Patient Generated Health Data in Ireland: A Study of the Patient Perspective

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Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university.

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Abstract

Introduction

In today's healthcare setting, the most common and recognised form of medical information is that which is generated by healthcare professionals about patients under their care e.g. investigation results, observations, notes etc. However, there is also a second, highly valuable source of data known as patient generated health data (PGHD). This is data created or gathered by patients or their family/caregivers about their state of health. While it can often be the same type of information generated by healthcare professionals, the process of collecting the data typically happens outside of medical appointments, for example in the home. There is increasing interest in the potential for this data to inform treatment plans, personalise healthcare and to motivate patients to self-manage their conditions. The latter is particularly pertinent in the case of chronic diseases, where patient engagement is widely touted to be a key factor for effective healthcare management. Despite the fact that patients are essential in the capture and sharing of this data, to date much of the research on PGHD has been from the perspective of the healthcare professional. The aim of this study is to investigate and report on the patient perspective.

Methodology

An in-depth literature review of this topic was performed, after which it became apparent that patient views on PGHD are less well understood. Therefore an inductive, exploratory investigation into the experience and views of a set of chronically ill patients in the Irish healthcare setting was chosen as a basis for this research. A semi-structured interview was designed as part of this study and 8 participants, with varying chronic illnesses, were interviewed during April 2017.

Results

Participants represented a range of chronic illnesses and ages. In general, the study found that patients are willing to engage in the capture of PGHD if requested to do so by their clinician or if they feel that it will inform and improve their treatment plans. While all participants reported benefits, there were also challenges related to ongoing motivation/engagement, security and confidentiality, lack of methods for sharing data, and a complex patient-clinician relationship.

Conclusion

While the study population for this research was relatively small, it allowed for in-depth investigation with participants. This was particularly important given the imbalance between a lack of studies related to PGHD from the patient perspective and the increasing focus on the ability for PGHD to reduce the burden on the healthcare system. This study contributes to the knowledge base by providing insight into the views and concerns that patients have with respect to capturing and sharing health data. Further acknowledgement of the importance of the patient's role and views on this topic is necessary if PGHD is to be successfully integrated into clinical care pathways and electronic healthcare systems.

Table of Contents

List of Tables

List of Figures

Abbreviations

BP	Blood Pressure
CCM	Chronic Care Model
CE	Conformité Européenne (meaning European Conformity)
EC	European Commission
EEG	Electroencephalogram
EHR	Electronic Health Record
EPR	Electronic Patient Record
FDA	Food and Drug Administration
GP	General Practitioner
HITECH	Health Information Technology for Economic and Clinical Health
HL7	Health Level Seven International
HSE	Health Service Executive
MDT	Multi Disciplinary Team
ODL	Observation of Daily Living
PGHD	Patient Generated Health Data
PHR	Personal Health Record
TCD	Trinity College Dublin
WHO	World Health Organization

1 Introduction

1.1 Background

In today's healthcare setting, the most common and recognised form of medical information is that which is generated by healthcare professionals about patients under their care. This data is typically comprised of investigation results, observations, notes, medical histories etc. and is normally stored in the patient's medical record. This record can be paper or electronic depending on the institution gathering it. While these records have traditionally been paper based, electronic patient records are becoming increasingly common with investment in technology within healthcare.

However, there is also a second, highly valuable, source of data known as patient generated health data (PGHD). This is data created or gathered by patients or their family/caregivers about their state of health (Wald and Sands, 2013). It can be the same type of information generated by healthcare professionals, but the process of collecting the data typically happens outside of medical appointments, for example in the home. Varying paper-based and electronic methods are used for collecting the data, including handwritten notes, medical devices, health trackers and smartphone apps.

PGHD has garnered more attention in recent years as it is increasingly considered a valuable source of data in the treatment of patients. There is a drive to have patients take a more active role in their health in order to improve treatment outcomes and PGHD is seen as a way to engage patients in their care. Since patients or their caregivers are the experts when it come to their health, symptoms etc., PGHD is also recognised as a method for generating a more comprehensive view of their health, which to date has primarily been based on a snapshot taken at medical appointments.

1.2 Motivation

Internet access and the use of smart technology has increased significantly in recent years and growth in the latter is expected to continue to rise in the near future. According to a Eurostat report, in 2015 approximately 80% of households in Ireland had internet access and 70% of 16-74 year olds reported that they use the internet daily (Eurostat, 2016). This level of internet penetration, along with the increasing use of health trackers, wearables, home medical devices etc. suggests that from a technology perspective, wider collection of PGHD is now possible. In fact, significant amounts of PGHD are already being collected, but as yet have not been introduced into the clinical encounter. As previously mentioned, there is enormous possibility for this data to influence healthcare delivery, particularly when gathered in a structured and electronic format, for example through the development of clinical decision support systems and in management workflows.

Due to the potential of PGHD to improve healthcare delivery and patient outcomes, health agencies and governments have begun to investigate the use of this data and are putting in place guidelines and incentives for the incorporation of the data into clinical workflows and conversations (Wald and Sands, 2013, Shapiro et al., 2012). However, a preliminary review of the literature on this topic suggests that much of the research to date has been looked at from the healthcare provider's perspective (clinician concerns) and the benefits that can be realised through the use of this data (workflow efficiencies). Despite the fact that patients play a critical role in the gathering of this data, there appears to have been less emphasis placed on understanding the topic from their perspective. What are their views on the process of gathering PGHD, as well as expectations for how it should be shared, used and stored? What practices currently exist among patients for electronically capturing health data between appointments?

The purpose of this research is to:

1. Review the literature to ascertain what is already known about this topic from the patient's viewpoint,
2. Use this knowledge to inform an exploratory investigation into the experience and views of a cohort of chronically ill patients in the Irish healthcare setting and
3. Report on findings.

It is hoped that the outcome of this research will:

1. Provide healthcare professionals with a more comprehensive understanding of patient expectations and motivations for gathering PGHD.
2. Inform patient advocacy groups of patient perspectives on this increasingly popular topic.
3. Influence the design of EPRs so that their functionality addresses patient expectations with respect to PGHD.

1.3 Research Question

This aim of this study is to address the following research question:

"To investigate the experiences, views and expectations of a cohort of individuals living with a chronic disease, with respect to the capture and sharing of patient generated health data."

In order to do this, the research question is broken down into the following:

1. What are the ways in which patients currently capture health related data in an electronic format? How are they collecting it in non-electronic formats and what can we learn from this for electronic capture of data?
2. What are the motivations behind patients capturing PGHD?
3. Are patients willing to share, or not share, this data with their medical team? Why?

1.4 Research Overview

This study began with a brief literature review in order to understand what has already been reported in relation to patient generated health data. This initial literature review helped to identify gaps in the research, which in turn led to the formation of the research question. As part of this review, the potential impact that PGHD could have on the management of chronic disease became apparent, which led to its incorporation into the study. Once the research question was constructed, an in-depth review of the literature was performed. The results of this review were used to inform and design the research methodology. Ethical approval to complete this study was requested from Trinity College Dublin after the methodology design was complete.

Once ethical approval was granted, the data collection phase began and took the form of semi-structured interviews with individuals living with a range of chronic illnesses. Adjustments were made to the interview technique after the pilot interview. Due to the fact that this was an exploratory study, the interviews were transcribed and analysed in sequence, with the results of each used to inform the next consecutive interview.

Having completed and analysed the interview, the emergent themes were identified and are discussed as part of this study. Suggestions for further work in this area were developed and are also included as part of this research.

1.5 Document Overview

Chapter 1 provides a brief background on the research topic and motivation for performing this study. It outlines the research question, aims and an overview of the research method.

Chapter 2 discusses the results of the literature review. This section is broken down into individual topics which form the overall research question, namely chronic disease, patient-clinician communication, patient generated health data and technologies which are supporting its generation. The chapter concludes with a review of research methodologies appropriate to this type of study.

Chapter 3 outlines the research method followed for this study. It includes information about the design process, logistics and ethical considerations.

Chapter 4 presents the results of the data collection. It includes key information from the interviews which will be used in the discussion in Chapter 5.

Chapter 5 consolidates the data presented in Chapter 4 into themes, relating back to the findings from the literature review.

Chapter 6 summarises the study and acknowledges limitations. Suggestions for areas which would benefit from further research are also included.

2 Literature Review

2.1 Introduction

In order to perform this research, a review of the literature, industry reports and internet was first completed to gain an understanding of what has already been reported on topics related to the research question. The following areas were covered as part of this review:

1. Chronic Diseases: Their prevalence, impact on the healthcare system and management frameworks.
2. Patient-Clinician Communication: What is known about this topic, frameworks for effective management of this relationship and what is known about the impact that PGHD can have on it.
3. Technology: Review of technological advances and corresponding applications which are enabling the electronic capture and sharing of personal health data.
4. Methodological Research: Review of studies with commonalities to this research to understand which methods may be most appropriate to use.

2.2 Key Definitions & Terms

There is an emerging appreciation for the benefits that patient recorded data can have on care delivery. Within the literature, this data is most commonly known as patient generated health data, but is also referred to as patient generated health information, patient generated data or observations of daily living.

Regardless of the term that is used, the data is defined as that which is "created, recorded, and gathered by and from patients… to help address a health concern" (HealthIT, 2017). Observations of daily living (ODLs) are considered a subtype of PGHD defined as "sensory and behavioral indicators for the purposes of health monitoring and behavior modification" (Backonja et al., 2012). In addition to this, the term mHealth is used to describe mobile medical applications as "medical devices that are mobile apps, meet the definition of a medical device, and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device" (Petersen and DeMuro, 2015).

2.3 Method

The previous terms were used during the course of this literature review to investigate what is currently published about the topic. Other terms used to discover relevant publications included those related to chronic illness and patient-clinician communication. In order to ensure that material pertinent to these topics was not missed, the following variations on these terms were included in searches:

Table 2.1: Literature Review – Initial List of Search Terms

Patient Generated Health Data	Chronic Illness	Patient-Clinician Communication	Methodological Research
PGHD	Chronic disease	Patient-provider communication	Qualitative research
Patient generated data	Chronic disease management	Patient-clinician communication frameworks	Qualitative research healthcare
Patient generated health information	Chronic disease management frameworks	Patient-centered communication	Qualitative research health
Observations of daily living		Shared decision making	Patient survey
ODLs			
mHealth			
Mobile health			

Once themes emerged from the literature, additional terms were used to expand on these. For example, *patient engagement*, *self-management*, and *expert patients*.

The databases used for searches were PubMed, Web of Science, Scopus and Google Scholar. The literature review also incorporated information related to international initiatives and programmes, found through Google searches, the WHO and HSE websites.

Information directly related to patient perspectives were first reviewed, followed by that which was related to healthcare professionals. Each of the four topics were analysed in isolation and then correlations between them were identified. The results of this analysis will be discussed in the remainder of this chapter.

2.4 Chronic Disease

A chronic disease, or non-communicable disease (NCD), is characterised by its long duration and mostly slow rate of progression (WHO, 2013). Chronic diseases are classified into four major categories: cardiovascular, diabetes, respiratory and cancer. These illnesses are considered to be largely preventable by paying attention to nutrition, activity levels, tobacco and alcohol use (WHO, 2017b).

The prevalence of chronic diseases is considered a global epidemic and it is thought that by addressing the aforementioned risk factors, 75% of cardiovascular, stroke and type 2 diabetes would be prevented, as well as 40% of cancers (WHO, 2017a). In Ireland, the HSE reports that it is expected that 40% of the Irish population will have at least one chronic disease by 2020 (HSE, 2016), with this increase due in part to our ageing population. In addition, a report by WHO in 2014 stated that there was an 11% risk among the 30-70 year old population in Ireland of dying from one of the four major groups of chronic disease (WHO, 2014).

There have been numerous reports into chronic disease which have highlighted the cost to both the healthcare system and patients' quality of life (IrishCardiacSociety, 2015, Tully et al., 2010, DOHC, 2008). In Ireland, it is thought that approximately three quarters of the health budget in 2008 was being used to manage chronic disease (DOHC, 2008). Heart failure alone is reported to account for 7% of HSE inpatient bed days, with its cost on the healthcare system further compounded by a high (24-44%) re-admission rate (IrishCardiacSociety, 2015). Patient reported costs include anxiety, depression and fatigue, as well as an economic burden that can be caused by self financing of treatments (IrishCardiacSociety, 2015, DOHC, 2008).

Due to the combination of high incidence of chronic disease and associated costs, much effort is placed on their prevention and management in order to relieve the strain that they are currently placing on healthcare resources, both nationally and internationally.

The internationally accepted model, Chronic Care Model (CCM), suggests that optimal care for chronic illnesses is achievable when patients are educated about and engaged in their illness. The Global Strategy for Prevention and Control of Noncommunicable Diseases, endorsed by the World Health Assembly in 2000 (WHO, 2015), was aimed at helping member states to prevent and control the

increase in chronic disease. In the US, where chronic disease is thought to account for more than 80% of health expenditure (Krawlec et al., 2015), models for chronic disease management have been in development for many years. Other examples include the Chronic Conditions Self-Management Strategic Framework in Western Australia (DOHWA, 2011) and Ontario's Framework for Preventing and Managing Chronic Disease (MHLTC, 2007). In Ireland, several national policies and programs have been developed in order to tackle this issue, including a Policy Framework for the Management of Chronic Diseases (DOHC, 2008) and more recently the Healthy Ireland initiative (HI, 2015).

All of these models and programs place a strong emphasis on the importance of self-management and patient engagement (Parekh et al., 2011). With evidence suggesting that patients themselves are key to changing how chronic illnesses are managed, it is important to look at how to engage and motivate individuals to become more involved in their care. The role that apps, wearables, home medical devices, and subsequently PGHD can play in this situation is of increasing interest, although the aforementioned frameworks do not directly address the significance of incorporating this data into the management of chronic disease. It is hoped that this study will contribute knowledge about patient processes and thoughts that can be used to influence models for chronic disease management into the future.

2.5 PGHD to Aid Patient-Clinician Communication

The importance of the relationship between patients and clinicians is well documented. Since the aim of this study is to investigate how patients' recorded data can be incorporated into their treatment, it is necessary to look to the literature to understand what is known about communication channels within the clinical encounter and whether the introduction of PGHD, particularly in electronic format, can influence the communication between patient and clinician.

Effective communication can result in a myriad of benefits for patients, including increased satisfaction, compliance to treatment plans, improved understanding and recall of information supplied by clinicians, better self-management and outcomes (Petersen and DeMuro, 2015). There are negative consequences to poor communication, including the missed opportunity to engage patients in their care and to encourage better self-management (King and Hoppe, 2013) e.g. in the case of

chronic illness, to address the risk factors mentioned previously. Therefore, the topic has received much attention over the years and many frameworks for effective communication have been developed. Studies from the patient perspective have shown that they value the opportunity to build a good relationship and communication channel with their clinician (Tully et al., 2010).

For the most part, studies and frameworks related to patient-clinician communication have been concerned with how the clinician should approach encounters with patients (Petersen and DeMuro, 2015). For example, Epstein and Street's framework for effective patient-centered communication in cancer care (Epstein and Street, 2007) highlighted information exchange as an important consideration for effective communication and while it acknowledges that patients play an important role by bringing disease related information to the encounter, it mostly focuses on how clinicians should be aware of individual patients information and emotional needs and tailor their exchanges with that in mind. This framework also includes patient self management as a key component, however, as before it is approached from the point of view of how clinicians can help patients to gain information about their illness and deal with the effects of their treatment, rather than how patients can capture information and use it to inform their treatment plan. Reviews of the literature (King and Hoppe, 2013, Ha and Longnecker, 2010) confirm the importance of patient-centered communication, however also show that the focus is placed on how clinicians can be taught to foster the necessary skills to achieve this with their patients. These frameworks do not directly address the role of PGHD in communication or the impact that it may have on the patient-clinician relationship.

While there is a large focus on the clinician perspective, there is still much to be gained from this knowledge that can inform how PGHD can influence patient-clinician communication. For example, studies report that clinicians are more likely to deliver patient-centered care to those that they believe to be more engaged in their health (Petersen and DeMuro, 2015). This would suggest that patients making the effort to record PGHD may be perceived in this light and therefore receive a more tailored level of communication from their clinician.

Some studies have also reported that clinicians believe that patients do not always tell them the truth, with one survey of patients suggesting that this may be correct about 50% of the time (Shrager, 2014). Therefore, the use of electronic data that is

collected by devices may be seen as more trustworthy and objective by clinicians (Petersen and DeMuro, 2015).

In conclusion, while it is commonly recognised that information provided by patients is an important aspect of information exchange within the encounter, and that patient self-management is also an important factor in care delivery, the topic is generally considered a clinical function (Ha and Longnecker, 2010). As a result of this, the responsibility for creating an effective patient-clinician relationship is mostly viewed as a clinician task and therefore information related to the role that patients can play in contributing to the clinical encounter has traditionally been lacking. This study aims to address this gap by gaining insight into patient thoughts on introducing PGHD into their clinical encounters.

2.6 Patient Generated Health Data

Traditionally, clinicians have based their decisions on data gathered from patients, vital signs, medical histories, laboratory results etc., during appointments. Therefore data gathered from patients is not a new phenomenon (Deering, 2013). However, with the increase in use of smartphones, mHealth, the availability of patient facing features in EHR systems, and the potential for the resulting data to enable patient-centered care, investigation into the feasibility and benefits of using data generated electronically by patients themselves between appointments is gaining momentum.

Evidence of this can be seen in the Meaningful Use, Stage 3 initiative in the US where there is now provision for PGHD. In 2011, the ONC recognised the potential of integrating PGHD into healthcare, commissioning reports and supporting several pilots to assess the value and best approaches for implementing solutions (Deering, 2013). One of these pilots, Project HealthDesign (Brennan et al., 2010), enabled patients to capture ODLs and share the data in ways which made it easy to integrate into clinical workflows. It also helped clinical teams to analyse and use relevant information to support patients in better self-management. This pilot has several touchpoints with this study in that one of the aims was to investigate how best to share PGHD with clinicians. However, much of the analysis was viewed from the clinician perspective and omitted the patient view of the process, a trend that is common across the literature related to this topic.

In fact, studies and pilots that have focused on the patient perspective are far fewer than those investing the clinical view. Patient focused studies include those investigating the impact that PGHD can have on clinicial trials, where it is thought it can "generate new insight into health and disease" (Wood et al., 2015). They have also researched how PGHD can be used to capture patient reported outcomes in order to understand how treatments have affected patients' healthcare experiences (Murthy and Wood, 2015). Additionally, the literature offers studies where patient views were considered in order to understand the correlation between technology designs and successful adoption. These studies generally assess patient feedback on the application itself rather than the healthcare process that it would be used within (Dang et al., 2017, Sanger et al., 2014).

The focus of this study is to investigate the patient experience when electronically recording PGHD and sharing it during the clinical encounter. The study also hopes to understand the process of recording that data and be able to inform EHR system development so that it can store this data with the patient perspective in mind. The remainder of this literature review contains examples that are mostly from the clinical viewpoint, but are still of relevance to this research.

2.6.1 Benefits

While the topic of PGHD is a relatively new one, it has garnered much attention due in no small part to the significant benefits that it can bring to healthcare. This section will review the benefits that are of most relevance to patients, rather than to workflow improvements etc.

2.6.2 Patients as Experts

It is widely acknowledged that patients, or their caregivers, are the experts when it comes to their health (Pomey et al., 2015, Woods et al., 2016). While healthcare professionals are knowledgeable about disease, diagnosis, treatment etc., they rely on information from patients in order to perform this role. Studies have also found that patients value being able to take an active role in their care by providing information that can be used in decision making (Petersen and DeMuro, 2015).

To date, programs have been designed to create expert patients, that is to educate them to be more effective partners in their care. The HSE Self Management Support

Programme offers a range of interventions aimed at helping patients to become more knowledgeable about and effective in managing their illness on a daily basis. In the UK, a similar initiative, the Expert Patients Programme, provides free self-management courses to people with chronic diseases (EPPCIC, 2017).

Therefore, given the expertise that is innate within patients and the effort that is being put into further developing the patient's expertise through health education programs, it is important to understand the role that PGHD can perform in capturing this knowledge so that it can be shared in a format that is useful to clinicians and healthcare systems in the delivery of care.

2.6.3 Patient Engagement

Patient engagement refers to individuals showing an interest in shared decision making, taking ownership of adherence to their care plans or actively trying to improve their health (Volpp and Mohta, 2016). A strong body of evidence has shown that when patients record data about their health (PGHD), it leads to increased engagement in their care which in turn results in reduced healthcare costs, increased communication between patient and clinician, improved health outcomes and increased patient satisfaction (Petersen and DeMuro, 2015, DOHC, 2008, Queally Foisey, 2015).

The increasing use and accessibility of mHealth means that it is now easier than ever for patients to take an active role in their health and that it is happening naturally (Queally Foisey, 2015). The potential associated with patients using electronic personal health records is also recognised as a promising way to support better patient engagement (Irizarry et al., 2015).

2.6.4 Improved Outcomes

Having individuals record health data results in clinicians no longer having to rely on snapshots of a patient's health at appointments. In some cases, PGHD shared between visits, in a timely manner, can prompt earlier intervention by clinicians and therefore lead to improved outcomes (Deering, 2013). One study reported that remote patient monitoring resulted in clincians making decisions about treatment plans up to 17.4 days sooner than they would have been made with appointments

alone (Cohen et al., 2016). Another found that 40% of people tracking health reported that it led them to ask additional questions of their clinician (Loos, 2016).

The availability of this data at appointments reduces the onus on patients to accurately recall from memory symptoms, issues, medication adherence and other information. This information provides the clinician with insight into the patient's longer term health status, which is important for informing ongoing treatment (Cohen et al., 2016).

2.6.5 Challenges

While the purported benefits of PGHD to inform and improve healthcare delivery are widely cited in literature, challenges have also been identified. Much attention has been placed on PGHD as viewed by clinicians, and it is useful to understand this perspective in order to be able to focus patient capture of the information in the most appropriate way. A review of the literature highlights the following obstacles to the integration of PGHD into the clinical care pathways.

2.6.6 Legal

One of the primary concerns raised in most studies where clinician views are represented, is related to increased liability if patients are sending them PGHD between visits. In particular, if a clinician fails to review this data, or doesn't do it in a timely manner, there are concerns that they would incur additional liability for situations that traditionally may not have been directly associated with them (NeHC, 2013, Deering, 2013).

Another source of legal concern is related to data ownership, particularly for mHealth. When a patient uses an mHealth device to record health related data, the transfering of that data between people and systems can affect its ownership. For example, if data is transferred between a patient's device and an EHR, both the patient and the owner of the EHR system have shared ownership (Petersen and DeMuro, 2015). Clinicians report concerns about the need for regulation in this area in order to be compliant with data privacy standards (Loos, 2016). These standards will become more stringent in May 2018 when the General Data Protection Regulation (GDPR) (DataProtectionCommissioner, 2017) comes into force, which may result in an increased concern in this area.

2.6.7 Workload

Healthcare professionals report concerns about the burden that the analysis and incorporation of large volumes of PGHD will have on their workload (Woods et al., 2016). Health apps, trackers, etc., have the capacity to record and report large volumes of data on a daily basis. It is important that this data is reported in such a way that it does not introduce the need for manual analysis by resources (healthcare professionals) who are already in high demand due to increasing incidence of illness and budget cuts (Burke et al., 2014). Unless the data is filtered in such a way that it makes less work instead of increasing workload, then it may be too difficult for clinicians to incorporate and yield benefits from it (Dolan, 2014).

2.6.8 Expectations

Both patients and clincians report concerns related to expectations around responses to electronic data shared by patient with clinicians between visits. Patients are concerned to know whether they will receive acknowledgement that their data was received, stored securely and is valued by their clinician (Deering, 2013). Clinicians report that they are concerned about patient expectations with respect to receiving responses after sharing PGHD (Deering, 2013, Cohen et al., 2016). The literature did not reveal challenges related to shared data at appointments, aside from concerns related to the patient-clincian relationship previously discussed.

2.6.9 Data Provenance

Provenance refers to the origin of data when it was first created i.e. its initial source, as well as information about any transformations or processing that it has undergone (Pritts, 2013). In order for clinicians to be able to use PGHD to inform diagnosis and treatment, they need to be able to trust that it has come from a reputable source and has not undergone any processing that may compromise its integrity and trustworthiness (ONC, 2014). Health records have varying ways in which they deal with data provenance, e.g. different levels of granularity (document level versus data element level) (Pritts, 2013). There is general agreement that standards are needed to address issues with data provenance (Pritts, 2013, HIMSS, 2014) with ongoing efforts to develop such a standard. For example the S&I Framework for Data Provenance (ONC, 2017) effort began in 2013 and the HL7 Standard for Data

Provenance (HL7, 2014) was released in 2014. Until there is an agreed standard for health IT, it may be difficult for clinicians to trust and reliably use some data that may be captured electronically by patients and shared at appointments.

2.7 Technology for Generating Patient Health Data

The proliferation of consumer targeted health wearables, apps and home medical devices suggests that many see potential in their ability to contribute to improvements in healthcare. The literature supports this deduction with an increasing number of studies investigating the benefits of using these technologies to inform healthcare decision making. This section will provide an overview of the state of the art technology and its emerging applications within healthcare.

2.7.1 Mobile Apps for Healthcare

Mobile apps for tracking general health are commonplace, with many smartphones coming to market with pre-installed health software (Apple, 2017). In 2016, it was reported that there were approximately 165,000 health related apps available across the Android and iOS platforms (TheEconomist, 2016). The ability for these apps to engage the general population in becoming more health conscious is well documented (Boulos et al., 2014). However, their usefulness beyond general health monitoring is less convincing. One study that reviewed more than 1,000 mobile apps which target people with chronic illnesses (Landi, 2016) reported that only 43% of the iOS and 27% of the Android apps appeared to be of expected use for engaging patients in their care. Furthermore, several reports on this topic suggest that the lack of regulation for particular kinds of health apps may pose harm to patients, for example those that provide more complex or disease-targeted functionality (Cortez et al., 2014, Gholipour, 2014).

Despite these concerns, there are an increasing number of reports and studies suggesting that health apps can result in improvements to healthcare and that physicians are willing to engage with patients who show interest in using them (Conn, 2015). Apps that have been approved for use by the authorities such as the FDA (United States) or have obtained CE certification (European Union) can be considered safe for medical use. However, extended vetting is required to manage the large number of health related apps available through mobile platforms (Boulos

et al., 2014). The following examples are of health apps that are currently undergoing trials with healthcare agencies or which have demonstrated promise in academic studies.

TickerFit (TickerFit, 2017) is one Irish-based example of a mobile app that is focused on specific health conditions, namely cancer, cardiac and chronic illnesses. Its aim is to enable healthcare professionals to engage patients in their care by prescribing lifestyle interventions, the results of which can be monitored using the TickerFit platform. It is currently undergoing trials with the Department of Health and the NHS (Keogh, 2016).

Diabetes is one of the chronic illnesses that receives much attention, likely due to its increasing prevalence and burden on healthcare resources and budgets. Traditionally paper records have been used by individuals to record their glucose readings between clinical appointments. These are associated with human data entry errors and lack of real-time feedback to promote better self-care (Goyal and Cafazzo, 2013). However, developments such as the OneTouch Reveal Mobile App now mean that individuals can use wireless transfer of glucometer readings to a mobile app, which can be shared onwards with their healthcare provider (LifeScan, 2017). Apps such as these, which support wireless integration with wearable health technology, are now commonplace and the next section will expand on the role that wearable technology can play in PGHD.

2.7.2 Wearables

The term 'wearables' is oftentimes associated with popular health trackers, such as those offered by FitBit, Jawbone etc., or mobile watches such as the Apple Watch or Samsung Gear. However, as suggested in the last section, there are now several examples of advanced applications of wearable technology in healthcare which many believe have the potential to transform disease management for both patients and healthcare professionals (Turakhia and Kaiser, 2016, Rollo et al., 2016, Deloitte, 2015).

From a patient perspective, having wearables that are unobtrusive is an important factor, as they are less likely to interfere with daily life. Recent innovations in wearable technology have utilised micro and nano fabrication technologies, as well as flexible circuits to create discrete wearable sensors and bio-sensors which are

capable of measuring physiological changes to produce data that can aid in the diagnosis, management and analysis of diseases (Patel et al., 2012, Li et al., 2017). The literature revealed many studies related to the benefits of using sensing technology to inform healthcare (Li et al., 2017, Kuehn, 2016). A study by Patel et al in 2012 (Patel et al., 2012) outlined categories of application for this technology in healthcare. These categories are set out below, along with relevant examples supplied by the literature:

2.7.2.1 Health & Wellness monitoring

With an ageing population and growing incidence of chronic disease, the ability to monitor patients within the home and community setting is thought to be of benefit for reducing the demand on health resources. A 'wearable wireless health monitoring system' can track the user's activity on a continuous basis, sending information back to both the individual and their healthcare professionals, allowing for appropriate clinical interventions based on the data collected. The ability to monitor individuals' health in their home shows promise for illnesses where activities performed in the home or free living environment can trigger symptoms that cannot be reproduced in a closed environment. One example is Parkinson's, where people affected by this disease can temporarily lose the ability to move, which in turn can lead to a fall (NPF, 2017). The literature contained several studies related to the benefits of using wearable technology with Parkinson's patients in order to remotely monitor for this symptom (Del Din et al., 2016, Giansanti et al., 2008). Other studies, such as Hickey et al in 2017, suggest that the use of wearables to perform gait analysis in the free living environment can out-perform the more traditional method of instrumented walkways (Hickey et al., 2017).

2.7.2.2 Safety monitoring

Wearables can also be used to alert caregivers or emergency services when emergencies occur or when they may be imminent (Soh et al., 2015). As mentioned in the last section, falls among individuals with Parkinson's can be commonplace. They are also common among the elderly and speedy response to these falls can reduce the risk of further health complications (Soh et al., 2015, Mukhopadhyay, 2015). Commercial solutions, such as the Wellcore Emergency System Response available in the US, use sensors to detect when a fall has occurred, alerting the appropriate contact (Preece, 2017). In Ireland, Falls Action (FallsAction, 2017), a prevention and monitoring service, provides the elderly with a

sensor enabled wearable device which will alert a monitoring team in the case of an emergency.

2.7.2.3 Home rehabilitation

It has been suggested that assessments performed in the clinical rehabilitation setting cannot supply a true evaluation of impairment or assess clinical interventions (Bonato, 2005). However, the ability to use data gathered in the community or home setting, through the use of wearable technology, can provide a better understanding of the effect that the impairment has on the individual's daily life and assist in evaluating the effectiveness of interventions (Bonato, 2009). Studies have shown that wearable technology can be used successfully to assess rehabilitation progress, for example recovery from stroke (Patel et al., 2010). The combination of wearable sensors and virtual reality technology is also thought to have potential in the rehabilitation of patients within the home environment, for both benefits associated with patient engagement e.g. gaming technology, and the ability to provide realtime feedback to patients and therapists on exercise performance (Saini et al., 2012, Patel et al., 2012).

2.7.2.4 Assessment of treatment efficacy

Another use of wearables is the support that they offer as a way of assessing the effectiveness of clinical interventions outside of scheduled appointments. As mentioned previously, some symptoms can be difficult to test for or reproduce at appointments, so being able to monitor patients in their daily lives can give clinicians a quantifiable way in which they can assess whether treatment is effective or can be fine-tuned to the needs of the patient. In particular, the literature review revealed several examples of studies related to the use of wearables when assessing treatment efficacy in the everyday setting for individuals with increased fall risk as a result of their chronic illnesses (Smith and Bagley, 2010).

2.7.2.5 Early detection of disorders

Sensors can be used to track physiological parameters such as body temperature, which can be used to detect stroke, heart attack etc. (Mukhopadhyay, 2015).

The literature also revealed several studies that reported benefits in the use of wearables to perform gait analysis over an extended period of time in the diagnosis of chronic illnesses, where traditionally assessment has been based on subjective observations or expensive laboratory testing (Mukhopadhyay, 2015).

2.7.3 Wearables: 3D printing

While the use of 3D printing for wearable technology does not feature prominently in the literature, industry reports have referred to its emerging use in the management of health conditions (White, 2015, HPMatter, 2017, Dodziuk, 2016). One such example is OneRing for individuals with Parkinsons, a 3D printed wearable device that monitors symptoms (such as tremors), feeds the data through an algorithm for analysis and reports results to patients. A patient in turn can share this with their clinician in order to inform treatment, such as medication effectiveness. Another example, a printed EEG headset, monitors emotion and mood over a prolonged period of time. Again, it is used in combination with a mobile app that can link the device's data with the user's location, the time of day and other variables in order to understand environmental effects on the user's emotions. One proposed application for this 3D printed device is in the treatment of ADHD (HolstCentre, 2015).

2.7.4 Home Medical Devices

Along with mobile apps and wearables, the use of medical devices that can be used by individuals in their homes to monitor their health is on the rise. These devices differ from wearables in that they are typically used intermittently rather than worn on a continuous basis. Commonly used examples include blood pressure monitors, glucometers, inhalers and oximeters. Traditionally patients use a device and either record the result manually or else review it and take action if necessary without recording the result. However, devices also exist that can communicate results electronically, most commonly using bluetooth technology. The following are examples of bluetooth enabled devices that are commercially available.

2.7.4.1 Withings Wireless Blood Pressure Monitor (Withings, 2017)

This device allows the user to take a blood pressure reading on an ad hoc basis, displaying the result in real time on a smartphone app using bluetooth technology. It displays historical information and allows the user to share the data with a healthcare professional through email. The device is compliant with both the FDA and European medical device regulations.

2.7.4.2 OneTouch Verio Sync Blood Glucose Monitoring System

This bluetooth enabled device can communicate the results of a blood glucose test with an iOS mobile app. The results can be viewed immediately as well as displayed on a historical basis. They can also be downloaded from the app which allows a

user to potentially share them electronically with a clinician or store them in a personal health record. The system was approved by the FDA in 2013.

The role that home medical devices plays in the management of chronic illnesses is considered an important one. They enable individuals to self manage and have the potential to relieve some of the burden on healthcare resources by supporting recovery and reducing unnecessary healthcare appointments (Fu et al., 2012). However, the ability to transfer this data electronically is a key function when considering its integration into electronic or personal health records. The trustworthiness of this data is also paramount, which can be addressed by FDA, or equivalent, approval such as the examples described in this section.

2.7.5 Personal Health Records

Alongside the aforementioned methods for electronically generating health data comes a requirement for individuals to be able to store it securely and privately, and share it onwards if so wished. A report by the EC in 2014 recommended giving "patients control over their own data, specifically the kind of information he/she wants to share, while maintaining the right not to share, as well as enabling the patient to see who is using data and for what purposes" (Deloitte, 2015).

A review of the literature and of current market offerings outlines two predominant approaches for storing this information, personal records where data is owned by patients and electronic records where the data is owned by the healthcare institution. The latter are generally known as electronic health or patient records (EHR or EPR) and have been promoted by health initiatives, such as the HITECH Act (HealthIT, 2017), for several years for their ability to improve quality and safety of healthcare delivery. Records which are owned and maintained by individuals, known as personal health records (PHR), are a more recent development in the health space.

Several commercial PHR solutions are now on offer which allow individuals to store and share their health information with their healthcare team. One example is Microsoft's HealthVault (Microsoft, 2017) which offers a service that allows users to create an account, store health data (which they are the owners of) and enables them to share it with others if they wish to do so. RevUp by MD Revolution also facilitates storing and sharing of health information, however it does so by having

healthcare professionals encourage their patients to access the system, which will integrate data that they capture within their organisation's EHR (MDRevolution, 2017).

It is interesting to note the different approaches that are in use, one targeting individuals directly and the other activating patients through their healthcare team. Earlier in this chapter, one of the challenges for PGHD, from the clinician perspective, was the increased liability resulting from receiving electronic health data from their patients in real-time, or at least outside of scheduled appointments. One of the benefits of having an individual owned PHR is that it resolves this issue since clinicians are not obliged to act on the data if they don't own the record. Whether the data is owned by individuals or healthcare institutions, PHRs that are tethered to EHRs are preferable since they allow for enhanced patient/clinician collaboration (Lester et al., 2016).

While this section demonstrated that there are varied tools that individuals can use to capture and share health data outside of appointments, the success of these technologies is very much dependent on their usability (Lester et al., 2016). In the case of chronic disease, the sustained use of these technologies is key to their ability to play a role in the improvement of patient care and hence the involvement of patients in their design is key (Chiauzzi et al., 2015).

2.8 Methodological Research

Qualitative research methods are increasingly being used in healthcare research to understand the views of participants (Al-Busaidi, 2008) with journals now dedicated to this topic (QHR, 2017). This approach can be used to understand people and their interactions. It can inform us about how people experience health and disease as well as how patients and their health teams communicate with each other (Nigatu, 2009).

One study, performed in 2016 to analyse the previously mentioned Project HealthDesign, used semi-structured interviews and a grounded theory approach to examine the perspectives of healthcare workers who participated in that project (Cohen et al., 2016). By using this approach, the researchers contributed emergent findings about the experiences of using PGHD in care delivery. The study also

recognised that additional research is required in this area to understand the patient perspective of using PGHD.

With respect to interviewing patients, a study by Pomey et al in 2015 (Pomey et al., 2015), also used qualititative methods to elicit information from patients about their views on the topic of patient engagement. As previously discussed, the literature has highlighted a link between the use of PGHD and patient engagement which makes these studies highly relevant to this research. In this study, the researchers conducted semi-structured interviews to explore patient views on specific themes within the topic. The interview guide was first tested for length and flow of questions. Grounded theory was used to allow for ideas to emerge as the data was analysed.

Other studies that have utilised surveys have used a mixed qualitative-quantitative approach, with some open ended questions being included in the survey that were then coded by the researchers. For example, in 2015 a study related to the clinicial perspective in the use of data from wearable health monitors, used a survey with both closed and open questions to understand clinician views on the topic (Loos, 2016). The researchers found the open ended questions most useful for gaining insight into the participants experiences.

Given that the aim of this research is to explore the views of participants on the process of capturing PGHD and its subsequent usage in the clinical encounter, the above examples of previous studies provide confirmation that it is appropriate to use a qualitiative method for this research and a grounded theory approach for data analysis. The next chapter will outline in detail the methodology used for this research.

3 Research Methodology

3.1 Introduction

This chapter will discuss the methodology used for this study. It includes an overview of the process and rationale for selecting the methodology, the steps for its development, plans for execution and other considerations.

3.2 Positionality

Qualitative research is a complex subject where many positions on the value of data collected through qualitative methods have been discussed in the literature (Ritchie et al., 2013, Silverman, 2016). One particular topic which receives attention is whether the beliefs and background of the researcher can affect, however unintentionally, the research process and results. The position offered by a positivist research paradigm is that the researcher attempts to be a neutral influence, with no pre-defined expectations for the research results (Turner, 2016). However, many believe that this can be a difficult task for researchers to achieve, and that it is important that a reflexivity approach is followed (Roller, 2012, Brink et al., 2006). This is sometimes referred to as “empathic neutrality” (Labaree, 2017), where the researcher is aware of their “assumptions, biases and values… while striving as far as possible to be neutral and non-judgemental in their approach” (Ritchie et al., 2013). Activities such as establishing the researcher’s positionality, considering this position at each step in the research process and maintaining a research journal are considered key to this approach (Cohen D, 2006, Holmes, 2014).

In following a reflexive approach for this study, the researcher considered their position on the topic in question, in order to establish a self-awareness that would aid in achieving a neutral approach during each step of the research process. This positionality is described below, and may be useful to others in understanding any potential influences on the research results.

3.2.1 Researcher's positionality

Having an education in computer science, experience working in the technology sector and being an avid user of health trackers, the researcher strongly believes that there are opportunities within healthcare for the application of technology to achieve better insight into patients' health status.

However, while the researcher has been a user of the health system intermittently in the past, they do not have a chronic illness. While they have close family members and friends living with chronic illnesses and are empathetic towards this cohort of the population, they are not intimately familiar with what it is like to experience it on a daily basis.

The researcher is of the opinion that oftentimes interactions with healthcare professionals are brief due to the increasing strain on the country's healthcare resources. They are also of the belief that this is a widespread view because of frequent reporting of this state in the media. Therefore, there is a possibility that the introduction of PGHD to the clinical encounter, especially if proactive rather than prescribed, may be viewed by clinicians as an unwelcome interruption and that patients may be reluctant to gather data for this reason.

3.3 Rationale for research approach taken

This section will discuss the reasoning behind the chosen methodology for this research, as well as other considerations that were made as part of this decision process.

The purpose of this research is to investigate the experiences, views and expectations of a cohort of individuals living with a chronic disease, with respect to PGHD. As outlined in the previous chapter, much of the research on this topic to date has focused on the clinical viewpoint rather than that of the individual/patient. While the literature does provide a general set of benefits and challenges for patients, the aim of this research is to understand what drives patients to collect health data outside of the clinical encounter, what methods they use to collect the data and what their viewpoint is on sharing that data with their clinician.

Due to the scarcity of information in the literature, an exploratory investigation into the experience and views of a set of chronically ill patients in the Irish healthcare setting was deemed most appropriate for this research. A qualitative approach was followed where the researcher used semi-structured interviews as a tool to examine this topic.

The process of interviewing provides a way in which the experiences and persectives of participants can be understood. In-depth interviewing, such as that afforded by semi-structured interviews, are considered "a particularly useful method for examining the social world from the points of view of research participants." (Silverman, 2016).

While developing the methodology for this research, the researcher considered and discounted other research tools and approaches. The reasons for each of these are now discussed.

3.3.1 Focus Groups

Focus groups are considered a useful method for generating new hypotheses and being able to explore topics with a larger number of participants. Several sources suggest that the ideal group size is 6-10 participants, with 3-5 groups per project (Morgan, 1997, Duke, 2005, Krueger, 2002). Due to the fact that the researcher did not have access to a sufficient number of participants, focus groups were not considered the most appropriate approach in this instance.

3.3.2 Questionnaires

Questionnaires are typically associated with statistical enquiry, and can oftentimes be prefaced by qualitative methods when the topic is in need of further understanding or exploration (Ritchie et al., 2013), as it is in the case of this research. Dependent on the findings of this research, it may be relevant to follow the proposed qualitative method with a wider reaching questionnaire to validate any emergent themes.

3.3.3 Structured Interviews

While structured interviews most commonly consist of closed questions and are considered quantitative in nature, they are also used in qualitative research in that open-ended questions can sometimes be included. One of the advantages of

structured interviews is that questions are asked in the same order and therefore within the same context/dialogue, which many consider to add credibility to the data collected (Cohen D, 2006). However, the aim of this research is to understand the topic in question and therefore the ability to be able to explore themes rather than adhere to a strict schedule of questions is important. The researcher therefore considered a semi-structured interview to be a more appropriate research method.

3.3.4 Observations

Observing how patients collect data related to their health condition would allow the researcher to document informal data collection processes that are already used by patients, in order to inform the wider community. This approach would ensure more consistent recording of the process(es) used across participants, as it would be done by the same individual (the researcher). This observation would also remove the need for patients to accurately recall and dictate how they capture the data. However, it was felt that it would be impractical for the researcher to perform this observation over a significant amount of time e.g. an entire day, and would be intrusive for participants.

3.4 Description of research method used

The following diagram outlines how the research methodology was chosen, developed and carried out. This section will discuss the development process and any known limitations associated with the methodology chosen.

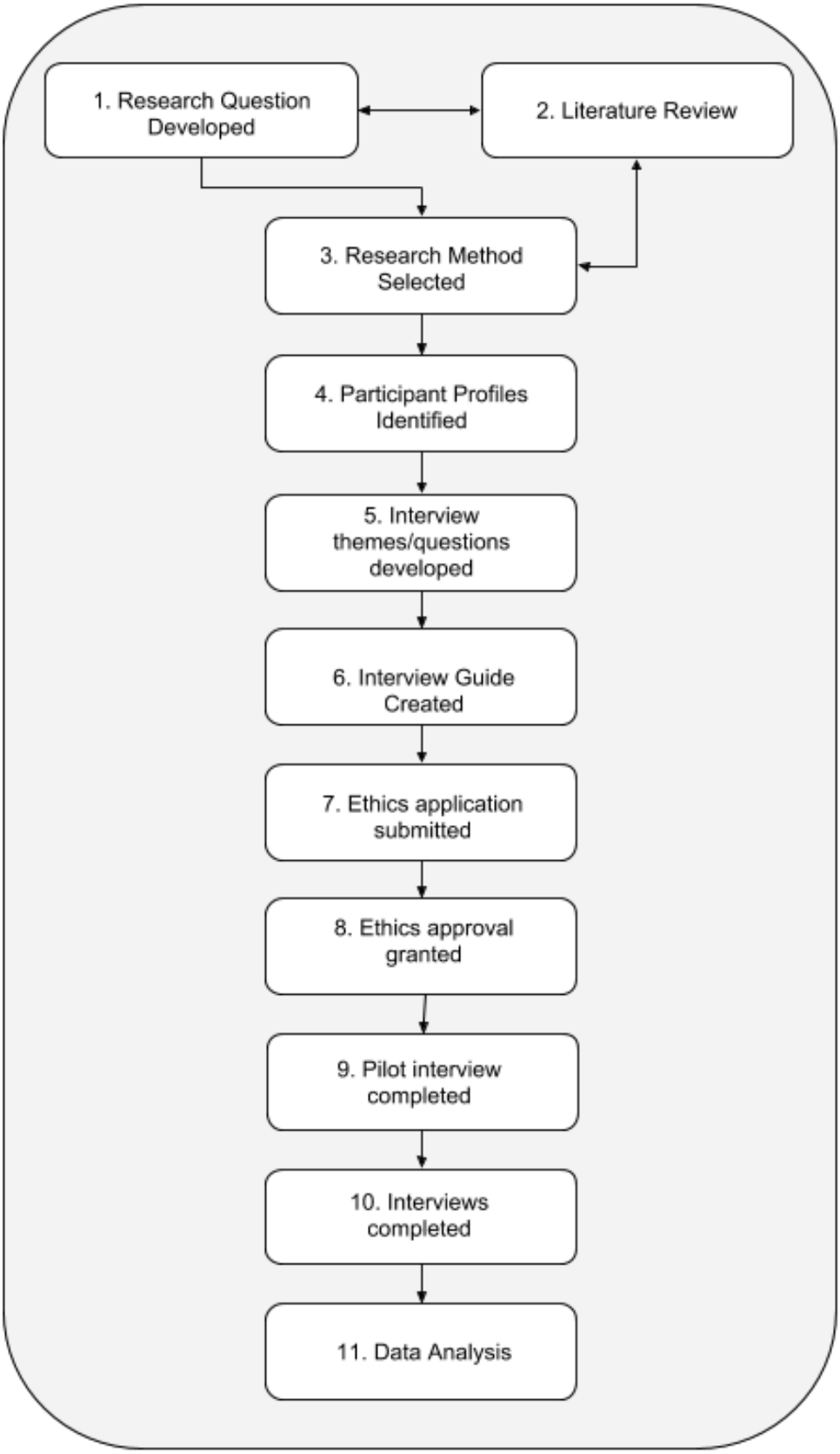


Figure 3.1: Methodology Development Process

3.4.1 Interview Development

3.4.1.1 Participant background

Once the research question had been developed, during which time a literature review of the topic and of research methodologies was undertaken, the researcher identified three types of potential participants before developing the interview themes/questions.

Table 3.1: Research participant groupings

Group	Description	Expected Contribution to the Research Question
Group 1	Patients already collect PGHD by electronic means outside of the clinical encounter, and may or may not be sharing this data with their healthcare team.	It is expected that participants in Group 1 would provide insight into all aspects of the question being researched: process for collecting data electronically, motivation for collecting data, expectations for the use of this data and willingness to share it with their clinician.
Group 2	Patients already collect PGHD by non-electronic means outside of the clinical encounter, and may or may not be sharing this data with their healthcare team.	It is expected that participants in Group 2 would provide insight into all aspects of the question being researched, however the process would not involve electronic methods for data collection : process for collecting data manually, motivation for collecting data, expectations for the use of this data and willingness to share it with their clinician.
Group 3	Patients do not collect PGHD outside of the clinical encounter.	It is expected that participants in Group 3 would provide insight into expectations for the use of PGHD as well as willingness to collect this data and share it with their clinician.

It was thought that this context would provide insight into correlations between past experience and willingness to engage in the capture of PGHD. The initial stage of the interview was then developed to generate an understanding of the background of the participant in relation to their experience of living with a chronic illness and frequency of interactions with their clinician. The following closed questions were created in order to capture this information. Each participant was asked these questions at the beginning of the interview, with *Question 4* only asked if a negative response was received for *Question 3*.

Table 3.2: Research questions; Participant experience

Question	Question Text	Rationale for Inclusion
1	How long is it since your condition was diagnosed?	Are there any correlations between the length of time that patients have been living with their condition and their motivation for capturing PGHD, expectations for its use or their willingness to share it.
2	How often do you have to see a healthcare professional as part of the management of your condition?	Are there any correlations between the frequency of clinical appointments and the process of capturing PGHD, motivation for doing so, expectations for its use or their willingness to share it.
3	Do you electronically capture/record information (readings, notes) about your health between hospital/GP visits?	Identifies the questioning path for the rest of the interview.
4	Do you capture or record information in a non-electronic format?	Identifies the questioning path for the rest of the interview.

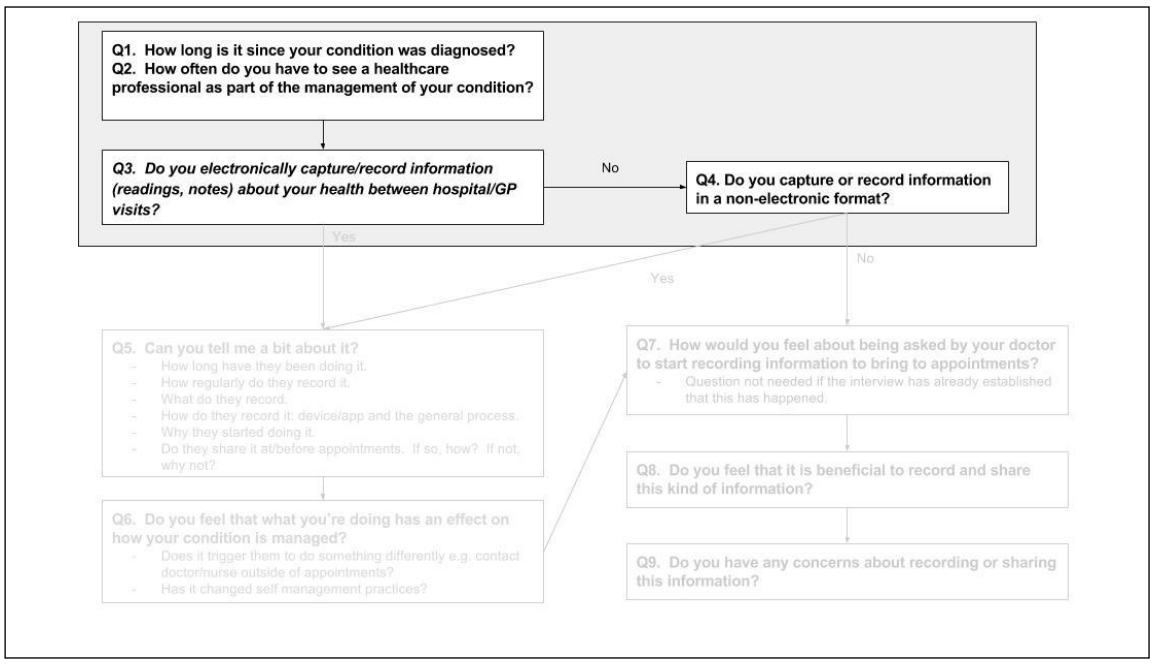


Figure 3.2: Participant experience interview section, in overall context

3.4.1.2 Process and motivation for gathering PGHD

Following on from this, the next aspect of the research question was addressed. The topic concerning the process of, and motivations for gathering PGHD was explored with participants in *Groups 1* and *2*. These participants were asked to describe how they record this type of data, with probing techniques used (such as silent probing, echoing) as appropriate to encourage additional information. They were then asked about the effect that they feel that gathering this data has on the management of their condition. The aim of this question was to understand the reasons that patients have for gathering this data, whether prescribed by their clinician or self motivated. Again, probing questions were used as necessary to explore this theme.

Table 3.3: Research questions; Process and Motivation

Question	Question Text	Rationale
5	Can you tell me a bit about it?	This aims to explore the process that participants use to capture PGHD, in order to inform the wider community of methods which may be harnessed for other patients for self management.
6	Do you feel that what you're doing has an effect on how your condition is managed?	The goal of this question is to understand what motivates patients to collect PGHD.

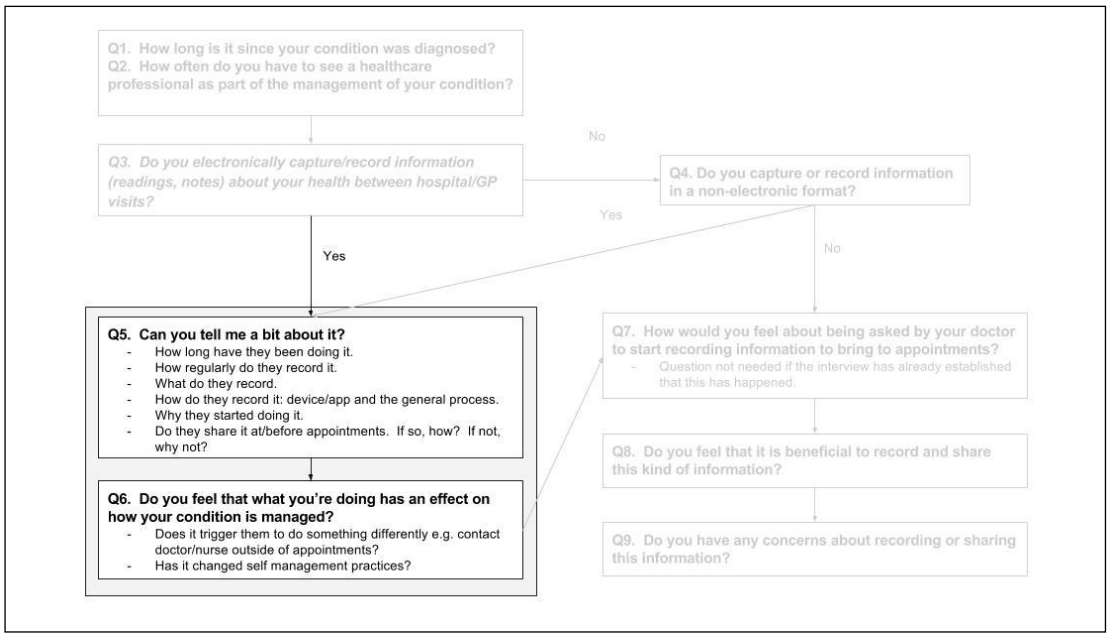


Figure 3.3: Process and motivations for gathering PGHD, in overall context

3.4.1.3 Expectations for, and willingness to share PGHD

The next stage of the interview was designed to explore the participants' views and expectations with regard to the use and sharing of PGHD. This stage was addressed to all three groups of participants. As discussed in previous chapters, patients are critical to the process of collecting and sharing what is considered valuable information in their care delivery. It is therefore important to understand whether there are barriers when asking them to perform these tasks, in order to be able to mitigate for them. Conversely, it is also important to understand positive attitudes and any associated driving factors to influence wider adoption of this data collection process among the patient community.

Table 3.4: Research questions; Process and Motivation

Question	Question Text	Rationale
7	How would you feel about being asked by your doctor to start recording information to bring to appointments?	This question will only be addressed to participants where it has been established that they have not already been asked to do this. The aim is to understand patients' willingness to engage in the process of capturing PGHD, when it is prescribed by their clinician.
8	Do you feel that it is beneficial to record and share this kind of information?	The objective of this question is to explore participants' views with respect to the expectations for the use of their PGHD and also their willingness to share it with their clinician.
9	Do you have any concerns about recording or sharing this information?	This follows on from *Question 8* and specifically aims to understand negative views related to PGHD collection and sharing, with a view to informing the wider community of issues that may need to be mitigated for through software design or education programmes.

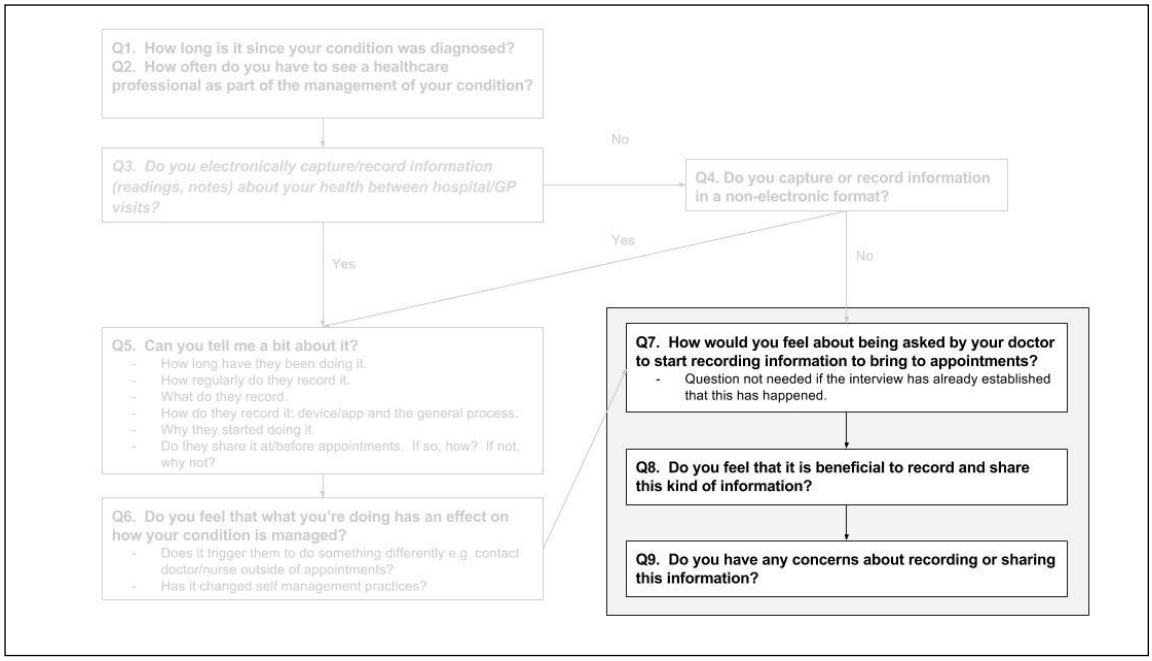


Figure 3.4: Expectations for, and willingness to gather PGHD, in overall context

3.4.2 Interview Guide & Protocol

Having developed the set of questions outlined in the previous section, the researcher developed a guide to be used consistently across all interviews. This guide (Appendix A) outlines the paths that the interview should follow in order to explore the topic, relative to each participant's experience with the subject (as earlier outlined in the participant groups). This guide was also incorporated into the interview protocol (Appendix B) which was used as part of each interview to ensure that they were performed in a consistent manner.

3.5 Pilot Interview

Several sources recommend as good practice that a pilot interview be undertaken in order to test the set of questions that have been developed and expose any aspects of the interview process that may be improved upon (Turner, 2010) and (Gill et al., 2008). The researcher identified a personal contact, an individual living with a chronic disease, that was willing to participate in this pilot and it was performed on 2nd April 2017.

As a result of this pilot, the following changes were implemented in the subsequent interviews.

3.5.1 Interview Process/Guide

After listening to and transcribing the pilot recording, missed opportunities for probing and clarifications were identified. Learnings included:

- Explain key terms – PGHD, healthcare professional, electronic/non-electronic formats - at the beginning of the interview rather than as part of questions, that latter felt like it distracted from the natural flow of conversation.

3.5.2 Interview Technique

As it was their first time conducting semi-structured interviews, the researcher also reviewed both the pilot and the next recording to identify improvements that could be applied to the interview process and probing techniques.

- Note keywords as the interview progresses, to act as reminders for areas to clarify during the interview.
- Take time to digest information to ensure that clarifications and probes were made in context rather than at the end of the interview.

3.6 Sampling/participants

3.6.1 Sampling

In order to perform the research in question, it was important to access individuals who were living with at least one chronic disease. It was also important that these individuals were living in Ireland and had experience interacting with the Irish healthcare system. This latter criterion would provide insight into the patient-clinician relationship that may be particular to the Irish setting.

In order to capture a general viewpoint on the research topic, the researcher felt that it would be beneficial to sample individuals with experience living with varying chronic conditions, rather than sampling a purposeful set i.e. a population from within one disease e.g. diabetes.

The researcher looked to patient advocacy groups in order to access individuals who would meet the criteria for participating in the study. However, due to lack of response, participants were recruited through opportunistic/convenience methods i.e. referrals through personal contacts.

3.6.1.1 Sample size

While the aim of qualitative studies is to reach saturation, the point at which no new information or themes are occurring, it is also recognised that it can be difficult to determine prior to data collection what the required sample size may be (Guest, 2006). Due to the time constraints involved in delivering the research, an initial sample size of 10 was considered achievable. It was also felt that with this sample size, the researcher would have the capacity to perform a deeper data collection and analysis to gain insight into a perspective on PGHD that is not well documented.

The intention of the initial sample size was also to determine whether consistent themes would emerge or whether additional sampling would be required to achieve saturation.

3.6.1.2 Inclusion criteria

For this criterion-based sampling approach, the following individual and ethical considerations were used during the participant selection process.

- Participants must be living with at least one chronic illness.
- Participants must be living in Ireland and interacting with the Irish healthcare system.
- Participants must be 18 years or older.
- Participants must be capable of giving informed consent.

3.7 Ethics

3.7.1 Ethical Approval

Since the purpose of the study was to explore the research topic with individuals living with chronic illnesses, ethical approval to proceed was sought from Trinity College Dublin in January 2017 (Appendix C). While the individuals being interviewed were receiving on-going treatment for their conditions, they would not be interviewed within the healthcare setting and therefore ethical approval from hospitals or other healthcare institutions was not deemed necessary. However, the ethics submission to TCD was made on the basis that the participants are considered patients since they are actively seeking treatment, and the application was therefore subject to increased scrutiny. During the process, additional

information about the location for storing the primary data as well as duration of storage was supplied to the ethics committee. As a result of the higher level of scrutiny, the process took 9.5 weeks and ethical approval was granted on 24th March 2017.

3.7.1.1 Ethical Considerations

Participants would be recruited on a voluntary basis and their freedom to withdraw consent to all or part of their contribution would be outlined to them before beginning the interviews. Participants would also be advised that they did not need to answer any of the questions if they felt uncomfortable doing so. No attempt would be made to mislead participants as the purpose of the study was to gain an understanding of the patient experience of the topic at hand and not to test it. The researcher planned to explain that the data collected during the interview would be anonymised and stored securely. The interview protocol also included a debrief for participants at the end of the interview about the process that the information would be put through as part of the study and that they could request a copy of the study and findings once they were complete.

3.7.1.2 Informed Consent

A *Participant Information Sheet* (Appendix D) was created in order to provide background information to prospective participants about the topic, why they may be interested in participating, how they were chosen for the study and their right to withdraw consent at any stage of the interview or before the research was completed. An *Informed Consent Form* (Appendix E) was also created to obtain consent from participants to continue with the data collection. Finally, an *Interview Protocol* (Appendix B) was developed in order to review the above information with participants to ensure that they were fully informed before beginning the interviews.

3.8 Data Analysis

There are two main methods of reasoning that are used in qualitative research analysis, namely inductive and deductive. A deductive approach allows a researcher to test a theory by forming a hypothesis and then using a qualitative method to test its truth or validity (Trochim, 2006). An inductive approach is more commonly used in situations such as this, where there is less former knowledge (Elo and Kyngäs,

2008). In this case, the data is analysed for patterns from which hypotheses and theories can be developed.

During the course of the literature review, hybrid approaches were identified which combine both inductive and deductive analysis in the interpretation of data such as that obtained from interviews. While less is known about the patient perspective on PGHD, it was thought that some of the information gleaned from the literature review related to the clinician persective could be used in the data analysis in the form of *a priori* codes. The data could then be analysed for emergent themes.

One hybrid approach, developed by Fereday and Muir Cochrane (Fereday and Muir-Cochrane, 2006), is based on a process of thematic analysis which includes both deductive and inductive elements. In this approach, content analysis does not feature, therefore individual comments are considered as important as those that were repeated across interviews. The researcher's interpretation of this approach resulted in the process depicted in Figure 3.5 being applied to the data analysis for this study.

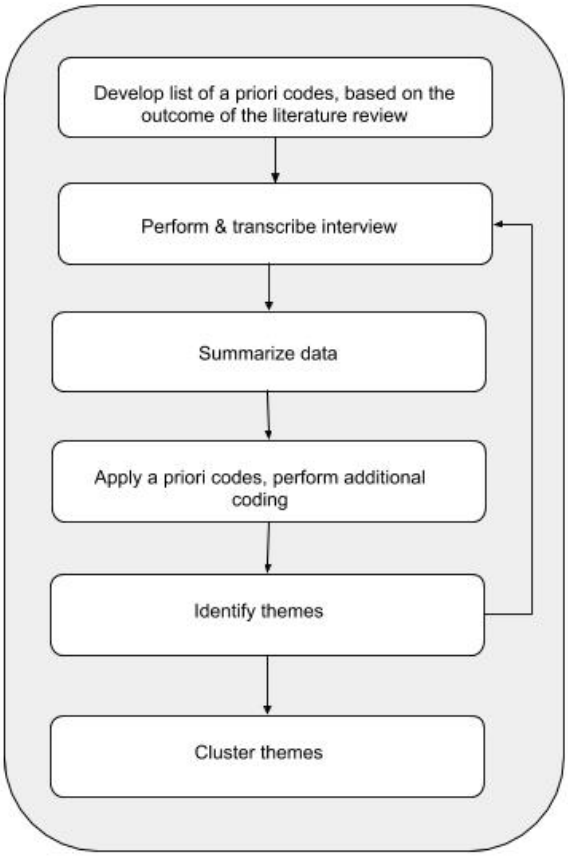


Figure 3.5: Data Analysis Process

3.9 Limitations of the methodology.

Despite the rationale for choosing this research method, the following list outlines some of the potential limitations that were identified by the researcher at the beginning of the data collection process.

- Performing individual exploratory interviews is time intensive. Similar results could potentially be obtained by using focus groups, if the researcher had access to a greater number of participants.
- As previously discussed, the researcher's positionality may affect how the interview proceeds (Silverman, 2016).
- The method relies on participants to be able to accurately recall/describe the process(es) that they follow when collecting data. While observations may have been a more accurate tool to use for this section of the research, the chosen method of interviewing provides a general understanding of these methods of data collection by participants which can give rise to further investigation if deemed appropriate.

4 Results

This chapter will present data related to the study population, as well as the data collected as part of the interview process.

4.1 Participants

4.1.1 Recruitment

Once ethical approval was granted for the study, the researcher began the participant recruitment process. Emails were sent to two Irish charity organisations which the researcher had previously been in contact with about the study. The purpose of these emails was to request assistance with accessing individuals who would meet the inclusion criteria outlined in the previous chapter. One organisation did not reply. The other organisation replied with an outline of their recruitment process. However, given the time constraints imposed by the lengthy ethics approval process, it was considered prudent to look to personal contacts and opportunistic methods to identify eligible and willing participants. Limitations associated with this recruitment method will be discussed in the next chapter.

Information about the study was emailed to participants prior to them agreeing to take part in the study. On one occasion, this *Participant Information Sheet* was supplied at the interview location and the participant agreed to continue after reading it through. At the beginning of the interviews, the researcher again reviewed this information with the participants and they were then asked to read and sign the *Informed Consent Form*. After the interview, participants were debriefed during which they were informed of their right to a copy of the information recorded during the conversation and/or the anonymised and aggregated data. They were also again informed of their right to rescind any or all of their contribution to the research before its submission to Trinity College Dublin.

4.1.2 Interviews

Eight interviews were performed, at locations suggested by each participant in order to ensure that they were comfortably able to discuss the topic in question (Turner, 2010). Four of the participants were identified through personal contacts and the

remaining four were recruited through opportunistic referrals. The interviews ranged in length from five to fifty three minutes.

4.1.3 Coding

As described in the last chapter, the data analysis methodology for this research follows a hybrid deductive-inductive approach. The data was first analysed using *a priori*, or 'start-list', codes which are derived from the research question and from information gathered as part of the literature review process. While this latter information was primarily based on the views of healthcare professionals towards PGHD, it was considered a good basis for analysing data gathered from patients. Eight broad code categories were also identified and assigned to both the *a priori* and *emergent* codes. The format of the codes that will appear in this and subsequent chapters is *<category>:<code>.*

Table 4.1 lists the code categories and descriptions. Categories are listed in alphabetical order, rather than order of considered importance.

Table 4.1: Code Categories

Code Category	***Description***
Appointments	Data related to the medical appointments that participants attend as part of the management of their conditions.
Benefit	Data related to participants' realised or perceived benefits for the use of PGHD.
Concern/Challenge	Data related to participants' realised or perceived concerns or challenges for the use of PGHD.
Individuals	Data related to the participants, for example condition management, levels of engagement etc.
Motivation	Data related to the motivating factors for participants that currently collect PGHD, or reported motivations should they do so in future.
Other	Used to capture emergent codes that may fall outside of the pre-defined categories.
Process	Data related to the processes for capturing PGHD currently followed by participants of Groups 1 and 2.
Relationship/Sharing	Data related to the patient-clinician relationship or to realised or perceived benefits/concerns for sharing PGHD.

Table 4.2 lists the *a priori* codes used for the deductive analysis, along with their assigned categories.

Table 4.2: Code Categories and 'A Priori' Codes

Code Category	***A Priori* Code**
Appointments	<none>
Benefit	:Benefit
Concern/Challenge	:Expectation :Privacy :Security
Individuals	:Disengaged :Engaged :Expert :Reluctant :Willing
Motivation	<none>
Other	<none>
Process	:Electronic :Non-Electronic :Self-Management
Relationship/Sharing	:Positive Clinician Relationship :Withholding Information

These codes were used to analyse the second and third sections of the interview, the results of which will be reported in this chapter:

- Section 4.2: Process and Motivation for Capturing PGHD
- Section 4.3: Expectations for, and willingness to share PGHD

A full set of emergent codes can be found in Appendix F, and excerpts of the same are discussed throughout the remainder of this chapter.

4.1.4 Participant Background

There were an equal number of male and female participants. They were not asked to provide an age, however all offered this information as part of the interview. These were grouped into ranges and the distribution can be seen in the following chart.

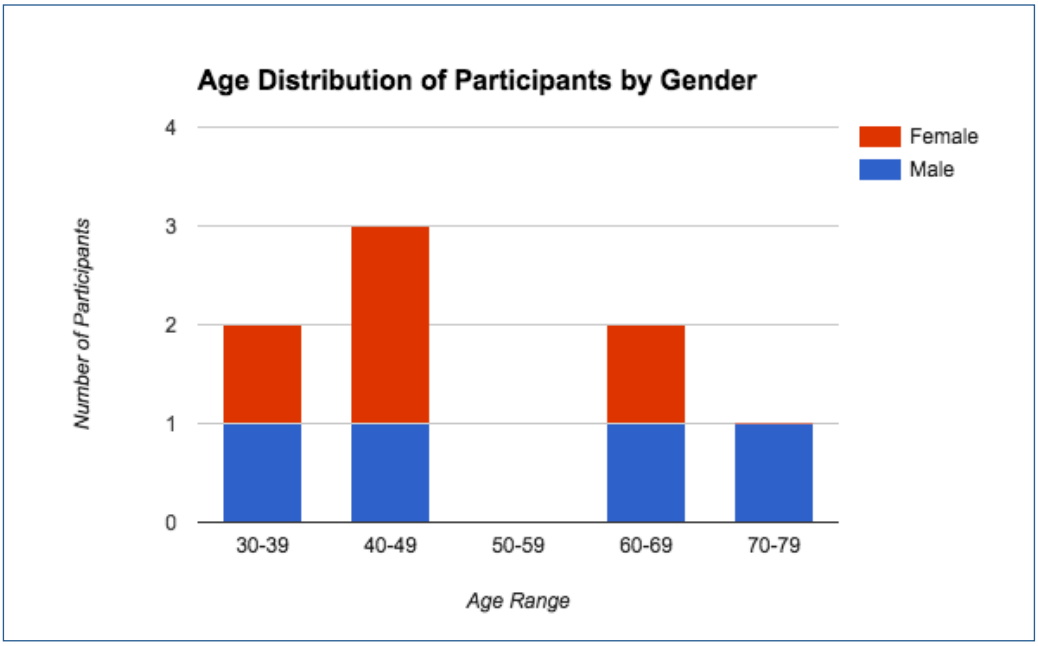


Figure 4.1: Age Range and Gender of Participants

4.1.4.1 Participant Research Groups

The previous chapter outlined three groups that the researcher defined in order to understand the participants' experience with PGHD to date. The distribution of participants across these three groups was as follows.

Table 4.3: Number of Participants by Research Group

Group	Description	Number of Participants
Group 1	Patients already collect PGHD by electronic means outside of the clinical encounter, and may or may not be sharing this data with their healthcare team.	**3**
Group 2	Patients already collect PGHD by non-electronic means outside of the clinical encounter, and may or may not be sharing this data with their healthcare team.	**2**
Group 3	Patients do not collect PGHD outside of the clinical encounter.	**3**

One of the participants measured data using a device capable of storing the results electronically. However, they admitted that they did not fully understand how the device worked so they were recording and storing the results on paper. In this case, the participant was considered to be in Group 2, despite the capability for them to be in Group 1. Another participant was recording PGHD on a mobile device, but was also contributing data before appointments through forms. In this case, both processes were described and analysed but the participant was considered to be in Group 1.

4.1.4.2 Length of Diagnosis

Participants were asked how long it had been since their conditions were diagnosed. Some participants gave time since becoming symptomatic as well as time since diagnosis. The latter data point was used in these cases for consistency.

Six of the participants were diagnosed with having a chronic illness within the last 12 years, and the remaining two received their diagnosis over 20 years ago.

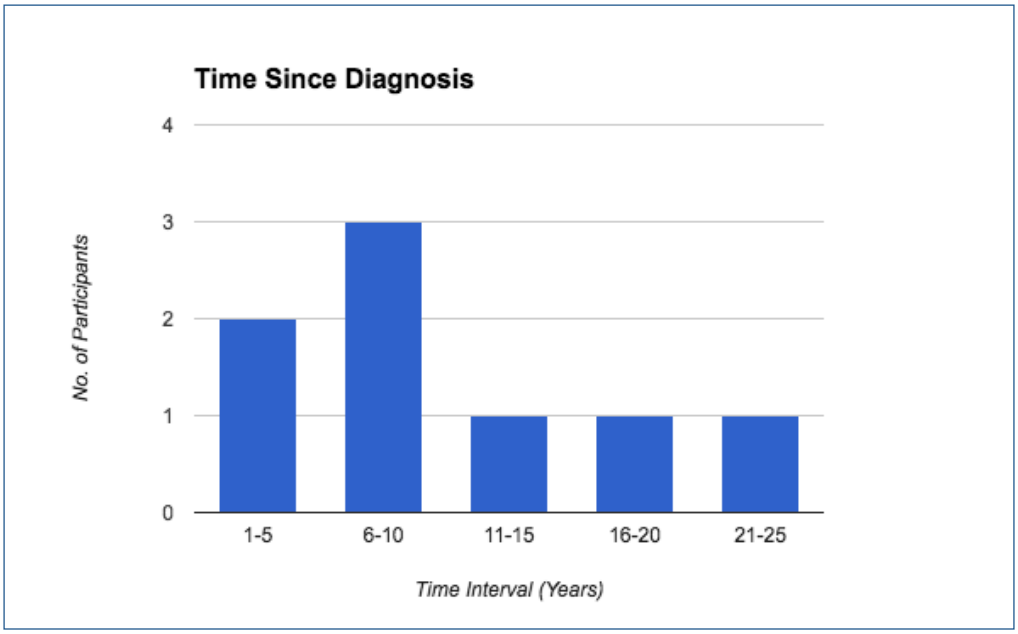


Figure 4.2: Participant Time Since Diagnosis (Years)

4.1.4.3 Appointment Intervals

Seven of the participants reported that they are requested to attend healthcare appointments at 6 monthly intervals or less. One participant has scheduled appointments at 18 month intervals.

Across participants, appointment intervals were driven by various factors:

- Prescription renewal : 3
- Scheduled procedures/tests : 3
- Clinician driven scheduling : 2

The following chart shows the appointment frequency by driving factor.

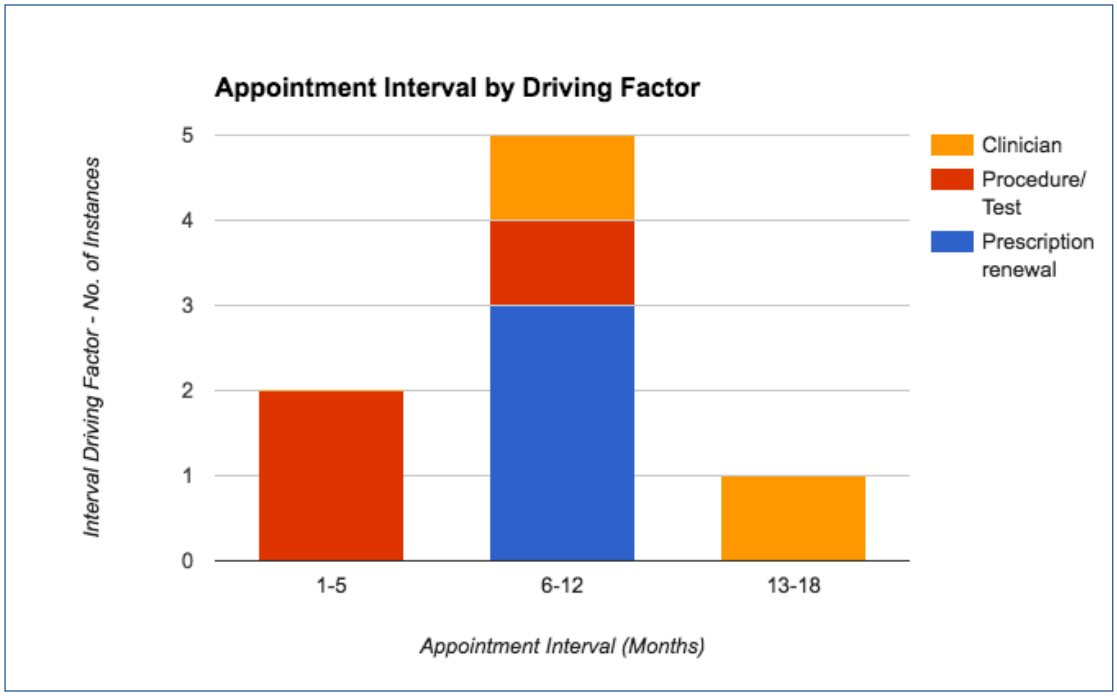


Figure 4.3: Appointment Interval & Driving Factors

One participant reported that while they are requested to attend their clinician on a 6 monthly basis, it can vary between 6 and 10 months. The reason given was that the participant felt that they did not benefit much from the appointments:

> *"I'm supposed to see her every 6 months… She tells me nothing I don't know. That I can't tell myself from my machine for testing my glucose."*

4.1.5 Research Group Vs Time Since Diagnosis and Appointment Interval

As outlined in Chapter 3, the purpose of the initial questions posed to the participants was to deterime whether there was any correlation between the length of time living with their chronic disease or the corresponding appointment intervals, with the number of instances where PGHD was being captured electronically, non-electronically or not at all. As the following chart shows, no correlation was detected. However, since the number of participants was low, a correlation cannot be ruled out.

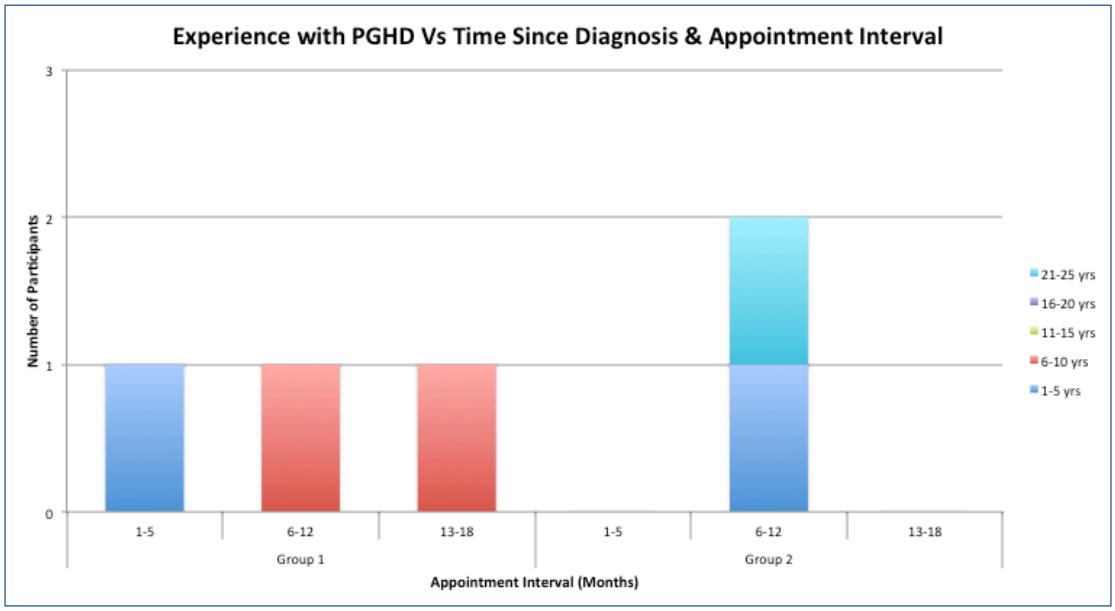


Figure 4.4: Participant Capture of PGHD Vs Time Since Diagnosis and Appointment Interval

4.2 Process and Motivation for Capturing PGHD

The next section of the interview was concerned with understanding the processes that participants had established for capturing PGHD and motivating factors for doing so. Since these questions were only posed to those in Groups 1 and 2, the sample size was reduced to five. However, two of the participants were collecting two separte sets of PGHD each so seven processes were described. As reported in section 4.1.4.1, three of the participants were capturing data electronically and three in non-electronic formats.

4.2.1 Process

4.2.1.1 Electronic

Of the three participants that reported capturing data in electronic format, two were diabetic and using glucometers to measure their blood sugar levels. The third

person had a condition that required regular appointments with multiple healthcare professionals and was capturing notes with a mobile app in order to relay information between the multi-disciplinary team. Two of the individuals had appointments at a frequency of 6 months or less and one had appointments every 18 months.

Table 4.4: Profile of participants capturing PGHD electronically

Participant	Condition	Collection Method	Appointment Frequency
Participant A	Diabetes	Glucometer	6 months
Participant D	Musculoskeletal Disorder	Mobile App	2-3 months
Participant G	Diabetes	Glucometer	18 months

4.2.1.1.1 Participants A and G

The two individuals with diabetes were provided with glucometers by their healthcare team and were using them at the request of their clinicians. Both were prescribed daily readings and were aware that it was for self-management. However, one participant reported that they were not compliant with their clinician's request and were taking the readings on a weekly basis or as needed to manage exceptions (low or high blood sugars that they detected as a result of becoming symptomatic). This was the same participant that reported attending appointments less frequently than requested.

The process of capturing the information is the same for both individuals. After feeding a blood sample into the machine, the result is displayed in a few seconds, the device turns itself off and can be put away. Both reported that they use it to self manage:

> *"Well, it's my information in the sense that it is for me to know when I'm high and when I'm not. And to manage it myself. "*
>
> *"It probably has an effect on self management. In that, if I wasn't doing it I would have no idea... Whereas the fact that I have it means that I check it and I find it's up so straight away I know, it's either the fact that I've forgotten to take my tablets or that I need to pull back straight away. "*
>
> *"If I've been concerned about a pattern… I'd go back and have a look over a month maybe and see if that's the way that it was the whole time." (referring to reviewing historical data on the device)*

They also reported that the device is portable and that they carry it with them.

Despite the fact that the diabetic patients had been prescribed daily readings by their clinician, neither had ever been asked at appointments for the information.

> *"They gave it to me and asked me to use it. And not once have they ever taken the device and downloaded the information…"*

> *"I had it in my bag the first time, hoping she wouldn't ask and she didn't. And she never has since."*

Instead, both have a blood test done in the weeks before their appointment which reports similar information across the 4 months prior to the test. The process for this test differed between participants. One of the participants attends the hospital prior to the appointment to have the blood test done and the clinician is able to call the results up on a computer at the appointment.

> *"I go in a couple of weeks before my appointment have the tests, the blood tests that is, HbA1c… It gives them a snapshot of months before that. And everything that they do is based on that."*

The other participant attends their GP to get a referral for the blood test, which is then done at a local hospital (different to the one where appointments take place). The GP receives the result and faxes it to the consultant at the hospital. When asked if these results were always available to the consultant at appointments, the participant remembered one occasion when they were not:

> *"Yes, once. And she was not pleased. She had to get the receptionist to ring the GP."*

4.2.1.1.2 Participant D

The third participant collecting data electronically attends a physiotherapist on a weekly basis for treatment and a hospital based consultant every 2-3 months for a procedure. In order to transfer clinical information from the physiotherapist to the clinician, the participant uses a generic mobile app for recording notes (that is, it is not an mHealth app). At the last physiotherapy session before their scheduled appointment with the clinician, the participant takes notes that are dictated by the

physiotherapist and then takes them to the appointment to show during the intake process for the procedure.

> *"It's up to me to gather information from the physios… I take notes as to the things that she's finding gone rock solid and immobile… And then when I'm checked in, I'll pull up my phone and show the nurse who is going through the protocol with me – 'Can you please write this down'. Because I can't take my phone downstairs. So, 'Can you please write this down on the intake. This is what he needs to know. This is from the physio, on Tuesday'."*

They do not retain or store this information after each hospital visit.

4.2.1.2 Non-electronic

Of the three participants that reported capturing data in non-electronic formats, one has maintained a journal periodically since diagnosis to capture information related to their mental health condition and they also capture paper-based notes prior to GP appointments. The second participant provides PGHD before appointments through paper based forms provided by the clinician. The third participant uses a blood pressure monitor between GP appointments for the management of hypertension. Two of the participants attend appointments every 6 months for prescription renewals, while the third attends every 2-3 months for a procedure.

Table 4.5: Profile of participants capturing PGDH in non-electronic formats

Participant	Condition	Collection Method	Appointment Frequency
Participant B	Mental Health Condition	Journal & Paper Based Notes	6 months
Participant D	Musculoskeletal Disorder	Paper Based Form	2-3 months
Participant E	Hypertension	BP Monitor & Paper Based Notes	6 months

4.2.1.2.1 Participant B

While participant B was not currently maintaining a journal of symptoms, they described the process as it is something that they do from time to time when prescribed by a clinician. The participant reported an unstructured process, in that

they were not told when or what to record. The data was often not recorded directly after symptomatic episodes:

> *"It's not so much during the day that you might, if you have a piece of paper, you might write down that that was a bad episode. But usually you're in social situations and you're not going to do that. So it's at the end of the day when you're by yourself you carve out 10 minutes to do all this."*

They reported that the process was tedious and time-consuming:

> *"After awhile it just became tedious… I just didn't want to do it after a couple of weeks. But you just kind of keep on doing it. "*

They also reported that the accuracy of the information was questionable:

> *"There are so many other things going on in your day, by the time you get to write everything down in the evening you might sort of forget exactly what happened, what triggered it."*

Despite being asked by various clinicans to record this information, it was never asked for at appointments or reviewed by the clinicians. Prior to appointments, the participant would try to review the journal in order to be able to summarise symptoms during the consultation. After each appointment, they disposed of the journal.

The participant is currently attending a GP and captures information prior to these appointments in order to ensure that they remember to mention particular things. These paper-based notes are made in the days leading up to the appointment, when the participant has time to gather their thoughts. At appointments, the participant offers the information and once the appointment is over, they again dispose of the paper.

4.2.1.2.2 Participant D

Partipciant D provides information through forms for their hospital visits. When attending for each procedure, they are asked to provide a history of past procedures. On some occasions they are not asked to provide the information if they are known to the nurse on the ward.

"If I'm on a particular ward in <hosptial>, they actually know me. And so, I come in and those nurses will ask 'Is there anything new?'. And then they'll write in 'See last entry form'. They'll try and circumvent because they know I've done this… at some point all of this has been captured."

When the participant attends consultant office visits, as opposed to procedures, they are asked to provide information about pain levels since the last visit versus what they are experiencing that day, as well as the location of the pain. Again, this is a paper based form. The data is then reviewed by the clinician during the appointment.

4.2.1.2.3 Participant E

Participant E attends a GP every 6 months for prescription renewal. The GP asked them to measure blood pressure on a daily basis, record it in a journal and to fax this information to the GP's surgery weekly. The participant used to have their BP checked at a local pharmacy but found that it was too time-consuming. The GP recommended a particular brand of BP monitor, which the participant then bought for home use. They are currently non-compliant with the doctor's request. They check their BP when they feel unwell instead of on a daily basis. They do not regularly fax the information to the GP. On occasion, when their BP has been particularly high at appointments, they have taken their BP regularly for a week and then dropped the information in to the GP surgery. If they take a measurement and the reading is high, they reported that they would take it regularly for a few days but would not typically share the information with the GP between or at appointments.

The participant also reported that the device records the readings, although they need to be transcribed to paper in order to share them with the GP. They also stated that they do not know how to store and retrieve the historical readings from the device:

"I could save all the results on the machine but I don't really know how to use it. "

4.2.1.3 Summary of *Process* Findings

Five participants reported that they record PGHD between or for appointments. However, two of these participants record two different types of data each so seven

processes were described. Three of these involved recording data electronically and four were non-electronic.

Of these seven data collections, five were performed at the request of the clinician but the process itself e.g. for sharing the data, was not formalised. Devices used by participants were either supplied or recommended by the clincians. In all but one case, clincians did not ask to review the data at any point after they requested participants to start collecting it.

None of the participants that collect PGHD reported that they kept it beyond their next appointment, and one expressed regret at having disposed of the data.

4.2.2 Motivation

Question 6 of the interview was designed to explore what drives patients to engage in the process of capturing PGHD, with the aim of understanding how wider adoption among the patient community could be encouraged. The following motivating factors were reported by the participants of Groups 1 and 2, despite the fact that some were non-compliant with their clinician's request or were reluctant to do so.

Table 4.6: Primary Motivations for Capturing PGHD

Participant	Motivation Factor(s)
Participant A	Self management: • Periodic checks. • Manage symptomatic episodes. • Discern patterns. Security/safety.
Participant B	Improve condition. Discern patterns. Gain perspective.
Participant D	Enable MDT communication.
Participant E	Manage symptomatic episodes.
Participant G	Self-management: • Regular checks, as prescribed.

4.2.2.1 Self Management

This was reported by 4 out of 5 of the participants who currently collect PGHD as a motivating factor. All participants had been requested by their clinician to capture the data. For the two diabetic patients, this had been so that they could self-manage their conditions and this was a continuous motivation for continuing to capture the data on an ongoing basis, albeit less frequently than requested in one case. For participant E, managing periods of unwellness was motivation for recording blood pressure readings. Finally, for participant B, their motivation for keeping a journal was the potential for it to improve their condition:

> *"I was quite gung-ho because this was a problem for me. And I thought this would be a helpful way… I still did it because I wanted to make myself better".*

4.2.2.2 Enable MDT communication

Participant D reported that the reason for collecting data between appointments was to ensure that clinical information was flowing from one member of her healthcare team to another. They reported that attempts made by the physiotherapist to provide clinical information to the consultant for the hospital appointments were not successful.

> *"We wanted it as close in time as me going into the procedure as we could get because you want the most up-to- date information for your going in. But that email might come into his secretary's inbox and if she's busy for a day or two, it may or may not get through the system and it certainly wouldn't become a print out in my file that he has in his hands when he's sitting with me before I go in. So, my physio's efforts to do it directly via email and provide substantive information for my next procedure wasn't working".*

Participant D also reported that they began to record notes from the physiotherapy appointments because they weren't able to remember muscle names etc. when they were with the consultant and he hadn't received the physiotherapist's email.

> *"I got there and couldn't remember what muscle it was. And so I started taking notes of what it was."*

4.2.2.3 Security

One of the diabetic individuals reported that they felt more secure having the ability to check blood sugar readings themselves:

"I sort of feel safer when I have it."

4.2.2.4 Gain Perspective

While it was not an initial motivator for capturing health information using a journal, participant B reported that despite finding the process tedious and time consuming, one of the reasons that they continued to do it was that it gave insight into the symptoms over time.

> *"Sometimes by recording it I did see some patterns emerging with the symptoms… And that when you record it during the day you actually realise that it didn't happen that often. So because you always remember the bad bits, it seems like it's 24 hours – or not 24 hrs but dawn to dusk. But actually when you write it down it wasn't quite so bad – sometimes anyway."*

4.2.2.5 Summary of Motivation Findings

Responses from participants during the second section of the interviews revealed four main drivers motivating their capture of PGHD. The most common of these was self management. For some, this was continuous management of their condition while for others it was used just for symptomatic episodes. Two of the other motivating factors reported were for personal benefit i.e. security and condition insight. For these motivating factors, sharing with a clinician was not necessary whereas for the final driver, enabling MDT communication, sharing the data with clinicians was a core feature.

4.3 Expectations for, and willingness to share PGHD

The goal of this section of the interview was to understand patients' willingness to engage in the process of capturing PGHD, benefits that they report (actual or potential), their attitudes towards sharing the information with their clinician and any resultant expectations. Finally concerns or challenges which may impede the wider adoption of this process were explored with the participants. This section of the questions was included in all interviews.

4.3.1 Willingness to Engage

As discussed in the last section, participants that were already collecting PGHD were doing so to varying degrees of compliance. However, this did not directly correlate to their answers when specifically asked whether they would be willing to record and share data if asked to do so by their clinicians. All of the participants in these groups indicated that they would be willing to capture data. Additionally, all remaining three participants in Group 3 also indicated that they would be willing to engage in this request/process. However, one of this latter group did not feel that they would be asked by a clinician to do so:

> *"I wouldn't mind. I'd do it. But there's nothing that I can record about it myself really. To get the information that she needs on me, I have to go through a very specialised test every 3 or 4 or 6 months."*

While all participants indicated willingness to engage with such a request from their clinicians, they also cited concerns and expectations. These will be now be discussed, along with potential benefits that were identified by participants.

4.3.2 Perceived Benefits

For participants who were already recording PGHD, the motivating factors described in Section 4.2.2 can be considered actual benefits. All participants were also directly asked whether they thought that it would be beneficial to be asked by their clinician to record data to bring to appointments. Seven of the eight participants answered positively. The eighth participant did not feel that there was any data that they could gather that would inform their treatment. The following table lists the additional, perceived benefits (by emergent code) provided by participants.

Table 4.7: Participants' Perceived Benefits of Recording PGHD

Category:Code	Participant A	Participant B	Participant C	Participant D	Participant E	Participant F	Participant G	Participant H	Total
Benefit:Monitoring	1						1	1	3
Benefit:Recall issues		1				1			2
Benefit:Counteract biased data (most recent symptoms)		1		1		1			3
Benefit:Potential to help		1							1
Benefit:Patient is expert		1							1
Benefit:Help to structure/inform conversation		1		1					2
Benefit:History when changing clinicians		1		1					2
Benefit:History/perspective for individual		1							1
Benefit:Quantify or accurately convey impact of symptoms		1		1					2
Benefit:Objectivity		1				1			2
Benefit:PHR summaries for healthcare mgmt (insurance, work)				1					1
Benefit:Comprehensive overview				1					1
Benefit:Manage by exception/change				1			1		2
Benefit:Data based decisions				1		1			2
Benefit:Convenient (automation)		1			1	1	1		4
Benefit:Personalisation						1			1
Benefit:Measure medication effectiveness								1	1

Additional examination of the transcriptions and codes resulted in further grouping of the benefits, which will be briefly presented.

4.3.2.1 Convenience

Emergent Codes: Convenient (automation)

This was one of the most reported benefits, with half of the participants reporting that capturing PGHD electronically would be an easier process:

> *"I think it's much easier I think to enter something electronically… Than it is to write on a piece of paper, for daily stuff. There are so many bits of paper there to carry around and make sure you keep them all in order as well. So if it was just a case of enter on your phone or something like that – you know, tick tick tick, these symptoms, this day – that would be much easier."*

> *"It's like weighing in if you're going to Weight Watchers, you've done it and don't have to think about it."*

4.3.2.2 Remote Monitoring

Emergent Codes: Monitoring; Manage by exception/change

Four of the participants reported that they thought clincians having the ability to remotely monitor their condition would be a benefit resulting from sharing PGHD between appointments.

> *"Firstly, it would be money… I think it would make more sense really. Than, as I said, going up, going in, and coming out and feeling they knew as little about you when you came out as when you were going in. They're only taking your word for it."*

> *"If everyone's data went in, it could actually be a computer program that flagged this one out of a thousand is having this really either highs or lows or crazy fluctuations. And then the computer program would tell the doctors, you need to call this patient in. Because there's something outside of the norm happening and they need to be called in. "*

> *"It's 120 euro for 20 minutes, to fill out a form that says 'Yes, I'm still in chronic pain and will be for the rest of my life and I need another round of treatments'…we both know what's coming because it comes every couple of months. So to go in and have an office visit for 20 minutes to go 'Oh we have to do another series of that again'... of course we do, this is chronic."*

"If I had a device to monitor my blood pressure, I would have no problem doing it. Every day. I would be very happy with that. Because I'd feel that it was being monitored properly."

In three of these cases, participants felt that monitoring would be beneficial if it meant that they did not have to go to appointments as frequently. These participants also reported that they felt that their appointments were a waste of time and mentioned financial savings resulting from not having to attend as often.

4.3.2.3 Enhance Conversation with Clinicians

Emergent Codes: Help to structure/inform conversation; Quantify or accurately convey impact of symptoms

Two of the participants, who currently record PGHD, felt that attending their appointments with the data supported the interaction with their clinicians:

"It kind of cuts to the chase and it's useful to have that rather than saying 'yeah I'm fine' – again, it's just going back to objectivity. It's nice to be able to give them something more concrete."

"He would see 'So I see it's a spike today, what's going on with that? Are you sleeping?' Because all kinds of things can inform pain on a given day. And 'Have you been sick, have you been sleeping'."

They felt that sharing the data both helps use time more effectively as well as being able to use the data to inform the discussion.

4.3.2.4 History

Emergent Codes: History when changing clinicians; History/perspective for individual; Summaries for healthcare mgmt (insurance, work)

The same two participants also revealed that they have used the data that they collect about their conditions as a historical record for various audiences. In one case, the participant felt that the daily recording of data was a useful way for them to gain perspective about their condition:

"For myself it was useful to see in some way, some objective way, that things hadn't been quite as bad as I remembered them. Over the last couple of weeks."

For this particular participant, the perspective gained was over the period of collection (approximately 6 months) and did not extend beyond that. However, the individual also expressed regret at not storing longitudinal data as they now feel that it would be beneficial to have a long-term view of the symptoms associated with their condition.

> *"I actually would quite like to be able to look back at some of the entries I did you know 20-something years ago and just see was it as bad as I remember… Part of it is not letting it consume you and take over your life. And I think a big part of that is putting it into perspective. So if you can look back over the years and see ok, well, it was just as bad then and you did all these things, you know it's not like it's going to hold you back."*

The second participant disclosed that they maintain a paper based healthcare record at home, containing records related to their condition. They have used the historical data from this record to compile reports for the occupational therapy department at work as well as to assess the appropriateness of their health insurance coverage.

> *"I've used it for a couple of things… in trying to convince occupational health to let me come back to work. I actually pieced together the chronology… what I had done to recover to a point where I thought I should be given a chance to come back… I've used it for keeping track of how many procedures I've had in a year, evaluating am I on the right <insurance> scheme."*

This suggests that data stored by individuals about their condition may have practical uses beyond informing their treatment.

Finally, both participants reported that they see benefit in using PGHD when transitioning between clinicians or to new clinicians.

> *"The GPs have changed over as well so I wouldn't even know the guy's name now. It would take them a good while to read my record but nobody ever does – that's the truth of it… when this new person bought out the practice and came in, I went in and it was 'So, how are things generally?'… How do you sum up 6 years in 5 sentences or less?"*

Both see summarized data as a tool to aid in this transition process.

4.3.2.5 Data Quality

Emergent Codes: Recall issues; Counteract biased data

Three participants reported either having difficulty recalling information at appointments or suggested that the data was often biased by more recent experience (of symptoms).

Participant B, who maintains a journal of symptoms sporadically, divulged that it was difficult at times when updating the journal to remember what happened that day, nevermind trying to remember it up to six months later at an appointment:

> *"By the time you get to write everything down in the evening you might sort of forget exactly what happened, what triggered it… At the end of a month or at the end of six months you can't, it just gets lost… you just can't recall every symptom and even the impact."*

Participant F, who attends a clinician regularly for procedures, also comented that it can be difficult to recall information beyond the previous 3 months:

> "*After 6 months you sort of forget what happened in the first two or three… A daily log would be better than trying to remember all in one go every 6 months. And just saying 'Oh yeah, the last 6 months were fine'."*

In addition to recall issues, three participants disclosed that the data that they offer at appointments is often biased by their most recent experience of symptoms, and that therefore it may not be reflective of the entire period since the last appointment or their overall health:

> "*When it's something to do with your mood or whatever, it's when you go see them that tends to bias you I think. They ask you 'How are things going?' and I often tended to answer how I'd been in the last few weeks. But that might have ignored all of the stuff that happened before then."*

> *"It is influenced by how you feel on the day. And a general sense of, do I feel better or worse. If I'm feeling worse today, then you would probably say the overall pain is lower and that today's pain is high. If you felt good today, you might say overall I don't normally feel this good. So maybe you would elevate it then. I think it's never going to be accurate."*

"It's quite a long time and usually what will happen is if I have been really good in the previous few weeks before then that's what I remember. If it's been really bad in the last few weeks, that's what I remember."

4.3.2.6 Enhanced Data

Emergent Codes: Patient is expert; Objectivity; Comprehensive overview; Data based decisions

Three participants felt that PGHD had the potential to enhance their interaction with clinicans by introducing a more comprehensive and objective overview of their health status between appointments, allowing for treatment decisions to be more data based:

"*Like every patient, you feel you know yourself best. You know your symptoms best because you're dealing with them. And you turn up to an appointment and you've only got a certain amount of time and to try give all of the information you can is impossible… you just want some kind of objective measure – you want someone else to be able to objectively see exactly how many times that affected you."*

"*I would think from his perspective that he wants to see a pain trend. So after I get a set of procedures, does it slowly go up until I've got to go back again? Do I have spikes at some point? If so, what was happening when that occurred? So I would think the value to my medical care is 'what's the trend and why?'"*

"*It's hard to be objective about it. To know exactly how long it lasted… If you did have this log and clearly the symptoms were coming back earlier than they had been, you could schedule an earlier appointment there and then in which case you would actually get it. So actually it would be helpful…"*

4.3.2.7 Improve Outcomes

Emergent Codes: Potential to help improve condition; Personalisation; Measure medication effectiveness

As well as providing an objective overview of symptoms over a period of time, participant F also suggested that recording PGHD could be used to persuade their clinician that the standard times between treatment was not effective and should be changed, or personalised.

"If you did turn up and have a one-pager showing the frequency of symptoms, that's when you could say 'Well, look I know the standard interval is 6 months for appointments but actually I think I need it in 4 months'. This data would seem to support that in a formal way."

Participant H also reported that PGHD, in the form of regular BP measurements, could help with medication effectiveness.

4.3.2.8 Summary of Perceived Benefits Findings

This section of the interviews generated seventeen emergent codes, whose total occurrence was thirty one. On further analysis, these codes were grouped into seven overall benefits. Two of these benefits were associated with more convenient or targeted healthcare delivery i.e. convenience and remote monitoring. The remaining five benefits revolved around improving the management of conditions by contributing quality data and facilitating enhanced communication between patient and clinician, potentially leading to the final reported benefit of improved outcomes.

4.3.3 Concerns and Challenges

Several concerns and challenges were identified by both the participants and reviewer throughout the interviews. Seven of the eight participants cited at least one concern/challenge. Participant C did not cite any since they were not of the opinion that the process of capturing PGHD was relevant for their condition. The following tables lists these concerns and challenges by emergent code.

Table 4.8: Concerns and Challenges Related to Recording PGHD

Category:Code	Participant A	Participant B	Participant C	Participant D	Participant E	Participant F	Participant G	Participant H	Total
Concern/Challenge:Expectation	✓	✓		✓	✓		✓	✓	6
Concern/Challenge:Privacy	✓	✓		✓		✓	✓		5
Concern/Challenge:Security		✓		✓					2
Concern/challenge: Data has purpose or is meaningful		✓		✓					2
Concern/Challenge:Requires maturity		✓							1
Concern/challenge:Little impact on condition		✓							1
Concern/Challenge:Optimum time to share data				✓					1
Concern/Challenge:How to share				✓					1
Concern:Patient assumes they are being monitored				✓			✓		2
Concern/Challenge:Increased workload for clinician				✓		✓			2
Concern/Challenge:Acceptance influenced by understanding/use of technology				✓					1
Concern/challenge:Clinicians would find it annoying				✓					1
Concern/challenge:Lack of understanding of condition	✓				✓				2
Concern/Challenge:Rejection/dismissive clinician					✓		✓		2
Concern/Challenge:Fear					✓				1
Concern/Challenge: Process cannot be time consuming		✓				✓			2
Concern/Challenge:Must get time interval for capture correct						✓			1

As with the previous benefits, additional examination of the transcriptions and codes resulted in further grouping of the concerns and challenges.

4.3.3.1 Expectations & Assumptions

Emergent Codes: Expectation; Patient assumes they are being monitored;

Six of the eight paritipcants reported that if they were asked by their clinician to record PGHD between appointments, they would have expectations in return. Since participant C did not see any need for PGHD, this means that just one participant did not report any expectation arising from being asked to collect the data.

Of the five participants who were already collecting PGHD, three expected the clinician to review the data at appointments. These participants had been asked by the clinician to capture the data.

> *"I had it in my bag the first time, hoping she wouldn't ask and she didn't. And she never has since."*

> *"You feel like you've done the work you might as well hand it over… I would expect that in my next or in every consultation, if I'd gone to the effort of entering that information every day, that they would pull that data up and look at it with me. And we get to go over the whole timeframe."*

> *"I still did it because I wanted to make myself better but from a motivation point of view it was discouraging… I didn't feel that it ever got due consideration."*

> *"They gave it to me, and asked me to use it. And not once have they ever taken the device and downloaded the information."*

In addition, another participant disclosed that if a clinician asked them to record data that they would expect them to read it.

In the previous, *Benefits*, section of this chapter it was reported that patients saw potential for PGHD to be used to monitor their condition. For the two patients with hypertension, this was also an expectation. They reported that if they were asked to record BP readings (which in one case the participant has been), that on submission of those readings, between appointments, that they would be reviewed by their clinician and followed up on if necessary:

> *"If it was high, she'd call me in straight away. She'd send me a text message to say come in to discuss the results."*

> *"A daily log that you could enter that would then be submitted and hopefully read in some way."*

4.3.3.2 Confidentiality

Emergent Codes: Privacy; Security

Five of the partipciants said that they would have concerns related to the privacy of the data. These included that the data would remain confidential and used only for the purpose for which it was collected or otherwise anonymised. Two participants also cited security of the data as a concern, one was a general statement about data security, while the second was related to the method of sharing the data:

> *"I wouldn't email it to the physician. I would like it to be on some kind of formal system… I wouldn't like to be emailing it to somebody and perhaps I enter the wrong email address like a gmail. I would like it to be that you enter your data on an app for example and then submit and you just know that's it. It takes the risk of losing confidentiality out of it I guess."*

4.3.3.3 Waste of Time/Effort

Emergent Codes: Data has purpose or is meaningful; Little impact on condition

Two of the participants, both currently recording PGHD, had concerns related to wasting time and effort collecting the data if it was not going to be of use for the treatment of their conditions. One also felt that the process of recording the data (keeping a journal of symptoms) did not have an impact on the management of their condition.

> *"I think it might have been helpful if I had, if what I was asked to do was more rigid. So you know, set out criteria… to write this information, it takes time… So it's at the end of the day when you're by yourself you have to carve out 10 minutes to do all this. And then you feel that 10 minutes every day is a lot, if it's not really being used in a meaningful way."..*

> *"There would probably have to be a conversation of 'If I have this data, would it be useful to you? Would you look at it? Would it inform you at all?'"*

4.3.3.4 Process Related

Emergent Codes: Optimum time to share data; How to share; Process cannot be time consuming; Must get time interval for capture correct

Three participants had concerns related to the process of recording PGHD. They felt that it should not be time consuming:

"Just for speed, I usually just write it down on a piece of paper… but it's one thing writing on a piece of paper for speed for notes before a GP consultation – it's one piece of paper. But doing it every day it would just drive you nuts. There are so many bits of paper there to carry around and make sure you keep them all in order as well. So if it was just a case of enter on your phone or something like that – you know, tick tick tick, these symptoms, this day – that would be much easier."

"If he gave me a simple way of keeping track every day, I can't say for sure that on a busy day that it's going to be done but I would absolutely record things, particularly if it was on an app and it went directly to him."

"Perhaps if you had a log of each day and whether it was a good or bad day overall, a red or green button, and over time you would see."

And also that it was important to understand the optimum time and method for sharing the data, as described in section 4.2.2.2 by participant D's attempts to have their physiotherapist share data before appointments for their hospital procedures.

4.3.3.5 Clinician Related

Emergent Codes: Increased workload for clinician; Acceptance influenced by understanding/use of technology; Clinicians would find it annoying; Rejection/dismissive clinician

Three of the participants reported concerns related to clinician's acceptance of PGHD into the process of managing their conditions. Two acknowledged that it would result in increased workload for the clinicians, with one reporting that they may find it annoying and the other citing it as a challenge to ensure that the data would be presented in condensed/summarised format.

"I think most doctors would… just be thinking like 'Oh my God, like I have the time to look at your <data>'. You know? I just need to treat you and get on to the next person. I have 22 people on my list today… If him having to read all this stuff meant that he has less theatre days and it takes 3 more weeks to get in for a procedure? No."

"To be fair to him it would have to be condensed in a way so that it is a one pager… I can't see it working practically for him to get the results every day. It wouldn't work because he doesn't have time to read that kind of thing."

One of these participants also suggested that clinicians' acceptance of PGHD may be influenced by their understanding of the technology, in the case of consumer products such as health trackers.

Participant E reported that due to time constraints associated with appointments, their GP may reject approaches with PGHD that had not been prescribed:

> "*She might take a look at it and say I don't have time for it, unless that's specifically what you went for.* "

4.3.3.6 Individual Related

Emergent Codes: Requires maturity; Fear

Two participants suggested challenges related to the individuals collecting the data. Participant B has been recording PGHD at intervals over two decades. They began the process when they were a teenager and found it more challenging at that time than they do now:

> *"When I was doing this, I was a teenager. In hindsight, I'm impressed that I did it at all because I didn't really want to be doing it… And then maybe just with a younger mind and a shorter attention span, I just didn't want to do it after a couple of weeks… I think as an adult I take it much more seriously."*

Participant E cited fear as a reason for not engaging in the process of capturing PGHD that had been requested by their GP:

> "*Maybe there's part of me that's half afraid to start doing it… I think because I've had all these tests I'm fine… I'm just too scared to do it."*

4.3.3.7 Summary of Concerns and Challenges Findings

Analysis of the interviews generated fourteen emergent codes related to concerns and challenges with a total occurrence of twenty. The three a priori codes in the *Concern/Challenge* category were reported thirteen times. Further analysis of these codes revealed six overall groups of concerns and challenges. The challenge with the highest incidence was related to expectations and assumptions held by patients related to PGHD that they collect. The most common concern was security and privacy of the data. Two of the concerns were related to process and appropriate

use of time/effort. The remaining two challenges were people related i.e. attitudes of patients and clinicians.

4.3.4 Sharing

The recent increase in focus on PGHD is partly related to the self management of chronic illnesses in order to reduce their burden on the healthcare system. In order to remotely monitor patients or ensure that they are self managing appropriately, it is important that the data that they collect in the everyday setting is shared with their healthcare team. Therefore, to help encourage wider adoption of this practice, it is necessary to understand the patient-clinican relationship and the patient view on sharing the data. All participants were asked three questions related to willingness to engage and share data. One of the participants did not offer any information related to their relationship with their treating clinician (a GP), although did report that they would have no issues with being asked to collect PGHD outside of appointments. Of the remaining seven participants, the following table outlines emergent codes related to their relationship with clinicians and their views on being asked to share PGHD with them.

Table 4.9: Patient-Clinician Relationship and Views on Sharing Data

Category:Code	Participant A	Participant B	Participant C	Participant D	Participant E	Participant F	Participant G	Participant H	Total
Relationship/sharing:Positive clinician relationship				✓		✓			2
Relationship/sharing:Withholding information	✓	✓							2
Relationship/sharing:Lack of relationship	✓	✓	✓				✓		4
Relationship/Sharing:Frequently is easier		✓							1
Relationship/Sharing:Value in sharing between appointments				✓					1
Relationship/sharing:Clinician reinforces need, no impact					✓				1
Relationship/sharing:Intimidating					✓				1
Relationship/Sharing:Between appointments not practical or necessary						✓			1
Relationship/Sharing:Impersonal							✓		1

Additional reviews of the above, as well as the transcriptions, resulted in further consolidation of the information into two broader codes.

4.3.4.1 Relationship

Emergent Codes: Positive clinician relationship; Lack of relationship; Clinician reinforces need, no impact; Intimidating; Impersonal; Withholding information;

4.3.4.1.1 Positive

Two of the participants reported having a positive relationship with their clinician. Both participants were attending their consultant at 2-6 monthly intervals for ongoing hospital based procedures to manage symptoms related to their conditions. Despite both also reporting that they felt that there were time constraints associated with these appointments, they felt that they had a good relationship with their consultants.

> *"He is certainly very approachable. "*
>
> *"I'm in a good position in that I'm with a particular consultant who takes on board this information… But I would not venture to say he's the norm."*

4.3.4.1.2 Negative

Five of the participants reported challenges related to their relationships with clinicians. Four of the participants felt that they did not have a relationship or that their encounters were impersonal. These individuals also reported that they felt that appointments were time constrained.

> *"I might have to wait, there's a queue in front of me, I only see her for a few minutes…coming out and feeling they knew as little about you when you came out as when you were going in".*
>
> *"The current GP that I'm with, I'm only with that person for quite a short time. So I've given them the previous history and the previous diagnosis but not that much in the way of how often I suffer the symptoms…"*
>
> *"She asks me if I've been using my eye drops and that's it."*
>
> *"The people at the <hospital> for the diabetic clinic that I go to once a year, once every 18 months, they almost never see you… I don't know them, I wouldn't know who I'm going to get on a given day… that conversation really feels worthless."*

While the fifth participant reported that they did appear at times to have a positive relationship with their clinician,

"You can have a little bit of craic with her when you know what kind of mood she's in."

They also found her to be intimidating:

"She can be quite intimidating when you go in there. But I have to go for my prescription. I know she's going to give out to me… there's a big sign saying that you need two appointments."

And that her attempts to motivate the participant to engage in the prescribed process of recording information outside of appointments were ineffective:

"The last time I went to her she said you're going to have to be regular with it…She keeps at me…"

4.3.4.2 Withholding Information

Two of the participants admitted to actively withholding information from their clinicians. Both of these participants had also said that they do not have a relationship with their clinicians. One was to hide the fact that they were not compliant with the prescribed schedule for monitoring blood glucose levels.

"She asks me if I keep a check on it myself. And I lie briliantly and say I do."

Participant B admitted to withholding information in order not to be seen to be complaining and to avoid over medicating:

"There's also an element of you want to be the good patient. You don't want to be the one saying each time that things are getting awful and I didn't really want to get any more medication so there was a certain bias from my end as well. You end up telling them things perhaps that they want to hear."

4.3.4.3 Sharing

Emergent Codes: Frequently is easier; Value in sharing between appointments; Between appointments not practical or necessary

Three of the participants provided information directly related to their views on sharing data between appointments. Two felt that it is worthwhile to share it between appointments, in one case they considered it to be an easier process to manage if it

was shared on an ongoing basis. In the second case, the participant saw benefit in sharing it between visits so that the clinician would have time to review it before the appointment.

> *"I'm going to give the same information to them at the end of the 6 months anyway so in some ways if I'm giving it to them every day or every week it's just one less thing to worry about."*

> *"I would be happy with it all being up to date and read and understood before I show up for my next visit. I'm not necessarily looking for them to monitor me on a daily basis because I have no idea how that kind of system would work from their perspective."*

The third participant that provided input in this area felt that there would be no additional value sharing PGHD between appointments, that the value lies in being able to produce summarised data at the appointment:

> *"I can't see it working practically for him to get the results every day. It wouldn't work because he doesn't have time to read that kind of thing. But even then I know that dept is so busy that you wouldn't be able to get an earlier appointment unless it was an emergency. But if you did turn up and have a one-pager showing the frequency of symptoms … This data would seem to support that in a formal way. "*

4.3.4.4 Summary of Sharing Findings

Responses to the final section generated seven emergent codes, whose total occurrence across the interviews was ten. The two a priori codes in the *Relationship/Sharing* category were reported on four occasions. These emergent and a priori codes were further grouped into four overall observations. Participants reported both positive and negative aspects to their relationships with clinicians. More participants reported having negative interactions than positive ones. Two participants also revealed that they have at times knowlingly withheld information from their clinicians. Finally, three of the participants provided insight into their views on sharing data with clinicians. While two felt this would be worthwhile to do between appointments, the third felt that it should be shared at appointments.

4.4 Analysis of Codes

As previously discussed, the research process included the identification of fourteen a priori codes which were classifed within the eight code categories. While coding the eight interviews, an additional seventy seven emergent codes were identified by the researcher and subsequently assigned to the code categories. The *Other* code category was used for two emergent codes, highlighting the appropriateness of the other seven code categories which were developed as a result of the literature review and research question. While portions of these codes have been discussed within previous sections of this chapter, they have not been displayed or discussed in full. This full set of a priori and emergent codes can be seen in Table 4.10.

Table 4.10: Code Categories, A Priori and Emergent Codes

Code Category	*A Priori* Code	*Emergent* Code
Appointments	<none>	:Prescription driven :Time constraints :Cost of visits :Inconvenient :Patient driven :Prescription driven :Repeated requests for same information :Values testing at/for appts :Waste of time
Benefit	:Benefit	:Data based decisions :Manage by exception/change :Comprehensive overview :Convenient (automation) :Counteract biased data (most recent symptoms) :Help to structure/inform conversation :History when changing clinicians :History/perspective for individual :Measure medication effectiveness :Monitoring :Objectivity :Patient is expert

		:Personalisation :Potential to help improve condition :Quantify or accurately convey impact of symptoms :Recall issues :Summaries for healthcare mgmt (insurance, work)
Concern/Challenge	:Expectation :Privacy :Security	:Patient assumes they are being monitored :Data has purpose or is meaningful :Process cannot be time consuming :Acceptance influenced by understanding/use of technology :Clinicians would find it annoying :Fear :How to share :Increased workload for clinician :Lack of understanding of condition :Little impact on condition :Must get time interval for capture correct :Optimum time to share data :Rejection/dismissive clinician :Requires maturity :Expectation;Clinician review of data :Expectation:Clinician engagement
Individuals	:Disengaged :Engaged :Expert :Reluctant :Willing	:Frustration at lack of MDT communication :Frustration that patient is conduit of information :Guilt :Need/want to share data :Non-compliant :Self awareness
Motivation	<none>	:Improve condition :Support
Other	<none>	:MDT

		:Not necessary/relevant
Process	:Electronic :Non-Electronic :Self-Management	:Controlled by patient :Barrier of outdated technology :Clinician prescribed :Device to written to verbal to written :Ease of use :Electronic is easier :Manage exceptions :Negative experience :Patient driven :Portable :Real-time or there are recall issues :Structure needed :Tedious :Time consuming :Trustworthy data source :Unstructured :Unsure about what to capture :Volumes
Relationship/Sharing	:Positive Clinician Relationship :Withholding Information	:Between appointments not practical or necessary :Clinician reinforces need, no impact :Frequently is easier :Impersonal :Intimidating :Lack of relationship :Value in sharing between appointments

Individual codes were not unique to participants, their occurrence across participants ranged from one to seven. None of the codes, a priori or emergent, arose across all eight interviews. Table 4.11 shows the occurrence of codes within each of the eight categories i.e. the number of single occurrences for the codes listed in Table 4.10.

Table 4.11: Occurrence of Codes Within Categories

Code Category	*A Priori* Code Occurrences	*Emergent* Code Occurrences	*Total Occurrences*
Appointments	0	22	22
Benefit	7	32	39
Concern/Challenge	13	26	39
Individuals	19	11	30
Motivation	0	2	2
Other	0	3	3
Process	9	28	37
Relationship/Sharing	4	10	14

The highest occurrences were within the *Benefits* and *Concerns/Challenges* categories. Two other categories, *Individuals* and *Process*, also scored highly with occurrences within the 30-40 range.

Appointments and *Relationship/Sharing* both had a mid-range occurrence, with 22 and 14 respectively.

The least occurences were in the *Motivation* and *Other* categories, with 2 and 3 occurrences.

While it is interesting to note the general areas which dominated the interviews, Chapter 3 outlined the hybrid deductive/inductive research approach for this study within which individual comments are considered as important as those repeated across interviews. Therefore, while the occurrences of codes within the *Motivation* and *Other* categories was low, the interview content which triggered the identification of these codes was considered equally as important as those within the *Benefits* and *Concerns/Challenges* when analysing the results.

4.5 Summary

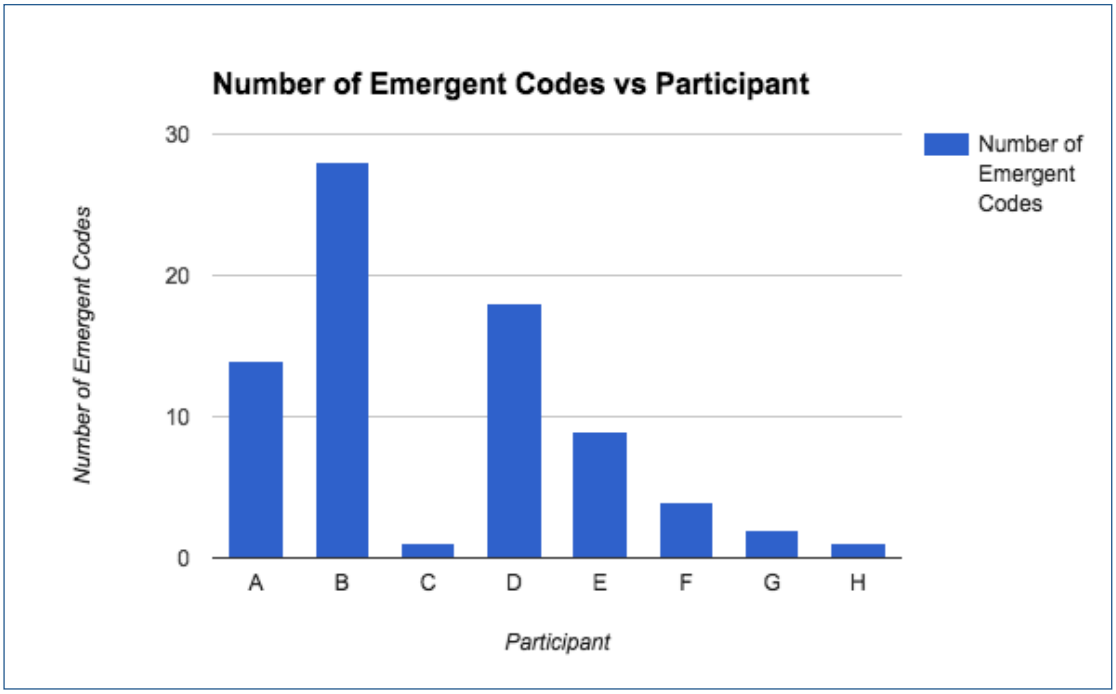
This chapter presented data from eight interviews with individuals living with a chronic disease in Ireland. The participant group was equally male/female, of mixed ages and with varying chronic diseases. Data reported was related to current processes of collecting PGHD; actual and perceived benefits, concerns and challenges; and information related to the patient-clinician relationship and participant views on sharing data with their clinicians. The following chapter will discuss these findings in the context of the research study and the wider body of research on this topic.

5 Discussion

5.1 Generalisability and Saturation

Due to the time constraints for completing the study, lengthy ethics approval process and the time intensity of performing the interviews, transcription, coding and analysis, the study included eight interviews as opposed to the initial target of ten. Despite the modest sample size, participants represented varying age groups and chronic conditions. While saturation was not reached with the eight interviews, the number of emergent codes steadily declined, with the last three interviews producing four, two and one code(s) respectively. The following chart shows the numbers of unique emergent codes resulting from each interview, in chronological order. As can be seen on the chart, the third interview was an outlier as this participant did not believe that PGHD was necessary for their condition.

Figure 5.1: Number of Unique Emergent Codes by Participant



It is sometimes reported that convenience methods of sampling can introduce bias due to an overselection or underselection of sections of the general population (Hardon et al., 2004). However, while the researcher did use personal contacts and

referrals to recruit participants, attention was paid to variation in gender, age and chronic condition in order to achieve maximum variation.

It is felt that these factors contribute to the generalisability of the findings. However, the sample size can be considered a limitation of the study and ideally interviews would have continued until saturation was achieved.

5.2 Findings and Themes

Chapter 1 introduced the research question and its individual components. These components were used to form the basis for the research methodology and the following findings and themes relate back to them in order to answer the research question:

1. *Process*: What are the ways in which patients currently capture health related data in an electronic format? How are they collecting it in non-electronic formats?
2. *Motivations & Expectations*: What are the motivations behind patients capturing PGHD?
3. *Sharing*: Are patients willing to share, or not share, this data with their medical team? Why?

5.2.1 General

The research found that patients are generally willing to engage in the capture of PGHD. While some of the benefits and concerns that were cited in the interviews were similar to those reported by clinicians in the literature, there were additional nuances that provide insight into the patient perspective. These will be discussed in subsequent sections of this chapter.

Over half of the participants felt that their appointments were a waste of time or were necessary only for prescription renewal. Those that did not report this were attending their clinicians for procedures or tests, suggesting that patients consider these activities worthwhile. However, the overall view was that PGHD could help to address the perceived inconvenience of appointments by either facilitating a longer period between visits or by enhancing the conversation with their clinicians at appointments.

The interviews revealed that patients have expectations in return for being asked to capture PGHD. One of these is that it is reviewed at appointments, which addresses question 3 above – patients are not only willing to share PGHD with their clinicians but they expect it to be. Only one of the participants was self motivated to record and share PGHD so it is not clear if the same expectations apply if the process is not prescribed by a healthcare professional.

Despite the growing availability of electronic personal health records, none of the participants were utilising this technology. One participant was maintaining a paper based record for personal, administrative purposes. Another participant reported that it would be beneficial to have access to historical PGHD in order to have insight into their condition over time. Chapter 2 discussed the drive by the healthcare profession to have patients engaged in their healthcare and for them to manage their own conditions. In order for them to do this, it may be prudent for healthcare professionals to educate, if not recommend, these types of platforms that may be able to support patients to engage in their chronic illnesses over what will be an extended period of time.

The following sections will discuss findings directly related to the sub-areas of the research question, as outlined in the interview design.

5.2.2 Process

Despite the range of apps, devices etc. that are now available, the participant group did not report any awareness or self motivation to use them. Neither of the two participants that record PGHD on their own initiative were using mHealth technology to do so. One was using a generic note-taking app and the other was handwriting notes. This raises the possibility that healthcare professionals may need to suggest and recommend appropriate electronic methods for capturing data if the goal is to have data from a trustworthy source shared with clinicians to inform treatment.

Given the long term nature of chronic illnesses and the drive to keep patients self-managing over this extended time, participants reported process related considerations that may play a part in keeping them engaged in recording PGHD, if it is to be utilised for this purpose. Participants reported that the process of recording data should not be time consuming. They also suggested that efficient use of time when sharing the data would be appreciated, particularly by having the data

automatically shared (assuming appropriate security measures are in place). Two participants also noted that if being asked to record data that it should be in a structured format, rather than a narrative version of events. While participants reported this from a time saving point of view, it also lends itself to the creation of quantitative data that could be actioned in an automatic manner. This point about structure is particularly of interest for the design of EHRs, apps and other software systems that may play a part in facilitating the introduction of electronic PGHD into the healthcare setting.

5.2.3 Motivation & Expectations

Theme 1: Patients do not believe that non-prescribed PGHD would be well received by their clincians.

Of those that were recording PGHD, the most frequent motivating factor was that they were asked by their clinician to do so. Once asked to do so, participants reported their own motivations for continuing with the process. However, the lack of self motivation may suggest a reluctance from partipants to instigate or introduce this process into conversations with their clinicians. Answers provided by participants further supports this theory as many reported that they did not feel that clinicians would be receptive to PGHD if it had not been prescribed, mostly because of perceived demands on their time. However, the experience of two individuals who were self motivated did not support this belief as neither reported that their PGHD was negatively received by their clincians.

Theme 2: Continuous patient motivation to collect PGHD is reliant on clincian engagement in the process.

Participants who were asked by their clinicians to record PGHD reported that they expected that it would be reviewed at subsequent appointments. In two of these three cases, the data was prescribed so that patients could self manage blood glucose levels. After receiving the glucometers, both participants brought them to their next appointment as they thought that the data would be downloaded or reviewed by the clinicians. In one case, the participant did not continue to monitor levels as prescribed but admitted that they would be compliant if the device readings were reviewed by the consultant. The second participant with diabetes did continue to monitor readings but expressed frustration at the device data being continuously ignored at appointments and instead being asked to manually or verbally produce the

readings. In the third case, the participant was asked to invest time between appointments in keeping a journal of their daily experience living with their condition. This participant reported that they were very motivated, or '*gung-ho*', to do so when asked. However, when the journal was not reviewed or "*given due consideration*" at the next appointment, their "*interest in it completely dropped off*" and that "*from a motivation point of view it was discouraging*". The clinicians' aim at prescribing PGHD in all cases might have been for self-management but this may not have been made clear to participants at the outset. However, whether it was for self-management or not, participants clearly expected that it would be used to inform their ongoing treatment. This is particularly important in light of the increase in focus on PGHD for its potential to reduce the burden on healthcare resources by encouraging self management, as discussed in Chapters 1 and 2. It would appear that while that potential is real, it does not remove the onus on clincians, at least from the patient perspective, to encourage and re-enforce its importance on an ongoing basis.

Clincian engagement in the process extends beyond this however, in that participants reported that they would be more willing to record data that they know will be of use to clincians. It would therefore appear that an important aspect to the introduction of PGHD into the clinical encounter is an initial conversation between patient and clinician that outlines the specific data that is meaningful for making treatment decisions.

5.2.4 Willingness: Benefits & Concerns

Theme 3: Patient motivation to record PGHD may be strengthened if the process results in less frequent appointments.

Since over half of the participants did not feel that they gained very much from their appointments, except prescriptions, and that they found them inconvenient (long periods in waiting rooms, effort to get to the hospital etc.), their willingness to engage in the capture of PGHD may be linked to potential for remote monitoring or attending appointments less frequently. This is supported by the fact that several also reported that resultant cost savings from less attendances would be welcome. This latter point about cost is interesting. The literature review reported a strong body of evidence showing that when patients record data about their health that it results in financial savings for the healthcare system. It also cited the economic burden on patients with chronic illnesses who self finance their healthcare. However, while this

typically would be considered an implication for private patients, those attending publically may also have costs associated with attending appointments such as time off work, transport etc. This study suggests that patients see benefit in reducing their own financial costs by using PGHD.

However, *Theme 2* suggests that reinforcement of the benefits of collecting PGHD appears to be important from a motivational standpoint. This typically would have happened at appointments so if PGHD were to result in less frequent appointments then alternative modes of messaging its importance from the clinical team might need to be found.

Theme 4: Patients are willing to engage in capturing and sharing PGHD if they feel that it will benefit their treatment.

While this may be obvious to some, it is interesting to note that participants reported that the effort involved in capturing PGHD is worthwhile if they know that it will be of use to their clinician and have a meaningful impact on the management of their condition. Participants who were already recording PGHD reported that it does take effort and time. This is connected somewhat to *Theme 2*, in that clinicians play a key role in setting out benefits for engaging in the process and that part of this is to explain specifically what data they need to inform that patient's treatment.

Theme 5: Patients are concerned about the security and confidentiality of their data.

Given that over half of the participants reported that they would be willing to engage in the recording and sharing of PGHD if it remained secure and confidential, it is important that this is a foremost consideration in the design of technology solutions for both recording and sharing the data. Any breaches, or concerns about breaches, of security or privacy would possibly have an impact on patient willingness to engage in the process. While healthcare professionals and their associated healthcare institutions can assume responsibility for patient data once it is in their systems, if they are recommending devices or electronic systems for storing/sharing data to patients they should first consider their security and privacy capabilities.

5.2.5 Sharing

Theme 6: PGHD has the potential to structure or inform patient-clincian communication which can perhaps improve outcomes.

While participants reported willingness to share PGHD with their clinicians, they also reported that the relationship with them can sometimes be challenging. In a 2015 article, Fiore-Gartland and Neff presented a view that the issues surrounding the introduction of electronic health data into the clinical setting are social and not technical (Fiore-Gartland and Neff, 2015). They define six "data valences" that capture the social expectations and values associated with health data. They suggest that for clinicians, the goal of this data is to diagnose, inform treatment decisions and encourage patient compliance, and that this same data is used by patients to initiate conversations and to take action.

Two of the valences directly relate to the experience reported by participants when discussing their willingness to share PGHD with clincians: *Connection* and *Truthiness*.

The *Connection* valence proposes that data provides "a structure and opportunity for conversation" (Fiore-Gartland and Neff, 2015) that both patients and clincians find beneficial. It suggests that data helps to forge a personal connection between patients and their clinicians which in turn can provide insight into the patient's home environment or other factors which may have an impact on their condition. Relating this to the experience reported by participants, most felt that they did not have a positive relationship with their clinicians. For participants that had been prescribed PGHD, not having that data reviewed by their clinician not only de-motivated them from continuing to do so but potentially also represented a missed opportunity to understand the patient's experience of living with their condition and to make personalised recommendations. For example, in the case of participant A who was non-compliant with their blood-glucose readings, reviewing the device data with their clinician would have uncovered this fact, created an opportunity to understand why and to re-motivate the patient. Ultimately this too could lead to improved outcomes as good management of blood glucose has been shown to reduce the chances of complications associated with diabetes (Patton, 2015). In the case of participant B, who was asked to maintain a journal, not having their data reviewed by the clincian again resulted in the patient not persisting with the task and was a missed

opportunity for the clinician to understand, or help the patient to understand, triggers for symptoms that they reported were *"debilitating from a social point of view"*. Using the participant's PGHD to provide insight into the impact that the symptoms had on their life may have led to more informed, personalised treatment which could have led to an improved quality of life.

The *Truthiness* valence asserts that people perceive quantified data to be "'more objective' and 'truer' for health understanding rather than other types of experience, symptoms, or evidence" (Fiore-Gartland and Neff, 2015). Quantifying symptoms, or experience is seen as a way in which people can prove their illness and make it "real through data" (Fiore-Gartland and Neff, 2015). Comments made by participants during this study support this belief as they felt that sharing quantitative data with their clinicians would help to provide insight into the effects of their condition and reflect a view that was more 'objective' than a general narrative during appointments. One participant reported that it would not only be easier and faster to record symptoms quantitatively, but that this measurement would provide proof of the impact

> *"You just want some kind of objective measure – you want someone else to be able to objectively see exactly how many times that affected you".*

Chapter 2 outlined evidence from the literature about the importance of the patient-clincian relationship in establishing compliance to treatment plans and improving outcomes. It also revealed that a poor relationship can result in patients not engaging in their care and lack of self-management. However, the article by Fiore-Gartland and Neff, supported by results from this study, also highlight that an engaged clinician is essential and that PGHD may provide a tool to help forge a stronger relationship between patient and clincian, which in turn may indeed lead to better outcomes for patients.

Theme 7: It is important to consider how PGHD can be shared by patients.

As outlined in Chapter 2, much emphasis is placed on the electronic recording of PGHD in the form of apps, devices etc. and their associated usability. However, Fiore-Garland and Neff suggest that there is less focus on developing methods for PGHD to transit into the clinical setting for interpretation by healthcare professionals. This research supports that with all participants in Groups 1 and 2 reporting that their

PGHD was discussed verbally at appointments and was never electronically shared. One of the participants was asked by their GP to fax results to their surgery. This involved taking readings electronically, writing them down manually and then in theory faxing them to the doctor. However, while the participant performed the first two steps, they handed the readings in to the office in person. In this case, the participant was asked to share data through a medium (fax) that may be convenient for the GP but which many patients would find difficult to access.

The experience of the participants when sharing their PGHD raises the possibility that focus needs to not only be placed on gathering the data but also ensuring that it can be shared in an efficient manner using a medium that patients have easy access to. It also emphasises the importance of patient-clincian communication given that it would appear that verbal communication is a common method for sharing PGHD.

Theme 8: Some patients do not tell the truth to their clinicians, but PGHD may be able to change that.

The literature revealed that clincians believe some patients do not always tell them the truth, with one study of patients reporting that this may be true. This research would appear to support this with two of the eight participants stating that they knowingly withhold information from their clincians. However, this patient insight suggests that this may not only be to disguise non-compliance but to avoid treatment that they do not want e.g. additional medication, or so as not to be considered a complainer.

This study suggests that PGHD may be able to help address this in two of the examples above; non-compliance and to avoid complaining. In both of these cases, the participants reported that they would be willing, and eager, to share PGHD with their clinician to facilitate a more open, truthful and fullsome conversation.

5.3 Summary

This chapter has presented and discussed eight themes related to the research question, resulting from the qualitative study designed and carried out as part of the dissertation. While these themes are supported by findings from the literature review, they provide a unique insight into the topic in question as they address the

patient viewpoint. However, given the modest sample size, these themes need to be tested through further qualitative and quantitative studies. The following chapter will discuss the potential for additional research on this topic, as well as provide conclusions for the study along with its strengths and limitations.

6 Conclusion

Patients have always been contributing data to their healthcare, in the form of verbal information about symptoms, blood/tissue samples etc. While to date this data transfer has mostly been confined to the healthcare setting, advancements in digital technologies and their adoption by the general population are challenging this model. Patients are increasingly equipped to capture and record information about their health status and wellbeing outside of the community healthcare and hospital settings. Ownership of smartphones, availability of mHealth apps/devices and uptake in wearables has resulted in a significant increase in patient generated health data.

The aim of this research was therefore to understand what is known about the patient view on the use of PGHD, how patients currently capture and record health information, why they do it and what their expectations and concerns are when sharing it with their healthcare team. The data gathered as part of this study addressed these questions and subsequently identified themes which can be used to develop hypothesis to form the basis for further research. The remainder of this chapter will summarise the research findings, highlight limitations and suggest areas for future work.

6.1 Summary of Research

The literature review revealed several benefits and challenges related to this topic, primarily from the clinician viewpoint. Data collected for this study suggested that patient concerns are somewhat similar. However, it provided additional insight into the topic from the patient perspective which may help to inform the wider healthcare, technology and patient advocacy communities.

The literature review highlighted that technology to capture PGHD should not intrude on the individual's daily life. Participants in this study who currently capture data supported this view. However, in addition they reported that the sharing of data should be unobtrusive. In particular, inaccessible technology should not be the primary communication channel requested by clinicians as a way to share the data e.g. fax. This study also highlighted that while much emphasis has been placed on

the collection and recording of PGHD, there remain limited options when it comes to electronically sharing this data with the healthcare system.

The study found that patients appear to be willing to engage in the process of recording PGHD and contributing it to help inform their treatment plans. The study group reported that while they may be intially motivated to capture data at the request of their clinicians, they are also motivated by its ability to support self management practices, to enable MDT communication (due to the current lack of information transfer between healthcare professionals and institutions) and to provide personal and administrative insight into their condition. They are also motivated by self-reported benefits such as remote monitoring (with a potential linkage to cost savings associated with their illness), the ability to improve their long-term relationship with their clinicians and the potential to improve the quality of information that they can provide to inform their treatment and improve outcomes.

While the literature review suggested that the introduction of PGHD was likely to be driven by patients and their increasing access to technology, this study raises the possibility that patients are reluctant to introduce PGHD that has not been prescribed. It also suggests that clinicians need to play an ongoing role in reviewing the data with patients in order to continue to ensure that they remain engaged in their care and motivated to use PGHD to self manage their conditions.

Should PGHD become a mainstream tool in healthcare to help manage chronic illnesses, this research revealed areas of concern that will need to be addressed by healthcare professionals and technology suppliers in order to ensure its successful integration into established care pathways and future visions for a healthcare system underpinned by technology. Participants revealed that they have expectations resulting from the effort expended in sharing PGHD with their healthcare teams. The data must remain secure and confidential, it must be easy/swift to capture and it must be useful to clinicians. Patients do not want to capture data unless there is good reason to.

Finally, the opportunity for PGHD to facilitate a more open, personal and informed conversation between patients and their clinicians was highlighted as part of this study. The research revealed that patients do not feel that they have a good relationship with their clincians and that they view data as a way to enhance their

conversations by providing proof of their illness or the impact that it has on their daily lives.

While this study has not conclusively answered any of the research questions, it has provided insight that can be built upon through additional work and adds to a body of knowledge related to PGHD by addressing an area which to date has not been the subject of substantial focus. The patient view needs to be an area that is further looked at and understood if the call to have a more engaged patient population, particularly for chronic illnesses, is to become a successful collaboration rather than an exercise in words.

6.2 Study Limitations

As previously discussed in Chapter 5, the sample size for this research was small. While this allowed for an in-depth discussion with each participant, saturation was not achieved.

The initial aim of the study was to recruit participants through patient advocacy groups. In order to increase the generalisability of the findings, the researcher considered it important to have a broad range of ages and chronic conditions represented in the participant group. Due to time constraints, it was felt that recruiting through personal contacts and referrals would yield a more diverse pool of participants and therefore this method was followed. However, the literature reports that this method of recruitment can lead to bias and therefore this must be acknowledged as a limitation of the study.

Despite the disparate age ranges and chronic conditions, there was little variation among participants with respect to the clinical setting for their appointments. All participants were attending clinicians (GPs and hospital based consultants) and only one reported attending an allied health professional. The lack of participants attending other healthcare professionals, such as community nurses etc. may have missed patient insights particular to those settings.

6.3 Opportunities for Future Work

As outlined in Chapter 5, this was an initial exploratory investigation into the views of patients. Given the modest sample size, it is recommended that the themes that emerged from this research are validated or expanded upon through further studies with patients. The use of focus groups to involve a wider participant pool may be an appropriate next step, with resultant findings and hypotheses tested through wider reaching quantitative methods such as questionnaires.

A second area for further investigation is related to how PGHD, and associated patient views on the topic, can be incorporated into healthcare systems and National Programmes, such as the National Shared Record, National EHR Programme and organisational EHR efforts. Healthcare professionals are widely consulted and involved in the design of these national and organisation systems and this research has also suggested that healthcare professionals play a key role in ensuring that patients remain motivated and engaged in their healthcare. It would therefore be useful to investigate how to highlight the importance of patient motivations and views on this topic so that they are understood and considered by healthcare professionals when changing the way in which care is delivered through technology and so that they can understand better how to support patients.

6.4 Conclusion

While it is now widely acknolwedged in the literature and in industry reports that healthcare should be more patient focused, there appears to be a lack of true engagement with patients to understand what this means for them or how they can participate to ensure that there is a successful and necessary change in the way that healthcare is delivered. The researcher's experience in carrying out this study was that the participants were very willing to engage in discussing this topic and were eager to contribute their experiences and views. It is the researcher's opinion that the delivery of healthcare needs to be seen as a partnership between patients, healthcare professionals and technology providers, where the views of all are heard and acted upon. While it is of course important to understand the clinician views on the usefullness of PGHD to inform and manage the treatment of chronic disease, it is also of the utmost importance that the patient view is understood given that they are integral to the process of capturing the data. This study focused on the patient for

this reason and it is hoped that further research will continue to emerge that highlights the patient perspective and the importance of considering it both during interactions within the clinical encounter and when designing healthcare systems.

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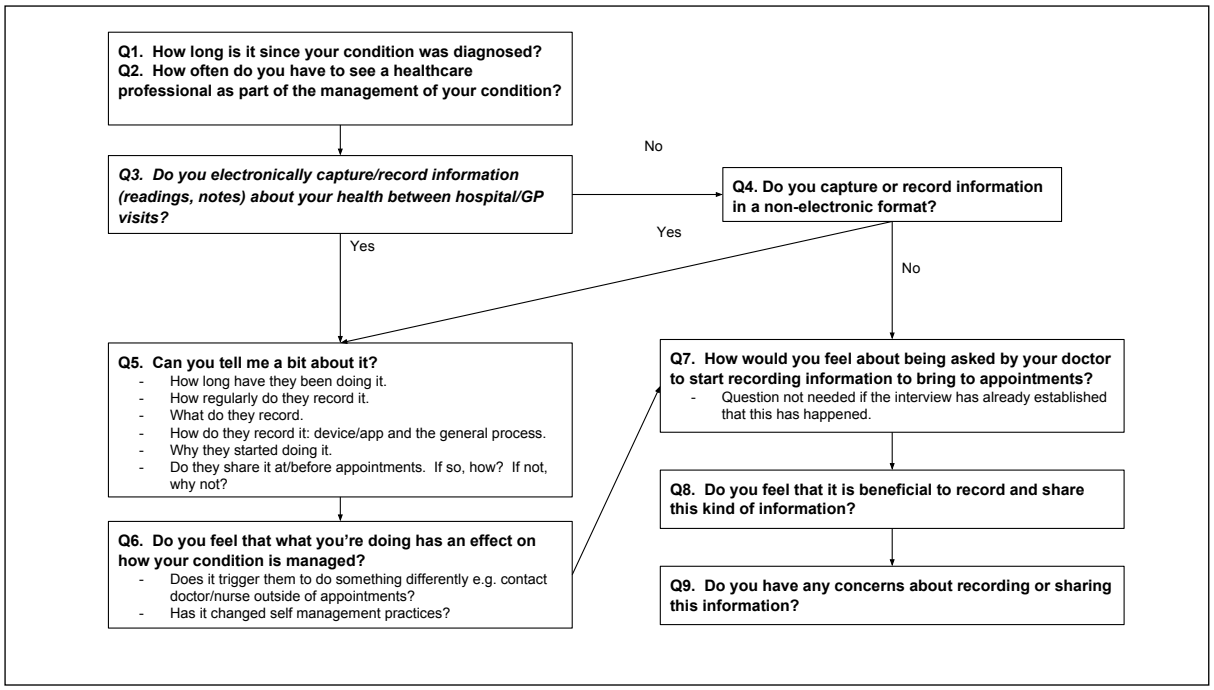
Appendix A: Interview Guide



Appendix B: Interview Protocol

INTERVIEW PROTOCOL

Research Study: "How can individuals with chronic illnesses electronically capture health related data in a form that they are willing to share with their medical team?"

Interviewee: _____

Date: _____

Location: _____

Interviewer: Katie O'Rourke

Participant Information Sheet Received and Read? Yes / No

Consent Form Read and Signed? Yes / No

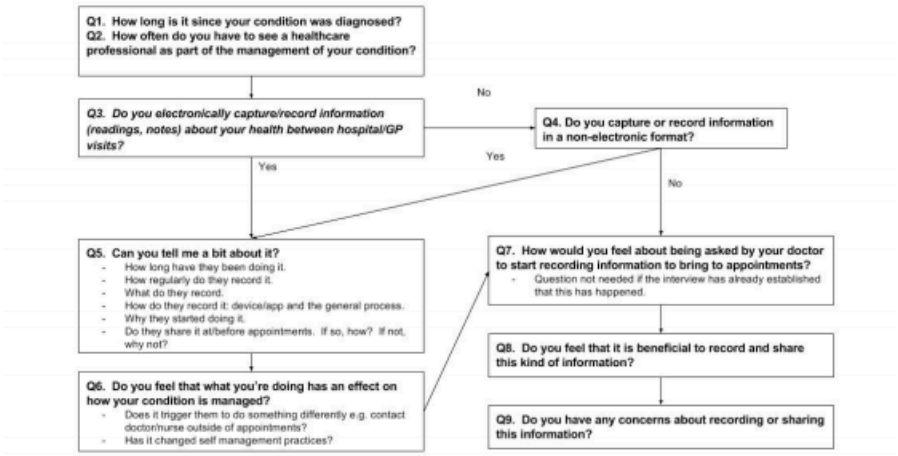
Introduction

As I have explained in the information sheet, I am going to audio record our conversation today to facilitate note taking. I will be the only one who will have access to the recording, it will be stored securely and will eventually be deleted when the study is complete. You have been asked to sign a consent form and if you have any questions about that, I'm happy to answer them now.

The interview is expected to last about 30 minutes and, depending on your experience with the topic, I have 6-8 questions that I would like to ask you. If time begins to run out, please excuse me if I interrupt you in order to get to all of the questions. Feel free to stop at any time or let me know if you would prefer not to answer a question.

You were chosen for the study as you have been diagnosed with a chronic illness and may be interested the topic of patient generated health data. The study is concerned with information that individuals gather about their health outside of medical appointments. I am interested in whether you record health information (measurements, activity level etc), and if so how you do this (smartphone apps, notes etc). I would also like to understand your thoughts on how this information should be used or any concerns that you have about it. This type of data is thought to be highly valuable in improving treatment plans and the results of this research are intended to provide the patient perspective on this topic and to make recommendations for the use of health information gathered by individuals.

Interview



Debrief

If you want a copy of any of the information that I've recorded as part of this conversation or the anonymised or aggregated results, feel free to email me and I can send that on to you. Also, if you change your mind about information from our conversation included in the research, let me know and I will delete it. Do you have any questions? If any come to mind, you can send me an email either and I'll get back to you.

Interview Notes

Appendix C: Ethics Application

School of Computer Science & Statistics
Research Ethics Application

Part A

Project Title: How can individuals with chronic illnesses electronically capture health related data in a form that they are willing to share with their medical team?

Name of Lead Researcher (student in case of project work): Katie O'Rourke

Name of Supervisor: Prof Lucy Hederman

TCD E-mail: <anonymised> Contact Tel No.: <anonymised>

Course Name and Code (if applicable): MSc Health Informatics

Estimated start date of survey/research: April 2017

I confirm that I will (where relevant):

- Familiarize myself with the Data Protection Act and the College Good Research Practice guidelines http://www.tcd.ie/info_compliance/dp/legislation.php;
- Tell participants that any recordings, e.g. audio/video/photographs, will not be identifiable unless prior written permission has been given. I will obtain permission for specific reuse (in papers, talks, etc.)
- Provide participants with an information sheet (or web-page for web-based experiments) that describes the main procedures (a copy of the information sheet must be included with this application)
- Obtain informed consent for participation (a copy of the informed consent form must be included with this application)
- Should the research be observational, ask participants for their consent to be observed
- Tell participants that their participation is voluntary
- Tell participants that they may withdraw at any time and for any reason without penalty
- Give participants the option of omitting questions they do not wish to answer if a questionnaire is used
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs
- On request, debrief participants at the end of their participation (i.e. give them a brief explanation of the study)
- Verify that participants are 18 years or older and competent to supply consent.
- If the study involves participants viewing video displays then I will verify that they understand that if they or anyone in their family has a history of epilepsy then the participant is proceeding at their own risk
- Declare any potential conflict of interest to participants.
- Inform participants that in the extremely unlikely event that illicit activity is reported to me during the study I will be obliged to report it to appropriate authorities.
- Act in accordance with the information provided (i.e. if I tell participants I will not do something, then I will not do it).

Removed

Signed: ..... Date: March 15th 2017
Lead Researcher/student in case of project work

Ethics Application Guidelines – 2016

Part B

Please answer the following questions.		*Yes/No*
Has this research application or any application of a similar nature connected to this research project been refused ethical approval by another review committee of the College (or at the institutions of any collaborators)?		No
Will your project involve photographing participants or electronic audio or video recordings?		Yes
Will your project deliberately involve misleading participants in any way?		No
Does this study contain commercially sensitive material?		No
Is there a risk of participants experiencing either physical or psychological distress or discomfort? If yes, give details on a separate sheet and state what you will tell them to do if they should experience any such problems (e.g. who they can contact for help).		No
Does your study involve any of the following?	Children (under 18 years of age)	No
	People with intellectual or communication difficulties	No
	Patients	Yes

School of Computer Science and Statistics
Research Ethical Application Form

Details of the Research Project Proposal must be submitted as a separate document to include the following information:

1. Title of project
2. Purpose of project including academic rationale
3. Brief description of methods and measurements to be used
4. Participants - recruitment methods, number, age, gender, exclusion/inclusion criteria, including statistical justification for numbers of participants
5. Debriefing arrangements
6. A clear concise statement of the ethical considerations raised by the project and how you intend to deal with them
7. Cite any relevant legislation relevant to the project with the method of compliance e.g. Data Protection Act etc.

Part C

I confirm that the materials I have submitted provided a complete and accurate account of the research I propose to conduct in this context, including my assessment of the ethical ramifications.

Removed

Signed: ..... Date March 15th 2017
Lead Researcher/student in case of project work

There is an obligation on the lead researcher to bring to the attention of the SCSS Research Ethics Committee any issues with ethical implications not clearly covered above.

Part D

If external or other TCD Ethics Committee approval has been received, please complete below.

External/TCD ethical approval has been received and no further ethical approval is required from the School's Research Ethical Committee. I have attached a copy of the external ethical approval for the School's Research Unit.

Signed: ..... Date: .....
Lead Researcher/student in case of project work

Part E

If the research is proposed by an undergraduate or postgraduate student, please have the below section completed.

I confirm, as an academic supervisor of this proposed research that the documents at hand are complete (i.e. each item on the submission checklist is accounted for) and are in a form that is suitable for review by the SCSS Research Ethics Committee.

Signed: Removed
..... Date: March 15th 2017
Supervisor

Completed application forms together with supporting documentation should be submitted electronically to the online ethics system - https://webhost.tchpc.tcd.ie/research_ethics/ When your application has been reviewed and approved by the Ethics committee, hardcopies with original signatures should be submitted to the School of Computer Science & Statistics, Room 104, Lloyd Building, Trinity College, Dublin 2.

CHECKLIST

Please ensure that you have submitted the following documents with your application:

1.	• SCSS Ethical **Application Form**	
2.	• **Participant's Information Sheet** must include the following: a) Declarations from Part A of the application form; b) Details provided to participants about how they were selected to participate; c) Declaration of all conflicts of interest.	
3.	• **Participant's Consent Form** must include the following: a) Declarations from Part A of the application form; **b)** Researchers contact details provided for counter-signature (your participant will keep one copy of the signed consent form and return a copy to you).	
4.	• **Research Project Proposal** must include the following: a) You must inform the Ethics Committee **who** your intended participants are i.e. are they your work colleagues, class mates etc. b) How will you recruit the participants i.e. **how** do you intend asking people to take part in your research? For example, will you stand on Pearse Street asking passers-by? c) If your participants are under the age of 18, you must seek both parental/guardian AND child consent.	
5.	• Intended **questionnaire**/survey/interview protocol/screen shots/representative materials (as appropriate)	
6.	• **URL** to intended on-line survey (as appropriate)	

Notes on Conflict of Interest

1. If your intended participants are work colleagues, you must declare a potential conflict of interest: you are taking advantage of your existing relationships in order to make progress in your research. It is best to acknowledge this in your invitation to participants.
2. If your research is also intended to direct commercial or other exploitation, this must be declared. For example, *"Please be advised that this research is being conducted by an employee of the company that supplies the product or service which form an object of study within the research."*

Notes for questionnaires and interviews

1. If your questionnaire is **paper based**, you must have the following **opt-out** clause on the top of each page of the questionnaire: *"Each question is optional. Feel free to omit a response to any question; however the researcher would be grateful if all questions are responded to."*
2. If you questionnaire is **on-line**, the first page of your questionnaire must repeat the content of the information sheet. This must be followed by the consent form. If the participant does not agree to the consent, they must automatically be exited from the questionnaire.
3. Each question must be **optional**.
4. The participant must have the option to '**not submit, exit without submitting'** at the final submission point on your questionnaire.
5. If you have open-ended questions on your questionnaire you must warn the participant against naming **third parties**: "*Please do not name third parties in any open text field of the questionnaire. Any such replies will be anonymised."*
6. You must inform your participants regarding **illicit activity**: "*In the extremely unlikely event that illicit activity is reported I will be obliged to report it to appropriate authorities."*

Appendix D: Participant Information Sheet

TRINITY COLLEGE DUBLIN

INFORMATION SHEET FOR PROSPECTIVE PARTICIPANTS

Research Study: "How can patients individuals with chronic illnesses electronically capture health related data in a form that they are willing to share with their medical team?"

Background

I would like to invite you to participate in this study, which is being undertaken as a requirement for an MSc in Health Informatics at Trinity College Dublin. Before you decide whether to take part, it is important that you know what it is about, what you will be asked to do and what the information will be used for. Please take the time to read this information leaflet and discuss it with others if needed. If you choose to participate, you will also be asked to sign a consent form. Should you decide to participate, you are free to change your mind at any point and will not need to give a reason.

What is the study about?

The study is concerned with information that individuals gather about their health outside of medical appointments. I am interested in whether you record health information (measurements, activity level etc.), and if so how you do this (smartphone apps, notes etc.). I would also like to understand your thoughts on how this information should be used, or any concerns that you have about it. The results of this research are intended to describe the patient perspective on this topic and to make recommendations for the use of health information gathered by individuals.

Do you have to take part in the study?

Your participation in this study is completely voluntary. You were chosen for the study as you have been diagnosed with a chronic illness and may be interested in the topic of the research. If you do not wish to take part in the study, you do not need to provide a reason. If you agree to participate, you are free to change your mind at any time before or during the study. You may ask to have some, or all, of your responses removed from the study at any point.

What your participation would entail

If you are interested in participating, please let me know by contacting me at the email address or phone number that I have provided.

1. I will contact you to arrange a time that is convenient for you to meet with me, at a location that suits you.
2. When we meet there will be one interview (with the audio recorded), which is expected to last approximately 30 minutes.
3. When I have completed the study, I will produce an anonymised study of findings. If you are interested in receiving a copy of this, I will be happy to share it with you.

Why might you want, or not want, to participate?

The value of information collected by individuals outside of appointments is gathering more attention, particularly for people with chronic illnesses. You might therefore find this topic interesting as it may come up at some point in your care in the future, if it hasn't already. If you already record information about your health outside of appointments, information about how and why you do this may be useful to other patients and to healthcare professionals.

On the other hand, you may not be comfortable sharing information about the management of your illness or your views on this topic. If so, you may stop the interview at any time.

Will your responses remain confidential?

If you agree to participate in the study, your name will not be recorded or shared with third parties. Your responses will be used solely for this project and I will not have access to any other information related to your healthcare. However, in the very unlikely event that you reveal illicit activity during the interview, I will be obliged to report it to the appropriate authorities.

The interview will be recorded on a password-protected smartphone and transferred to an encrypted disk image on a personal computer within 24 hours of the interview. A backup will also be stored on researcher's personal, password-protected filestore on a Trinity College Dublin server. The recording will then be removed from the original recording device. The interview will be transcribed and anonymised. The resulting transcription and analysis will be stored on the encrypted disk image and TCD personal filestorage. The passwords for these two devices and filestore will only be known to the researcher and will not be shared. The recording will be solely available to the researcher and will not be played in any public

forum. The recording and transcriptions will be deleted from the encrypted disk image by 31st December 2017. They will be retained on the TCD filestore for a further year, until 31st December 2018.

Your information will be anonymised and will only be identified by false names or codes. The data will be analysed by myself and the results used as part of my dissertation. I will not use any direct quotations from our conversation before first checking with you that it is ok to do so. In this case, the quote would be anonymised and I would provide you with the text and context within which it will be used. If you do not want the quote to be used, or feel that the context is incorrect, then you are free to ask me to amend it or omit it entirely from the dissertation. The anonymised, aggregated results may also be used for peer reviewed journals or conference presentations. Participants will not be identifiable in any of these publications. Your information will remain strictly confidential at all times.

What should I do next?

If you are interesting in participating, please contact me to let me know. If you have any additional questions before deciding whether to participate, please feel free to contact me and I will be happy to answer them.

Many thanks for reading this information sheet and for considering your participation in this study.

Yours sincerely,

Katie O'Rourke
Email: <anonymised>
Phone: <anonymised>

Appendix E: Informed Consent Form

TRINITY COLLEGE DUBLIN

INFORMED CONSENT FORM

RESEARCH STUDY: "How can individuals with chronic illnesses electronically capture health related data in a form that they are willing to share with their medical team?"

LEAD RESEARCHER: Katie O'Rourke

Please read the following information about this research before you consider agreeing to the subsequent declarations or signing this consent form.

Background

You have been invited to participate in this study, which is being undertaken as a requirement for an MSc in Health Informatics at Trinity College Dublin. Before you decide whether to take part, it is important that you know what it is about, what you will be asked to do and what the information will be used for. Should you agree to participate after reading this information/declarations, and sign the consent form, you are free to change your mind at any point and will not need to give a reason.

What is the study about?

The study is concerned with information that individuals gather about their health outside of medical appointments. I am interested in whether you record health information (measurements, activity level etc.), and if so how you do this (smartphone apps, notes etc.). I would also like to understand your thoughts on how this information should be used, or any concerns that you have about it. The results of this research are intended to describe the patient perspective on this topic and to make recommendations for the use of health information gathered by individuals.

Do you have to take part in the study?

Your participation in this study is completely voluntary. You were chosen for the study as you have been diagnosed with a chronic illness and may be interested in the topic of the research. If , after reading this, you do not wish to take part in the study, you do not need to provide a reason. If you agree to participate, you are free to change your mind at any time before or during the study. You may ask to have some, or all, of your responses removed from the study at any point.

The interview

1. This interview is expected to last approximately 30 minutes and the audio will be recorded.
2. When I have completed the study, I will produce an anonymised study of findings. If you are interested in receiving a copy of this, I will be happy to share it with you.

Why might you want, or not want, to participate?

The value of information collected by individuals outside of appointments is gathering more attention, particularly for people with chronic illnesses. You might therefore find this topic interesting as it may come up at some point in your care in the future, if it hasn't already. If you already record information about your health outside of appointments, information about how and why you do this may be useful to other patients and to healthcare professionals.

On the other hand, you may not be comfortable sharing information about the management of your illness or your views on this topic. If so, you may stop the interview at any time.

Will your responses remain confidential?

If you agree to participate in the study, your name will not be recorded or shared with third parties. Your responses will be used solely for this project and I will not have access to any other information related to your healthcare. However, in the very unlikely event that you reveal illicit activity during the interview, I will be obliged to report it to the appropriate authorities.

The interview will be recorded on a password-protected smartphone and transferred to an encrypted disk image on a personal computer within 24 hours of the interview. A backup will also be stored on researcher's personal, password-protected filestore on a Trinity College Dublin (TCD) server. The recording will then be removed from the original recording device. The interview will be transcribed and anonymised. The resulting transcription and analysis will be stored on the encrypted disk image and TCD personal filestorage. The passwords for these two devices and filestore will only be known to the researcher and will not be shared. The recording will be solely available to the researcher and will not be played in any public forum. The recording and transcriptions will be deleted from the encrypted disk image by 31st December 2017. They will be retained on the TCD filestore for a further year, until 31st December 2018.

Your information will be anonymised and will only be identified by false names or codes. The data will be analysed by myself and the results used as part of my dissertation. I will not use any direct quotations from our conversation before first checking with you that it is ok to do so. In this case, the quote would be anonymised and I would provide you with the text and context within which it will be used. If you do not want the quote to be used, or feel that the context is incorrect, then you are free to ask me to amend it or omit it entirely from the dissertation. The anonymised, aggregated results may also be used for peer reviewed journals or conference presentations. Participants will not be identifiable in any of these publications. Your information will remain strictly confidential at all times.

DECLARATION

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, the information within this document about the research. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I understand that I may stop electronic recordings at any time, and that I may at any time, even subsequent to my participation have such recordings destroyed (except in situations such as above).
- I understand that, subject to the constraints above, no recordings will be replayed in any public forum or made available to any audience other than the current researchers/research team.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I have received a copy of this agreement.

PARTICIPANT'S NAME:

PARTICIPANT'S SIGNATURE:

Date:

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

RESEARCHER'S CONTACT DETAILS: Katie O'Rourke, <anonymised>

INVESTIGATOR'S SIGNATURE:

Date:

Appendix F: Emergent Codes

		Category:Code	Participant A	Participant B	Participant C	Participant D	Participant E	Participant F	Participant G	Participant H	Total
A priori		Benefit:Benefit	1	1		1	1	1	1	1	7
		Concern/Challenge:Expectation	1	1		1	1		1	1	6
		Concern/Challenge:Privacy	1	1		1		1	1		5
		Concern/Challenge:Security		1		1					2
		Individuals:Disengaged	1	1			1				3
		Individuals:Engaged		1	1	1		1	1	1	6
		Individuals:Expert				1			1		2
		Individuals:Reluctant	1	1			1				3
		Individuals:Willing		1		1		1	1	1	5
		Process:Electronic	1			1	1		1		4
		Process:Non-electronic		1			1				2
		Process:Self-management	1	1					1		3
		Relationship/sharing:Positive clinician relationship				1		1			2
		Relationship/sharing:Withholding information	1	1							2
Emergent	Participant A	Appointments:Cost of visits	1	1		1	1				4
		Appointments:Waste of time	1			1			1		3
		Appointments:Inconvenient	1						1		2
		Appointments:Values testing at/for appts			1						1
		Benefit:Monitoring	1			1			1	1	4
		Expectation:Clinician engagement	1	1		1	1		1		5
		Individuals:Non-compliant	1				1				2
		Individuals:Guilt	1				1				2
		Individuals:Self awareness	1	1							2
		Motivation:Support	1								1
		Process:Ease of use	1	1		1					3
		Process:Clinician prescribed	1	1			1		1		4
		Process:Manage exceptions	1				1				2
		Process:Portable	1								1
	Participant B	Appointment:Prescription driven		1			1				2
		Benefit:Recall issues		1				1			2
		Benefit:Counteract biased data (most recent symptoms)		1		1		1			3

		Appointment:Time constraints		1		1	1	1			4
		Benefit:Potential to help improve condition		1							1
		Benefit:Patient is expert		1							1
		Benefit:Help to structure/inform conversation		1		1					2
		Benefit:History when changing clinicians		1		1					2
		Benefit:History/perspective for individual		1							1
		Benefit:Quantify or accurately convey impact of symptoms		1		1					2
		Benefit:Objectivity		1				1			2
		Concern/challenge: data has purpose or is meaningful		1		1					2
		Concern/Challenge:Requires maturity		1							1
		Concern/challenge:Little impact on condition		1							1
		Individuals:Need/want to share data		1		1			1		3
		Motivation:Improve condition		1							1
		Other:MDT		1		1					2
		Process:Unstructured		1							1
		Process:Negative experience		1							1
		Process:Time consuming		1		1	1				3
		Process:Structure needed		1							1
		Process:Real-time or there are recall issues		1							1
		Process:Unsure about what to capture		1							1
		Process:Volumes		1							1
		Process:Tedious		1		1					2
		Process:Electronic is easier		1				1			2
		Relationship/sharing:Lack of relationship	1	1	1				1		4
		Relationship/Sharing:Frequently is easier		1							1
	Participant C	Other:Not necessary/relevant			1						1
	Participant D	Appointments:Repeated requests for same information				1					1
		Benefit:Summaries for healthcare mgmt (insurance, work)				1					1
		Benefit:Comprehensive overview				1					1
		Benefit: Manage by exception/change				1			1		2
		Benefit: data based decisions				1		1			2
		Concern/Challenge:Optimum time to share data				1					1
		Concern/Challenge:How to share				1					1
		Concern:Patient assumes they are being monitored				1			1		2
		Concern/Challenge:Increased workload for clinician				1		1			2

		Concern/Challenge:Acceptance influenced by understanding/use of technology				1					1
		Concern/challenge:Clinicians would find it annoying				1					1
		Expectation: Clinician review of data				1					1
		Individuals:Frustration that patient is conduit of information				1					1
		Individuals:Frustration at lack of MDT communication				1					1
		Process:Patient driven				1					1
		Process:Trustworthy data source				1					1
		Process: Controlled by patient				1					1
		Relationship/Sharing:Value in sharing between appointments				1					1
	Participant E	Appointments:Prescription driven					1				1
		Appointments:Patient driven	1	1		1	1				4
		Benefit:Convenient (automation)		1			1	1	1		4
		Concern/challenge:Lack of understanding of condition	1				1				2
		Concern/Challenge:Rejection/dismissive clinician					1		1		2
		Concern/Challenge:Fear					1				1
		Process:Barrier of outdated technology					1				1
		Relationship/sharing:clinician reinforces need, no impact					1				1
		Relationship/sharing:Intimidating					1				1
	Participant F	Benefit:Personalisation						1			1
		Concern/Challenge: Process cannot be time consuming				1		1			2
		Concern/Challenge:Must get time interval for capture correct						1			1
		Relationship/Sharing:Between appointments not practical or necessary						1			1
	Participant G	Process:Device to written to verbal to written							1		1
		Relationship/Sharing:Impersonal							1		1
	Participant H	Benefit:Measure medication effectiveness								1	1