

After the above procedure was undertaken to validate the missing data, three missing values remained from round two (those values were associated with three factors: intervention usage, patient information and goals motivators). To handle the two missing values, the type of data needs to be clearly defined. Generally, there are three types of missing data (Outhwaite & Turner, 2007):

- **Missing completely at random (MCAR):** The missing data is independent from any value, or any potential values (Rubin, 1976). Pickles (2004) defined the MCAR as a

value which has equal chance as any other value. The probability of the missing data is equal for any value.

- **Missing at random (MAR):** From the probability perspective, there is an equal opportunity for data to be missed similar to any other value. The difference between this type and MCAR is that the value may not be dependant and affected by other values.
- **Not missing at random (NMAR):** The data can be considered NMAR if any of the two classifications above are not met.

In this study, the missing data can be categorised as MCAR as the participants responsible for the missing data cannot be distinguished from the participants responsible for the complete data (Outhwaite & Turner, 2007; Pickles, 2004; Rubin, 1976). To address the missing values, the imputation methods were overviewed. Imputation is a common strategy to deal with missing quantitative data to element uncertainty because of missing values in statistics (Tang et al., 2005). Bennett (2001) categorised the imputation methods into three main categories based on the amount of missing data:

- Methods which ignore missing observations

These methods ignore the missing data and drop it from the analysis. The two main methods used under this category are: 1) complete case analysis, in which the missing data is dropped from the analysis; and 2) available case analysis, which uses the largest set of available data to estimate the desired output.

- Single imputation methods

These methods aim to analyse the current data, estimate the missing data and impute new values. These tools include: 1) Last value carried forward: this tool is used in longitudinal studies—if there is missing data from a particular time or date, the previous available data is carried forward and used to impute the missing data; 2) Mean substitution: the mean value from other participants is used to impute the missing data; 3) Regression method: in this method, the current data is used to create a regression equation which can be used to create variables that can be used to predict the missing value; 4) Hot-deck imputation: this method replaces the missing value with value taken from participants with matching variables; and 5) Cold-deck imputation: This method is

similar to hot-deck imputation. The difference is that, in cold-deck imputation, the imputation value is estimated based on the external knowledge rather than depending on the existing data.

- Other imputation methods

These tools tend to solve the problem of the single imputation, wherein the latter one understates the variability in the database. These tools include: 1) Multiple imputation: this method replaces the missing data with 5–10 imputations to complete the dataset; and 2) Markov-chain imputation: this tool is used in longitudinal studies (repeated patterns of data). It imputes the missing value with transient states such as known disease stages to replace the value mechanism.

The percentage of the data missing in round two was less than 5%, which makes imputation methods inapplicable (Harrel Jr., 2015; Marshall et al., 2009).

Two main factors contributed to determining the method of dealing with missing data (Bennett, 2001):

1. The participants had a second chance (in round three) to complete and modify their answers to the questions. This being the case, the missing values were dropped only from this round.
2. The proportion of missing data was small (less than 5%), and the dataset was not large as it included answers from 12 panellists. Therefore, the method which was used was 'ignore missing data'.

According to the above, the method which was used to deal with missing data at this stage was 'ignore missing data' and the associated analysis method in the SPSS software was the 'available case analysis'. In this method, SPSS uses the largest set of available data to estimate the missing data. (Bennett, 2001).

11.2.4 Results Overview and Analysis

In round one, adherence factors merged from the open-ended questions. After collecting the results from the panellists, the answers were reviewed before moving to the next step of the study. The following points were observed:

- There was a 100% response rate, which may reflect an understanding between panellists of the value of the research and their contribution to it.
- There was missing data. This amount was around 5% of all the answers. The method of dealing with the missing data is described above.
- Few comments were added. This had no impact on round two or the following round. However, it provided individual feedback about adherence.

At this point, a statistical analysis of the results was carried out to establish initial understanding about the panellist's agreement on the importance of the adherence factors. SurveyMonkey.com and SPSS were used to create a general picture of all the collected statistics from all the panellists. The data analysed using SurveyMonkey.com showed a rough agreement on the level of importance between the panellists. The figures (Figure 11.1, Figure 11.2, Figure 11.3 and Figure 11.4) provide a visual overview of the answers and how the majority of the answers fell on the right side of the scale (High and Very High).

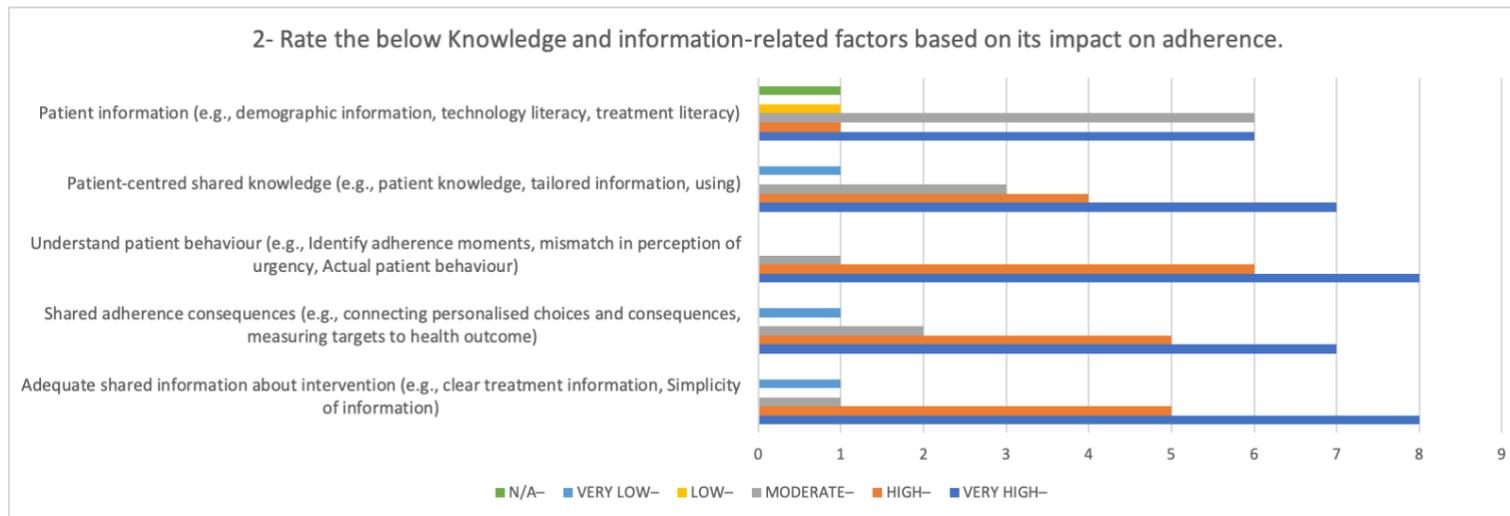


Figure 11.1 Visual chart of round two answers for question 1 (SurveyMonkey.com)

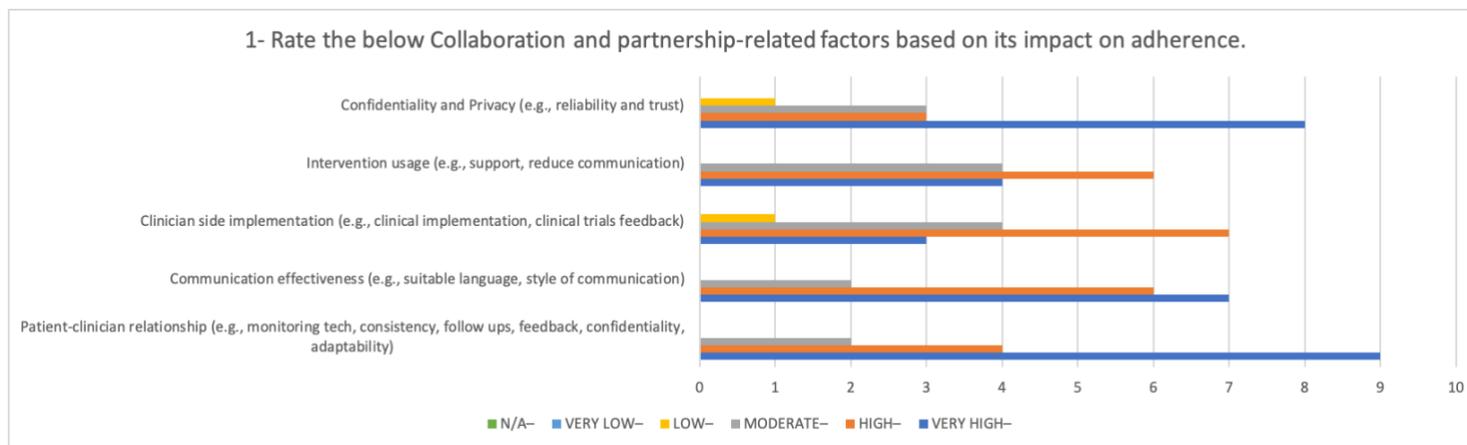


Figure 11.2 Visual chart of round two answers for question 2 (SurveyMonkey.com)

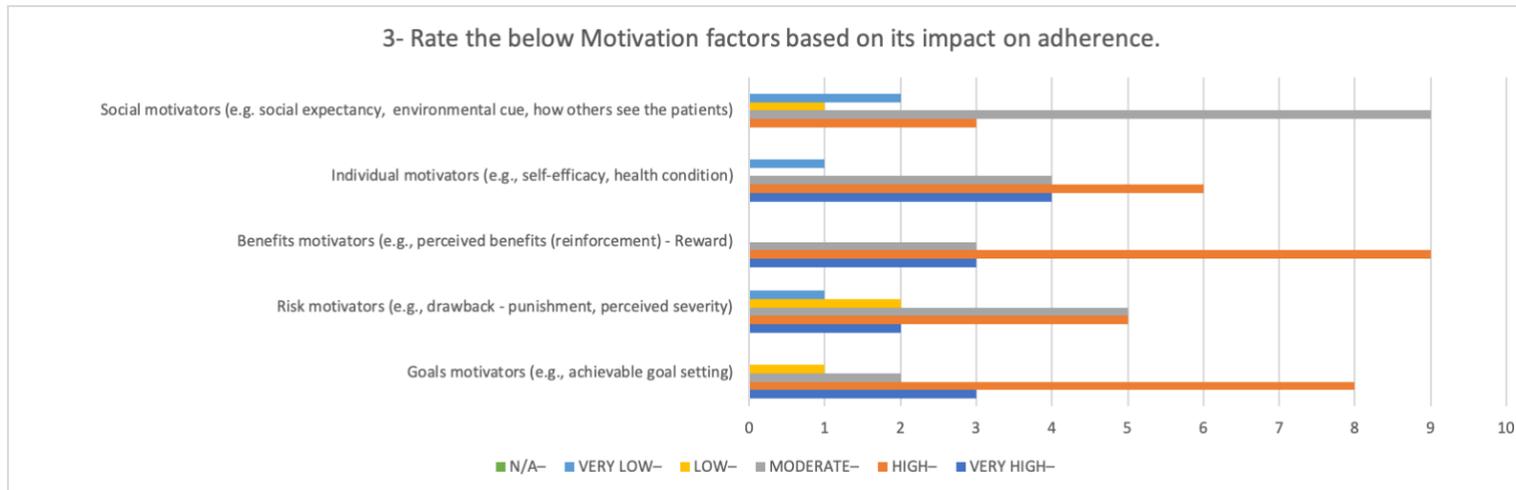


Figure 11.3 Visual of chart round two answers for question 3 (SurveyMonkey.com)

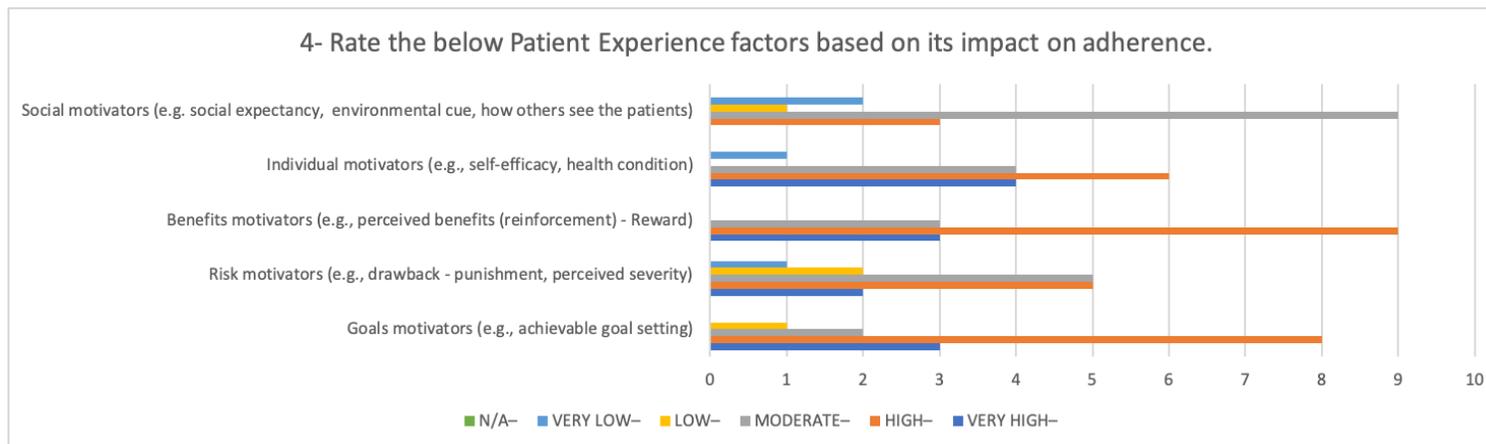


Figure 11.4 Visual chart of round two answers for question 4 (SurveyMonkey.co

SPSS software was used to identify the level of agreement between panellists by observing the standard deviation (SD) around the mean. The Descriptive Statistics commands (Descriptive and Frequencies) were used to calculate the mean and SD for the 20 adherence factors as shown in Table 11.7.

Factors	N	Min.	Max.	Mean	Std. Deviation
Collaboration & Partnership					
Patient Clinician Relationship	15	3.00	5.00	4.4667	0.74322
Communication Effectiveness	15	3.00	5.00	4.3333	0.72375
Clinician Side Implementation	15	2.00	5.00	3.8000	0.86189
Intervention Usage	14	3.00	5.00	4.0000	0.78446
Confidentiality and Privacy	15	2.00	5.00	4.2000	1.01419
Knowledge & Information					
Adequate Shared Information about Intervention	15	1.00	5.00	4.2667	1.09978
Shared Adherence Consequences	15	1.00	5.00	4.1333	1.12546
Understanding of Patient Behaviour	15	3.00	5.00	4.4667	0.63994
Patient-Centred Shared Knowledge	15	1.00	5.00	4.0667	1.16292
Patient Information	14	2.00	5.00	3.8571	1.09945
Motivation					
Goals Motivators	15	0.00	5.00	3.6667	1.29099
Risks Motivators	15	1.00	5.00	3.3333	1.11270
Benefits Motivators	15	3.00	5.00	4.0000	0.65465
Individual Motivators	15	1.00	5.00	3.8000	1.08233
Social Motivators	15	1.00	4.00	2.8667	0.91548
Patient Experience					
Product Design Characteristics	15	3.00	5.00	3.8000	0.67612
Patient-Centred Design	15	3.00	5.00	4.6667	0.61721
Design for Adherence	15	2.00	5.00	4.4000	0.91026
Design Research	15	3.00	5.00	4.3333	0.61721
Device Usage	15	2.00	5.00	4.4000	0.82808
Valid N (listwise)	13				

Table 11.7 The standard deviation of round two's answers.

Below are comments on the second round SD table:

- Table 11.7 indicates that the average of the mean value between the adherence factors is around the ordinal value of 4.0. However, the mean column shows an agreement around the mean as the values bias toward the right side of the ranking system, which shows a varied level of agreement on the importance of each adherence factor. An overview for the SD values reveals there is high agreement on some of the factors such as: understanding of patient behaviour, benefits motivators, patient-centred design and design research. For these values, the minimum level of importance is 2 and the maximum level is 5.
- In contrast, some adherence factors show a high SD level of more than 1.0. These include: adequate shared information about intervention, shared adherence consequences, goals motivators and risk motivators. The high SD indicates a wide range of rating values, so the minimum 1.0 and the maximum rating level is 5.0.
- The above values show the level of agreement on the importance of adherence factors in Delphi round two.
- The two main benefits of observing the panellists' data at this stage were: 1) understanding the initial answers of the panellists on the importance of adherence factors; and 2) understanding how the panellists changed their opinion after giving them the chance to review the overall answers from the whole panel.
- These values are primary data and are expected to change in round three as the panellists will have the chance to modify their answers.

11.2.5 Conclusion of Round Two Results

Round two provided a method for triangulation of the code analysis from round one, literature, and interviews. The adherence factors organised in categories and subcategories and then, they were provided for the panellists to rate their importance. It represented a pivotal stage for understanding the factors of adherence—and their importance—which should be considered during the design and development of treatment technology. The analysis overview from both Surveymonky.com and SPSS software showed evidence of a level of agreement between the panellists; this observation is supported by the value of the standard deviation around the mean of each factor. Therefore, the third round of the Delphi

process aimed to identify the consensus between the panellists on the results from round two.

11.3 Delphi Round Three

The initial plan of the Delphi study in this part of the research was to have three rounds. These rounds aimed to explore the panellists' agreement on the factors which affect adherence during the development of treatment technology. Accordingly, the results from this round were expected to achieve the goal of the study.

In this round, the same questionnaire from round two was circulated amongst the panellists. This time, they were able to see the combined answers from round two showing the overall rating from the panellists. The revealed data was anonymised, and they were able to see specific answers. While they could see the combined answers from the whole panel, they were able to see their previous answers in case they forgot their inputs in round two. The procedure aimed to allow the panellists to check the panel answers and provide them the chance to change their mind. They had the choice to skip questions or the whole questionnaire if they did not want to change their minds.

11.3.1 Administration and Questionnaire Population

The nature of round three dictated several changes in how the questionnaire was constructed and shared with the panellists. These changes included the following:

- As each of the panellists would be able to see everyone else answers, a separate copy of the questionnaire was created. Each copy had a different circulation link. This procedure aimed to ensure the security and anonymity of data at this stage.
- Above each question, two tables were added to show the individual panellist's answer and the combined answers from all the panel members.
- Panellists were allowed to skip questions or the whole questionnaire if they wanted to keep their answers from round two unchanged.
- The panel members were given a chance to reply by email to confirm if they did not want to change their answers or wanted to change one or two factors only, and

- Panellists who missed answering any of the questions from round two agreed to complete those questions in round three.

The invitation to complete round three was sent to the panellists separately through email. Each invitation included a unique link to each of the panellist's questionnaire. They were asked to answer the questionnaire based on the below regulations:

- *'You will check and review your answers from Round Two and compare them with the anonymised answers from all members of the panel.'*
- *To modify your rating, answer the question with your new answer.*
- *If you do not want to change an answer, skip to the next question.*

Please see details below about the questions and timeline:

- *Number of questions: four optional Likert questions*
- *Estimated time to complete: 5–15 minutes*
- *The anonymity of data: answers are anonymised between panellists*
- *Deadline for response: answers are required within one week from receiving the email. If you need more time (especially NHS panellists), please let me know via email.*

Note: The link above shows a unique survey link for each of the panel experts to ensure anonymity. So, your answers are private.'

The above statement was added at the top of each questionnaire, and it reflected the regulations of the round three questionnaire. Copy of the Invitation and the questionnaire are available in Appendix 11.6 and 11.7.

11.3.2 Results Overview and Analysis

The collection of the round three data used the same procedure applied in round two with consideration of the modifications highlighted above in the questionnaire administration section. The following were observed in the round three results:

- All 15 panellists answered all of the questions. Some of them required several follow-up emails to answer the questionnaire.

- Five panellists changed their answers, including filling in the missing answers from round two. One of the 15 only answered the missing question and kept the rest of his answers unchanged.

As there was a separate questionnaire for each of the panellists, I imported the data to SPSS software to analyse them, using the Description command to show the mean and SD for the adherence factors. Table 11.8 shows a description of the data including the mean and the standard deviation around the mean:

Adherence Factors	N	Min.	Max.	Mean	Std. Deviation
Collaboration & Partnership					
Patient Clinician Relationship	15	3.00	5.00	4.5333	0.63994
Communication Effectiveness	15	3.00	5.00	4.4667	0.63994
Clinician-Side Implementation	15	3.00	5.00	3.9333	0.70373
Intervention Usage	15	3.00	5.00	4.0667	0.79881
Confidentiality and Privacy	15	2.00	5.00	4.2667	1.03280
Knowledge & Information					
Adequate Shared Information about Intervention	15	3.00	5.00	4.4667	0.74322
Shared Adherence Consequences	15	3.00	5.00	4.4000	0.73679
Understand Patient Behaviour	15	3.00	5.00	4.4000	0.63246
Patient-Centred Shared Knowledge	15	3.00	5.00	4.3333	0.81650
Patient Information	15	3.00	5.00	3.7333	0.96115
Goals Motivators	15	2.00	5.00	3.8667	0.74322
Motivation					
Risks Motivators	15	1.00	5.00	3.4000	1.12122
Benefits Motivators	15	3.00	5.00	4.0000	0.65465
Individual Motivators	15	3.00	5.00	3.8667	0.74322
Social Motivators	15	1.00	4.00	2.9333	0.79881
Product Design Characteristics	15	3.00	5.00	3.7333	0.70373
Patient Experience					
Patient-Centred Design	15	3.00	5.00	4.5333	0.63994
Design for Adherence	15	2.00	5.00	4.4000	0.91026
Design Research	15	3.00	5.00	4.2667	0.70373
Device Usage	15	4.00	5.00	4.5333	0.51640
Valid N (listwise)	15				

Table 11.8 The description of round three results including the mean and standard deviation.

The comparison between round two and round three showed that the panellists modified their answers in a manner which led to a reduction in the SD around the mean, which reflects an agreement between the panellists on the level of importance of each factor for improving adherence. Most of the values were biased to the centre and left side of the scale (Very important, Important and Moderate). The importance ratings for two factors had a SD of 1 or more (Confidentiality and Privacy, and Risk Motivators).

The first factor, Confidentiality and Privacy, had the minimum rate of low importance (2) and a maximum of very important (5). The second factor, Risks Motivators, had the minimum value of very low importance (1) and a maximum value of very important (5). Design Usage had the lowest SD with minimum value of Important (4) and maximum value of very important (5), which showed the highest level of agreement of all the panellists.

Upon reflecting on the previous literature, and the case study interviews, there are two observations:

- These results are based on general treatment adherence without considering that these values and/or their level of importance may change with certain diseases and in some cases.
- While the levels of importance are based on the Delphi panellists' agreement, this level may change in real life situations. The extent of change may also vary based on the treatment, its development and the SME.

11.3.3 The Point of Saturation

The initial Delphi method plan was to have three rounds, and this number of rounds is supported by literature studies. This decision was made prior to the study start due to the following:

- The timeframe of the study
- The availability of the panel members
- The COVID-19 pandemic and the national lockdown

Another approach is to stop the rounds once the consensus between the panellists has been reached (Keeney et al., 2010). In this study, the decision was made to stop at the third

round as an acceptable level of consensus between the panellists had been reached. Accordingly, while the study was set to three rounds, the level of agreement between the panellists was monitored after each round in order to achieve the goal of the Delphi study.

11.3.4 Application Wilcoxon Signed-Rank Test

To evaluate the significance of the change in responses between round two and round three, I applied the Wilcoxon signed-rank test. The decision to use it was based on understanding the nature of the statistics as follows:

1. Ordinal, with no specific distribution normality
2. The statistics can have dependant or independent relationships, and
3. The data can be considered an imprecise quantity rather than exact numbers.

According to the above three characteristics, the statistics in this study can be considered non-parametric statistics (Taheri & Hesamian, 2012).

The Wilcoxon signed-rank test is based on three assumptions (Sheskin, 2003):

1. The sample has been randomly selected from the population it represents
2. The original scores obtained for each of the ranked objects are in the format of intervals (ratio data), and
3. The underlying population distribution is symmetrical, so the mean, median and mode showed equal values.

The first two assumptions can be applied to the population (the population was quite small, so all 15 panellists were used in the sample). The nature of the statistics was based on the ordinal data set. To evaluate the applicability of the first assumption, the frequencies of round two and round three statistics were generated using SPSS software.

Table 11.8 below shows the mean, median and mode of round two. The table shows 10 factors with three values equal to each other (the values were rounded up to the nearest value). For example, in the 'intervention usage', all the mean, median and mode values equal four, which means there is symmetric distribution around the mean.

	Number	Mean	Median	Mode	SD
Patient-Clinician Relationship	15	4.4667	5	5	0.74322
Communication Effectiveness	15	4.3333	4	5	0.72375
Clinician-Side Implementation	15	3.8	4	4	0.86189
Intervention Usage	14	4	4	4	0.78446
Confidentiality and Privacy	15	4.2	5	5	1.01419
Adequate Shared Information about Intervention	15	4.2667	5	5	1.09978
Shared Adherence Consequences	15	4.1333	4	5	1.12546
Understand Patient Behaviour	15	4.4667	5	5	0.63994
Patient-Centred Shared Knowledge	15	4.0667	4	5	1.16292
Patient Information	14	3.8571	3.5	3	1.09945
Goals Motivators	15	3.6667	4	4	1.29099
Risks Motivators	15	3.3333	3	3	1.1127
Benefits Motivators	15	4	4	4	0.65465
Individual Motivators	15	3.8	4	4	1.08233
Social Motivators	15	2.8667	3	3	0.91548
Product Design Characteristics	15	3.8	4	4	0.67612
Patient-Centred Design	15	4.6667	5	5	0.61721
Design for Adherence	15	4.4	5	5	0.91026
Design Research	15	4.3333	4	4	0.61721
Device Usage	15	4.4	5	5	0.82808

Table 11.8 The mean, media and mode of round two results.

	Numbers	Mean	Median	Mode	SD
Patient-Clinician Relationship	15	4.5333	5	5	0.63994
Communication Effectiveness	15	4.4667	5	5	0.63994
Clinician-Side Implementation	15	3.9333	4	4	0.70373
Intervention Usage	15	4.0667	4	4	0.79881
Confidentiality and Privacy	15	4.2667	5	5	1.0328
Adequate Shared Information about Intervention	15	4.4667	5	5	0.74322
Shared Adherence Consequences	15	4.4	5	5	0.73679
Understand Patient Behaviour	15	4.4	4	4	0.63246
Patient-Centred Shared Knowledge	15	4.3333	5	5	0.8165
Patient Information	15	3.7333	3	3	0.96115
Goals Motivators	15	3.8667	4	4	0.74322
Risks Motivators	15	3.4	4	4	1.12122
Benefits Motivators	15	4	4	4	0.65465
Individual Motivators	15	3.8667	4	4	0.74322
Social Motivators	15	2.9333	3	3	0.79881
Product Design Characteristics	15	3.7333	4	4	0.70373
Patient-Centred Design	15	4.5333	5	5	0.63994
Design for Adherence	15	4.4	5	5	0.91026
Design Research	15	4.2667	4	4	0.70373
Device Usage	15	4.5333	5	5	0.5164

Table 11.9 The mean, median mode and SD of the round three results.

The frequency values (Table 11.9) of round three show equal value between the mean, median and mode of the majority of the adherence factors. Sixteen factors showed equal values. Four factors showed close values (the values were rounded up to the nearest value).

11.3.5 Application of Wilcoxon Signed-Rank to SD

I applied to the Wilcoxon signed-rank test to the SD collected in round two and round three in order to identify the changes which occurred when eliminating the changes due to chance. The test was run using SPSS software on the data in Table 11.10. The Wilcoxon signed-rank test is based on the following assumptions:

- a) The sample has been randomly selected from the population it represents
- b) The original scores obtained for each of the ranked objects are in the format of interval/ratio data, and
- c) The underlying population distribution is symmetrical (Sheskin, 2003).

	Round 2 SD	Round 3 SD
Patient-Clinician Relationship	0.74322	0.63994
Communication Effectiveness	0.72375	0.63994
Clinician-Side Implementation	0.86189	0.70373
Intervention Usage	0.78446	0.79881
Confidentiality and Privacy	1.01419	1.03280
Adequate Shared Information about Intervention	1.09978	0.74322
Shared Adherence Consequences	1.12546	0.73679
Understand Patient Behaviour	0.63994	0.63246
Patient-Centred Shared Knowledge	1.16292	0.81650
Patient Information	1.09945	0.96115
Goals Motivators	1.29099	0.74322
Risks Motivators	1.11270	1.12122
Benefits Motivators	0.65465	0.65465
Individual Motivators	1.08233	0.74322
Social Motivators	0.91548	0.79881
Product Design Characteristics	0.67612	0.70373
Patient-Centred Design	0.61721	0.63994
Design for Adherence	0.91026	0.91026

Design Research	0.61721	0.70373
Device Usage	0.82808	0.51640
Valid N (listwise)	15	15

Table 11.10 The SD of the 20 factors in round one and round two.

		N	Mean Ranking	Sum of Rankings
Round_2_SD - Round_1_SD	Negative Rankings	11 ^a	8.73	96.00
	Positive Rankings	3 ^b	3.00	9.00
	Ties	1 ^c		
	Total	15		
a. Round_2_SD < Round_1_SD				
b. Round_2_SD > Round_1_SD				
c. Round_2_SD = Round_1_SD				

Table 11.11 Wilcoxon signed-rank test on SD.

In the rank Table 11.11, 11 values showed negative rankings, which means that the SD values in round two were lower than round one. Three of the values have been ranked positive, which means that the SD for three factors increased from round one. One of the values is ranked as a tie, which means that the value in round one and round two is the same. Table 11.11 shows that the level of consensus between the panellists has improved in round three compared with round one.

In this study's Wilcoxon test, the null hypothesis is defined as: 'there is no change in SD in round one and round two, and the difference between round one and two follows a symmetric distribution around zero'. Table 11.12 below shows the test statistics:

	Round_2_SD - Round_1_SD
Z	-2.731 ^b
Asymp. Sig. (2-tailed)	0.006

- Wilcoxon Signed Ranks Test
- Based on positive ranks.

Table 11.12 The test statistics for the Wilcoxon ranked-signed test.

In Table 11.12 above, the assumption of significance is 0.006, which is lower than the significance level standard ($\Theta = 0.05$) (Wilcoxon, 1947). Accordingly, the null hypothesis is

rejected and there is a significant change between the SD in round one and round two. Round three showed significant agreement between the panellists on the level of importance of the adherence factors for self-administered treatment devices, which is a contribution to knowledge as there is a lack of literature studies which discuss the adherence factors related to medical technology. Table 11.13 shows the adherence factors, categories, sub-categories and their importance levels based on final results of round 3.

Category	Sub-category	Level of importance
Collaboration and Partnership	Patient–clinician relationship (e.g. monitoring tech, consistency, follow-ups, feedback, confidentiality, adaptability)	5
	Effective communication (e.g. suitable language, style of communication)	5
	Clinician side implementation (e.g. clinical implementation, clinical trials feedback)	4
	Usage intervention (e.g. support, reduced communication)	4
	Confidentiality and privacy (e.g. reliability, trust)	5
Knowledge and Information	Adequate information shared about intervention (e.g. clear treatment information, simplicity of information)	5
	Shared adherence consequences (e.g. connecting personalised choices and consequences, measuring targets for the health outcome)	5
	Understand patient behaviour (e.g. identifying adherence instances, mismatch in perception of urgency, actual patient behaviour)	4
	Patient-centred shared knowledge (e.g. patient knowledge, tailored information, usage)	5
	Patient information (e.g. demographic information, technology literacy, treatment literacy)	3
Motivation	Goals (e.g. setting achievable goals)	4
	Risks (e.g. perceived severity (suffering–drawbacks))	4
	Benefits (e.g. perceived benefit (reinforcement–reward))	4
	Individual (e.g. self-efficacy, health condition)	4
	Social (e.g. social expectancy, environmental cues, how others perceive the patient)	3
Patient Experience	Product design characteristics (e.g. aesthetic, packaging and usage process)	4
	Patient-centred design (tailoring) (e.g. usability, patient characteristics, psychological factors)	5
	Design for adherence (e.g. compliance measurement, concordance, patient participation in treatment process, guidance on factors influencing adherence)	5

	Design research (e.g. field research and testing, prototyping iteration)	4
	Device usage (e.g. practicality, affordability, comfortability, self-administration of treatment, social support, facilitation)	5

Table 11.13 General adherence factors and their importance (median) based on the Delphi results.

11.4 Findings and Summary

To understand how the study could contribute to building an Adherence Canvas which can provide a guideline for companies to consider the factors that can improve patient adherence to self-administered treatment technology, the findings from the literature, interviews and observations were synthesised after having overviewed the collected and analysed data.

The aim of the Delphi procedure was to assess adherence factors that can underpin a framework and identify the elements of a resource which can guide companies to measure their consideration of adherence during the development stages. A further aim was that the instrument could be easily adapted and modified by companies as they develop their knowledge about their patients, the medical condition they are addressing and the treatment long-term usage of the intervention. The aim of the Delphi method was to assess the following:

- The categories of adherence factors
- The general factors that affect patient adherence
- The adherence factors which relate to treatment technology
- The importance of these adherence factors

The consensus of the panellists on the adherence factors and the data triangulated from the previous stages contributed to introducing a Design-Focused Adherence Canvas which can:

1. Guide companies to the adherence factors which should be considered, especially those new companies or companies who develop new technology which do not have a clear idea of the factors which affect patients' adherence to the treatment, and

2. Help companies to evaluate the consideration of adherence factors during the design and development of the treatment technology intervention.

Part 6

Discussion and Conclusion

Chapter 12: Discussion of Findings

This chapter reviews the findings of each stage in the study and how these findings were triangulated against each other. Furthermore, this chapter provides an overall discussion of the findings, how these findings contribute to answering the research questions and how they are used to realise the primary aim of this PhD research.

Key Topics:

12.1 Discussing the Literature Review

12.2 On the Case Studies Interviews

(Investigate)

12.3 On the WearCare II Project

Observation

12.4 On Assess: Delphi Method

12.5 Findings and Summary

In this chapter, the findings from each research study will be summarised and discussed from the perspective of the primary aim of the research, i.e., to explore the role of design thinking in improving adherence in self-administered medical technology treatment. Toward this aim, three goals were introduced:

- 1) Investigate the current design processes in the development of treatment technology.
- 2) Explore the contribution of design thinking in the development of the treatment.
- 3) Assess how the consideration of adherence factors during the design of treatment technology impacts the intervention outcome.

From the practical perspective, the findings in response to the research aim and related goals will contribute to paving the road to building framework, which can be adopted during the design thinking process to help improve the adherence to a medical regimen, especially in chronic disease cases.

To achieve the research's aim and goals, research questions were chosen to guide the research stages. These research questions are:

- What is the role of design and innovation in medical treatment technologies?
 - What is the current state of innovation in medical technology?
 - What are the barriers to and opportunities for innovation in medical technology?
 - What is the role of medical technology in driving patient empowerment?
 - How does design influence the innovation of patient-administrated treatment technologies?
 - What are the characteristics of design thinking?
 - What are the current development processes which are applied in medical technology?
 - What are the barriers to and opportunities for adopting design thinking?
- What is the impact of adherence in self-administered treatment technology?
 - What are the theoretical frameworks of treatment adherence?

- How are treatment technologies considered in clinical trials or alternative procedures?
- How is adherence considered in product development and clinical trials?

The first group of questions aimed to understand the role of design in self-administered medical technology innovation. To achieve this goal, the questions were divided into two sets. The first set of questions aimed to understand the current contribution of innovation in medical technology, and the second set of questions aimed to understand the influence of design innovation on self-administered interventions. The second group focused on adherence and explored how it is considered in literature reviews, design processes and clinical trials.

Guided by these research questions, three main activities were undertaken to design the research process:

- **Study the knowledge:** Data collected through desk and field research were examined and analysed to learn about the design process and understand how adherence is considered in the process.
- **Analyse the knowledge: The knowledge that was collected was analysed to** determine how adherence factors are considered during the design process.
- **Assess the knowledge:** The modelled knowledge was assessed by a panel of professionals.

The research process progressed through three main stages: Investigate, Explore and Assess. The Investigate stage had two steps, which were design research and case studies interviews. The first stage aimed to understand the design thinking process, theoretical frameworks related to adherence, and the current state of the medical technology innovation. The second step (case studies interviews) involved interviewing representatives of five SMEs working in developing medical treatment (and treatment-support) technologies. The aim of these interviews was to explore the application of design in the development process and understand how adherence is considered during the development of the medical device. The Explore stage (observation) involved exploring the consideration of adherence during the design thinking process. The Assess stage included a triangulation

of the data collected from the previous stages in order to gain the consensus of a panel of professionals on the adherence factors and importance of each factor. This chapter summarises and discusses the findings at each step and stage and identifies how these findings contributed to progression of the research.

12.1 Discussing the Literature Review

This literature review covered in Part 3 of this study aimed to understand key knowledge linked to the study, including: patient adherence and its factors (Chapter 6), the characteristics of design thinking (Chapter 7) and medical technology innovation (Chapter 8). The following summarises the findings of the literature review undertaken in these three chapters.

12.1.1 Adherence and its Factors

Major theoretical factors which affect patient adherence to treatments were reviewed and discussed in Chapter 7 to answer the question: 'What are the theoretical frameworks of treatment adherence?'. It also reviewed and discussed the literature related to patient empowerment and the role of communication between patient and clinician in patient adherence. Most of the theories fell under two main categories: Stimulus Response and Social Learning (Bosworth, Weinberger, & Oddone, 2005). In terms of the factors in each theory, the adherence factors fell under three categories: Motivation, Knowledge and Communication. A fourth category, Experience, was added to the categorisation because of the nature of the treatment as a physical or digital product. The Experience category included the design-related factors which may affect the patient experience and therefore the adherence to the treatment. Another theory was considered while building the adherence framework: The Three Factor Model. In this theory, the adherence factors were categorised into Information, Motivation and Strategy. While the first and second categories share the same factors with the above adherence theories, the Strategy category included the communication opportunity and how the social network (and social support) plays an essential role in patient adherence. The factors of the latter category and the other

literature studies are related to the 'patient empowerment' and its role in improving patient adherence.

From the perspective of medical technology (Chapter 8: Medical Technology Innovation), a number of findings have been identified from investigating the literature, interviewing case studies and observing WearCare II project. The findings, highlighted below, generated insights that were reflected in the theoretical frameworks of adherence (Chapter 6: Theoretical Frameworks of Adherence):

- There is a lack of theories which consider adherence in medical technology devices, especially when they are self-administered. The majority of theories focus on the factors which affect patient adherence (behaviour), yet there is no focus on the treatment design nor on other communication factors (i.e. the relationship between patients and clinicians). Treatment devices have further design aspects, such as creativity, aesthetics, function, affordability and usability, which are related to the design of the device and user experience. These design-related factors play an essential role in patient adherence to the treatment.
- The current theoretical models of adherence do not consider the practical application of the theory in real life contexts. The nature of adherence is complex, and the theoretical frameworks do not provide a solution for this major problem while also making it more complex by neglecting the practicality of the theories. The interviews with case studies and observation of the WearCare II project identified that participants did appreciate the importance of adherence yet did not consider its complex nature.

The current adherence theories don't consider the factors related to treatment technology such as some communication factors and the design-related factors. Therefore, a framework that focus on the adherence in treatment technology is needed. Additionally, the complex nature of adherence and lack of practicality in adherence theories present challenges related to considering adherence in medical technology. Accordingly, a resource is needed in order to help companies to consider adherence while designing treatment technology.

12.1.2 Adherence and Self-Administrated Treatment Technology

The healthcare system faces several difficult challenges. This burden has increased due to the COVID-19 outbreak in early 2020. Lack of adherence to treatment interventions accounts for some of the healthcare burden. Failing to adhere to treatment interventions has negative health and financial consequences, which may include patient death.

Medical technology (especially self-administered technology) plays a significant role in the healthcare system, as it can address a variety of current challenges and builds a patient-centric approach to medical intervention, which reduces the cost of invasive intervention, reduces the number of admissions to hospitals and visits to GPs, involves patients in the treatment decision through empowering patients and moves toward a mutual partnership between patients and clinicians.

However, poor adherence stands is a barrier to effective sustained use of medical technology, especially self-administered treatment technology where the patient controls the usage of the non-invasive medical technology. A low level of adherence can cause medical evaluation procedures, such as clinical trials and patient advisory groups, to produce misleading efficiency results. From the patient's perspective, the failure to adhere to the treatment regimen leads to failing to achieve the goal of the intervention, such as improving the status of the disease or stopping the degradation of the medical condition (e.g. case study YMX). Two aspects of the treatment intervention can increase lack of adherence:

- 1) The administration of the treatment. For instance, treatments which are fully administered by patients away from clinical control are only affected by the adherence factors that drive patients to adhere to the treatment.
- 2) The lack of consideration of these factors in the design of the medical technology can increase the probability of non-adherence.

In the case of chronic disease, patients are required to adhere to the treatment for a long period of time or even for the rest of their lives. Extending the period of the intervention increases the chance of changes in behaviour and the possible negative impact of adherence factors, which increases the risk the occurrence of non-adherence. The above discussion addresses the research question: ‘What is the impact of adherence in self-administered treatment technology?’.

Based on the above, adherence factors play a key role in the success of self-administered treatment. This role becomes even more important with self-administered treatment technology. Accordingly, considering adherence factors during the design of the medical treatment in the way that drives patients to adhere to the treatment may present an opportunity for both patients and the healthcare system to overcome several challenges. From the patient’s perspective, adherence to the treatment device can improve the medical condition, avoid surgical intervention and reduce the burden of traveling to the hospital or GP. From the hospital perspective, it can reduce the costs of the surgical intervention, wasted medication and hospital admissions and remove the workload on overworked staff.

The above discussion provides an overview of the detailed discussion that occurred in Chapter 8: Medical Technology Innovation, which addressed the research question: ‘What is the role of medical technology in driving patient empowerment?’.

In relation to the adherence literature, this study investigated the design literature and claims that there is a significant lack of studies focusing on patient adherence and the practical consideration of adherence during the development of self-administered health technology. This finding is highlighted as a sub-claim in Chapter 14 (14.2 Research Claims and Contribution to Knowledge).

12.1.3 Design Thinking and Innovation

Design thinking plays a key role in the aim of this research, as it supports the human focus needed to consider adherence and connect this to the solution space during design innovation. The process of design thinking can provide an opportunity for SMEs to have

greater success in their innovation of medical technology. One of the most important characteristics of a creative design process is the ability to explore the problem from different perspectives in the problem space. This can help to develop a comprehensive definition of the problem and consider solutions relation to a value arena space - which you need to define (Dorst, 2010). The characteristics of design thinking that can add value to medical technology innovation include the following:

- Driver of creativity and innovation: Design thinking creates processes that turn creative ideas into innovative products (Cox, 2005). The reason behind this is the deep exploration in the problem/solution space.
- Focus on human needs: A focus on human needs is one of three pillars in design thinking processes, the others are business viability and technology feasibility, (Brown 2011). As a result, usability factors and treatment effectiveness can support patient adherence to the treatment regimen.
- Prototyping and iteration: The Develop stage of the Double Diamond Model (Design Council, 2015) provides an opportunity to visualise solutions and test whether the product/service solution addresses patients' needs.

Consideration of design thinking perspectives and practices provides an answer to the research question: 'How does design influence innovation in patient-administrated treatment technologies?'. However, current considerations of adherence in technology projects often fail to exploit these positive opportunities. This may be especially true in relation to how and when it is considered, as was discussed in the latter part of the case studies interviews and the observation of the WearCare II project (Chapter: 10 WearCare II Project). The above overview of design thinking supports discussion of the role that design can play in medical technology innovation, which addresses the research question: 'What is the role of design and innovation in medical treatment technologies?'.

12.1.4 Adherence and Medical Technology

Medical technology innovation has many applications in the healthcare system and various literature has highlighted its benefits. One of the primary benefits is improving on patient adherence, especially in self-administered treatments (Bryant, Van, & Christensen, 2013).

On the one hand, patients can save the time and effort of visiting hospitals, and on the other hand, hospitals can reduce the workload on staff and long waiting lists. Investigating the benefits of self-administered medical technology for patients highlighted two terms which are linked to the human-centric focus within Brown's (2011) design thinking, which are unmet and unrealised needs. Exploring the problem and observing it from multiple perspectives can provide the opportunity to identify these needs and subsequently address them.

12.2 On the Case Studies Interviews (Investigate)

Stage one included semi-structured interviews with the five case study SMEs developing treatment (or treatment-support) technology in the UK. The aim of these interviews was to investigate the design process and the consideration of adherence factors during the design of treatment devices as well as during their testing and clinical trials. The design of case studies step is discussed in Chapter 3: Case Studies Methodologies, and the details related to its application are covered in Chapter 9: Interviews Overviews.

The process of recruiting the five companies revealed a clear understanding of the medical technology ecosystem as only 11 companies (out of 353) met the requirements of the scope of the research. It is interesting to note that there are very few companies which focus on self-administered treatments. Considering the benefits of adopting self-administered treatment solutions (12.1.4 Adherence and Medical Technology), there is a lack healthcare solutions that can self-management for treatment intervention. Expanding the technological interventions in this category can support patient self-administration of the treatment intervention, saves costs and reduce the pressure on the NHS.

12.2.1 Opportunities and Barriers for SMEs

The companies' setups and founders played an essential role in determining the opportunities that are available to them. For example, companies such as LW7 and ESA were able to involve themselves with healthcare innovation activities that provide support to SMEs working in the medical innovation sector. They were able to get financial support, which reduces one of the biggest barriers that faces new companies. Another benefit is access to evaluation procedures, such as clinical trials and patient focus groups, which provides a unique opportunity to test the application with real patients in hospitals environment.

In contrast to the above examples, other companies were not integrated within a healthcare system. For example, 3AB experienced a lack of continuous dedication to and work on the product design and commercialisation. DE7 were established in the United States of America and recently moved to the United Kingdom. Therefore, it may be too early to evaluate their integration with the healthcare system.

The companies in this study experienced similar barriers to SMEs working in other industries. Most of the internal barriers were related to experience, management and technology. The external barriers included access to funding and complex regulations for access to different markets. These barriers hindered the companies' ability to adopt a design thinking process. The most prominent barriers were experience and management (in part answering the research question: 'What are the barriers to and opportunities for innovation in medical technology?'). Therefore, the companies who had access to academic support in relation to the design process used this collaboration to build patient-centred treatment such as YMX's product. Other companies, such as ESA, were able to adopt some design thinking practices, such as involving patients in the design process and developing iterative prototypes for testing.

12.2.2 The Application of the Design Thinking Process

In SMEs that have started recently, the organisational culture is driven by the team who start the company. This was observed in all five companies which participated in this study. Therefore, the adoption of a design-driven strategy depends on the team and their capabilities and experience. Companies such as LW7, 3AB and YMX had a design background; therefore, the design process in these companies was adopted in a more systematic way than in other companies, such as ESA, which only partially applied design thinking characteristics. In contrast, DE7 did not have any design background, and this was reflected in the product design and the lack of involvement of patients in the product iteration and development. Exploring the above case studies contributed to addressing the question: 'What are the barriers to and opportunities for adopting design thinking?'

12.2.3 Adherence Consideration and Clinical Trials

Generally, there was an agreement between all the companies on the importance of adherence. However, the complex nature of adherence was not clearly understood. Different interviewees considered individual factors of adherence without considering the wide scope of adherence and how they might build a mechanism which considers patient adherence to self-administered treatment. Companies who got the chance to work with patients and receive frequent feedback from clinicians (ESA) were able to consider adherence. Frequent meetings and testing of the product helped the company to consider patient adherence in relation to their solution. Application of design thinking characteristics improved consideration of adherence factors, as the process focussed on patient needs and involved patients in the design of the treatment device. Accordingly, applying design thinking can help companies (e.g. YMX and LW7) to consider adherence factors alongside patient's needs.

The complex nature of adherence and the lack of practicality in the theoretical frameworks of adherence (Martin, Haskard-Zolnierek, & DiMatteo, 2010) is likely to contribute to the current level of consideration in companies. Having a practical guide to help companies consider adherence during the design of the treatment device may have a positive impact

on patients' level of adherence. The above discussion about adherence provides answers to the research question: 'How does adherence is considered in product development and clinical trials?'.

Another observation I made while talking to the companies in relation to improving adherence to the product is that considering adherence in an early stage of the development is more affordable than modifying the product after delivering it. The reasons for this are financial, technical and team related. After building the product and pushing it to the market, the company usually has spent most of its budget and cannot afford changes (especially major changes) to improve adherence. From the technology perspective, technological barriers can inhibit improving adherence in the product, such as the size of the batteries or internal components. Team availability and the time dedicated to making the changes can be another reason which prevents the company from making modifications that increase adherence.

Medical technology treatment faces specific barriers in relation to clinical trials which are related to the setup of the clinic trials themselves. The setup of clinical trial protocol requires a clear consideration of the nature of the medical treatment technology, as highlighted by interviews with representatives from YMX, to produce accurate and representative results regarding the effectiveness of the treatment technology. This includes considering adherence factors (especially in long-term and chronic diseases). Examples of factors which could be considered in YMX's trials are the communication between the clinicians and patients during follow-ups to the treatment and consideration of the minimum usage required to achieve effective results.

LW7's experience with clinical trials showed a positive impact, especially when patients provided positive feedback and asked to extend the use of the device. This result may be related to the kind of treatment, as LW7's device was designed to improve patient adherence to physiotherapy through gamification. The experiences which YMX and LW7 had in clinical trials inform the answer to the research question: 'How do treatment technologies are considered in clinical trials or alternative procedures?'.

12.3 On the WearCare II Project Observation

The observation of the development process of the self-administered treatment technology was not applicable due to the limitations highlighted in Chapter 10: WearCare II project. Accordingly, WearCare II project presented an opportunity to observe the development of healthcare ideas and how adherence is considered through the development process. It is essential to understand the role of this stage and do not over-estimate nor underestimate its contribution to the study. This observation provided an opportunity to see how different ideas evolve and how adherence is considered at an early stage of the design process. The observation contributed to understanding how design influences the innovation of patient-administrated treatment technologies.

While all the teams showed appreciation of the value of adherence, teams varied in how well they considered it. Some teams did not consider or only poorly considered adherence factors, and other teams showed partial consideration of some factors of adherence. Yet this consideration may have changed as the teams progressed in designing the solution. This was reflected in the final presentation where the teams presented their suggested solution. The above observation highlighted another perspective which is how adherence is considered in product development contributed to the second claim of this study (Chapter 14: Conclusion and Contribution to Knowledge).

12.4 On Assess: Delphi Method

The time frame of this PhD research study and commercial risk considerations ruled out an action research methodology where an adherence framework was tested within product development. Assessment replaced action research, with the Delphi method implemented to assess the results of the research through the consensus of a panel of academics and practitioners in different fields related to the study. Refer to Chapter 11: Delphi Method Application for detailed information related to the Delphi panel and application of the Delphi method.

The Delphi method played two main roles in the study: a triangulation tool to the findings of the previous steps (literature review, case studies interviews and WearCare II observation), and assessment of the factors affecting adherence to self-administered treatment technology. The main purpose of round one was to understand adherence factors as seen from the Delphi panel and compare it with the factors identified from the theoretical frameworks of adherence and the interviews of the case studies (refer to 11.1 Round One Questionnaire in Chapter 11). The analysed results of the the first round align with the literature studies and the case studies' interviews, such as Follow-up and Reminders in the Communication category (Dayer et al, 2013; DiMatte, Haskard-Zolnierrek, & Martin, 2012; Vervloet et al, 2012), Perceived susceptibility – Belief selection in Knowledge category and Self-efficacy in the Motivation section (DiMatte, Haskard-Zolnierrek, & Martin, 2012; Martin, Haskard-Zolnierrek, & DiMatteo, 2010; Williams, 2014). In the conversation with YMX company, Follow-up and Reminders factor has been highlighted as one of the factors that improves patient adherence to the intervention regimen (refer to Table 11.2 *Content analysis and categorisation for Delphi round one questionnaire* in Chapter 11).

The aim of round two and three was to identify the level of importance of each factor or group of factors. Round three has shown significant agreement between the panellists on the importance level of importance in each factor. This reflected on the Standard Deviation (SD) as majority of the factors lays below the 1.0. Also, the Null hypothesis of agreement due to chance was rejected in Wilcoxon test (the assumption of significance is 0.006). For more details on the results of the SD of each factor and the calculation of Wilcoxon test, refer to 11.3.5 Application of Wilcoxon Signed-Rank to SD in Chapter 11.

12.5 Findings and Summary

This chapter summarised the findings resulting from the research and highlighted the findings which answered the research questions related to the design process, medical technology innovation and the consideration of adherence. The literature review provided an opportunity to explore the role of design in the medical technology innovation sector, the current state of the sector, barriers and opportunities and how medical technology contribute to driving patient empowerment.

The overview of the case study interviews explored the application of design thinking in the SMEs working on self-administered medical treatment technology. The discussion covered the consideration of adherence and how this consideration can affect the results of the clinical trials using the evaluation and testing procedures as an example. The observation of the WearCare II project provided an opportunity to observe the design of treatment devices from a different perspective, especially in an early stage of treatment design and how adherence is considered in the process.

Chapter 13: Introducing a Design-Focused Adherence Canvas

This chapter introduces a Design-Focused Adherence Canvas. A resource which results from the progress of activities that resulted the Adherence Framework. This Adherence Canvas is introduced to improve consideration of patient adherence in the use of self-administered medical technology. The framework is the result of a Delphi process that was grounded in the earlier studies. An example (with dummy data) is used to describe the steps of using the model in organisation context.

Key Topics:

13.1 Introduction to the Design-Focused Adherence Canvas

13.2 Description of the Design-Focused Adherence Canvas

13.3 Tracking Design Changes

13.4 Adherence Canvas Resources and Support Materials

13.5 Findings and Summary

Over the course of this research, the roles that design thinking can play in empowering patients and improving medical technology innovation were identified. From the perspective of adherence, the literature studies reviewed agreed on its importance, especially when the treatment is patient-administered. However, there are various challenges when considering adherence factors. This chapter introduces a Design-Focused Adherence Canvas which can be used during a design process to assess consideration of adherence factors at each stage. The factors used in this model are based on the consensus on the adherence factors in the Delphi method. The Adherence Canvas presents a synthesis of the findings in this study and has not been tested in practice due to time limitations and commercial risk.

The relevance and importance of specific adherence factors and how the framework is used are subject to adaptation and customisation based on the testing and evaluation of the treatment technology. Accordingly, two models will be discussed in this chapter: an Adherence Canvas, and an Adaptable Adherence Canvas.

13.1 Introduction to the Design-Focused Adherence Canvas

The proposed Design-Driven Adherence Canvas arises from the results of the Delphi method and is influenced by three areas of knowledge: the literature studies, the findings of the current research and the design practice observation, as highlighted below:

13.1.1 Literature Studies

The literature studies provided a key element in forming the Design-Driven Adherence Canvas. These studies focused on both adherence as well as evidence-based design.

13.1.1.1 Lack of Full Practical Adherence Framework

As highlighted earlier in this study (Chapter 6: Theoretical Frameworks of Adherence and Chapter 12: Discussion of Findings), three main points were observed in the theoretical frameworks of adherence:

- Although various studies discussed the theoretical models of adherence, few of them presented a practical framework which can be adopted by companies in professional practice.
- Existing Adherence Theories mainly targeted clinically administered medical intervention without specifically considering patient-administered intervention, especially the treatment technology.
- The design research literature has shown a significant lack of studies that focus on patient adherence and the practical consideration of adherence during the development of self-administered health technology.
- It was understood that factors may change from one disease to another, yet no practical model was presented which considers how the various factors manifest in professional practice.

To address the above three issues in the resource (Design-Focused Adherence Canvas) should consider the following:

- **Practical:** The resource should be simple, easy to understand, and viable in different types of companies and different stages of the product design, development and testing.
- **Inclusive:** The resource should consider the factors which affect adherence to patient-administered treatment technology, including the design factors.
- **Adaptable:** The resource be adaptable to the varied adherence factors related to specific diseases. While the model includes factors which the Delphi method agreed as important, some diseases require a focus on specific factors. Therefore, the model has two versions: a generic model and an advanced model.

13.1.1.2 Evidence-Based Design

The evidence-based design has been used in the healthcare system as an approach for decision making in implementing designs projects in the healthcare systems such as space design in hospitals (Ulrich et al., 2011). Based on the three methods covered earlier (7.6 Evidence-Based Design), the Health Environments Research & Design Journal (HERD) model (Table 13.1) presents a relevant scaling mechanism to treatment technology.

Based on the findings of both the interviews and the observation, the consideration of adherence factors in the initial plan of the design process may be affected by various factors, which may affect its consideration in the final product or service. Accordingly, an evaluation mechanism can assess consideration of different Design-Focused Adherence Canvass during the design stages. The implementation of evidence-based design may contribute to maintaining the consideration of adherence factors through the design process, prototype iteration and product testing.

High credible evidence		Level 1	Systematic reviews of multiple randomized controlled trials (RCTs) or nonrandomized studies; metaanalysis of multiple experimental or quasi-experimental studies; meta- synthesis of multiple qualitative studies leading to an integrative interpretation.
		Level 2	Well-designed experimental (randomized) and quasi-experimental (nonrandomized) studies with consistent results compared to other, similar studies.
		Level 3	Descriptive correlational studies, qualitative studies, integrative or systematic reviews of correlational or qualitative studies, or RCT or quasi-experimental studies with inconsistent results compared to other, similar studies.
		Level 4	Peer-reviewed professional standards or guidelines with studies to support recommendations.
High credible evidence		Level 5	Opinions of recognized experts multiple case studies.
		Level 6	Recommendations from manufacturers or consultants who may have a financial interest or bias.

Table 13.1 The HERD Evidence Based Levels (Stichler, 2010).

13.1.1.3 Adherence Factors

The Delphi method aimed to assess and triangulate the results of the previous research stages. In particular, it aimed to assess the general factors which can be considered during the design of the self-administered treatment technology to improve adherence. The consensus of the panellists on general adherence factors categorised into four categories (Table 13.2).

13.1.1.4 The Influence of Design Practice

The third area which contributed to designing the Design-Focused Adherence Canvas. An overview of design practice and how the design process works was conducted. In general, design practice is used to determine (vote) the level of consideration (how it is used) and observe the maintenance of this consideration (when it is used) as below:

- When to use the Adherence Canvas

As an evaluation tool, it can be used between the stages of the design process and before the testing to evaluate the level of consideration of adherence factors in each version of the product. For example, the Adherence Canvas can be used in the Discover stage of the Double Diamond (Design Council, 2015) as a resource to guide companies (especially new SMEs) to adherence factors that they need to consider in the design of treatment device or application. It presents a guide to explore the problem space related to adherence. In the Define stage, the Adherence Canvas defines the adherence factors that need to be considered during the design of the treatment solution and their importance. In the Develop stage, the Adherence Canvas presents a resource with which to evaluate the consideration of adherence factors in the treatment prototypes. In this case, the factors that receive a low rating in the consideration scale are iterated and improve in further versions. The Deliver stage provides an opportunity to test products and use patients' feedback to understand the adherence factors and their impact on patient adherence.
- Evaluate the consideration of adherence factors

Several practices within companies use a yes/no voting system for designs and prototype options to determine the viability of a design from different perspectives. An example to this practice is the Google design sprint, where the team votes for the ideas in order to select the workable one (Larusdottir et al., 2019; Martinez et al.,

2018; Wichrowski et al., 2015). Another example which applies the voting system is the affinity diagram tool, which is used to organise product features into categories. Part of this practice is to determine the importance of these features (Alänge, 2009; Widjaja & Takahashi, 2016).

13.2 Description of the Design-Focused Adherence Canvas

The Design-Focused Adherence Canvas presented in this chapter presents a visualised resource for companies to guide them and measure the consideration of adherence factors in the design process. These factors are based on the Adherence Framework which was developed based on the Delphi process (Chapter 11: Delphi Method Application). The adherence factors and the level of their importance (Table 13.2) presents the main structure of the Design-Focused Adherence Canvas which is described below

13.2.1 Design-Focused Adherence Canvas: What is it?

The Design-Focused Adherence Canvas is a one-page Likert Scale Radial Graph that allows companies to evaluate how adherence is considered in the treatment device during and after the design process. It evaluates the consideration of the general factors which affect adherence. There are two versions of the Adherence Canvas:

- **Design-Focused Adherence Canvas:** This is the general model which is based on the consensus of Delphi process (Figure 13.1) on an Adherence Framework for treatment technology including the factors affecting patient adherence and the importance of each factor. These factors were agreed upon by the panel of academic and professionals during the Delphi method. It can be used in to address major diseases, evaluate new products and by companies who do not know the exact adherence factors affecting their treatment intervention are. In this case, companies can use it as a starting point before refining the factors.

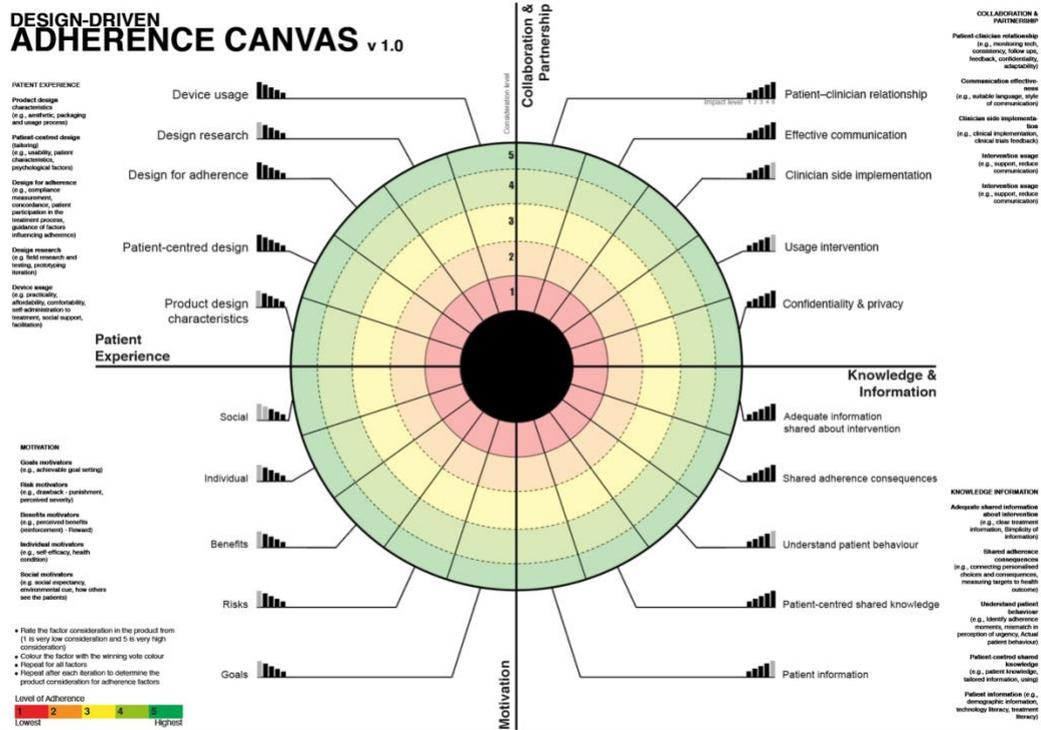


Figure 13.1 The Design-Focused Adherence Canvas.

- Advanced Design-Focused Adherence Canvas:** This model does not include any factors nor any levels of importance. It can be used by experienced companies who have a clear idea of the factors which affect their patients' adherence.

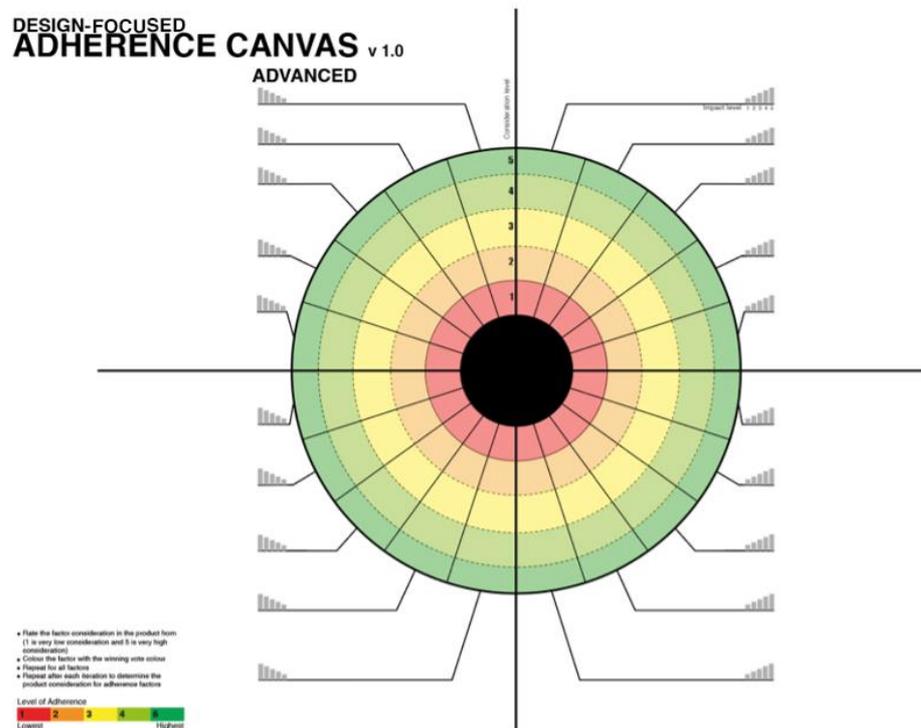


Figure 13.2 The Advanced version of the Design-Focused Adherence Canvas.

The Adherence Canvas consists of the following components:

- The adherence canvas (Figure 13.2) consists of a Likert Scale Radial Graph. The shape is divided into four sections. Each section represents a category of adherence factors (Collaboration and Partnership, Knowledge and Information, Motivation and Patient Experience).
- The radial scale consists of five coloured circles which progress from red (centre) to green (outer circle). The red circle, or level one, refers to a very low consideration of the adherence factor, and the green circle, or level five, refers to the highest consideration.

Below is a brief description of the Advanced Design-Focused Adherence Canvas and how it can be used to explore how treatment technology considers the related adherence factors.

The above findings influence the process below:

1. The model consists of a Likert Scale Radial Graph
2. . The scale consists of five coloured circles which have a corresponding number. The red inner circle corresponds with the number one and indicates a very low consideration of the adherence factor. The green outer circle corresponds with the number five and refers to the highest consideration.
3. The circle is divided into four sections. Each section represents a general category of factors. These factors are drawn from the investigation of adherence theories covered in the literature review. The four sections are: 1) knowledge; 2) motivation; 3) communication; and 4) patient experience. These sections are defined based on different adherence theories and adherence factors defined by the WHO and the NICE. As a result, a total of 20 adherence factors are listed.
4. Each adherence factor has a level of importance scale which rates the importance from 1-5, where 1 is the lowest importance and 5 is the highest importance. The default importance rating uses the data resulted from the Delphi method (Table 13.2). The importance rating provides an idea of which factors should be considered the most.

The advanced model is very similar to the generic model (13.3). The only difference between the two is that the advanced model does not include any factors or a rating.

The company's team needs to add the factors and rate them based on the company's own experience.

13.2.2 The Physical Description of the Design-Focused Adherence Canvas

The model will be made available online for companies to download and use under the Creative Commons Licence **Attribution-NoDerivs CC BY-ND**, which states: 'This license lets others reuse the work for any purpose, including commercially; however, it cannot be shared with others in adapted form, and credit must be provided to you.' (Creative Commons, N/A. p.1). 13.3 Adherence Canvas Resources and Support Materials included details on the resources that will be available to provide support for the Adherence Canvas usage.

13.2.3 How Can it be Used?

The below example provides a step-by-step visual guide to the usage of the Design-Focused Adherence Canvas. This example will use placebo (dummy data) answers in the Adherence Canvas to visualise how it works in a real organisational setup. The below example assumes that the team consists of five employees from different departments, and they are evaluating a prototype's consideration of adherence, which is the Develop stage in the Double Diamond process (Design Council, 2015).

13.2.3.1 Before Using the Model

The following steps occur before the voting process to organise the team and decide which type of model to use:

- 1) The model uses votes from team members with different expertise who are involved in designing the treatment technology. Accordingly, the first step is to assign a team for the process.
 - Determine if the company will use the Generic Design-Focused Adherence Canvas or the Advanced Design-Focused Adherence Canvas based on the existing experience with the treatment and target patient.

13.2.3.2 The Voting Process

Voting is a commonly used method to determine team's selection on multiple of choices such as the affinity diagram where the participants vote for the priority of multiple elements or severity level of several problems such as software problems (Alänge, 2009; Elmansy, 2016). Design sprinting is another method that uses the voting system to select between a number of layout design options (Banfield, Lombardo, & Wax, 2015; Elmansy, 2016).

In this process, the team reviews and discusses the treatment device details, features and possible prototypes. This revision helps the team members recall the product specifications. Next, the company needs to determine the voting method to use. Usually, there are two methods: 1) Voting using dots and counting the dots, or 2) If anonymity is required, using a simplified version of the eDelphi method consisting of two rounds.

Once the above practice is defined, the team may move forward as below (the steps below use a two round Delphi method):

1) The team facilitator codes the factor by colouring it based on its consideration.

Irrelevant factors are coded with the colour black (Figure 13.3).

- The team anonymously votes on how adherence factors are considered in the design idea. In Figure 13.3, the votes are marked with an X.

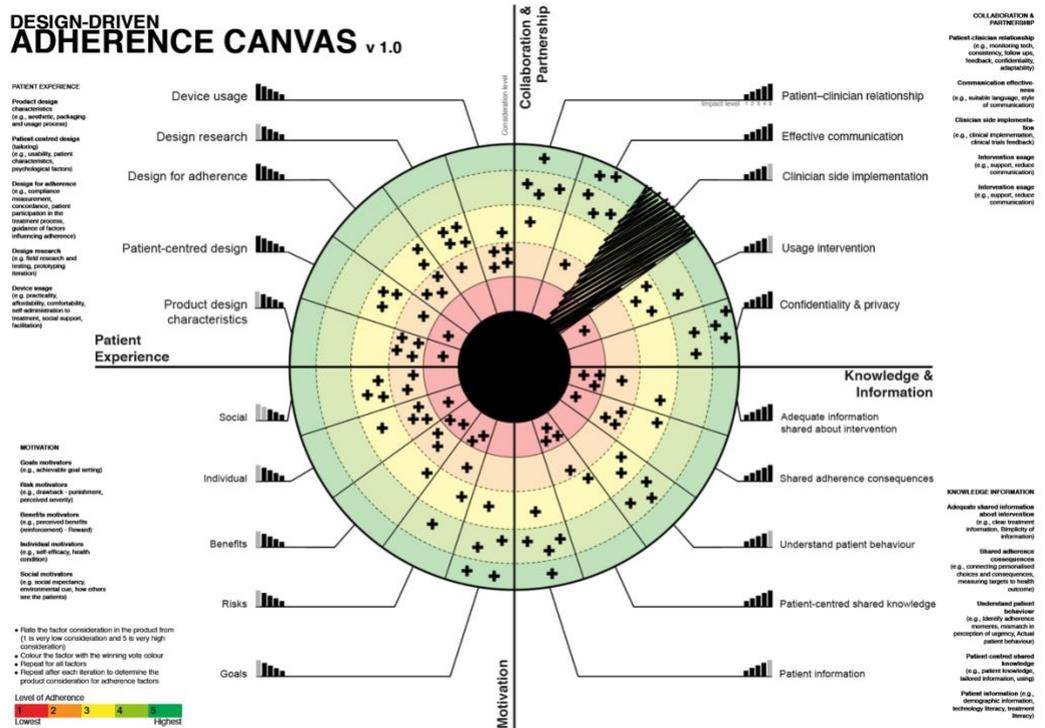


Figure 13.3 Round one of anonymised voting on the consideration of each factor.

2) After finishing the first round, the team votes again in a second round, this time with the ability to see each-others' votes anonymously. If more than one consideration level shares the same importance, the voters should repeat the voting by considering that each level should have a unique level of importance (Figure 13.4).

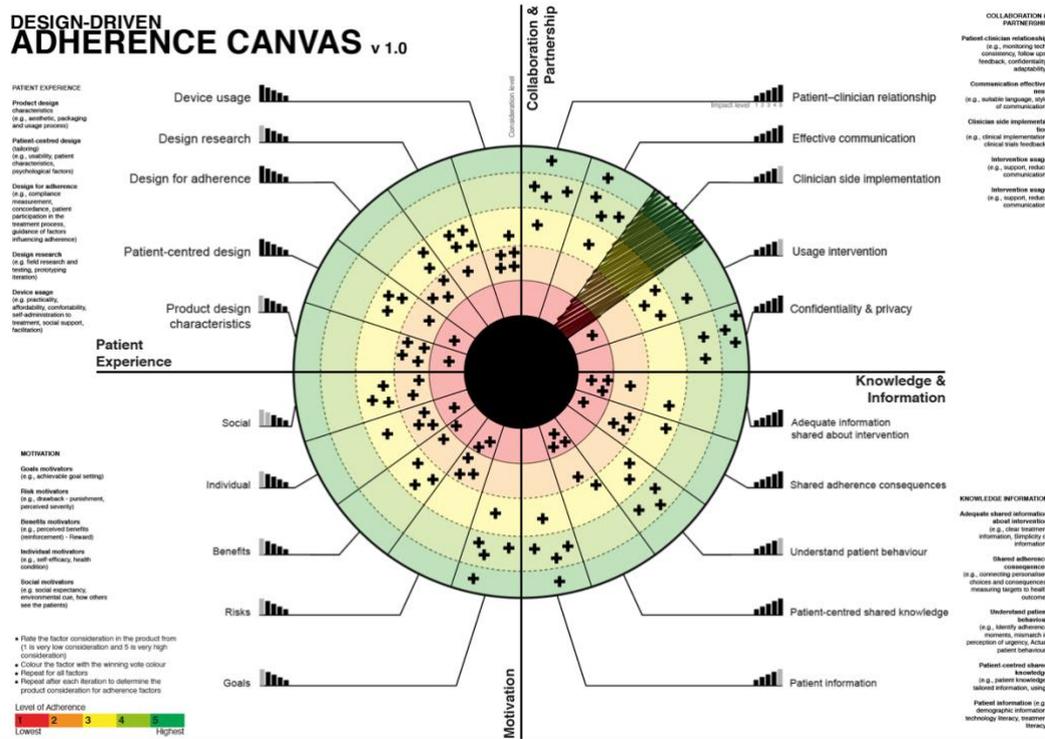


Figure 13.4 Round two of the voting session, with the chance to modify answers.

3) The team repeats the process for all factors. If there is an irrelevant factor, the team facilitator can ignore or block it out with the colour black.

13.2.3.3 Post the Voting Process

The results of the first round of voting are used to iterate the product to improve the consideration of the adherence. The process is repeated in different stages to improve the product, then the team can visualise the different votes to overview how the adherence factors were considered in each prototype (Figure 13.5 and Figure 13.6).

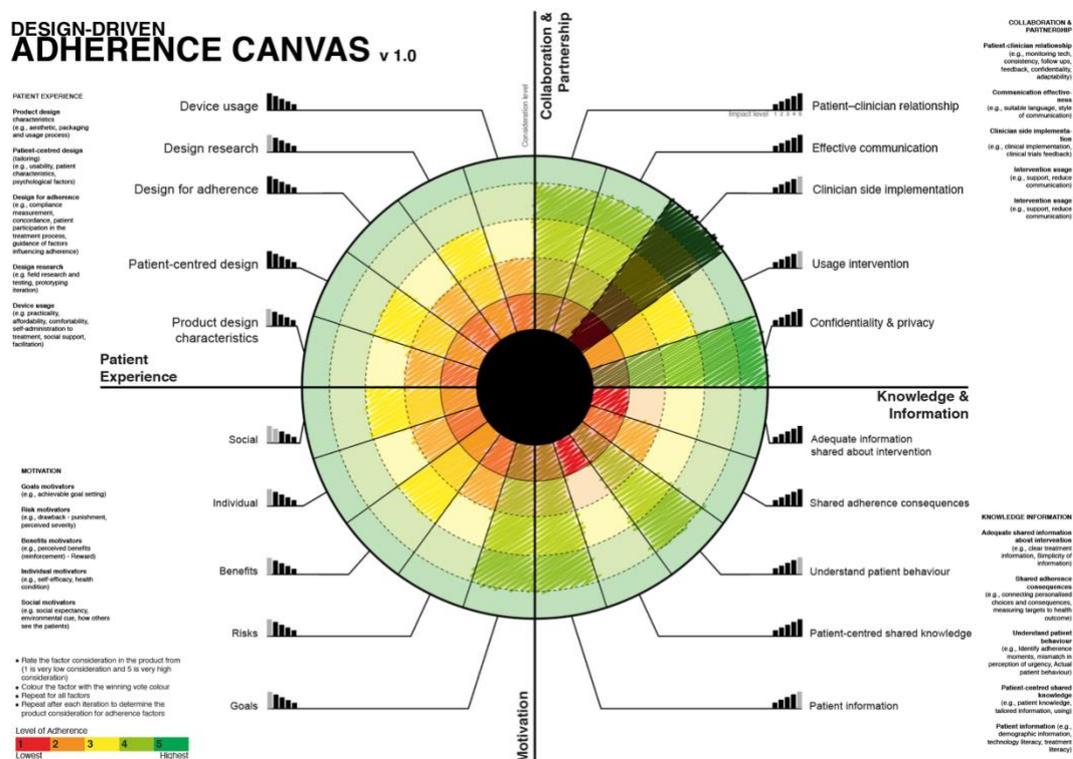


Figure 13.5 The results of first usage of the model.

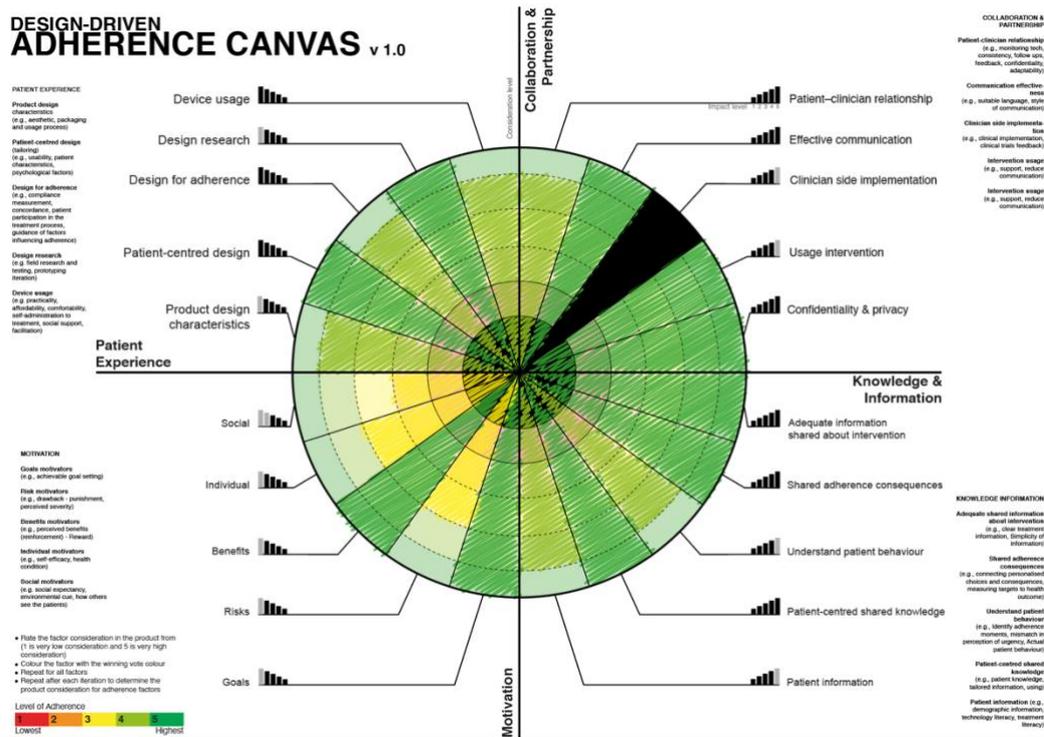


Figure 13.6 The results after improving the product's consideration of adherence.

The voting process can be also applied to different stages of the design process (Double Diamond). After the voting process, team members discuss the results of Design Driven Adherence Canvas voting and implement it to improve of future prototype versions.

13.3 Tracking Design Changes

The changes in the voting throughout the rounds can provide interesting observations about the adherence factors consideration. The comparison between design consideration for the adherence factors in Figure 13.5 and Figure 13.6 presented three scenarios:

1. Some factors can be improved using the development process through applying iteration and prototype evaluation or testing.
2. Some factors cannot reach the highest consideration rate because of internal and external development factors (i.e. treatment requirements, regulations or technological barriers).
3. Some factors were ignored (excluded) either because they are irrelevant or can't be changed due to internal or external factors, such as the second case of factors.

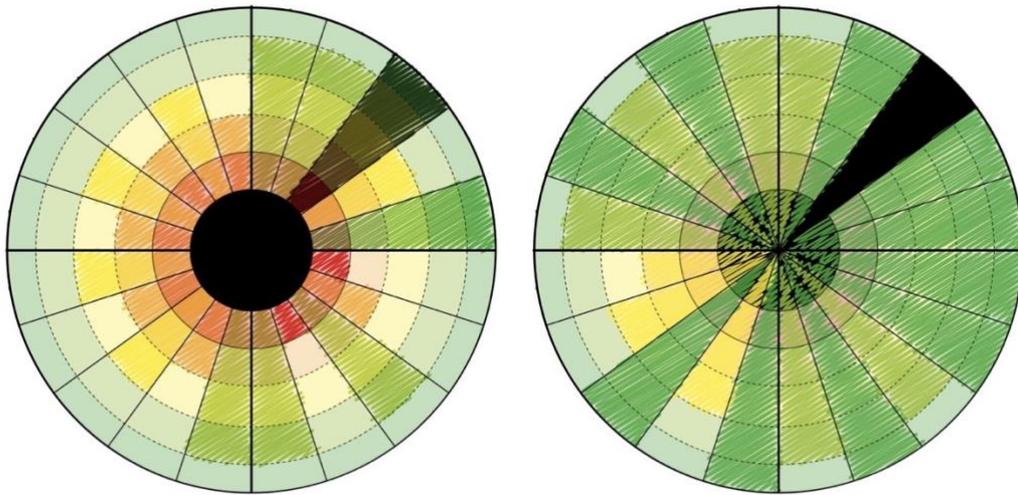


Figure 13.7 The development of adherence factor consideration from round one on the right to round 2 on the left.

The frequent usage of the Adherence Canvas improves the team's understanding of the patients' nature and the adherence factors that should be considered, especially in relation to specific diseases. By this time, the Adherence Canvas' role shifts towards an evaluation tool to ensure that the factors are considered in future products.

13.4 Adherence Canvas Resources and Support Materials

The Adherence Canvas will allow companies to download the tool and implement it into health technology development. The following resources will be provided along with the Adherence Canvas.

The Adhere Canvas website (available at: <https://www.adherencecanvas.com>): The website will include:

- The Adherence Canvas in PDF format to download
- Video tutorials and visualised articles to guide companies on how to use the canvas

- Contact information to get in touch with the researcher for more information and book online sessions if needed
- YouTube videos: video resources will be available on my YouTube channel and the Adherence Canvas channel to provide a usage guide and video presentation about the Adherence Canvas usage
- Industrial articles on my website: <https://www.designorate.com>: these articles will cover the usage of the Adherence Canvas and case studies related to it

From the academic perspective, the following resources will be provided:

- Conference and journal publication to introduce the Adherence Canvas and background research
- Conference poster and speaking participation to introduce and discuss the Adherence Canvas
- Publish a book that provides a complete guide to the Adherence Canvas

13.5 Findings and Summary

This chapter presented the Design-Focused Adherence Canvas, which synthesises the findings of this study. It provides a tool to map the consideration over different design stages. Two models were introduced—the Generic Design-Focused Adherence Canvas and the Advanced Design-Focused Adherence Canvas—the latter of which can be used by skilled companies who already have knowledge of the adherence factors which relate to the designed technology. This chapter provided an example of the application of the model using placebo (dummy) data to show the steps which companies need to follow to use the Adherence Canvas.

Chapter 14: Conclusion and Contribution to Knowledge

This chapter provides a summary of the research, claims and contribution to knowledge, study limitations, future work and conclusion.

Key Topics:

14.1 Research Overview

14.2 Research Claims and Contribution to Knowledge

14.3 Study Limitations

14.4 The Opportunity of Exploring Designers Practice in Considering Adherence

14.5 Future Work

This chapter will briefly overview the research and discuss its contribution to knowledge, which will be presented as two claims. The contributions to knowledge will be presented and mapped to the research process (Chapter 12: Discussion of Findings). Also, the research limitations will be discussed. Finally, this chapter will recommend future work based on the research findings.

14.1 Research Overview

This section will briefly summarise the research aims, objectives, methodology, and process as a guide for the discussion of claims in the following section. The main research aim was to explore the role of design thinking in improving adherence to self-administered treatment technology. To this goal, three main initial objectives have been presented: 1) *investigate* current design processes in treatment technology; 2) *explore* the contribution of design thinking to development of the treatment technology; and 3) *assess* the impact of considering adherence factors during treatment technology design. To address these objectives, the research questions below were asked:

- What is the role of design and innovation in medical treatment technologies?
 - What is the current state of innovation in medical technology?
 - What are the barriers to and opportunities for innovation in medical technology?
 - What is the role of medical technology in driving patient empowerment?
 - How does design influence the innovation of patient-administrated treatment technologies?
 - What are the characteristics of design thinking?
 - What are the current development processes which are applied in medical technology?
 - What are the barriers to and opportunities for adopting design thinking?
- What is the impact of adherence in self-administered treatment technology?
 - What are the theoretical frameworks of treatment adherence?

- How are treatment technologies considered in clinical trials or alternative procedures?
- How is adherence considered in product development and clinical trials?

The answers to the above questions were discussed in Chapter 12: Discussion of Findings.

14.1.1 Methodology and Process Brief

The research consists of three main stages: Investigate, Explore, and Assess. Research design and methodology were determined according to each objective and questions need to be addressed. Research stages and their aims are briefly highlighted below:

Stage 1: Investigate

- Step 1: Desk research

This step aims to investigate the literature from three perspectives: the theoretical frameworks of adherence, design thinking, and medical technology innovation.

- Step 2: Field research

Five case studies involved in semi-structure interviews (face-to-face and online) to investigate design process and how adherence is considered during it.

- Step 3: Data Analysis

The interviews' transcripts have been analysed using content analysis. The transcripts have been imported into nVivo and analysed to identify the emerged themes. Data from both literature and interviews' analysis were triangulated on the following steps.

Stage 2: Explore

- Step 4: WearCare II project observation

Overviewing the early state of the design process stood as a limitation in the case study interviews. Therefore, WearCare II project was observed to explore how adherence is considered in early steps of the design thinking process.

Stage 3: Assess

- Step 5: Delphi method

Data used from previous steps were triangulated and used to build an adherence framework which is assessed through three-round eDelphi method.

14.2 Research Claims and Contribution to Knowledge

The research makes two main contributions to knowledge:

- **1st Claim:** This research has developed an adherence framework that identifies factors that affect patient adherence to self-administered treatment technology and the level of importance of each of these factors.
- **2nd Claim:** A design-focused Adherence Canvas, based on the adherence framework (1st claim), which is a practical resource for companies to consider adherence factors and their level of importance when developing self-administered treatment technologies

As a sub-claim of the 2nd claim, the design research literature has shown a significant lack of studies that focus on patient adherence and the practical consideration of adherence during the development of self-administered health technology.

The two claims and findings that lead to those two claims are discussed below:

14.2.1 An adherence framework that identifies factors that affect patient-administered technology treatment adherence and their level of importance

The adherence framework (Chapter 13: Introducing a Design-Focused Adherence Canvas) integrates findings from literature (Chapter 6: Theoretical Frameworks of Adherence), case studies interviews (Chapter 9: Case Studies Interviews), and Delphi method (Chapter 11: Delphi Method Application). Literature highlighted the below:

- Existing adherence theories and frameworks don't consider the specific forms of medical technology interventions (i.e. treatment devices and software apps).

To address these two findings, the study investigated adherence factors that affect patient-administered treatment technology through two steps:

- Interview answers from five case studies highlighted adherence factors that are relevant to their product (medical technology)
- Round one of the eDelphi method collected panellists' answers on open-ended questions about general factors that affect adherence in patient-administered technology. Data generated from this step was reviewed by two inter-rater (reliability procedure). Cohen Kappa test was applied to understand the significance of the answers after eliminating the agreement based on the chance.

Based on the above two steps' findings, several adherence factors have been highlighted and organised into four categories (segments). This organisation was based on the literature about the relation between each group of factors (Martin, & DiMatteo, 2013). Each category includes a sub-category (sub-segment) of adherence factors. Inside each sub-category, there are examples of adherence factors that need to be considered. Table 13.2 in Chapter 13: Introducing a Design-Focused Adherence Canvas. Additionally, the adherence factors' importance (impact) was identified as below:

- The 2nd round of Delphi method asked the panellists to rate adherence factor's importance through Likert-based online survey. In the third round, they were given the same survey from 2nd round (with showing anonymised total answers from round two). Panellists were asked to check their answers and change it if they want to change their minds. The result's significance was evaluated using Wilcoxon test to eliminate agreement by chance.

Over the course of the study, two main research results contributed to building the adherence framework: the feedback from the cases studies interviews and the 1st round of the Delphi method. The first feedback from interviews reflected each company's experience about the adherence factors that affects their target patient's adherence. The 1st round of the Delphi method involved asking 15 panellists from related background (designing for medical devices, medical psychology academics, NHS, AHSN, CPI, and Philips Design). Accordingly, a consensus has been reached on the framework from both academic and practitioner perspectives.

14.2.2 A design-focused adherence canvas, based on the adherence framework (1st claim), which is a practical resource that records how adherence factors are being considered and their level of importance.

The second claim is a canvas visualisation of the framework that provides a practical resource for companies to track consideration of adherence during the design of the treatment technology. The finding in literature (Chapter 6: Theoretical Frameworks of Adherence) that guided the research toward this gap in knowledge:

- Existing adherence theories don't provide a practical mechanism for companies to consider adherence in their product or service.

the observation from both case studies interviews and Wearcare II project observation highlighted the following findings:

- While SMEs appreciated the importance of adherence (Chapter 9: Case Studies Interviews), there is no guide to help SMEs to sufficiently consider possible adherence factors. Therefore, some companies consider adherence factors based on previous experience (YMX), previous experience (LW7), or no experience (DE7).
- Observing adherence consideration in an early stage of WearCare II project (Chapter 10: WearCare II project observation) highlighted that while some teams considered adherence at the project's beginning, this consideration faded or was obscured by other factors as they progress in the design thinking process.

The adherence canvas presents a visualisation for the adherence framework supported in the first claim. The above two observation presented the need for a resource that can help companies and guide them consider adherence factors. However, the current literature theories don't present a practical method for companies to consider adherence (Chapter 6:

Theoretical Frameworks of Adherence). Accordingly, this study developed an Adherence Canvas, a resource that can guide companies to consider adherence factors and measure this consideration as they progress in the design process (Chapter 13: Introducing a Design-Focused Adherence Canvas).

As a sub-claim of the 2nd claim, the design research literature has shown a significant lack of studies that focus on patient adherence and the practical consideration of adherence during the development of self-administered health technology.

14.3 Study Limitations

During the study, several limitations faced the research practice. These limitations and their impact on the research process and results are highlighted below:

14.3.1 Case Study Limitations

The first group of study limitations was related to recruiting SMEs for step two's interviews. There were two limitations highlighted below:

- Few SMEs are working in patient-administered treatment technology. While 353 companies were reviewed, only 11 companies met the requirements of the research scope and were invited to the study.

The limitation above highlights the question: why is there a lack of companies who address patient-administered treatment technology? Also, it highlights a gap in the healthcare industry related to self-administered health technology interventions. Although various studies highlighted the benefits of self-administered health technology (Eaton, 2019; Wamble et al., 2019), there is a lack of patient-administered interventions. Therefore, 1) this gap presents an opportunity for further research on the self-administered treatment technology and how to fulfil this gap and encourage patient empowerment, and 2) this gap can be one of the reasons behind the insufficient studies related to health technology interventions such as mental health apps (Grist, Porter, and Stallard, 2017).

- It wasn't easy to persuade companies to join the study. Out of 11 companies, only five companies agreed to join the study and proceed in the interviews. Companies who declined to join the study gave reasons such as the lack of availability and fear that participating would distract their team.

The second limitation highlighted the question: what are the reasons that prevent companies from participating in the research? Part of the barriers that face the research in health technology may be related to the companies themselves, such as their limited resources (see Chapter 3: 3.4 Case Studies Recruitment). The discussion with case studies highlighted other barriers such as lack of experience, the fear of affecting their funds and revealing private information related to their products. The companies' refusal to join the study can be considered another barrier facing studies in healthcare technology.

Another limitation was related to the content analysis is the application of a reliability procedure. The interviews provided an understanding of adherence from the perspective of established SMEs, which was part of the triangulation towards the final Assess stage (the Delphi method).

The limitations above had no significant impact on the step's outcome and the aim of the interviews with the case studies (investigate the consideration of adherence in the design process).

14.3.2 WearCare II Observation Limitations

The second stage (Explore) aimed to understand how the adherence factors were considered early in the design thinking process. However, two main limitations were identified:

1. The medical technology development process takes a long time compared with the timeframe of the study, which stood as a limitation to observe companies in an early stage of the design process.
2. Companies are cautious about exposing their new product information, especially at an early stage, as other companies could steal it.

Based on the two limitations above, the WearCare II project was observed. The project provided an environment setup that allowed design groups to work together in exploring the problem space and define the solution space of the health technology. While there are differences related to financial and legal priorities, those differences do not significantly impact the aim of the observation. There are significant differences, such as the aim of the project and the practice.

Hence, WearCare project provided an opportunity to observe how adherence is considered at an early stage of the process. From the latter perspective, this limitation did not have a significant impact on the study. However, two main limitations were highlighted: 1) observing the whole design process inside an organisation setup from beginning to end was not possible, and 2) some elements, such as the project budget, documentation and project management, were not available to observe.

A clear scope of the target of the WearCare II observation is needed to identify its contribution to the study. The observation of the WearCare II project aimed to observe the consideration of adherence from the design practice perspective. The findings from the observation, interviews, and secondary data were triangulated in the Delphi method, particularly how adherence's factors were considered and evaluated in the PDP (refer to the second claim, see 14.2 Research Claims and Contribution to Knowledge).

14.3.3 Delphi Study Limitations

The medical technology development process is longer than the PhD study duration. Accordingly, testing the findings with an actual organisational setup was inapplicable. So, the final stage involved assessing the outcome of the previous stages. The Delphi method resulted in an agreement between the panellists on the final adherence framework and the importance of adherence factors. While the final stage presents two contributions to knowledge (14.2 Research Claims and Contribution to Knowledge), further work will provide the opportunity to test the adherence framework and adherence canvas in an actual SME setup.

The decision to use the Delphi method to assess the triangulated findings from the Investigate and Explore stages highlighted the timeframe of the research as one of the barriers that face adherence in self-administered health technology studies. The study of adherence, especially in chronic diseases, requires long term studies that can test the results over the years of using the intervention, especially when adherence to the treatment decreases over the intervention time.

14.4 The Opportunity of Exploring Designers Practice in Considering Adherence

On reflection, whilst the researcher considers that the study presents a sufficient overview of the design practice that led to address the main research question, the limitations associated with literature review (Chapter 7 Design Thinking), interviews (Chapter 9: Case Studies Interviews) and WearCare II project (Chapter 10: WearCare II Project) affected the ability to strengthen and expand the evidence related to how designers consider adherence in self-administered treatment technology development. The below reflections highlight the opportunity to expand and strengthen the evidence related to how designers consider adherence during the PDP. During the reflection below, both terms of companies and designers are used interchangeably as the product design is developed by designers or employees with design expertise (Cross, 2011; Michlewski, 2016):

- The number of case studies recruited in the study was limited by the research timeframe and the limited number of companies working in self-administered treatment technology. Without timeframe limitation, recruiting case studies could provide the opportunity to explore a broader range of designers' practices, particularly in considering adherence and its factors. The choice of companies could consider:
 - Company size: the recruitment of more medium-sized firms could also allow a broader exploration of how adherence is considered within these companies.
 - Company maturity and experience: Expanding the recruitment criteria to involve companies with various experiences in developing self-administered

treatment technologies. Exploring the PDP in these companies could allow the study to explore the design practice and how it is affected by its expertise in product development.

- WearCare II project observation aimed to explore the design practice and how adherence is considered during the early stage of the PDP. The limited timeframe presented the main barrier in this stage. This limitation stood against the observation of the PDP within companies' environment, especially with considering project length and its current development stage. Without this limitation, this stage's observation could be conducted inside SMEs starting new health technology products to observe and record design practice and how adherence is considered in this early PDP stage. This observation setup would increase the strength of evidence related to adherence consideration in the early PDP, which could feed into a more comprehensive implementation of the Adherence Canvas. For example, designers with no experience in adherence could use the canvas as a guide to the adherence factors to consider improving adherence.
- The above awareness of limitations and opportunities to understand the consideration of adherence in design practice presented an essential role in planning the future of this research and how designers can use the Adherence Canvas during the PDP. The Adherence Canvas will be available to use in their PDP, so the researcher will observe companies to explore how the canvas can help them consider adherence. For instance, companies can focus only on the factors that are relevant to their target patients.

14.5 Future Work

The proposed Adherence Canvas (including the adherence framework) is a resource that can guide companies to consider a comprehensive evidence-based framework of adherence factors. However, due to the study's timeline limitation, testing the canvas with companies was not possible. Accordingly, future research should introduce the Adherence Canvas (v 1.0) to:

- SMEs working in designing and developing patient-administered medical technology. The canvas will be introduced as an open-access resources for companies and collect data about its effectiveness in addition to feedback from companies to improve the canvas
- Healthcare organisations (i.e. AHSN, NHS, NIHR, and CPI) to discuss it implementing in health technology pathway as one of the resources provided for start-ups

The Adherence Canvas will be made available online to be used under the copyright Attribution-ShareAlike 3.0 Unported (CC BY-SA 3.0) (Creative Commons, NA).

Companies will be invited to download and use the Adherence Canvas and provide feedback to evaluate its impact on adherence outcome. The feedback from the companies will be anonymised and published in academic publications to provide an evaluation on the canvas effectiveness.

14.5 Conclusion

This study aimed to investigate the role of design thinking process in improving adherence in patient-administered medical technology. Over the course of the study, a mixed method research strategy has been adopted to investigate the design process and the consideration of adherence in SMEs designing patient-administered treatment technology in the UK. Several findings have been identified. From the perspective of adherence, literature studies have highlighted the negative impact of poor adherence, the benefits of medical technology innovation, and the opportunities for applying design thinking in medical technology innovation. However, the advantages of medical technology innovation and the application of design thinking cannot be achieved without a clear understanding and consideration of patient adherence for self-administered treatments. Accordingly, two main gaps were identified in the literature related to adherence: there is a lack of theoretical adherence frameworks that address treatment technology devices and applications, and current

adherence frameworks provide no practical mechanisms for companies to consider adherence while designing treatment technologies.

Throughout the research process findings were identified. Based on the interview with five case studies working in developing patient-administered medical technology, there is a general agreement on the importance of patient adherence. However, there is no effective consideration for adherence factors during the developing of the treatment products. Companies have varied in applying the design process and considering adherence during it. During the observation of WearCare II project, the teams working in the project applied the design thinking process. Part of the process was considering patient adherence using the MPPF method. However, the consideration of adherence faded as the teams progressed in developing the medical technology.

Based on the above findings, the study claims two contributions to knowledge: the first claim is the development of an adherence framework that identifies factors that affect patient-administered technology treatment adherence and their level of importance. This claim is based in integration of findings from the literature, case studies interviews, and the Delphi rounds. The second claim is the development of a design-focused adherence canvas, based on the adherence framework (1st claim), which is a practical resource that records how adherence factors are being considered in relation to their level of importance. The later claim is influenced by the findings of by the literature, case studies interviews, and WearCare II project observation. The Adherence Canvas presents a visualised resource for the Adherence Framework to guide and help companies to consider adherence factors that affect patient-administered treatment technology. Limitations of the current findings indicate the need for future work, including testing the Adherence Canvas with existing SMEs to collect a good sample of anonymised data on its effectiveness. Additionally, it will be presented to the healthcare organisations in the UK to provide for companies as a resource to improve adherence.

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