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My Diabetes My Way

 an electronic personal health record for NHS Scotland

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My Diabetes My Way: an Electronic Personal Health Record for NHS Scotland

Scott Gordon Cunningham

Doctor of Philosophy
University of Dundee
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Acknowledgements

Declaration of the Candidate

I declare that I am the author of this thesis, I have consulted all references cited,

the work of which this thesis is a record has been done by me, and this thesis

has not been previously accepted for a higher degree.

Scott Gordon Cunningham

Declaration of the Supervisors

The conditions of the relevant Ordinance and Regulations have been fulfilled.

Professor Annalu Waller   Professor Andrew D Morris

Publications and Awards Related to this Thesis

Refereed Journal Papers

Cunningham SG, Pandharkame S, Greene AC, McAlpine RR, Emslie-Smith A, Wake D, Walker J, Waller A, Morris AD, Wyatt JC (2013) Patients' expectations of electronic records access. *Journal of Medical Internet Research,* In press.

Cunningham SG, Wake DJ, Waller A, Morris AD, Walker J (2013) My Diabetes My Way: an electronic personal health record for diabetes. *The British Journal of Diabetes & Vascular Disease,* 13(**3**):143-149

Wake DJ, **Cunningham SG** (2013) 'Digital Diabetes'- Looking to the future. *The British Journal of Diabetes & Vascular Disease,* 13(**1**):13-20

Cunningham S, McAlpine R, Leese G, Brennan G, Sullivan F, Connacher A, Waller A, Boyle DIR, Greene S, Wilson E, Emslie-Smith A, Morris AD (2011) Using Web Technology to Support Population-Based Diabetes Care. *Journal of Diabetes Science and Technology,* 5(**3**):523-534

Book Chapter

Cunningham SG, Wake DJ, Waller A, Morris AD (2013) Definitions of eHealth in Gaddi A, Capello F, Manca M *eHealth, Care and Quality of Life,* Springer-Verlag Italia, Milan, 15-30

Conference Abstracts

Cunningham SG, Wake D, Morris AD, Waller A, Walker J (2013) My Diabetes My Way: an electronic personal health record for people with diabetes, *Diabetologia* 56(Suppl. 1):S430

Cunningham SG, McAlpine RR, Brillante M, Wilson L, Waller A, Emslie-Smith A, Walker J, Morris A, Wake D (2012) My Diabetes My Way: Empowering people with diabetes through electronic record access, *Diabetologia* 55(Suppl. 2):S407

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Awards

Best initiative supporting self-care, Quality in Care Diabetes Awards, Guildford, October 2013

Second Place, NHS Tayside Quality Awards 2012, Ninewells Hospital, Dundee, December 2012

Patient and Public Involvement Award, Diabetes in Scotland Conference, Heriot-Watt University, Edinburgh, March 2010

Abstract

Background: Diabetes prevalence in Scotland is increasing at ~4.6% annually; 247,278 (4.7%) in 2011. My Diabetes My Way (MDMW) is the NHS Scotland information portal, containing validated educational materials for people with diabetes and their carers. Internet-based interventions have potential to enhance self-management and shift power towards the patient, with electronic personal health records (PHRs) identified as an ideal method of delivery. In December 2010, a new service was launched in MDMW, allowing patients across Scotland access to their shared electronic record. The following thesis aims to identify and quantify the benefits of a diabetes-focused electronic personal health record within NHS Scotland.

Methods: A diabetes-focused, population-based PHR was developed based on data sourced from primary, secondary and tertiary care via the national diabetes system, Scottish Care Information - Diabetes Collaboration (SCI-DC). The system includes key diagnostic information; demography; laboratory tests; lifestyle factors, foot and eye screening results; prescribed medication and clinical correspondence. Changes are tracked by patients over time using history graphs and tables, data items link to detailed descriptions explaining why they are collected, what they are used for and what normal values are, while tailored information links refer individuals to facts related to their condition.

A series of quasi-experimental studies have been designed to assess the intervention using subjectivist, mixed-methods approaches incorporating multivariate analysis and grounded theory. These studies assess patient expectations and experiences of records access, system usage and uptake and provide preliminary analysis on the impact on clinical process outcomes. Survey questionnaires were used to capture qualitative data, while quantitative data were obtained from system audit trails and from the analysis of clinical process outcomes before and after the intervention.

Results: By the end of the second year, 2601 individuals registered to access their data (61% male; 30.4% with type 1 diabetes); 1297 completed the enrolment process and 625 accessed the system (most logins=346; total logins=5158; average=8.3/patient; median=3). Audit trails show 59599 page views (95/patient), laboratory test results proving the most popular (11818 accesses;19/patient). The most utilised history graph was HbA1c (2866 accesses;4.6/patient). Users are younger, more recently diagnosed and have a heavy bias towards type 1 diabetes when compared to the background population. They are also likely to be a more highly motivated 'early adopting' cohort.

Further analysis was performed to compare pre- and post-intervention clinical outcomes after the system had been active for nearly two and a half years. Results of statistical significance were not forthcoming due to limited data

availability, however there are grounds for encouragement. Creatinine tests in particular improved following 1 year of use, with type 1 females in particular faring better than those in patient other groups. For other clinical tests such as HbA1c, triglycerides, weight and body mass index improvements were shown in mean and/or median values.

96% of users believe the system is usable. Users also stated that it useful to monitor diabetes control (93%), improve knowledge (89%) and enhance motivation (89%). Findings show that newly diagnosed patients may be more likely to learn more about their new condition, leading to more productive consultations with the clinical team (98%). In the pre-project analysis, 26% of registrants expressed concerns about the security of personal information online, although those who actually went on to use it reported 100% satisfaction that their data were safe. Engagement remains high. In the final month of year two, 44.6% of users logged in to the system. 55.3% of users had logged in within the previous 3 months, 78.9% within the previous 6 months and 91.4% within the previous year. Some legacy PHRs have failed due to lack of uptake and deficiencies in usability, so as new systems progress, it is essential not to repeat the mistakes of the past. Feedback: "It is great to be able to view all of my results so that I can be more in charge of my diabetes".

Conclusion: The MDMW PHR is now a useful additional component for the self-management of diabetes in Scotland. Although there are other patient access

systems available internationally, this system is unique in offering access to an entire national population, providing access to information collected from all diabetes-related sources. Despite its development for the NHS Scotland environment, it has the potential to connect to any electronic medical record. This local and domain-specific knowledge has much wider applicability as outlined in the recommendations detailed, particularly around health service and voluntary sector ownership, patient involvement, administrative processes, research activities and communication. The current project will reach 5000 patients by the end of 2013.

Chapter 1:   Introduction

"Spend more on education, spend less on medication."

Thoughts of Steve Graham, patient representative on the SCI-DC

Steering Group

This thesis describes the development methodology, processes and evaluation results for a unique electronic records access system that enhances self management for the diabetic population of NHS Scotland. Never before has a system of this type been developed for an entire national population. Furthermore, its uniqueness is augmented by providing a focused diabetes record that is sourced from multiple healthcare systems. By not being tethered to a single data source it provides a multi-source environment specifically for diabetes.

Electronic records access is still a relatively new addition to the eHealth portfolio, with many disparate silos of good work led by enthusiasts and private healthcare companies, particularly in the United States. In the United Kingdom, self-management has emerged as a priority area, given that the prevalence of long-term conditions continues to rise and healthcare resources become more stretched. This prioritisation of electronic records access can be shown, for example, in the Department of Health Information Strategy (Department of Health, 2012b) which aims to allow access to general practitioner records for

patients by the end of 2015. Despite this objective, there is still a limited evidence base as will be highlighted later. This current chapter outlines the narrative structure and objectives of this thesis and how this project aims to contribute to the literature.

Chapter 2 is one of two background chapters setting the scene and context for the author's work, prior to the formal literature review. It focuses on the burden of long-term conditions, before concentrating on diabetes and its increasing impact on health services worldwide. This context shows the increasing need for alternative approaches to successfully manage the condition as prevalence continues to rise. It has been stated that *"a person with diabetes will spend on average 3 hours with a health care professional and will take care of themselves for the remaining 8757 hours in a year"* (Scottish Executive, 2005a). This clearly shows scope for the improvement in the availability of suitable self-management tools. This chapter describes the advent of Managed Clinical Networks before moving on to highlight some of the existing NHS Scotland infrastructure, without which these studies would not have been possible. In the mid-nineties a research project created the first regional register for diabetes care and this has evolved into a national diabetes information system for NHS Scotland which now provides the data upon which this work depends. The My Diabetes My Way (MDMW) patient portal provides a user entry point, while the Citizen Account provides the user provisioning and authentication. Each of these building blocks shall be described in further detail.

The second background chapter (Chapter 3) begins by providing an overview of what is meant by the term 'eHealth' and what it aims to achieve. It discusses some of the key considerations including devices and hardware, data management, usability and accessibility and examples of applications. Many of these existing healthcare technology applications concentrate on the needs of the healthcare providers rather than those of the patient. These applications are used to aid point-of-care services, patient management and administration during healthcare processes and care pathways. The shift towards patient self-management support has been a long journey, with traditional healthcare decision-making processes allowing healthcare providers to dictate objectives and treatment to the patient (Kaplan and Brennan, 2001, Eysenbach, 2000). While many patients still prefer to be told what to do, other alternatives are now available. Shared decision-making means that options are discussed in consultation between the patient and healthcare professional to ensure that care plans are fully discussed, understood and agreed. eHealth can play a significant part, by providing patients with tools and knowledge resources that aid their self-management when they are not with their healthcare teams, thus providing a genuinely patient-centred approach. This chapter discusses what is meant by 'Consumer Health Informatics' and explains some of the medico-legal processes that are in place to protect patient privacy and confidentiality as well as safeguards that ensure the security of clinical data within the UK. The chapter

ends by highlighting some of the challenges of eHealth including the 'digital divide' and health literacy.

Following on from the background in the previous chapters, the main literature review in chapter 4 shows how technology can be used to aid self-management in the form of electronic personal health records (PHRs). This begins by documenting historical and alternative approaches to records access, before directing attention to the specifics of those made available via the internet. The review covers examples of PHRs from across all clinical domains and in various forms. Key components and considerations are highlighted, from design, user profiling, standards and stakeholder perspectives. It discusses the findings of many evaluations in the field, most of which are currently based around surveys of user experience and stakeholder opinions, before documenting potential benefits and barriers. It continues with an overview of security aspects including authentication processes, privacy and confidentiality. Case studies of some of the key PHR system in the United Kingdom and United States follow on from this, highlighting notable successes and failures. The chapter concludes by providing a critique of the review before highlighting the research questions that this thesis aims to answer. The main objectives are to determine:

What are the benefits of a diabetes-focused electronic personal health record?

Before commencing the research activities completed for this PhD, the system design in chapter 5 carefully considers the requirements capture and design of the intervention, its focus on user-centred design and how stakeholders were consulted to contribute to the objectives. The administrative workflow processes underlying the architecture are described in detail, prior to an in-depth technical outline. This covers many aspects including authentication, security, data management and information governance. Although these final sections are purely technical in detail, they were essential in providing a robust architecture that was both scalable and fit for purpose.

Once the system had been successfully built, a series of studies were carried out to answer sub-questions which aimed to contribute to the wider research question, and subsequently the evidence base. The first of these is in chapter 6, which aims to answer:

What are patients' expectations of electronic records access?

Rationale: to assess the perspectives of people with diabetes in Scotland to their use of a diabetes-focused PHR and use this as a basis for future analysis to assess how experiences compare to expectations.

Methods: a formative evaluation of user expectations administered during the system development phase. A survey questionnaire was emailed to participants containing open and closed questions for a mixed-methods analysis. The questionnaire responses were then anonymised and analysed using a mixed methods approach. A multivariate analysis was performed on the closed

questions, while open-ended free-text questions were analysed using grounded theory approach, with responses coded into common categories.

The results of this cross-sectional survey covered the potential impact that patients anticipated for their own self-management, prior to learning more about what the system would offer. In addition to providing these results, it also supplied a useful insight into areas that had not been previously considered. The results section of this chapter provides data on demographics of responders and the overall response rate, before precisely scrutinising details surrounding current internet use and the answers to the remaining closed questions posed. These data were analysed on their own merits prior to multivariate analysis and correlation. The discussion of these results highlights the key findings and limitations of this study, before comparing them with previous work.

Following two-and-a-half years of live use, the analysis changed to focus on user activity trends to answer the second research question shown in chapter 7:

What do patients do when accessing to their shared diabetes record?

Rationale: to assess demographic profile and usage to identify patterns of use amongst various groups, popular features and to identify areas requiring further refinement.

Methods: the methodology used in this quantitative analysis focuses on the interrogation of system usage logs and demographic profiling of the active user-base. User data are compared to the background diabetic population of NHS

Scotland, with this analysis essential in pinpointing the types of individual most likely to sign up for electronic records access.

Usage trends in years one and two offer some engaging data regarding the main areas of system activity, days and times of access. Recommendations are presented based on the experiences of active use and approaches that have proven successful in keeping users engaged. This analysis provided essential insights into the frequency of access and the types of data that users were most interested in reviewing.

Chapter 8 documents the second qualitative analysis based on a follow-up of user experiences with the aim of answering:

What are patients' experiences of access to their shared electronic record?

Rationale: to assess patients experiences to provide data on barriers and enablers to use and to assess the impact on motivation, self-management and patient satisfaction. To highlight how initial expectations compare with subsequent experiences.

Methods: a summative evaluation of user experience following one year of live user. The methodology of this analysis again takes the form of a cross-sectional survey questionnaire, containing both open and closed questions. These results are then discussed along with the outputs of the patient expectations highlighted in chapter 6 to provide a before and after analysis of user responses.

This research provided some useful insights into the reasons behind usage

patterns highlighted in chapter 7, particularly around those users who failed to

complete enrolment and those who receive user credentials, but never logged

on. In addition to highlighting potential reasons for user disengagement, the

commentary on best and worst features allowed the author to document potential

areas for improvement and further development as the project continued to

evolve.

The second quantitative analysis follows in chapter 9 with the aim of showing the

impact of this records access intervention on clinical measurements:

What is the impact on process outcomes for patients who access their

shared diabetes record?

Rationale: to assess the impact on key process outcomes data to identify

whether or not access to a diabetes-focused PHR has any significant impact.

Methods: a retrospective before-and-after analysis of was performed on key

routine clinical tests (e.g. HbA1c, blood pressure, body mass index, cholesterol,

etc), comparing the final pre-intervention parameters with those recorded at least

one year after first login. A Mann-Whitney U test was the statistical methodology

applied to the data to show the significance of changes in clinical outcomes

during the first year of use.

The results show how records access affects clinical indicators and routine tests and introduces further recommendations to improve the power and significance of the figures produced for future studies.

The final chapter in this thesis provides a discussion of the research, its key findings, limitations and recommendations. As the intention is to continue the project beyond the end of this PhD, it discusses proposed next steps and new developments that are currently undergoing consideration. The final section of this chapter, and this thesis, summarises the conclusions that have been drawn and the author's opinion on its successes, failures and overall impact in comparison with previous research in this area.

This thesis, the novel approach and the research outputs go some significant way to extending the understanding of electronic records access and its benefits, particularly for people with diabetes living in Scotland. There does, however, remain some significant scope for the further development of a robust evident base, especially beyond long term conditions, focusing more on acute care.

Chapter 2: Long-term Conditions and Government Strategy

"People need information and skills to maintain optimum wellbeing"

(Long Term Conditions Alliance Scotland, 2008)

2.1 Introduction

The following chapter provides an overview of long-term conditions, touching briefly upon the worldwide burden and focusing particularly on the case of diabetes. It highlights some of the statistics published both internationally and across the United Kingdom, showing that diabetes prevalence rates continue to rise at an alarming rate, with health services straining to meet the additional clinical demand. The focus then moves on to the local context within NHS Scotland, explaining the relevant government strategy and rationale which led to the work completed in support of this thesis.

In addition to providing an overview of these issues, this chapter describes some of the existing systems that are in place in Scotland to address them, and how these were used as building blocks upon which this new research and development evolved. It begins by describing the pioneering Diabetes Audit and Research in Tayside Study (DARTS) project and details how this evolved into the national programme; SCI-Diabetes Collaboration (SCI-DC). The chapter concludes with a discussion of the initial development of the My Diabetes My

Way (MDMW) information website, discussing its evolution from research project to a national information resource for people with diabetes and their carers. It should be made clear that this covers the work completed prior to that which is being assessed for the author's PhD. Each of the areas discussed in this chapter aim to set the scene for the developments and research documented within this thesis.

2.2 Methodology

The following chapter is a descriptive narrative of the areas outlined above, focusing on long-term conditions and including the previous work in which the author has contributed regarding the creation of an electronic patient record for diabetes in Scotland, used by healthcare professionals in their daily patient management. This chapter is not a systematic review of the literature, but aims to provide the reader with sufficient knowledge to understand the burden of diabetes, relevant government strategies designed to alleviate the problem, and the local context within which this new work was based, before the scene is finally set for the formal literature review regarding personal health records.

2.3 Long-term Conditions

Long-term, or chronic conditions are non-communicable diseases (NCDs), that cannot be cured at present (Department of Health, 2012a), limit what a person can do and may require ongoing medical care (Partnership for Solutions, 2002).

These conditions include cancer, epilepsy, respiratory conditions (such as chronic obstructive pulmonary disease (COPD) and asthma), cardiovascular disease and diabetes. In 2005, the World Health Organization (WHO) published its report *"Preventing chronic diseases: a vital investment"* (World Health Organization, 2005). This presented some significant data highlighting the effect that these conditions have on the general population. Figures provided in these reports state that 60% of deaths are due to long-term conditions and that 80% of premature heart disease, stroke and diabetes is preventable.

Following on from this report, in 2012 WHO published their "World Health Statistics" (World Health Organization, 2012c). This report highlighted that rates of obesity are rising, with figures almost doubling between 1980 and 2008. Obesity increases the risk of type 2 diabetes mellitus, coronary heart disease, stroke and some cancers. WHO also reports via its Global Health Observatory (World Health Organization, 2012a), that NCDs are the leading cause of mortality in the world, and that in low and middle-income countries, premature NCD mortality is prevalent:

> *"29% of NCD deaths in low- and middle-income countries in 2008 occurred*
>
> *before the age of 60."*

In the UK, it is estimated more than one in five people are affected by a long-term condition (Audit Scotland, 2007), they account for 50% of all general practice appointments, 64% of outpatient appointments and account for more than 70% of total healthcare spend (Department of Health, 2012a).

2.4   What is Diabetes?

Diabetes is a long-term condition that occurs when the body cannot produce enough insulin or cannot effectively use it. (Harris and Zimmet, 1997). According to the International Diabetes Federation, there are three main types of diabetes:

- type 1 diabetes: *"caused by an auto-immune reaction, where the body's defense system attacks the insulin-producing cells in the pancreas. As a result, the body can no longer produce the insulin it needs. The reason why this occurs is not fully understood. The disease can affect people of any age, but it usually occurs in children or young adults. People with this form of diabetes need injections of insulin every day in order to control the levels of glucose in their blood."*

- type 2 diabetes: *"the body is able to produce insulin but it is either not sufficient or the body is not responding to its effects, leading to a build-up of glucose in the blood."*

- gestational diabetes: *"the body is unable to make and use enough insulin needed for pregnancy"*

(International Diabetes Federation, 2012)

While the reasons for the development of type 1 diabetes are not clearly understood, type 2 diabetes tends to manifest itself as a result of risk factors, including poor diet, obesity and physical inactivity. Those with type 1 diabetes are

dependent on insulin to survive, while those with type 2 diabetes may be treated by diet, tablets, insulin or any combination of these.

2.5   Diabetes Internationally

The intervention developed and assessed for this PhD focuses on improving the self-management of people with diabetes. This chapter now focuses on this specific disease area internationally before moving on to the setting within NHS Scotland. The monitoring and targeted improvement of diabetes outcomes has been high on the healthcare agenda since the publication of the St Vincent Declaration in 1999 (World Health Organization / International Diabetes Federation, 1999). This declaration created a set of standards aimed at improving clinical outcomes related to blindness, end-stage renal failure, amputation and cardiovascular disease in people with diabetes. The clinical needs for improved services are obvious, as people are living longer worldwide (World Health Organization, 2012b) and the burden on health services continue to rise.

The International Diabetes Federation (IDF) published the fifth edition of its "Diabetes Atlas" in 2012, which stated that the global prevalence of diabetes stands at more than 371 million (8.3%) (International Diabetes Federation, 2012) within the 20-79 age group. It also states that:

- *"4 out of 5 people with diabetes live in low and middle-income countries".*

- *"Half of those who die from diabetes are under 60".*

- *"The number of people with diabetes is increasing in every country".*

- *"$471 billion USD were spent due to diabetes in 2012".*

According to the IDF report, known diabetes prevalence varies across the globe, with the highest reaching 10.5% in North America and the Caribbean and the lowest 4.3% in Africa. The low figures in Africa are not likely to be representative, given that 81.2% are believed to remain undiagnosed. Data for Europe indicates that there is a prevalence of 6.7%, with 38.6% undiagnosed. Globally, diabetes prevalence is expected to reach 552 million (9.9%) in the 20-79 age group by 2030. This equates to an increase of over 67% from 2012. These figures outline the growing burden of the condition across the globe and highlight the human and financial costs that remain to be addressed.

2.6   Diabetes in the United Kingdom

In 2008, a report by Diabetes UK estimated that diabetes accounted for around 10% of all NHS expenditure (Diabetes UK, 2008), equating to £9 billion per year, or £1 million every hour. This was double the 2001 estimate by the Department of Health (Department of Health, 2001), showing the impact of a rising prevalence across the UK. A subsequent report in Diabetic Medicine (Hex et al., 2012) predicts NHS annual spending on diabetes will increase from £9.8 to £16.9 billion over the next 25 years, reaching 17% of the entire NHS budget.

It is estimated in the UK that more than one in 20 people in the UK has

diagnosed or undiagnosed diabetes (Diabetes UK, 2012b). The prevalent

national diabetes population of Scotland has increased from 103,835 (2%) in

2002 to 247,278 in 2011 (Scottish Diabetes Group, 2012), representing 4.7% of

the Scottish population. 11.4% had type 1 diabetes, 88% had type 2 diabetes

and 0.6% other types of diabetes.

One in ten people in hospital have diabetes and 60% of people with diabetes

admitted as inpatients have been admitted as emergencies (National Health

Service, 2008). A study using SCI-DC data between 2005 and 2007 estimated

that admissions for people with diabetes accounts for 12% of Scotland's total

hospital inpatient costs of £2.4 billion (Govan et al., 2011, Information and

Statistics Division, 2009). The financial costs associated this figure were £26

million for type 1 diabetes and £275 million for type 2 diabetes.

In addition to the financial implications there are also the physical costs affecting

a patient's quality of life. In 2011, the Scottish Diabetes Survey (Scottish

Diabetes Group, 2012), reported that 10,496 (4.3%) of patients were reported as

having ever had a foot ulcer and 1359 (0.6%) a lower limb amputation. Lower

limb amputation rates are 15 times higher in people with diabetes than those

without (National Health Service, 2006). Diabetes is the leading cause of

blindness in people of working age in the UK (Diabetes UK, 2004). In Scotland,

68,843 (28.1%) of those with data available had retinopathy present in one or

both of their eyes, with 1,847 (0.8%) people with diabetes recorded as blind (Scottish Diabetes Group, 2012).

23,271 (9.5%) patients have a record of a previous myocardial infarction, with 12,118 (4.9%) recorded as having had a cerebrovascular accident (stroke) (Scottish Diabetes Group, 2012). Others will have had an MI or CVA but not survived as 80% of people with diabetes will die from cardiovascular complications (Diabetes UK, 2004). 292 (1.0%) of those with type 1 and 1009 (0.5%) of those with type 2 diabetes have been recorded as having end stage renal failure (Scottish Diabetes Group, 2012). In addition to these outcomes, and in some cases contributing to them, many patients maintain poor lifestyle, with 32.2% overweight (BMI 25-29.9kg/m^2), 52.0% obese (BMI 30kg/m^2 or over) and 19.1% being current smokers (Scottish Diabetes Group, 2012).

2.7   The Diabetes Audit and Research in Tayside Study

The Diabetes Audit and Research in Tayside Scotland (DARTS) project was launched in 1995, using electronic record linkage to join multiple data sources to identify all patients with known diabetes mellitus in Tayside (Morris et al., 1997). This created the first long-term conditions register of its kind within the UK, covering an entire regional population. Since manual data collection and validation began in 1996, Tayside has been in the position to provide aggregate statistics on the incidence and prevalence of diabetes and its associated risk factors. DARTS was clinically led and driven, and in addition to gaining an

understanding of the condition, the data showed how consistent clinical

diagnoses were with international standards, leading to data quality

improvement. In 1999 there were 9,005 (2.3%) people with known diabetes

registered with a general practitioner in the region (Tayside Diabetes Managed

Clinical Network, 2013). The Tayside Diabetes Network Annual Report 2012

(Tayside Diabetes Managed Clinical Network, 2012) stated an updated

prevalence figure of 20,060 (4.9%) known diabetes diagnoses.

In October 1999, the Tayside Diabetes Managed Clinical Network (MCN) website

(http://www.diabetes-healthnet.ac.uk) was launched (Tayside Diabetes Managed

Clinical Network, 2013). This website contains information contributed by

patients, health professionals and researchers and includes details of Network

team members and many of the services offered. Patient information leaflets and

electronic guidelines for the management of diabetes are available in the Tayside

Diabetes Handbook, providing regional protocols in accordance with national

clinical guidelines (Scottish Intercollegiate Guidelines Network, 2010).
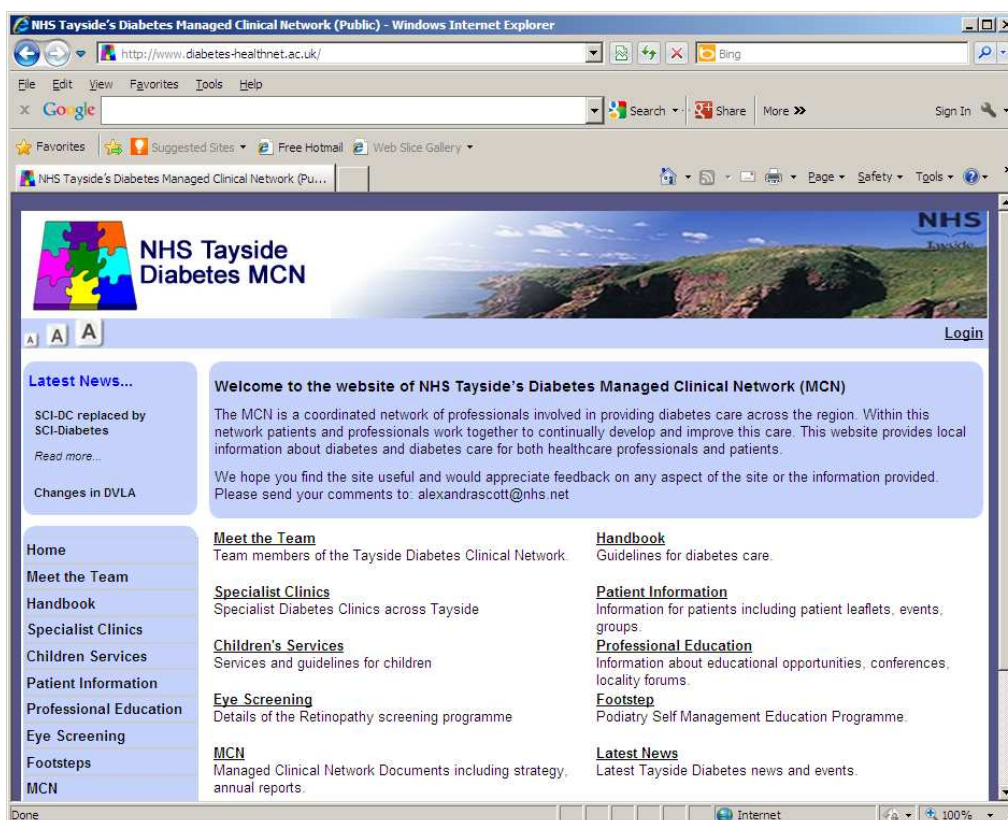
Figure 1: The Tayside Diabetes Managed Clinical Network website

The Managed Clinical Network (MCN) care model has been adopted as a vehicle

to co-ordinate chronic disease management (Edwards, 2002). Clinical Networks

are defined as: *"linked groups of health professionals and organisations from*

primary, secondary and tertiary care, working in a co-ordinated manner,

unconstrained by existing professional and health board boundaries to ensure

equitable provision of high quality and clinically effective services" (Baker and

Lorimer, 2000). The focus is therefore on organised collaboration and multi-

disciplinary team working. In Scotland, MCNs for stroke, cardiovascular disease

(Scottish Executive Department of Health, 2001b), cancer services (Scottish

Executive Department of Health, 2001a) and diabetes (Scottish Executive

Department of Health, 2002) have developed. In England, cancer networks have

reported significant benefits as a result of being able to focus on the needs of their patients, and in critical care, networks have been used to increase efficiency and responsiveness (Edwards, 2002). A key factor in the success of MCNs is the implementation of equitable "joined-up" care with the use of integrated clinical information systems that span primary to tertiary care.

In November 2000, DARTS 2000: an integrated clinical management system, developed using data from the DARTS register, was made available securely on the MCN website to all healthcare professionals involved in the care of people with diabetes in Tayside. This system aimed to provide clinically useful tools and supported continuous general practice, hospital clinic and regional-level audit which was then used to promote quality assurance of diabetes care.

Later that year, the Scottish Health Plan, *Our National Health: A plan for action, a plan for change* (Scottish Executive, 2000) identified diabetes as a priority condition for NHS Scotland. After an options appraisal was commissioned to identify the most effective method of delivering centralised information technology, the DARTS system was selected along with a hospital clinic information system (the Lanarkshire Diabetes System) as the vehicle to deliver these objectives, under the Scottish Care Information programme.

In NHS Tayside, it has been shown that information technology can play an important facilitative role in quality improvement (Greene et al., 2009). The author

of this thesis reported on experience that shows that MCNs and multi-disciplinary team-working can be supported effectively by web-based information technology while managing constantly changing clinical requirements (Cunningham et al., 2011). Further studies have shown that existing interoperable electronic health records can improve patient safety, result in more effective use of staff time and lead to more timely care for patients. In addition, socio-economic benefits eventually exceed costs and become substantial (EHR IMPACT, 2009). This particular report was however based on selected case studies and as a result cannot be seen as comprehensive.

2.8 SCI-Diabetes Collaboration

Scottish Care Information – Diabetes Collaboration (SCI-DC) (NHS Scotland, 2013, Scottish Diabetes Group, 2013b) was launched in April 2002, with the DARTS system rebranded as SCI-DC Network, to support a national rollout. The existing functionality of the original system was maintained, with patient and practice specific information available over a secure NHS connection to authenticated users.

The SCI-DC team have demonstrated sustained development and implementation of clinically useful tools for the care of people with diabetes in Scotland using data captured from ~1050 general practices, 39 hospital clinics, screening services and laboratories across Scotland. SCI-DC supports inter-disciplinary team working, patient education, professional education, a national

retinal screening programme and a suite of audit functionality for individual,

practice, regional and national reporting. It is the main source of data for the

annual Scottish Diabetes Survey (Scottish Diabetes Group, 2012), which shows

that the prevalent national diabetes population of Scotland has increased from

103,835 (2%) in 2002 to 247,278 (4.7%) at the end of 2011.

Figure 2: SCI-DC Network – Scotland's first shared diabetes record (anonymised data)

SCI-DC is based on national clinical datasets (Information and Statistics Division,

2012, Scottish Intercollegiate Guidelines Network, 1998) and supports record

linkage using the NHS Scotland unique patient identifier, the Community Health

Index (CHI) (National Services Scotland, 2013). A single-point of data entry is

supported using the 'back-population' functionality, where non-primary care data

are passed back to GP systems. This reduces the potential manual data entry error and ensures that systems are updated as quickly as possible.

Audit and reporting remains at the core of SCI-DC systems, with functionality available to assist healthcare teams and support MCNs with the implementation of local enhanced services. SCI-DC has supported the Scottish Diabetes Survey since 2001. It is arguably the most comprehensive picture of diabetes information on an entire national population outlining measures and monitors trends in support of service planning and quality improvement.

In April 2013, the SCI-DC team delivered and completed the national implementation of its latest technical product, SCI-Diabetes. This takes the functionality of its existing product base, including SCI-DC Network and the hospital record, SCI-DC Clinical, and consolidates these components using a consistent technical architecture. This work was also used as a driver for a technology refresh, which included new specialist functionality for paediatrics, dietetics, podiatry and diabetes specialist nursing. Until the advent of My Diabetes My Way, access to this rich data repository was limited to members of the healthcare team, making it a clear candidate for reuse as part of an electronic personal health record for patients. This idea forms the basis of this PhD and will be discussed in further detail throughout later chapters.
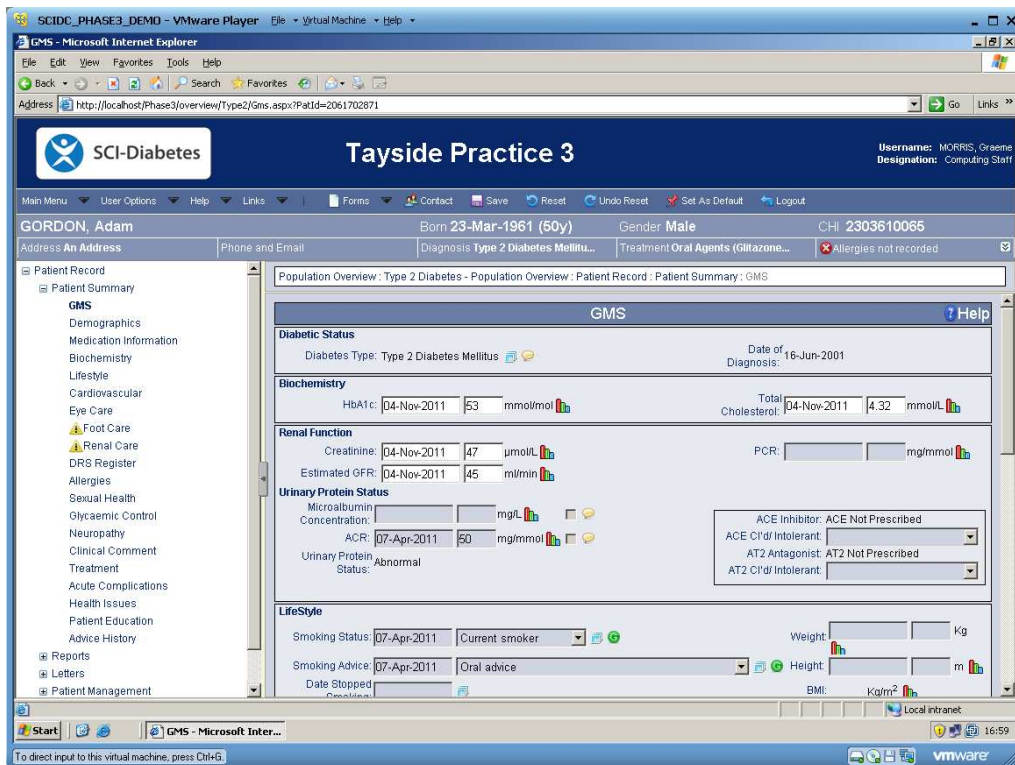
Figure 3: SCI-Diabetes – the fully integrated web-based diabetes record (anonymised data)

2.9 Scottish Government Strategy

"a person with diabetes will spend on average 3 hours with a health care professional and will take care of themselves for the remaining 8757 hours in a year" (Scottish Executive, 2005a).

A focus on early management, education, self-monitoring and complication prevention can clearly have a huge economic impact:

"for every £100 spent on encouraging self-care, around £150 worth of benefits can be delivered" (Department of Health, 2002)

With the ageing population (Scottish Executive, 2007) being at higher risk of type 2 diabetes, reducing diabetes-related complications is essential given that these already contribute to significant costs. In its report "Delivering for Health" (Scottish Executive, 2005b), NHS Scotland set out a fundamental shift in its health delivery strategy, focusing on providing care which is quicker, more personal and delivered closer to home.

The Scottish Government launched a strategy for self management with the aim of empowering patients to become partners in the decisions that affect their own care (Long Term Conditions Alliance Scotland, 2008). It states that:

"*People need information and skills to maintain optimum wellbeing*".

Kaplan and Brennan describe patients as *"the largest unused resource in health care"* and as representing a partial solution to cost and time pressures for providers and patients alike (Kaplan and Brennan, 2001). Gustafson et al. concur that encouraging patients to participate in their care can alleviate a *"critical blind spot"* (Gustafson et al., 1999).

The clinical need to improve figures related to diabetes can be assisted using appropriate technology. For example, by improving learning and education, much of which can be facilitated electronically (Nicholas et al., 2012, University of Dundee, 2013b). The Scottish Diabetes Action Plan (Scottish Government,

2010a) focused the self-management objectives for the diabetes community in three significant ways. It aimed to:

1. Encourage the optimal use of information technology to "*maximise the use of the diabetes care system by patients to enhance self management and improve patient/professional communication*" by increasing "*the number of patients directly accessing their own data electronically.*"

2. Put people with diabetes at the centre by ensuring that information is "*available in formats to meet different educational and language needs, and in formats for those with sensory and other disabilities.*"

3. "*improve the information available, for example on cardiovascular disease, on www.mydiabetesmyway.scot.nhs.uk, and increase use of the website by people with diabetes.*"

The NHS Scotland Healthcare Quality Strategy (Scottish Government, 2010b) reinforced these objectives when it outlined its three quality ambitions to put *"people at the heart"* of the NHS, provide *"the best possible care"* and make *"measurable improvement"* using 6 dimensions of quality that are:

1. Person-centred.
2. Effective.
3. Safe.
4. Timely.
5. Efficient.
6. Equitable.

These ambitions can be achieved by putting the by allowing patients to become partners in their clinical data monitoring and actively contributing to it. Services should be provided to all that could benefit based on scientific knowledge. Information should be accurate, quality assured and regularly reviewed clinically. Rapid access to contemporary clinical results for both patients, and healthcare professionals means that it is *"timely"*, while automated data capture and analysis avoids waste and duplication. Finally, services offered should not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

In 2011 the Scottish Government launched their eHealth Strategy for 2011-2017 (Scottish Government, 2011), further consolidation the existing national objectives by focusing on 6 main aims:

1. *"maximise efficient working practices, minimise wasteful variation, bring about measurable savings and ensure value for money".*
2. *"support people to communicate with the NHSS, manage their own health and wellbeing, and to become more active participants in the care and services they receive".*
3. *"contribute to care integration and to support people with long term conditions".*

4. *"improve the availability of appropriate information for healthcare workers and the tools to use and communicate that information effectively to improve quality".*

5. *"improve the safety of people taking medicines and their effective use".*

6. *"provide clinical and other local managers across the health and social care spectrum with the timely management information they need to inform their decisions on service quality, performance and delivery".*

The main objectives in this latest report which are relevant to this thesis are point 2, which encourages patients to actively participate, and point 3 which targets long-term conditions. All remaining aims can be assisted by more effective communication and enhanced availability of information, facilitated by the use of appropriate technology. This is an area in which diabetes has had an established presence in Scotland for some time.

2.10 My Diabetes My Way

The My Diabetes My Way website (Scottish Diabetes Group, 2013a) was launched in October 2008 as the official NHS Scotland portal containing validated and verified educational materials for people with diabetes, with the aim of supporting national self-management objectives. My Diabetes My Way offers two distinct resources:

1. A general information website
2. The electronic personal health record that this thesis relates to

It is essential to specify the distinction at this stage, as the section in this chapter describes only the general information website, rather than the records access intervention assessed for the author's PhD.

The general information content has been formally validated both by clinicians and patients and it includes information leaflets, videos and interactive tools. While some content has been developed in-house, validated external resources are also referenced where appropriate, to prevent duplication of effort and provide easy access to useful tools. These features help users learn more about diabetes and how the condition can be managed effectively.

My Diabetes My Way initially began as a research project named Building Information Resources for Diabetes (BIRD) which was funded by Diabetes UK, Its aim was to develop accessible and usable multimedia resources for education and self-management, while identifying relevant complementary content available on the internet. During its development, the Scottish Diabetes Group was developing a parallel website co-ordinated by its sub-group, the Patient Focus Implementation Group. This website contained videos and static information leaflets that had been identified and flagged by patients as being the "best" available nationally. My Diabetes My Way merged these two resources under the technical lead and co-ordination of the author of this thesis, prior to the official launch.
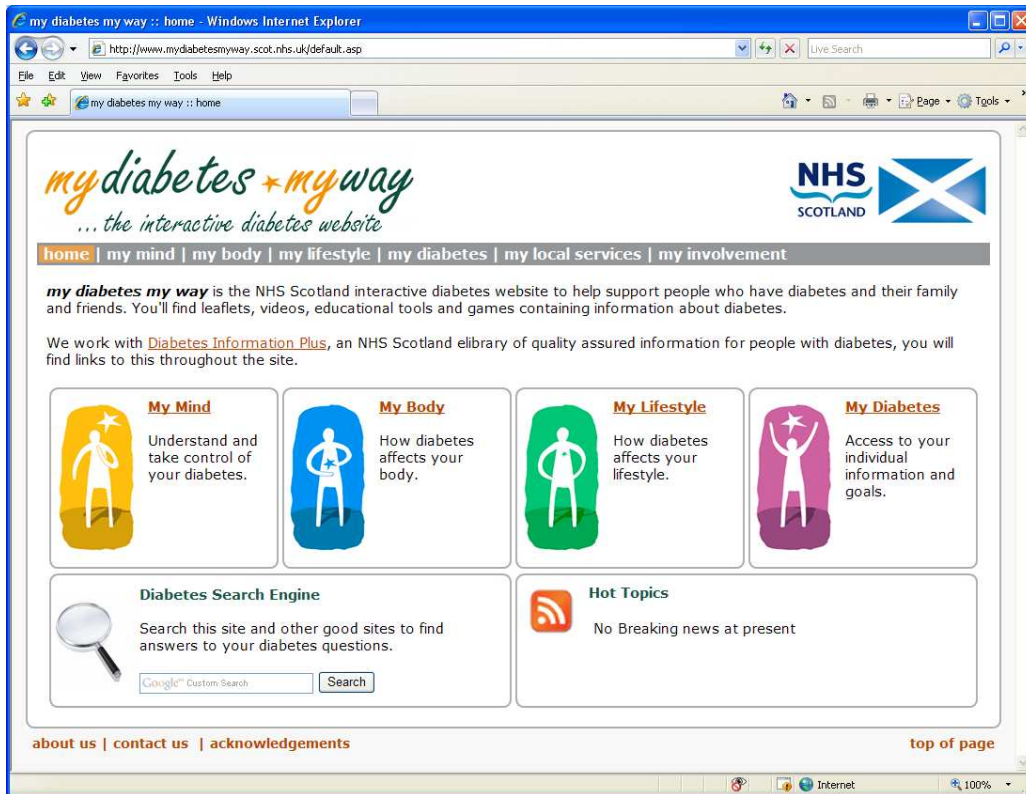
Figure 4: The My Diabetes My Way website

The MDMW website has now established a strong branding and is widely

advertised through all diabetes MCNs across NHS Scotland. Evidence of this can

be shown in the MDMW utilisation graph (Figure 5: My Diabetes My Way usage)

which has seen user activity steadily increase since its launch. Two notable

spikes in activity are also evident during this period. The first is between

December 2010 and March 2011 during which time the initial records access

pilot ran. The second spike occurs during August and September 2012, when the

Scottish Government launched an awareness campaign (Diabetes UK, 2012a).

These periods will be discussed in more details later in this thesis.
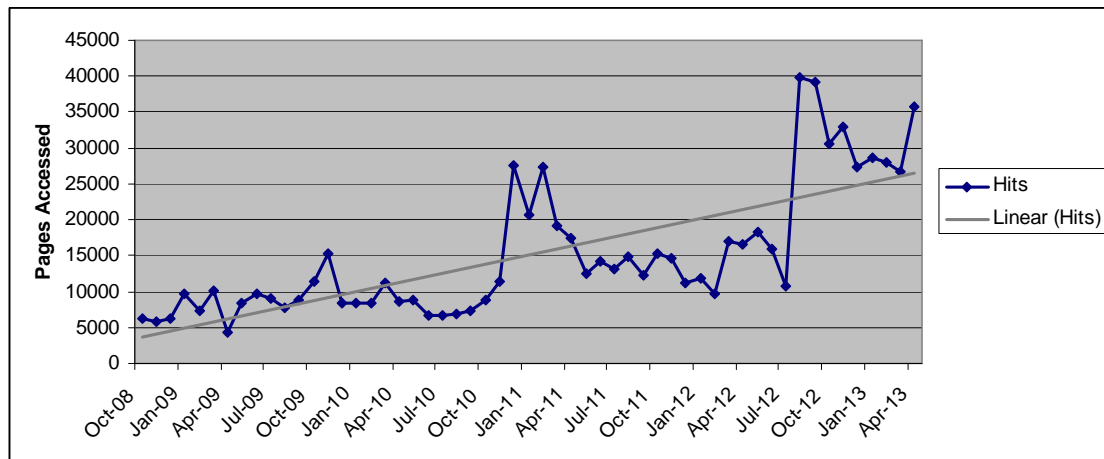
Figure 5: My Diabetes My Way usage: October 2008 to end April 2013

The combination of a rich information resource and a strong and established brand identifies the MDMW website as the ideal platform upon which to build a system to allow patients access to their own information.

2.11 Summary

In the UK, more that one in 5 people are affected by a long-term condition. Diabetes has long been known as a condition requiring significant health service resource, particularly once complications develop. The St. Vincent Declaration defined a series of clinical benchmarks which have proven difficult achieve, however, despite rapidly increasing diabetes prevalence, significant improvements have been made through effective monitoring and targeted service changes. For example, NHS Scotland has reported a 40% reduction in amputation rates and 40% reduction in sight threatening retinopathy from 2003 to 2010 (Scottish Diabetes Group, 2011), facilitated by the successful implementation of clinical networks to support diabetes services.

The Scottish Government self-management strategy has documented changes required to ensure that patients become more informed and knowledgeable about their long term conditions. This message has been reinforced within several government publications since then, including the Scottish Diabetes Action Plan, the Healthcare Quality Strategy and the eHealth Strategy 2011-2017. The My Diabetes My Way website is acknowledged by the Scottish Diabetes Group as the technical conduit to meet these objectives for the diabetes community across NHS Scotland.

This chapter has also provided an overview of some significant components that are ideal for re-use to further extend self-management in Scotland, by enabling access to a national, population-based clinical record. The most important of these components is SCI-DC, which following on from the groundwork established by DARTS, has the necessary data for the entire diabetic population in Scotland. This provides the opportunity for a novel approach to records access, which does not rely on one specific data source of data. As SCI-DC captures data from multiple sources including primary care, secondary care, specialist screening services etc, it has the opportunity to offer patients access to a diabetes-focused shared electronic record, that they can ultimately contribute to.

My Diabetes My Way has already been established as the patient information branding for diabetes in NHS Scotland, so this is therefore the ideal candidate as the entry point for the proposed records access system. Interacting with another third-party may have slowed progress and led to a solution that may not have been sustainable in the longer term.

The research completed for this PhD builds upon the existing work outlined in this chapter and the extension required in order to allow patients direct access to their own clinical information. Before documenting the system that was created and the research that was carried out by the author, Chapter 4 presents a literature review explaining current and previous developments in this area, and an outline of the research questions formulated, and their rationale.

Chapter 3:   Overview of eHealth

"I don't care whether I belong to primary or secondary care ... I just

want a service that covers all my needs"

Patient representative, NHS Tayside

3.1   Introduction

The advent of consumer and industry-standard technology has brought dramatic

changes since the early nineteen-nineties, with these technologies becoming

rapidly more commonplace throughout interactions in day-to-day lives. The

ubiquitous nature of these devices, transactions and services mean that it is quite

possible to be dealing with technology without even realising it. These

technologies aim to speed up daily interactions and ensure that delays,

inefficiencies and poor service become a thing of the past.

One notable example of this form of intervention can be found in the banking

industry. At one time, all transactions were handled using systems based around

human interaction, paper and microfiche, while now electronic services are

abundant. A similar expansion can also be observed in commerce, where it is

now possible to obtain products and services online and payments are made

using credit cards, rather than cheques and physical currency.

Health services worldwide are no different, and while in many areas human interaction remains prevalent, there are many good examples of electronic services designed to make patient and clinical interactions more streamlined.

3.2   Methodology

The following chapter aims to describe, using a high-level narrative, the current understanding of the term 'eHealth' and how it continues to evolve and expand. As with the previous chapter, this chapter is not intended to deliver a systematic review of the literature in this area. Instead it aims to provide an overview of the term from the grey and research literature, in order to provide some background and introduce and inform the literature review. It begins by defining what is understood in the literature by the term 'eHealth' and continue by describing many of the multitude of areas that are understood to contribute to it.

3.3   Definitions of eHealth

Historically, the delivery of healthcare has been based around paper case notes (e.g. health records, discharge summaries, etc), which in many cases provided an incomplete picture of the patient story. This would lead to the duplication of data recording in unlinked, disparate silos, which could not easily be joined. Electronic technology has the potential to bring health care into the 21st century, reducing inefficiencies and leading to the creation of a new overarching term 'eHealth'.

Electronic Health, or 'eHealth', is the term used to describe interactions with health services that can be performed using computer-based communication technologies. It evolved from telemedicine and telehealth where telecommunication is the delivery method for health care (Hovenga et al., 2010). Many have argued around the precise definition of the term 'eHealth', and how far it extends.

The first definition was coined in 1999 by Mitchell (Mitchell, 1999) who stated that it was *"a new term needed to describe the combined use of electronic communication and information technology in the health sector"*, comprising *"digital data - transmitted, stored and retrieved electronically"*.

Eysenbach expanded on this further to focus on Internet-based technologies and described eHealth as *"referring to health services and information delivered or enhanced through the Internet and related technologies."* (Eysenbach, 2001). A non-systematic analysis conducted in 2005 (Pagliari et al., 2005) concluded that this definition accurately reflected the situation at that stage in its evolution. Over subsequent time, the definitions have changed to consider advances in healthcare and new examples of the application of technologies. A systematic review on the topic explained that *"eHealth encompasses a set of disparate concepts, including health, technology, and commerce"* and that it involved several stakeholders, roles, locations and expected benefits (Oh et al., 2005).

The World Health Organisation (WHO) referred to eHealth simply as "*the use of ICT* (information and communication technologies) *for health*" in its 2011 Atlas of eHealth country profiles (World Health Organization, 2011). Despite the evolution of eHealth and the lack of a clear consensus on its definition, it is apparent that the term can, and has, been used to describe any joined-up application of electronic-, or computer-based technology within a healthcare environment. The WHO definition has been adopted for this thesis chapter as it places least restrictions on the types of acceptable communication, connectivity and storage.

eHealth encompasses many areas, including health records for professionals and patients, telehealth interventions, education and learning, mobile technologies and research. It can be used to support point-of-care clinical services operated by health care teams, or by the patient themselves in order to support their own self-management. Carers can also use eHealth services to assist them in obtaining necessary information and data when necessary. There are no limits to its application, assuming that it continues to meet the broad definition outlined above.

3.3.1 Objectives

There are several key objectives aspired to by eHealth systems. They can support consistent implementation of best practice leading to better services and better treatment, in turn leading to improved clinical outcomes, quality of life and life expectancy for patients.

Examples:

eHealth can be used to support systematic assessment and treatment using coherent approaches e.g. those that achieve through consensus guidelines. For example, a clinical system may implement a standard screening and assessment tool for a particular specialty, which when used by all involved in patient care will lead to a consistent approach. These systems may then be altered consistently for all users should clinical guidance change in future.

High quality, rich data sources can lead to improved performance by healthcare teams and benefits to patients. With the right information being made available at the right time and in the right place, appropriate decisions regarding care are more likely to be made. This is an essential requirement, particularly while there is a drive towards equality of access, regardless of physical location (urban and rural), socioeconomic status or demography. Patients can potentially benefit through a reduction in interaction with physical services (inpatients, outpatients, routine appointments), when traditional boundaries are replaced by electronic services.

The use of eHealth is not restricted to the clinical environment for use by healthcare teams. Patients and their carers can also make use of these technologies at home, work or while they are on the move, exactly as they would for commerce or banking.

Patients are currently the most underused resource in health care, and the ones with the most to gain from improvements. Engaging with eHealth provides a vehicle to empower and motivate patients, giving opportunity to take wider ownership and control over their own health.

In addition to the examples described previously, there are many other applications of electronic communication technologies within health services worldwide. The following section describes examples of some of the more common and innovative uses.

3.4   Applications of eHealth

The following section describes how eHealth technologies may be applied within the clinical and patient context. This section focuses on some of the hardware and software technologies available, how they have been applied to support data linkage, presentation, usability and accessibility.

3.4.1 eHealth Technologies

Much of the technology used in eHealth applications is already found around us in our daily lives. Most resources are either accessed or driven using personal computers, laptops, mobile phones or tablets. Many pharmacies and health providers also offer small scale technology devices e.g. home blood glucose and blood pressure monitors that patients may use to understand their clinical process outcomes and share them with their clinical teams (Diasend Inc, 2012).

More high-tech telehealth devices are being used to record multiple clinical measurements at one time (e.g. record heart rate, temperature, detect motion etc), before transmitting them electronically to members of the healthcare team for remote analysis and follow up (Benezet-Mazuecos et al., 2007, Dinesen et al., 2012). These types of intervention can improve patient satisfaction, by limiting the need to interact with clinics or surgeries through effective remote monitoring. They can also save considerable amounts of time and money and improve patient safety when used appropriately.

eHealth in its simplest form could be a computer check in on arrival at an appointment or an information kiosk used for health information delivery e.g., at health centres and hospital clinics. It may also replace reliance on these facilities altogether, with teleconsultation systems being shown to be reliable and cost-effective alternatives (Verhoeven et al., 2010). All of these potential uses can improve patient experience and potentially improve cost-effectiveness due to a reduction in traditional face-to-face services.

3.4.2 Software and Data Linkage

The software components of eHealth comprise a multitude of applications. Health care is gradually phasing out paper based systems in a drive to go 'paper free', or at worst 'paper light'. Multifunctional, linked electronic systems have the ability to allow health care providers to find the relevant information necessary to treat patients at the point of care. Although not currently widespread practice worldwide, this is a fundamental aim and aspiration of modern healthcare

systems, ensuring that data are no longer residing in stand-alone silos. Sophisticated data linkage techniques and clinical portals should allow a health care professional to be able to find all of the information required to treat a patient appropriately. In turn, this should mean that clinicians are no longer required to log in to multiple systems or remain fearful of missing a crucial piece of information. Duplication of effort is also reduced, as a clinical result recorded in one healthcare environment may be made available to the wider healthcare team. For example, a blood pressure recorded at a cardiology screening has just as much relevance to the diabetes services when looking at the data collected for the patient as an individual. These advances lead to a more efficient and data-driven delivery of care.

The delivery of these *"joined up"* applications relies on the transfer of data so that it is available where and when it is required, in a format that is appropriate. Many clinical systems rely on structured coding systems such as SNOMED-CT (International Health Terminology Standards Development Organisation, 2012) and Read Codes (NHS Connecting for Health, 2012) as the nomenclature upon which clinical conditions are described. To facilitate the movement of these data, Health Level Seven (HL7 (Health Level Seven International, 2012)) provides standards for the interoperability of healthcare applications. Its framework and standard for information exchange, sharing and retrieval aims to support *"clinical practice and the management, delivery and evaluation of health services"*.

These frameworks are amongst many used in clinical applications to join systems, and their data together. Many traditional healthcare applications resided in silos that would not communicate beyond their clinical or organisational boundaries. Data integration, transformation and loading techniques enable services to be developed to break down these boundaries.

Example:

NHS Scotland has developed a shared electronic record for diabetes care (Cunningham et al., 2011, NHS Scotland, 2012) which facilitates the collection of data from multiple sources within primary, secondary and tertiary care into one fully consolidated, patient-focused view of diabetes, covering an entire national population. The data can then be viewed by all authorised users at the point of care, therefore avoiding any duplication of effort. SCI-DC systems are described in more detail later in this thesis.

Legacy systems have previously been designed to operate in a batch processing environment, where incoming and outgoing data are identified and processed at regular schedules, potentially leading to scheduled maintenance windows where system access is restricted. More modern approaches focus on real-time, high availability systems with minimal disruption, aiming for the availability of user access 24 hours a day, 7 days a week. The design of these systems are generally based on agreed user requirements, but clearly, access to essential and mission-critical systems are likely to fall into the latter category, where 'up-time' is maximised.

An alternative to this data collection approach is to provide a 'window' into existing systems, using clinical portals. An example is the NHS Wales Clinical Portal (NHS Wales Informatics Service, 2012) which aims to provide more information to doctors when they are treating their patients. Rather than transferring data and consolidating it into an overarching electronic patient record, web services have been developed to obtain a view into relevant systems to provide an overall picture of a patient's condition. The Welsh portal claims benefits including improved efficiency and an increase in positive patient outcomes via a system that requires a single log in. Prior to this initiative, in order to capture the same level of detail for a patient, access to multiple systems would be required, taking time, granting of access rights and the ability to remember a variety of authentication credentials.

3.4.3 Data Presentation

The presentation of clinical data is another key consideration. In the UK, Microsoft has developed a common user interface for health (Microsoft Corporation, 2010), which aims to *"address a wide range of patient safety issues faced by healthcare organizations worldwide."* It has published a series of guidelines and best practices for data presentation to ensure that data are shown in a consistent way, regardless of the underlying development platform. Examples include guidance on how prescribing data entry may be implemented and the core components of a patient banner, containing the most pertinent patient demographics. This means that, if widely implemented, users will know

where to find the information they require regardless of the system they are using, without the need to learn inconsistent navigation structures, layouts and user options.

One of the main difficulties identified in presenting and capturing information is how to convey a patient's risk of developing certain complications. "Risk Communication" is defined as the open two-way exchange of information and opinion about risk, leading to better understanding and better decisions about clinical management (Eysenbach, 2000, O'Connor et al., 1999).

Problems with 'risk language' have been identified where one patient's interpretation of a word may be different from another's. For example, one person's understanding of "likely" may be a chance of 1 in 10, whereas another may think it means a chance of 1 in 2 (Edwards et al., 2002). Attempts have been made to standardise interpretations of this kind of ambiguous language to promote a more accurate perception of risk.

Further problems with data presentation can be made when 'framing effects' are taken in to consideration. These can be described as presenting logically equivalent data in different ways. For example, data can either be expressed as 'death rate' or 'survival rate', with 'positive framing' (survival rate) proving more persuasive (Edwards et al., 2002).

3.4.4 Usability and Accessibility

It is one requirement to create a system or resource that people can access, but another extremely important requirement to ensure that it is usable and accessible. Usable systems can be utilised with the minimum amount of training, are intuitive and do not contain elements unfamiliar from previous computing experience. Due to the large number of potential data that may be shown, it is important to ensure that this doesn't detract from the overall experience or cause frustration. Usability leads to increased user satisfaction and is vital for the success of any system.

Accessibility means a website is designed in such a way that all members of the user community will be able to view the information regardless of physical or sensory ability. It also calls for simplified language to accommodate users with intellectual or communication difficulties. For an example, it may be as simple as offering enlarged text options or supporting screen readers and having the ability to "save" settings for future use.

3.5   Decision-making and eLearning

Continual learning is a key need for healthcare teams and patients as they aim to obtain optimal care and knowledge about relevant conditions. While information would traditionally have been provided using paper leaflets, journal articles or textbooks, a multitude of information can now be obtained electronically. Interactive CDs and DVDs have come and gone, with most replaced by websites,

such as My Diabetes My Way described later in this thesis. It is therefore important to ensure that users of these websites know where to find them, and don't stumble across unvalidated or unverified resources which may contain questionable information, or links and advertising which may cloud the learning process. If people are relying on the Internet to make treatment decisions, including whether to seek care, deficiencies and variability in information could negatively influence decisions (Berland et al., 2001, Shepperd and Charnock, 2002).

Information technology and the ability to allow patients to access medical information via computers are becoming integral parts of the modern concept of healthcare. The Internet offers consumers an unparalleled opportunity to acquire health information (Licciardone et al., 2001) with health-related web-sites being some of the most commonly used on the Internet (Wilson, 2002). People want the same services in health care that are now available via the Internet within the financial services industry (Kaplan and Brennan, 2001). The Internet provides consumers with access to a wide range of health information and services allowing access the same information online as those directly involved in their care (Essex, 1999). Patients have ample opportunity to become informed of their condition (Calabretta, 2002) and appear to be positively inclined towards on-line solutions as they can offer breadth, depth and timeliness currently unattainable through other media (Tetzlaff, 1997). Studies have found that the greatest interests of patients using the internet was to find information about a disease,

medication, the questions they should be asking during a consultation and information to enlighten their health care decisions (Sciamanna et al., 2002). Potts and Wyatt also polled 748 doctors and found that they believed that social support was another key benefit to patients (Potts and Wyatt, 2002).

3.5.1 An Evolution in Healthcare Decision-making

For at least forty years, informatics development has assumed the superiority of the patient-provider consultation and applications developed have been based on the needs of providers (Kaplan and Brennan, 2001). The focus of healthcare has shifted from this paternalistic approach, to one that is more consumer-oriented. Health service consumers that are better informed tend to understand and act upon instructions, while asking more insightful questions (Eysenbach, 2000).

Despite a strong international trend shift towards 'shared decision making', many consumers still find themselves interacting with health care providers who are in favour of the classic paternalistic model of consumer-provider interaction. In other cases, consumers face providers advocating the 'informed choice' where consumers make the decision themselves after being given the necessary information by the care provider (Eysenbach and Jadad, 2001, Shaddock, 2002). An informed patient is one who is likely to waste less time, understand decisions and modify behaviour (Landro, 1999).

Shared decision making is the concept of allowing patients to become active participants in the decision making process, with two-way exchange of data

(Eysenbach and Jadad, 2001). Incorporating computer systems into this model facilitates a 'patient-provider-information technology partnership', a virtual, rather than physical health care structure and health care as an integrated part of one's life (Kaplan and Brennan, 2001). It is important for clinicians to educate their patients in order to encourage empowerment (Weed, 1997). Patients can afford to focus narrowly on their own conditions and, with first-hand experience of living with a disease and its symptoms, they can ultimately become specialists in their illness (Calabretta, 2002).

3.5.2 Consumer Health Informatics

Consumer Health Informatics is a rapidly developing area of research which has been placed as a subset of Medical Informatics (Tetzlaff, 1997, Kaplan and Brennan, 2001). It has been defined as *"the branch of medical informatics that analyses consumers' needs for information; studies and implements methods of making information accessible to consumers; and models and integrates consumers' preferences into medical information systems"* (Eysenbach, 2000).

What differentiates consumer informatics from its parent discipline is not so much the technical aspects, but the users served. Medical Informatics professionals are accustomed to focusing on the needs of providers and a different perspective, encompassing other specialties, may be required to develop products specifically for consumers (Tetzlaff, 1997, Kaplan and Brennan, 2001).

3.5.3 Patient Education and Behaviour Change

Email and SMS messaging interventions have the ability to reach groups that are difficult to engage with. 'Sweet Talk' is a text messaging system providing motivational messages to young people with diabetes which reported improved self-efficacy and adherence to medication (Franklin et al., 2006). 'txt2stop' provided a similar support system to aid smoking cessation (Bennett and Emberson, 2011, Free et al., 2011). A systematic review of SMS reminder systems found that these systems lead to improved attendance rates when reminders are send prior to appointments (Hasvold and Wootton, 2011). Furthermore, a recent randomised controlled trial based around electronic messaging, data upload, patient reported data and personalised advice achieved improvements in HbA1c (Tang et al., 2013). Other successful approaches to self-management have included online peer-support, personalised coaching and goal setting (Ramadas et al., 2011). Further discussion of behaviour change methodologies is provided in Chapter 4.

3.5.4 Patient Participation

The Internet is now much more than a communication medium and patients now use it to manage their health. This is in spite of the fact there has been little evidence produced regarding the effect of its use on health outcomes and status (Giménez-Pérez et al., 2002, Bessell et al., 2002). According to Tetzlaff (Tetzlaff, 1997), websites designed specifically for the patient should be sensitive to the simultaneous need for hard information and emotional support.

Examples of electronic health records were provided earlier in this chapter, allowing healthcare teams to manage health using secure clinical information systems. Joined-up approaches lead to a more cohesive healthcare environment from which the patient has great potential to benefit. Recent developments have focused on initiatives to allow patients to become active participants in their own care and redress the balance of their position as the most underused resource in health care. Interaction with a personal health record allows patients to do this, meaning that they can review results recorded in the trusted clinical care provider setting, while contributing those they have recorded themselves at home. Examples of Personal Health Records will be explored in detail during Chapter 4 of this thesis.

When adults with little or no functional speech due to severe physical impairments are admitted to hospital it can be a difficult and traumatic experience. Research indicates that communication breakdown between patients with severe speech and physical impairments and hospital staff who care for them results in preventable accidents while in hospital (Zinn, 1995). Paper care books, providing information on the needs and habits of disabled patients are currently the most commonly used method for improving communication. These are generally overlooked by nursing staff, and patients themselves feel they are of little, if any use (Prior, 2011). Enhanced electronic patient profiles have the potential to improve healthcare delivery for these patients. The CHAMPION project (Prior, 2010) explored the feasibility of enabling disabled adults to input

information on their own care needs into a database using a combination of text, video and photographs. This technology makes it possible for a 'healthy' disabled patient to, for example, upload a video showing them using their communication device so that medical staff can interact directly with them when they are in hospital.

3.5.5 Decision-Making

Continual learning for both patients and health care staff is an obvious objective and one to which eHealth now contributes significantly. Continuing professional development for staff is now facilitated regularly using online eLearning courses. Add to this the fact that clinical guidelines and standards are now published online, and in some cases linked to the clinical systems in day-to-day use, the potential for the acquisition of knowledge and decision support is without limits using technology. Ever more sophisticated decision making software continues to emerge. These can aid clinical decision making in real time, embedding evidence based practice for populations into applicable treatment decisions for individual patients, alerting the clinician when management may need to be changed (Heselmans et al., 2012, MedicExchange.com, 2012).

The same concept is applicable to patients and carers, with an abundance of information websites describing the symptoms, details and prognosis for various acute and long-term conditions. These systems are gradually advancing to a comparable level of detail to those used by clinical peers, but significant revision is required to take clinical guidance into the lay field. These systems guide the

patient through medical options and elicit their preferences in order to facilitate choices or shared decisions about treatment (Reisman, 1996, O'Connor et al., 1999). Decision aids contain explicit components that enable users to clarify their values and preferences. These values, used alongside the scientific evidence and historical records, can then be used to identify what care path the patient should follow (Eysenbach, 2000). Simple technology with embedded clinical care algorithms are currently being used successfully to direct patients to the most appropriate clinical services for their needs (NHS 24, 2012). The challenge of using this technology in longer term disease management is not insurmountable and several good examples are freely available online.

3.5.6 Social Media

Further online learning and peer support is available via social media websites such as Facebook and Twitter where on-line groups have been set up by healthcare organisations for the exchange of information to aid self-management (Diabetes UK, 2013, British Medical Journal, 2013). Psychological support is also provided by allowing individuals to liaise with others who may be experiencing similar conditions. Peer learning can be taken further when integrating directly with clinical records. PatientsLikeMe is one example of this approach, where people with long-term conditions are already being paired with each other in order to provide personal support and first-hand testimonials (Wicks et al., 2011). The aims are to pass on the benefit of experiences within healthcare services and to reassure the wider community that help is at hand when required (Sahama et al., 2012).

3.5.7 Secondary Data Use

Electronic systems capture vast volumes of data that may be exploited for public

benefit, to enhance the clinical evidence base and to provide benchmarks from

which to influence change and service improvement. Clinical audit occurs at all

levels of health care from distinct clinical location (e.g. hospital clinic, general

practitioner surgery), sub-regional, regional, national and international levels

(International Diabetes Federation, 2011, EUBIROD Consortium, 2012). Indeed,

by using personal health records, patients can effectively employ self-

assessment audit on their own conditions by monitoring their own clinical

outcomes such as blood results and lifestyle factors.

Clinical research networks are being formed worldwide (National Institite for

Health Research, 2012, SDRN, 2012) to support the secondary use of clinical

data in epidemiological research and clinical trials (Govan et al., 2011, Colhoun,

2009). Use of data in this way requires the secure linkage and anonymisation of

data from relevant datasets, prior to analysis. This process does not detract from

the quality of the data being analysed, but ensures that the identities of those

whose records contribute are protected. The following section discusses some of

the most important considerations when handling sensitive electronic clinical

records.

3.5.8 Information Security and Governance

Clinical systems contain a variety of information, much of which is personally

identifiable and may cause vulnerability or harm to patients if it were to be leaked

into the public domain or used inappropriately, especially if it is particularly

sensitive, for example, in relation to mental health (Ennis et al., 2011).

It is the responsibility of those developing information systems to ensure that they

transfer, process and hold data securely. Industry-standard encryption

techniques are now in common use, including Secure Sockets Layer (SSL)

(Internet Engineering Task Force, 2011) which is used widely in web-based

applications across other industries handling sensitive personal data.

It is essential to ensure that users of clinical information have access to the data

they require to do their jobs. Many systems now offer role-based access where,

for example, a podiatrist looking after a patient with diabetes can access relevant

data and functions, while a dietician using the same system, may use a different

subset of functionality, specifically focused on their requirements. In addition to

applying access control, user activity must be closely monitored. A system audit

trail will log user operations, record accesses, search criteria and any other

relevant action initiated by an individual when using information systems as part

of their routine tasks. It is therefore possible to analyse usage patterns and

identify incidents and trends of inappropriate activity. It is not sufficient simply to

log these data, so proactive interrogation and retrospective review is essential to

maintain levels of accountability. Specialist software is available within healthcare

to allow activity within clinical systems to be monitored and any privacy breaches

to be detected and subsequently escalated (McAfee., 2013, FairWarning, 2013).

With the proliferation of mobile devices discussed earlier, safeguards are required to ensure that the contents remain secure and that access to eHealth systems remains uncompromised. Many devices are now routinely encrypted using techniques such as Pretty Good Encryption (PGP) (Zimmerman, 1995). Alternative software allows devices to be remotely wiped if lost or stolen, further enhancing the safety of these data.

In addition to the implementation of these technical safety measures, system users have a professional responsibility to ensure that they do not abuse their rights. Information Governance (NHS Connection for Health, 2012) is generally described as a framework of accountability for the appropriate use of data, including how it is processed, used and shared for the benefit of the organisation and individuals that it serves. While the specific details of these accountability frameworks may vary by organisation, the underlying principles remain the same, and it is the responsibility of the individuals accessing information to ensure that they are doing so appropriately.

The Department of Health in England and Wales published a set of information standards regarding the use of clinical data. The Caldicott Report (Department of Health, 1997) documented six key principles:

- Justify the purpose(s).
- Don't use patient-identifiable information unless it is absolutely necessary.

- Use the minimum necessary patient-identifiable information.

- Access to patient-identifiable information should be on a strict need to know basis.

- Everyone with access to patient identifiable information should be aware of their responsibilities.

- Understand and comply with the law.

Following a review of these standards in April 2013 (Department of Health, 2013), a seventh "Caldicott Principle" was defined:

- The duty to share information can be as important as the duty to protect patient confidentiality.

This new principle is further qualified by stating that professionals should have the *"confidence to share information in the best interests of their patients within the framework set out by these principles"*. This was perhaps in reaction to the perception that the original legislation often acted as a barrier to the appropriate sharing of medical data.

In the UK, the Data Protection Act (HM Government, 1998) defined the law for the processing of identifiable information on living individuals. In June 2012, an NHS Trust in England was fined £325,000 (Information Commissioner's Office, 2012) by the Information Commissioner's Office as a result of a serious breach of the Data Protection Act. It is clear therefore that "*Public health information*

systems should be carefully engineered only after a clear strategy for privacy

protection has been planned' (Di Iorio et al., 2009).

3.6   eHealth Challenges

Despite the documented aims and benefits of eHealth technologies, it is

important to discuss some of the underlying barriers that may affect successful

implementation. Although exposure to technologies and internet access are

rising (Office for National Statistics, 2011), gaps still remain to provide solutions

that are universally acceptable and usable.

For some, embracing new technology leads to difficulties caused by lack of skills

or interest in developing necessary competence to fully utilise relevant

interventions (Milewski and Chen, 2010). There is a risk of widening the gap

between those who have access to new technology and those who do not

(Pencheon, 1998) with disadvantaged individuals within society having the

poorest health and worst access to information (Eysenbach and Jadad, 2001).

Access to appropriate information is in many cases most difficult for those who

need it most (Eysenbach, 2000). A 'digital divide' can refer to inequalities

between socioeconomic groups and individuals and may cause significant

barriers. Clearly consideration must be given to the diversity of patients and

healthcare professional groups at an early stage in the design process.

Disadvantaged groups are most at risk, particularly when technology creates more barriers than it aims to resolve. Those with visual or physical impairment can potentially benefit from technologies, but only if systems allow them to do so by providing tools, e.g. screen reading technology and system shortcuts, to aim human-computer interaction.

It is important that technology use in health is driven by appropriate, genuine need, rather than human desire to use the latest devices and gadgets. For example, although many would prefer to interact with patients using smartphones, the reality is that this would alienate a large proportion of potential users. This is particularly obvious in less affluent countries, where second generation mobile phones are still the most prevalent. In these environments, an appropriate mobile intervention is more likely to have the widest impact if it is based around SMS messaging as opposed to multimedia messaging or smartphone apps.

Most systems, particularly in a clinical environment, support only one language and multilingual capabilities are not available. In countries where there are a variety of first languages, this is significant concern as it may again raise more barriers than those that are broken down. The ability to self-manage may be affected by culture and language which influence an individual's beliefs, attitudes and health literacy (Nam et al., 2011).

3.6.1 Health Literacy

Health literacy has recently been gaining more interest and profile in the peer-reviewed literature. Both health and general literacy levels must be borne in mind when developing eHealth systems, as if they are not used or interpreted correctly, they are likely to lead to disengagement or possibly harm. Clinical outcomes may actually deteriorate in some groups as health systems rely increasingly on internet-based resources (Sarkar et al., 2010, Sarkar et al., 2011).

Health literacy has been defined as:

"The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make [informed] health decisions." (Institute of Medicine, 2004)

Low health literacy also frequently impairs the understanding of health messages and limits the ability of patients to deal with their health problems, often leading to poor outcomes even when the data presented is of high quality (Eysenbach and Jadad, 2001, Potts and Wyatt, 2002). In an elderly population, limited literacy has been shown to be associated with worse self-rated access to care, lower self-rated health, higher rates of some chronic diseases and higher mortality (Sudore et al., 2006). People with diabetes who have limited literacy and who attend public hospitals are more likely to have poor glycaemic control and/or complications (Schillinger et al., 2002).

Poor health literacy has been shown to impact negatively on the face-to-face clinical consultation. It impedes the understanding of technical information and explanations of self-care (Fang et al., 2006) and impairs shared decision-making (Schillinger et al., 2004). The speed of dialogue, extent of jargon and lack of interactivity are determinants of effectiveness of communication (Castro et al., 2007). It also impairs the communication of information about medications, therefore jeopardising patient safety (Schillinger et al., 2003)

3.7   Summary and Conclusions

This chapter has described the growing area of eHealth, explaining how it has been defined and the tools and technologies that contribute to it, before highlighting several examples of existing best-practice and legal responsibilities. It has described how the healthcare decision-making has evolved from a 'paternalistic' model to one where the patient is firmly placed in the centre. This has implications, particularly with the patient having more responsibility for their own care and interacting with technologies designed to enhance self-management.

The need for improved interactions and self-management tools are obvious, as people are living longer worldwide (World Health Organization, 2012b) and the burden on health services continue to rise despite limited resources as discussed

in Chapter 2. While technology can be used to drive efficiency improvements and lower costs, it may also exclude disadvantaged groups.

eHealth should not be seen as a separate entity associated with health and healthcare, but a key component part. As technology advances and it becomes even more embedded within our day-to-day lives, using technology to manage our health will be an expected part of health service provision. So much so that the distinct term 'eHealth' will gradually fade into insignificance, as the terms 'eCommerce' and 'eBanking' have done previously. The technologies will continue to prosper and evolve as a fundamental building block underpinning quality care, but the demand for these services will make it simply part of 'health' in the 21st century. Chapter 4 builds on the background information presented in chapters 2 and 3 to deliver the formal review of literature regarding personal health records.

Chapter 4:   Literature Review and Research Outline

"More information available to me means I can play a more positive

role in my treatment"

Feedback from a My Diabetes My Way registrant

4.1   Introduction and Aims

Since the early 1980's, there has been growing momentum in allowing patients

access to their medical information, data that were traditionally only available to

members of the healthcare team. Much of this drive is due to the evolution of the

patient-provider healthcare model and the increased focus on self-management

to ease the burden of long-term disease as highlighted earlier in this thesis.

While early records access focused mainly on the ability to view paper notes or

receive copies of letters, more recent, innovative systems offer electronic access

to data, with some containing data sourced directly from provider electronic

medical records (EMRs). There are several examples of these types of systems

worldwide, described as 'Patient Accessible Electronic Health Records'

(PAEHRs) and also those referred to as electronic 'Personal Health Records'

(PHRs). The author has selected internet-based electronic personal health

records as the area of study for this thesis for the following reasons:

- There is the strategic will (as discussed earlier in this thesis) to make

  these come to fruition within NHS Scotland.

- In the author's current specialty area of diabetes informatics, the core components (SCI-DC, My Diabetes My Way) are in place to help make this a reality.

- The author has an interest in helping patients to help themselves by improving their knowledge, motivation, empowerment and ultimately their own self-management.

This aim of this literature review is to detail the evolution of patient records access, sourcing information from the relevant peer-reviewed and grey literature. It documents the key considerations when developing these types of system, along with the results and outcomes reported. This chapter concludes by highlighting the areas in which evidence is lacking so as to inform the development and rationale behind the research questions. This review documents the current evidence on personal health records, by assessing:

1. What are the effects of personal health records in support of patient self-management?

2. Which patient groups are most likely to access their medical record?

3. Do personal health records have any negative effects?

4. What are the attitudes of patients and healthcare professionals towards personal health records?

5. What is the most effective delivery method for a personal health record?

6. What legislative and security standards must electronic personal health records conform to?

4.2   Methodology

The methodology used by the author to carry out this systematic review of the literature was based on the guidelines published by the Centre for Reviews and Dissemination at the University of York (Centre for Reviews and Dissemination, 2013). The article inclusion criteria are based on the methodology detailed below.

The articles used to assemble the information documented in this review were gathered from a number of sources. Systematic searches were performed on the MEDLINE, CINAHL Plus, PsycINFO and Library, Information Science & Technology Abstracts (LISTA) databases using the following search terms:

- 'personal* health* record*'.
- 'record* access*'.
- 'patient* access*'.
- '*PHR' (common abbreviation for 'Personal Health Record' or 'Patient-Held Record').

In addition, the reference lists of review papers were scanned by the author for relevant studies. Using these search terms and further references, 1555 articles were identified via the NHS knowledgebase (www.knowledge.scot.nhs.uk). These were immediately reduced to 1221 by removing exact duplicates. Following a review of the titles, 597 candidate papers were highlighted and these were further reduced to 372 following review of abstracts. Subsequent review of

full articles deemed 220 relevant and suitable for further analysis and reference in the following literature review. All analysis was performed by the author and references were catalogued using the software product Endnote X4.

Articles Identified n = 1555	**Duplicates** n = 334
Articles after removing duplicates n = 1221	**Excluded based on title** n = 624
Articles after review of title n = 597	**Excluded based on abstract** n = 225
Articles after review of abstract n = 372	**Excluded based on full text** n = 152
Articles included in literature review n = 220	
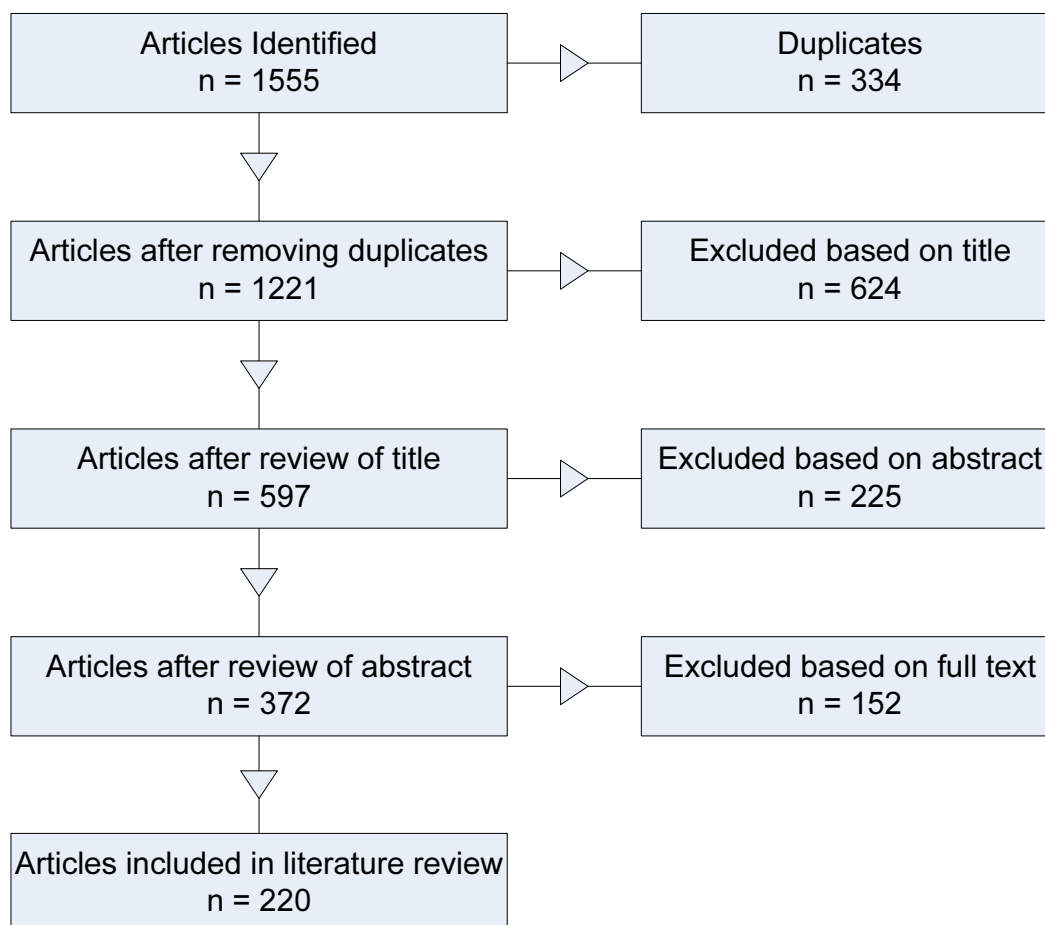
Figure 6: Literature review search strategy

Articles were deemed relevant and selected if they referred to patient access to their medical information via any means, whether that was via modern electronic means, or historical paper-based methods. As such, no date restrictions applied. There were also no restrictions placed on the methodology used and conference abstracts were acceptable, with limitations are highlighted where relevant during this chapter. The review was completed at the end of April 2013, so articles

published from May 2013 were beyond the scope of this thesis. No exclusion

criteria were placed over the country in which the research was generated

although all journals used to collate the review were English-language journals.

Although it is acknowledged by the author that this may lead to bias, analysis of

non-English studies was not possible due to lack of resources including facilities

for translation.

While some results did relate to records access, the search term "patient*

access" mostly returned most results referring to access to healthcare and

hospital services. Similarly, the search term '*PHR' provided a number of results

related to genetics and biology and these, like the service-specific examples

above, were excluded.

Articles referencing non-internet-based PHRs were included as background, but

articles in the main body of this chapter focus on those available to use on the

worldwide web. The following high-level headings were based around the

questions defined in the aims of the review and used to categorise the articles

assessed:

- Commentary: general articles describing PHRs and providing an overview
  of the field, but not explicitly contributing to the evidence base. These
  articles were useful background reading, but few provided meaningful
  references.

- Background and Definitions: articles providing definitions of a 'personal health record' from high-profile organisations and influential authors.

- Review articles: comprehensive overviews of the status of PHR systems, sourcing findings from systematic literature reviews.

- Design: articles covering system design and architecture.

- Stakeholder perspectives: findings from evaluations aiming to obtain the opinions of patients, healthcare professionals and other relevant stakeholders regarding their opinions of records access systems .

- Evaluation: PHR studies using various relevant methodologies that include more than just stakeholder perspectives, for example, impact on clinical outcomes and behaviour.

- Security and Privacy: papers describing security considerations and best practices, along with those focusing on the privacy of patient data.

- Existing systems: a selection of key systems that contribute significantly to the evidence base in this field, documenting the benefits and challenges faced. Those demonstrating a track-record of relevant publications were selected for short case-studies by the author.

Several articles overlapped across the categories defined, but were allocated to the heading with which the strongest focus was determined by the author. The following sections of the thesis discuss each of these headings and their sub-categories, with the exception of 'commentary', which contained mainly overview

information or general articles that in the author's opinion did not add any new or relevant data.

Where relevant, a checklist was used as an aid when critically analysing articles, using the following criteria:

1. Was the user population (age, gender, ethnicity, etc) and study aim clearly defined?

2. Was the methodology appropriate for the study?

3. Were adequate details presented to recreate the study independently?

4. Was the timescale of the intervention sufficient to obtain meaningful results?

5. Were steps taken to minimise bias in the results?

6. Do conclusions accurately reflect the findings within the article?

4.3 Background

While the PHRs studied for this thesis are those made available electronically via the Internet, this is by no means the only delivery method available either currently or historically. The earliest references to patient accessible records were in the form of a paper-based personal health log (Dragstedt, 1956), with the term 'personal health record' first surfacing five years later (Public Health Reports, 1961). Since these articles were published, many more paper-based records have become available to patients, resulting in reported increases in patient satisfaction due to increased involvement (McFarlane et al., 1980, Liaw,

1998, Liaw et al., 1996, Roth et al., 1980, Stein et al., 1979, Vaz, 1995, O'Flaherty et al., 1987).

More recent developments have resulted in various computer-based solutions being developed. These have been created based on a variety of devices and media, including USB flash drive (Shetty, 2006, Maloney and Wright, 2010, Jian et al., 2012), kiosks (Fisher et al., 2007), mobile- (Tawara et al., 2013) and smartphone (Kharrazi et al., 2012, Rossi et al., 2009), and those made available via the internet (see Internet-based PHRs). Digital interactive television (Blackburn et al., 2011) and iPod-based systems (Luque et al., 2013) are novel approaches that may provide a further options in future, but it is clear that there is no single approach that can be defined as a "standard".

4.3.1 Personal Health Record Definitions and Purpose

A number of definitions for Personal Health Records have been identified in the literature. The following section highlights three of these definitions and discusses the common themes presented:

"an electronic application through which individuals can access, manage and share their health information in a secure and confidential environment" (Markle Foundation, 2004)

"a tool for collecting, tracking and sharing important, up-to-date information about an individual's health or the health of someone in their care" (American Health

Information Management Association / American Medical Informatics

Association, 2008)

"a repository of information from multiple sources (eg patient, family, guardians,

physicians, and other health care professionals) about the health and health care

of an individual or designated people" (Council on Clinical Information

Technology, 2009)

While there is no universal agreement in these definitions, they contain broadly

similar themes, focusing on a data repository that can be used to securely store

and manage personal medical information for tracking and monitoring purposes,

without mandating any specific method of implementation. As it contains the

broadest definition of the three, the author has selected the Markle Foundation

definition as the most appropriate in order to define the following analysis.

4.3.2 Categories of Web-based Personal Health Records

The focus of this thesis is on internet-based PHRs, which are far less susceptible

to loss or destruction than other types and are the most commonly implemented

form (Detmer et al., 2008). The convenience of systems delivered via the internet

allows for tailored educational messages to be sent out in a timely manner,

increasing levels of engagement (Brown et al., 2007). Web-based PHR

repositories can be classified into three distinct sub-categories based around

their integration and communication with provider systems (Tang et al., 2006):

- Stand-alone: unconnected to any external system, containing solely patient-recorded health information, capturing concerns, problems and symptoms.

- Tethered: a view into an electronic medical record or a subset of its data, in some cases containing functionality to request medication and appointments and to communicate with physicians (Nazi et al., 2013).

- Interconnected/integrated: collecting data from multiple data sources while incorporating asynchronous communications and functionality.

These categories of PHR vary in complexity, depending on their interconnectivity. The stand-alone version is the most basic, pushing responsibility to the patient to maintain and manage. Those that link to the EMR of a healthcare provider offer much richer data and expand the available functionality, but these are perhaps best suited for tethered links to primary care records, which offer a broader spectrum of data (Blechman, 2009). PHRs that integrate with the healthcare provider EMR can give a high level of individualised guidance, allowing patients to take action for preventative care (Krist et al., 2011). Some are provided by insurers, but potential users report concerns around sharing health data with these organisations (Grossman et al., 2009). Those that are genuinely interconnected with multiple healthcare data sources and allow patients to contribute to the medical record are the most complex, but with that complexity comes a much richer user experience, which is why these are seen as potentially offering most benefits (Tang et al., 2006). This was reiterated by Detmer and

colleagues who stated that integrated records may be the most appropriate way to transform patients' ability to manage their own care (Detmer et al., 2008).

While the three categories discussed are very relevant, they do represent a very provider-centric view of personal health records, where the electronic medical record remains in control and at the centre of any communication. In contrast, a patient-centric personal health record could be owned, operated and updated by the patient in collaboration with any provider they chose to interact with during the course of their lifetime health care.

4.4   Personal Health Record Reviews

There are few systematic reviews of PHR literature, but this section aims to capture the main findings of those that exist, before drilling down further into the detail of specific studies during the remaining sections of this chapter. The earliest review paper summarising the literature on patient access to medical records within this thesis was published in 2003 (Ross and Lin, 2003). It stated that at this time there were few robust studies with sufficient statistical power or quality to provide definitive evidence on the benefits or risks. It did however acknowledge that there may be the potential for modest benefits in approaches to patient-provider communication and risks related to patient anxiety. In general however, this review was broadly inconclusive, showing that further studies and later reviews would be required.

By 2007, momentum was beginning to gather, with the publication of two further reviews. Ferreira et al performed a systematic review in the field, concluding that communication, patient participation and understanding of their condition can be enhanced as a result of these interventions (Ferreira et al., 2007). Potential barriers including confusion and anxiety when patients were presented with medical records were found to be minimal. However, some studies highlighted concerns about security and interpreting what was written by medical staff. These findings were presented despite being based on only 14 articles, showing scope for further improvement.

A Nuffield Trust report in the same year (Pagliari et al., 2007a) summarised a round table debate from key stakeholders involved in the implementation of early PHR systems. It stated that:

> "*ePHRs have the potential to improve communication between providers and patients by sharing information, to enhance the quality of records by highlighting inaccuracies, and to reduce the burden of care by engaging patients in managing their own health and illness*"

Detmer et al followed this up to explain that they discussed the three types of PHR described earlier in this chapter, extolling the benefits of the fully integrated version, including the maximum potential for improvements in communication and information access, leading to improved self-efficacy (Detmer et al., 2008). Challenges were perceived to remain within health system culture, consumer

confidence and awareness of benefits, the digital divide and quantifiable patient demand for these systems. While documentation of this meeting and input from key stakeholders clearly provides some extremely useful insights for future work, it in no way constituted a systematic review based on documented evidence.

A further review of PHR literature was published in the Journal of the American Medical Informatics association three years later (Archer et al., 2011). This included a much larger total of 130 articles in its final synthesis. The article pointed out that more modern, integrated PHRs had a heavy reliance on provider's EMRs, meaning that they have to be suitably maintained and routinely used by members of the healthcare team to ensure data were complete and reliable. This finding further supports this author's assertion that reliance on provider systems must not dictate what the patient can and cannot do with their record and that patients should have much more flexibility and control. The article also states that unless the user has a long-term condition, disability, or is a carer for a patient, then adoption is likely to be low given that they will not be routinely engaging with health services. This seems entirely logical to the author of this thesis in a similar way that internet banking users would be unlikely to engage with online banking without any money in their account.

The final publication covered in this section consists of an evaluative review of PHR literature, focusing on the 'persuasiveness' of their functionality (Saparova, 2012). The most effective ways of engaging patients were found to be through

personalised, or tailored, recommendations and decision support. These concepts are discussed further later in this chapter. Most qualitative studies found that patients felt more involved and had positive attitudes towards PHRs, but randomised controlled trials showed that behaviour change and evidence of improved self-efficacy were not necessarily associated with PHR access. At this early stage in the evolution of PHRs, multiple research methodologies remain equally acceptable and relevant in order to draw as broad a response as possible.

All of the reviews highlighted the fact that there remains significant research required to prove the benefits of patient accessible PHRs, with many of these papers highlighting specific research questions that remain unanswered. Following the main body of this review of the literature, the author will highlight some of these outstanding questions and propose an approach to address them using MDMW.

4.5   Design Considerations

When designing a new PHR, a number of considerations must be taken in to account to produce a system that is both usable and acceptable to a variety of demographic groups. Pagliari et al described some of the potential functional areas of electronic health records (Pagliari et al., 2007b), including:

- Access to a provider's EMR.

- Diary and personal health organiser for appointments and treatments.

- Self-management support, including care planning and decision aids.

- Secure communication.

- Self-recorded outcomes data.

These features may or may not be of relevance to all of the target audience, so it is essential to ensure engagement with potential users so that any intervention is used efficiently, in addition to having a good grounding in the background literature (Kim et al., 2011).

The following section discusses some of the findings in each of the relevant design areas including user profiling, standards and guidelines, user-centred design and implementation.

4.5.1 User Profiling

The ideal PHR will be useful, and be of use, to all users of healthcare, regardless of age, ethnicity, education, or literacy. Unfortunately, no such system exists at present. The literature shows that potential use of a PHR has been associated with experience of computer use, previous use of the internet to manage healthcare and usability and perceptions regarding the benefits of PHRs (Patel et al., 2012, Ross et al., 2005, Emani et al., 2012, Day and Gu, 2012, Leonard et al., 2008b). Further studies have found that a higher level of education is another primary determinant (Sarkar et al., 2011, Morton, 2012).

With regards to actually logging on to PHR systems, African-Americans and Latinos have lower odds when compared to non-Hispanic Caucasians (Sarkar et al., 2011, Kahn et al., 2010, Yamin et al., 2011, Grant et al., 2008). These studies were carried on cohorts of patients in the United States, so may not be representative of the general population, particularly in the UK. Systems focusing on long-term conditions may require disease-specific features, meaning that healthcare status is a highly relevant factor to be considered for system design (Lafky and Horan, 2011).

4.5.2 Standards and Guidelines

While there is no mandated standard for PHR design, some have presented their approach as a possible framework (Vincent et al., 2008) and made recommendations for successful implementation (Wiljer et al., 2008). Despite these efforts, the author believes that there will be no general situation that will fit all disease and locality environments, so while these papers can be used as guidance, domain knowledge should seek out pragmatic solutions for each known environment. Variability in requirements, such as required datasets and the timing of data release, have implications meaning that standardisation of functionality would prove challenging (Collins et al., 2011).

There is no consensus on PHR certification, but some argue that would lead to the development of minimum standards for issues such as security and interoperability (Foxhall, 2007). Adopting standards into design can improve interoperability (Do et al., 2011) and one route that this may progress is via the

Continuity of Care Record (ASTM International, 2013). This is gaining

momentum as a standard for clinical information interchange between healthcare

providers and related organisations (Lu, 2007). Gaining buy-in to these

approaches is likely to remain patchy unless mandated by government strategy.

Further discussion regarding security and privacy standards and legislation can

be found later in this chapter (see Privacy).

4.5.3 User-centred Design

A review of available PHR systems found that suppliers were frequently

designing their systems based on healthcare provider and nursing perspectives

(Alkhatlan, 2011, Lee et al., 2006) and have no patient representation within their

governance structures (Reti et al., 2009). Systems evaluating usability amongst

patients found that testing highlighted several issues for improvement, regardless

of whether they were designed by 'experts' or not (Fonda et al., 2008, Haggstrom

et al., 2011). This is not the case across the board though as there are examples

of projects guided by patient advisory panels (Do et al., 2011), which the author

believes to be an essential component in any design.

User involvement in design may increase utilisation and acceptance (Wagner et

al., 2010) and improve the quality of the product following iterative refinement

(Tran et al., 2005). If these factors are not taken into account then user

interfacing issues may limit use (Kim and Johnson, 2002). Due to a general lack

of user-centred design it is not clear which features are important to patients

(Lafky and Horan, 2011). Opportunities must therefore be provided to consumers in system design, testing and development (Leonard et al., 2008a, Segall et al., 2011), which some have described as *"irreplaceable"* (Massoudi et al., 2010).

Careful design can improve readability and ensures that complex clinical terms are relayed to patients in a way that they will understand (Keselman et al., 2007, Zeng-Treitler et al., 2007, Fisher et al., 2007). PHRs need to *"move beyond the view of 'medical record' and become consumer focused"* (Thede, 2009), with improvements required to enhance 'patient centredness' (Reti et al., 2010) and the sharing of responsibilities (Quantin et al., 2011). The author's experience in working with "hard-to-reach" groups such as young adults supports this assertion, as these groups are unlikely to accept interventions that are seen to be forced on them by health services.

4.5.4 Implementation Considerations

Dataset design is a key consideration, particularly when sourcing data from a provider-focused EMR. It is important to use data that holds meaning for the patient and that these data are presented in a user-friendly way (Charters, 2009). Providing information alongside clinical measurements can be shown to aid patient education and consumers desire information that addresses their individual concerns (Kaplan and Brennan, 2001). As discussed earlier in this thesis, tailoring an intervention to a consumer can positively affect health behaviour more than targeted, personalised or generic interventions (Revere and Dunbar, 2001). Generic interventions are those which can be applied to all

patients, personalised messages simply have the patients name on the information they receive and targeted interventions merely focus on specific sub-groups of a population.

Tailored interventions on the other hand are based on an individual's characteristics and are specific to the patient at one point in time. They are based on algorithms that select the information to be presented to the user on the basis of data held in the individual's health record (e.g. risk factors), or according to their behavioural, motivational characteristics or personal preferences (Revere and Dunbar, 2001, Edwards et al., 2003). These are clearly likely to have more impact as they effectively customise the system to the individual. For example, the author believes that a patient with type 2 diabetes treated with tablets is unlikely to read general information on insulin injection technique, whereas further details of their specific oral medication is likely to hold more interest.

This presents an interesting trade-off between inexpensive, mass-produced generic materials which are less likely to motivate, and labour-intensive individual attention which will have more effect (Gustafson et al., 1999). While existing computer-based health-behaviour interventions have been shown to be effective in the past, there is very little data comparing the different types of intervention such as targeted, personalised or generic interventions (Revere and Dunbar, 2001). However, when compared with tailored information, appropriately fitting non-tailored materials may perform as well or better (Kreuter et al., 2000). The

author believes that the likelihood of this happening is more likely to be down to chance than good planning.

Further tailored approaches have focused on decision support using case-based reasoning (Wagholikar et al., 2012), patient reminders to improve preventative care (Wright et al., 2012) and guided searching for disease information, including recommendations for home medicines (Luo et al., 2012, Luo, 2013). While no formal definition has yet been stated, these systems have been coined intelligent Personal Health Records (iPHRs), an area which is still at an early stage of evolution. Clearly there is great scope to incorporate artificial intelligence techniques into PHRs for this purpose.

Although there are several examples of systems focusing on the general adult population and those suffering from long-term conditions, there have been calls for the development and adoption of PHR systems for the paediatric community (Council on Clinical Information Technology, 2009). Adolescents have in the past been excluded from these systems due to legal concerns including the ability of this group of individuals to enter into agreements with their healthcare providers and understand the information delivered. These issues can be overcome with parental consent, while being expected to deliver the positive benefits described for the adult populations. It is important that patients are not consciously excluded based solely on age, given the previously discussed concerns around an increasing digital divide.

References to negative historical events may cause unnecessary upset (Ennis et al., 2011), so it is important for patients to be fully aware of the potential contents of their records when they sign up for access. Patients may see results before their doctors (Herbert, 2007), meaning that it may be necessary to incorporate a time delay to allow ample time for review, depending on the data that is offered (Johnson et al., 2010, Charters, 2009). Patients may become frustrated with these delays (Hess et al., 2007), but not adopting this approach may hinder provider use and acceptance (Do et al., 2011). While it is agreed that these are potential scenarios, they do not address the positive experiences that faster access may bring to many users. In fact, these positive experiences are likely to outweigh the negative in the opinion of the author, particularly when access allows the patient to consider them and make better use of their consultation. Controlling access to data may be seen as hiding information and the health service maintaining control, concepts that PHRs were intended to avoid.

Van Deursen describes a method to provide an indication of the quality of health data within a PHR, based on the reputation of the system supplier and the quality of measurement devices (van Deursen et al., 2008). This can have benefits for both patient and provider in terms of the trust and reliability that can be placed on these data, based on its perceived ranking. This is a sensible approach, particularly when dealing with shared records sourcing data from multiple systems. For example, biochemistry results from laboratory systems are more

likely to be accurate than manually transcribed records from a GP or hospital clinic database.

4.6   Stakeholder Perspectives

There are many varying views on the benefits and risks of PHRs, with patients and policy makers generally having more positive attitudes compared to those expressed by members of the healthcare teams (Ross et al., 2005, Earnest et al., 2004). The following section outlines the reported opinions of both patients and healthcare professionals.

4.6.1 Patient Perspectives

Patients are more interested in seeing their electronic records than their paper records (Honeyman et al., 2005) and believe they would find access to their records reassuring and helpful (Fisher and Britten, 1993). They generally want to become active participants in their own care (Huba and Zhang, 2012) and see access to their medical records as offering improved motivation, understanding, partnership, communication and ease of access (Wagner et al., 2010, Britten et al., 1991, Nazi et al., 2013, Honeyman et al., 2005), enhanced by the possibility of timely and readily available information (Fonda et al., 2010). Computers can help people to access information when they need it without clinic hour restrictions, ask questions which may be difficult or embarrassing to ask health-care professionals, deal with complex issues at their own pace and seek support and guidance based on testimonies of other patients (Gustafson et al., 1999).

Some cite positive impacts such as increased responsibility, health awareness and efficiency savings as a main influence on usage (Smith et al., 2012), leading to fewer mistakes and improved motivation and satisfaction (Nielsen, 2008). Generally, studies have shown that the appetite for the use of PHRs amongst patients is high (Patel et al., 2011b, Menon et al., 2012). These positive attitudes are most likely to come from those who are internet users, less likely to be above the age of 65 and those whose doctors always ensured their understanding of health issues (Wen et al., 2010). Of these, the most significant predictors of support include previous internet use (Ross et al., 2005). Patients with a higher degree of satisfaction with their healthcare provider and those who perceive its tools to be of empowering and of value, are more likely to desire access (Agarwal et al., 2013).

Many patients are happy to share all of the information they record with their health authority or with another family member acting as their carer (Zulman et al., 2011, Burke et al., 2010), but less likely with a non-hospital provider (Weitzman et al., 2012, Patel et al., 2011b). They want systems tailored to their needs and medical conditions, serving to make them more comfortable maintaining and using them (Alkhatlan, 2011). They also want a comprehensive record that will allow them to perform a variety of tasks (Patel et al., 2011a).

Those with special need requirements prioritise access over security concerns and in general, individuals are less concerned about the security of their healthcare data than their financial data (Lafky and Horan, 2011). This is reinforced by the studies of Pyper et al (Pyper et al., 2004, Pyper et al., 2002), who found that patients believe that potential security problems are outweighed by the potential benefits. Further work in this area has shown that initial security concerns actually reduce after engagement, once the individual has reassured themselves of system safety (Bartlett et al., 2012).

4.6.2 Healthcare Professional Perspectives

Physicians who do not believe that patients are partners in their care tend to have negative attitudes towards records access (Dorr et al., 2003), with many of these barriers focusing on their own interests (Britten et al., 1991). Many physicians are still unaware of what PHRs are and what they can offer (Fuji et al., 2008). Most see them as an alternative when EHRs are not available (Witry et al., 2010), but 57% of physicians would only use PHRs in this way if they took less than 5 minutes to access due to the constraints of time within a consultation (Menon et al., 2012).

Female physicians are less likely to engage with PHRs than their male peers (Wynia et al., 2011), but in general most physicians do remain willing to share records (Menon et al., 2012), particularly those in rural areas where accessing health services may be more difficult and less frequent. Both patients and physicians believe that PHRs would improve communication outwith

appointments and they would rather use PHRs for this purpose, instead of email (McInnes et al., 2011), likely to be due to the enhanced security that can be applied. Earlier perspectives in this area found that some clinicians believed that records access could hinder frank communication between healthcare providers (Short, 1986), change the way in which letters are written (Britten et al., 1991) and increase workload (Nielsen, 2008, McInnes et al., 2011). Following evaluation, this is generally not the case (Earnest et al., 2004, Bartlett et al., 2012), a view that is backed-up by the author's awareness of clinics that have been sharing letters with patients since around 2000, showing that letters can be adapted without losing necessary meaning. Workload increases are largely based around the availability of additional information, however most value this new data provided by patients (Huba and Zhang, 2012).

Clearly physicians have more concerns regarding sharing medical records than patients and in order to achieve widespread adoption, these perceptions must be reconciled (Ross et al., 2005). Clinical endorsement and engagement is seen as being an essential factor in the successful implementation of PHRs (Nazi, 2013). The author acknowledges that this will involve widely embracing change in the care delivery models with patients being seen as equals, rather than being advised what to do. It is expected that progress can be made based on the influence of government strategies and patient enthusiasm.

4.6.3 Behaviour Change Methodologies

In order to address issues with engagement, interventions aiming to achieve behaviour change can be designed and categorised using structured methods such as the *"Behaviour Change Wheel"* (Michie et al., 2011). This approach can be used to characterise new approaches and allows targeted behaviour to be analysed based on three essential conditions: capability, opportunity and motivation. Characterising how these conditions relate to the local environment can lead to a better understanding of the approaches necessary to achieve the desired outcome. Complex interventions can also be evaluated using approaches such as *"normalisation process theory"* (May et al., 2011). The authors propose a simplified web-enabled toolkit based around a set of heuristics to identify potential integration and implementation problems in practice. These approaches are two of many formal structures that may be considered to achieve a successful intervention for personal health records.

4.7   Evaluation Results

The following sections describe some of the additional benefits and barriers reported in literature based on the results of various types of evaluation, expanding on some of the concepts covered in the previous section.

4.7.1 Further Benefits

Consumers are increasingly using PHRs and other self-management tools when dealing with long-term conditions in order to gain access to credible information

(Paton et al., 2012) and improve understanding (Patel et al., 2011b). The portability of these records is likely to be a contributing factor (Li et al., 2012), meaning that access to these records should be maintained as a patient moves between care providers, a point that it particularly pertinent in the United States.

It is believed that patients use access to their records to allow them to prepare for appointments and to recap afterwards (Fisher et al., 2007). Pre-visit use of a PHR allowing the patient to author a 'Diabetes Care Plan' before appointments has been shown in a randomised controlled trial to lead to higher rates of medication adjustment to reduce risk factors, showing patients acting as participants in their own care (Grant et al., 2008). This approach has also assisted patients in preparing for visits and articulating more accurate and relevant data and asking more appropriate questions (Wald et al., 2009). This level of participation has been linked to improve adherence with medication in patients with HIV (McInnes et al., 2013). The ability to provide useful information can contribute to the accuracy and completeness of medical records (Staroselsky et al., 2006), ultimately decreasing the number of mistakes (Nielsen, 2008).

Health benefits and improvements in clinical outcomes are the key objectives aspired to by any new intervention, and PHRs are no different. A randomised effectiveness trial found that active usage resulted in a reduction in blood pressure, but this was largely in a younger, more computer literate group (Wagner et al., 2012). PHR use has been associated with improved diabetes

outcomes, but this is believed to be due to a higher level of engagement with health issues, rather than PHR use on its own (Tenforde et al., 2012).

PHRs can deliver savings and improved productivity, although the evidence is limited (American Health Information Management Association / American Medical Informatics Association, 2008), however a framework for assessing the value of PHRs has been developed (Johnston et al., 2007). Beyond the direct benefits to patients and healthcare teams managing them, records access will be relevant to general public health reporting if benefits are realised and data quality is improved, meaning patients become genuine partners (Bonander and Gates, 2010).

4.7.2 Barriers

In order to assess the ease at which web-based resources can be implemented successfully, it is important to understand the potential barriers to their use in order to overcome them. As mentioned earlier in this chapter, there are many potential reasons for concern and issues within the world of PHRs. Password recall, computer access and computer literacy (Smith et al., 2012) may cause access problems, while data quality (Strassburger, 1975) and completeness (Robeznieks, 2007) may encourage patient feedback, resulting in a requirement for technical support and assistance (Wiljer et al., 2010b). Patients generally anticipate that there will be some errors (Honeyman et al., 2005), but their input can assist in records improvement when they are provided with a review tool to

report discrepancies (de Lusignan, 2010), for example in medications (Schnipper et al., 2012).

Patrick et al stated that consumers are not always familiar with professional vocabulary and concepts, and conversely, health care providers are not always familiar with concepts used by consumers (Patrick et al., 2001). Patient records should be clear and concise when presented to patients, whilst letter sentence structure should be simple without being condescending (Tetzlaff, 1997).

Physicians have concerns around changes to data and practice management and changes in the patient-physician relationship (Yau et al., 2011). These potential barriers include patient privacy, data accuracy, patient misinterpretation, increased patient anxiety and lack of payment (Wynia et al., 2011, Yau et al., 2011, Johnson et al., 2010, Britten et al., 1991, Keselman et al., 2007). Some authors have highlighted lack of payment and identification of appropriate financial resources as the most significant barrier (Urowitz et al., 2008, Short, 1986, Robeznieks, 2007), with some advocating financial incentives for their implementation (Hargreaves, 2010). To support estimating of PHR implementation in the United States, a cost model has been proposed to provide guideline figures (Shah et al., 2008). While financial compensation will help drive the development and access to PHRs, the author believes that healthcare professionals must be encouraged to look at the bigger picture and appreciate

that improved decision-making will result in improved clinical outcomes, which in themselves bring cost savings.

Computer literacy (Patel et al., 2011a), health literacy (Mitchell and Begoray, 2010, Kim et al., 2009, Noblin et al., 2012) and low income (Yamin et al., 2011) remain barriers to PHR use, particularly in an elderly population (Lober et al., 2006, Kim and Kim, 2010). Some report that even on-site training is insufficient to engage with new computer users (Hilton et al., 2012). Limited awareness regarding the benefits and effectiveness (Hargreaves, 2010) and poor usability limit the potential of information delivered via the internet (Yu et al., 2012, The Kings Fund, 2008). It is therefore essential that healthcare organisations embrace patient access to records to ensure that PHRs achieve their maximum potential.

A two-arm cluster randomised controlled trial evaluated the effectiveness of a multifaceted self-management support intervention for long-term conditions across 43 general practices in England (Kennedy et al., 2013). The intervention was led by the existing primary care teams and based around assessment tools, guidebooks and a web-based directory of resources, but concluded that it did not add any significant value to the care of people with long-term conditions. A failure was believed to be due to the challenges in changing daily working practices to embed self-management support. This again highlights the fact that healthcare

teams must fully engage interventions for them to stand any chance of becoming successful.

Legal liability and accountability for the content of PHRs has sparked debate in some quarters (Beard et al., 2012, Wynia and Dunn, 2010). Issues discussed surround responsibility for the accuracy of the record when it includes data from both providers and patients and who, if anyone, assumes responsibility for the monitoring and feedback on home-recorded data. Decision aids and automated messaging may offer opportunities to alleviate these concerns. The author maintains that if patients wish to become active participants, then they must share responsibility for monitoring home-recordings and be encouraged to raise issues with the healthcare teams when they have any concerns.

4.7.3 General Findings

More general findings indicate higher rates of PHR uptake in men than women (Nazi, 2010). PHRs are more useful to those with long-term conditions who consume health services more frequently (Miller et al., 2007), but they do not change the number of encounters or phone calls as only secure messaging increased (Hess et al., 2007). Although physicians perceive patient anxiety as a barrier, evaluation has shown that access to PHRs do not increase anxiety levels in breast cancer patients (Wiljer et al., 2010a).

A narrative review of web-based diabetes management tools found that patient satisfaction is at its peak when web-based systems allow them to *"track blood*

glucose, receive electronic reminders, schedule physician visits, email their

healthcare team, and interact with other diabetic patients" (Brown et al., 2007).

4.8   Security, Privacy and Confidentiality

Some authors have described security as the most important requirement of a

PHR (Kim and Bates, 2011, Patel et al., 2011b), something highlighted

significantly regarding the failings of USB-based alternatives (Wright and Sittig,

2007). This section highlights some of the key considerations regarding security,

privacy and patient confidentiality.

4.8.1 Authentication

User authentication is a key component of security surrounding PHRs.

Traditional Personal Identification Number (PIN) or passwords-based systems

may offer weak security, if insufficiently complex or poorly implemented. An

alternative solution would be to use a legitimate credential supplied by an

authentication authority (Win et al., 2006), for example a security phrase in

addition to username and password, but procedures should be minimised and

simplified as much as possible (Nordfeldt et al., 2010). An adjunct to these

traditional techniques is their use in combination with biometric characteristics,

such as fingerprint or iris scanning (Bonney, 2011), although many technical

barriers remain to be resolved before these techniques are likely to be widely

implemented. For those wishing to implement a PHR within a Cloud computing

framework, Chen et al have defined a new access control scheme based around

public and private key cryptography (Chen et al., 2012). Regardless of the

approach used, the patient becomes responsible for the safe storage and memory of security credentials they require to access the system once they have received them, as is the case with internet banking (Fisher et al., 2007, Halamka et al., 2008).

4.8.2 Privacy

Patients accessing a PHR must be advised on methods of good practice in order to protect their information (Fetter, 2009). In 2013, the British Computer Society published a guide on the safe use of online health records (British Computer Society, 2013). These guidelines covered areas such as creating strong passwords and good practice when using shared computers, encouraging people to log out when using services in a public environment such as an internet café or library. These guidelines also discouraged the sharing of user credentials with others and factors to consider when choosing to do so.

Providers of PHRs should seek to maintain a 'privacy policy' containing information advising how a user's information is managed by the system. A recent review found that most systems published this document, but the majority did not cover the security measures they had implemented in adequate detail (Carrión Señor et al., 2012).

4.8.3 Traceability

A fully integrated PHR allows an individual to contribute to their provider's electronic medical records, but many systems do not offer this level of data

sharing (Carrión Señor et al., 2012). For systems that do however, traceability

over the source of data is essential (Allaert and Quantin, 2010). System usage

logs can provide the necessary levels of detail to support this.

There has been some debate over these asynchronous communications and one

area of research puts patients in full control over access to their data by

incorporating context-based access for clinicians depending on processes

initiated within daily workflow and patient requests (Mytilinaiou et al., 2010).

4.8.4 Confidentiality

Early perspectives on medical records were that they were considered the

property of healthcare provider (Schwartz and Rachlin, 1985). In the UK, there is

clear legislation surrounding the rights of individuals regarding access to their

personal medical data (HM Government, 1998). While this applies also to paper

records, as described earlier in this thesis (Information Security and

Governance), any electronic transfer of identifiable data must be made in

compliance with the Caldicott Principles (Department of Health, 1997,

Department of Health, 2013).

In the United States where PHRs are most prevalent, there is similar clarity

regarding the legal obligations of entities offering access to records. The Health

Information Portability Accountability Act (HIPAA) is the US government's

security and privacy law covering the protection of this sensitive data and

ensuring the right of access for the individual (U.S. Department of Health &

Human Services, 2013), which have led to fines for the denial of access to

records (Zigmond, 2011). Most PHR systems attempt to meet the criteria

specified (Wang et al., 2004), although these only apply to healthcare providers,

so organisations such as Google and Microsoft have been exempt (Chen et al.,

2012). In 2012, it was found that around two-thirds of available systems were

based on HIPPA principles, or those closely related (Carrión Señor et al., 2012),

although it has been argued that HIPPA legislation should not be formally

extended to cover all PHRs (Rakestraw, 2009).

4.9   *Existing Personal Health Records*

There are many examples of PHR systems available worldwide. This section

highlights some of the most prominent as highlighted in the literature, both in the

UK, the US and beyond.

4.9.1 PHRs in the United Kingdom

The NHS in England and Wales has recently published its Information Strategy

(Department of Health, 2012b) in support of using personal health records to

educate patients and assist in their self-management. It states an objective to

make the general practice record available to all by 2015, with a clear emphasis

on patient ownership (Wyatt, 2012). The strategy outlines that patients should be

assisted to better understand their clinical results.

At present in the UK, there are a limited number of online systems which allow access to clinical records. EMIS Patient Access (Egton Medical Information Systems Ltd, 2013) allows access to a subset of clinical data from primary care. It evolved in collaboration with PAERS (PAERS, 2013) and provides access to over 230,000 individuals, allowing patients to arrange appointments, request prescriptions and to view their GP record. A survey of stakeholder experiences found that it was easy for patients to integrate into their daily schedules, while healthcare professionals reported no increase in queries or consultations (Pagliari et al., 2012). Most believed it had led to improved communication and mutual trust. Despite EMIS Patient Access being pushed as one of the key systems aiming to meet the information strategy objectives, it is surprising that there is a lack of historical and contemporary research that has been carried out on it, beyond the paper listed above.

Renal PatientView (Renal Information Exchange Group, 2013, Mukoro, 2012) gives people with renal disease access to their secondary care test results alongside information about their diagnosis and treatment. By August 2011, the system had registered over 17,000 individuals, had linked to 51 of the UK's 72 renal units and reported that 1,000 patients were accessing their results daily (The Renal Association, 2011). Evaluations of its uptake also reported benefits including improved understanding of kidney health, disease management, concordance with treatment, improved patient-professional communication, reduction in administration overheads, and an improvement in appointment

attendance as a result of record access (Bartlett et al., 2012, NHS Kidney Care, 2012). This system is currently the most prominent records access system within the UK and the only one offering access to a hospital-based clinic record across the whole of the country.

While Renal PatientView operates in Scotland, only one other previous PHR has been available to the people of Scotland and this was a subset within one health board. The Ayrshire and Arran Patient Online Portal Project was an eHealth 'demonstrator' project costing £200,000, focusing on the needs of patients with COPD and diabetes at two GP practices within this health board. The project expanded on software developed at Townhead Practice in Irvine and provided access to GP summary data and laboratory results. Users were also able to request prescriptions and appointments and record personal information such as weight, blood pressure, exercise and mood. The evaluation of this project (Axiom Consultancy, 2011) reported that 49.6% of initial registrants (194 of 391) went on to use the system.

NHS HealthSpace (National Health Service, 2012b) was an ill-fated personal record available to anyone over the age of 16 in the UK. Once touted as *"set to become the worlds first fully national system"* (Pagliari et al., 2007b), it allowed the user to record and track their test results and linked to appointment booking through NHS Choose and Book (National Health Service, 2012a). Following poor uptake and a lack of user engagement, it was written off as *"neither useful nor*

easy to use" (Greenhalgh et al., 2010), leading to its ultimate demise in December 2012. Some of the reasons why it failed to gain the mass uptake expected were based around the overly complex security procedures and the lack of integration to an electronic medical record, leaving the patient to populate data on their own. These are hugely important learning outcomes to be learned from any future PHR.

4.9.2 PHRs in the United States of America

By far and away the most prolific and prevalent development of PHR systems occurs in the United States where, despite its dominance in this field, the evidence-base remains sparse. myphr.com (American Health Information Management Association, 2013) allows citizens the opportunity to browse and choose from a selection of 69 free or cost-based PHR systems.

Early PHRs from the United States include Patient-Centred Access to Secure Systems Online (PCASSO) which was launched in 1996. This was a system designed to allow patients access to their clinical data, with a strong focus on security (Baker and Masys, 1999). However, as a result of the complex security applied, usability was rated low, limiting access (Masys et al., 2002). The Patient Clinical Information System (PatCIS) was designed as a technical framework that was integrated with multiple clinical applications allowing patients to more effectively manage their clinical information and health (Cimino et al., 2000). Again usage remained very low, with only 13 users accessing the system over a 36 month period, varying in activity from frequent users (one or more accesses

per day) and infrequent users (once a month or less) (Cimino et al., 2002). These

systems were very similar in design, but surprisingly not rolled out widely

following the capture of initial evaluation data. Despite their limited use, these

systems provided a baseline for the evidence base around PHRs, highlighting

that a clear balance needs to found between usability and security.

Kaiser Permanente's My Health Manager (Kaiser Permanente, 2013) is one of

largest and most advanced patient access systems, claiming upwards of five

million active users. It has reported results similar to EMIS and Renal

PatientView, describing significant decreases in primary care office visits and

telephone contacts (Zhou et al., 2007), however a retrospective cohort study five

years later reported that use was associated with an increase in the use of

clinical services (Palen et al., 2012), although the methodology used in the

follow-up study has since been challenged (Koppel and Soumerai, 2013). These

results must be queried and clarified, as a change in either direction is crucial to

the evidence base upon which future implementation decisions may be based.

When it came to actually logging on, African-Americans and Latinos had lower

odds when compared to non-Hispanic Caucasians (Sarkar et al., 2011), although

this is likely due to the higher proportion of users in the latter group receiving

health services through this organisation.

My HealtheVet is another online personal health record used by US veterans

which has a user base of around 500,000 and incorporates a 'Blue Button'

allowing the download of data to share with other care providers, etc (United

States Department of Veterans Affairs, 2013 , Chumbler et al., 2011). They

reported that veterans who were younger, more educated, white, married and

had higher incomes were more likely to use the internet (Tsai and Rosenheck,

2012) and that these individuals are happy to share their information with another

family member acting as their carer (Zulman et al., 2011, Burke et al., 2010).

Patients reported high levels of satisfaction with My HealtheVet (Nazi, 2010) and

they believe the system positively affected communication with physicians,

improved participation and enhanced knowledge and self-management (Woods

et al., 2013). Secure messaging was seen as they key component in enhancing

patient self-reporting and improving the patient-provider relationship (Nazi, 2013,

Turvey et al., 2012).

Google Health and Microsoft's Health Vault are two high-profile examples of

'untethered' PHRs, freely available online. They have allowed users to manually

enter details of their clinical results, assessments and outcomes, along with

medications, diary entries and comments, without any intervention from the

healthcare team. Google Health was launched in 2008, but failed to take off as

expected and was ultimately retired in January 2012 (Google, 2011). Google

indicated that while technically knowledgeable individuals had adopted the

system, it had not reached the millions of regular users expected. Despite

developments including a data transformation interface developed to map

provider sources to Google Health (Wu et al., 2009), limitations surrounding

communication and data sharing have been cited as a significant influencing

factor in this decision (Hoeksma, 2011). Following the demise of Google Health,

Microsoft HealthVault (Microsoft Corporation, 2013a) is now the key player in this

domain. The American Diabetes Association has linked with Microsoft and

launched Diabetes 24/7 (American Diabetes Association, 2013), using

HealthVault as its underlying infrastructure. This is an application focused on

diabetes management using patient-specific content, tips, and tools.

Other systems are currently in use in the US, based around HIV/AIDS (Kahn et

al., 2010, Gordon et al., 2012), physical activity (Massoudi et al., 2010), low

income, elderly and disabled (Kim et al., 2007), immunisation records (Popovich

et al., 2008), support for the families of children undergoing transplants (Popkin

et al., 2009). While most are now offered by healthcare providers, many

employers are now collaborating to offer PHR systems in an effort to allow users

to manage and organise their information in a way that they will find most useful,

with the aim of gaining healthier, more productive staff (Weitzman et al., 2009).

One example of its use was in the assessment of impact on influenza in the

workplace (Bourgeois et al., 2008), although this reported minimal impact, in part

due to the small sample size.

4.9.3 PHRs Elsewhere Worldwide

Very little evidence of electronic PHRs was found beyond the UK and US. There

are minor exceptions in Italy where an architecture for a regional record is

proposed (Moen et al., 2011) and France where an off-the-shelf product (Sanoia)

was customised for patients with Idiopathic Thrombocytopenic Purpura (ITP) and trialled for usability by a small sample of 28 patients (Chiche et al., 2012). It is believed that many exist in the grey literature (e.g. The Danish eHealth portal (Sundhed, 2013)), but they remain to published in peer-reviewed journals. Beyond Europe, lessons are being learnt from established PHRs to identify gaps in infrastructure for the benefit of developing countries (Ahmadi et al., 2012).

4.10 Review Conclusions

Although there are many articles published in the field of PHRs, most evaluation and analysis has been performed using methodologies, such as surveys, focus groups and interviews (Kim et al., 2011). These often which carry less weight than the more robust randomised controlled trials, meaning that there is broad scope to provide more significant evidence. They do however provide useful baseline research upon which new interventions can obtain important experience and learning.

There are three main implementations methodologies related to PHRs; stand-alone, tethered and integrated, with an integrated, linked record potentially providing most benefit. By far and away the most prolific and prevalent development of PHR systems occurs in the United States where the healthcare model differs significantly from that in the UK. Despite this fact, the UK can learn many important lessons this experience. It has been shown, for example, that people with long-term conditions are most likely to benefit from electronic records

access due to their more frequent engagement with healthcare services and wider availability of clinical results. Security may initially be perceived as a problem, but this tends to dissipate once access and confidence are gained.

Healthcare professionals, rather than patients are more likely to have concerns regarding access, particularly around increase workload, but it is acknowledged from both parties that communication is likely to improve (McInnes et al., 2011). The evidence shows that patient satisfaction and self efficacy are also likely to improve, allowing users to make positive choices in their healthcare (Nielsen, 2008). To ensure that a wide range of perspectives are captured, patients and healthcare professionals must be involved in all stages of the design, evolution and evaluation of PHRs (Leonard et al., 2008a, Segall et al., 2011, Massoudi et al., 2010) and must take into account the wide and diverse cultural and demographic profiles of the target population, their family and carers. The digital divide may shrink, but the elderly and less computer literate must not be forgotten so that the divide that exists at present does not extend. Many of the concerns amongst clinicians comes from recouping costs from offering a new service, although in the UK, cost saving by virtue of improved clinical outcomes is the main driver.

Lack of standardisation may be an issue in some quarters (Wiljer et al., 2008, Vincent et al., 2008). Depending on the target market "one size fits all" is unlikely to be acceptable and is something that the author believes will stifle creativity

and innovation. Dataset design must ensure that key clinical markers are highlighted appropriately and not "lost" amongst other less relevant terms (Charters, 2009). Marking and ranking of the sources of data may be an effective way of highlighting the quality of data (van Deursen et al., 2008) and delays in data transmission delay should not stand in the way of a complete record. If the information is available and the patient has expressed the desire to see it, then they are legally obliged to do so (Hess et al., 2007). Tailoring of materials can aid decision making (Revere and Dunbar, 2001), while more sophisticated methods can actively prompt users to alter their health behaviours. There are however no significant data on cost savings or outcome improvements yet.

Security considerations must be robust, but not overly complex as to dissuade potential users from participating. Those with disabilities and complex health needs are less likely to be concerned about security and do not hold it with the same weight as financial data (Lafky and Horan, 2011). Systems must not let technical issues lead to disengagement and attrition. Utility logs are essential to monitor commonly used features and to report on user access and trends so as to inform new developments and highlight areas for improvement.

Healthcare professionals must be educated on the benefits of PHRs, and must engage and be willing to promote them with their patients. It is an important task to explain the benefits to potential users, as they may otherwise remain unknown. There is a clear shift in responsibility with the advent of PHRs, but

healthcare professionals must engage with this as old methods are no longer

sustainable with the rapid increase in long-term conditions in particular. Attitudes

must change as patients enhance their participation on their own care and

strategic drivers must ensure that this approach is implemented successfully.

Some patients may not yet be ready for this change in dynamic, but it is essential

to encourage the "patient-centred" strategy that is an integral part of modern

healthcare.

Change in working practices are essential, most significantly in the way in which

letters are dictated, but that can only lead to greater transparency and trust

(Earnest et al., 2004, Bartlett et al., 2012). Liabilities remain a topic for

discussion, particularly when patients may have the ability to amend records held

by healthcare providers, but clear policies outlining the enhanced responsibility of

the patient can ensure that all parties are aware of their roles (Beard et al., 2012,

Wynia and Dunn, 2010).

The author believes that providing access to data in itself is not enough.

Engaging functionality is required to motivate users to continue to use systems

and allow them to actively develop the benefits that so far have only been proven

as having 'potential'. There needs to be one or more 'carrots' to encourage

continued use and engagement. Home-recording of results removes the need for

patients to maintain their own bespoke spreadsheets, databases or paper

records and this is one way in which this may be achieved. PHRs have the

potential to allow for preparation before and after appointments, leading to greater participation, adherence and more productive consultations. Patient involvement can lead to the "quality assurance" of health data, with the patient being the gatekeeper and providing feedback necessary to resolve issues at source.

Health data are stored in multiple locations, making the creation of a complete PHR challenging, but those that can provide this functionality are best placed to deliver the rich features and subsequent benefits that all stakeholders desire. This must be the aim of any new system to ensure the greatest value can be achieved from PHRs.

4.11 Research and Development Possibilities

There is still very little empirical evidence on the impact of records access and PHRs. Tenforde stated in 2011 that there were only three prospective randomised trials that had evaluated the use of PHRs in chronic disease management, all of which were in diabetes care (Tenforde et al., 2011). It has been highlighted that the implementation of the necessary technology is "*highly context dependent and research within the UK is essential to inform strategic decision making"* (Pagliari et al., 2007b).

In 2008, a viewpoint paper published some perspectives on the areas of research requiring further analysis (Kaelber et al., 2008). Kaelber and colleagues

summarised that methods to improve adoption in populations of the elderly, underserved and those with long-term conditions require addressing. In addition, assessment of provider and patient attitudes, potential barriers and user engagement require further focus. In 2012, Pagliari stated that there were several unanswered research questions including the profiling of patients using PHRs and the effectiveness of public awareness (Pagliari et al., 2012). Cultural awareness of potential users is essential in designing any resource. A systematic review highlighted that minority ethnic groups have poor reported self-management of their diabetes, meaning that strategies must be developed to engage with these hard to reach individuals (Wilson et al., 2012).

Taking in to consideration the insights learned from this review of the literature, a research outline is proposed.

4.12 Research Questions and Methodologies

While there are many examples of Record Access systems, many have one, if not more, limitations that affect their usage and uptake. Many rely on the consumer manually entering the results reported to them by their healthcare teams, rather than a fully integrated solution that updates automatically when results are stored electronically. Others rely on data captured from one silo of information that is incomplete when compared to the data available from all care providers. Some systems, while technically advanced, do not allow access to the

full patient population for the geographical area that it represents, due to the health service and insurance infrastructure.

Where developments involving MDMW differ from existing systems is that data can be captured from multiple data sources, for a national population via SCI-DC, rather than one distinct clinic or GP practice. This means that longitudinal histories and the complete shared electronic record for diabetes can be viewed by the patient, leading to a more complete record.

This thesis aims to provide evidence to explain whether an automatically updated, population-based, shared personal health record for diabetes would provide benefit to an individual with the condition. While accepting that the system would be disease-specific (i.e. diabetes), the highly 'focused' nature of this record allows the patient to concentrate on this specific aspect of their health care which, especially with newly diagnosed diabetes, is essential given the amount of knowledge required to deal with it. The infrastructure is designed in such a way that, if it proved successful, it could be extended to other long-term conditions.

The main question that this thesis aims to answer is:

What are the benefits of a diabetes-focused electronic personal health record?

In order to assess this work, several sub-questions have been identified:

1. **What are patients' expectations of electronic records access?**

2. **What do patients do when accessing to their shared diabetes record?**

3. **What are patients' experiences of access to their shared electronic record?**

4. **What is the impact on process outcomes for patients who access their shared diabetes record?**

The introductory chapter to this thesis explains the rationale behind these questions, along with the methodologies applied in each of the forthcoming chapters. Chapters 6-9 explain the methodologies in further detail, showing how the research questions were answered using a subjectivist, mixed-methods approach incorporating multivariate analysis and grounded theory.

4.13 Summary

This chapter has covered a review the existing literature related to PHRs and explained how they are defined and presently used. It has covered the evolution of these systems, from the early days of paper-based records, to more modern, novel electronic approaches. This thesis focuses on internet-based PHRs, describing the various methods of implementation that have evolved to introduce the concept of 'intelligent' PHRs containing maximum functionality, decision support and interoperability.

This chapter has described design considerations, stakeholder perspectives, results of previous evaluations and security and confidentiality, before highlighting several notable case-studies. All of this information has provided the groundwork for the next stages of the studies required for this thesis. The discussion of the literature highlighted the key points, before the research questions were stated.

The following chapter (Chapter 5: Requirements and Technical Design) describes the design and methodologies of a new system created to answer these research questions based on the experiences of a subset of the diabetes population in NHS Scotland.

Chapter 5: Requirements and Technical Design

"…it will be an invaluable tool for me and also will encourage me to be

more positive about my diabetes"

A registered user of My Diabetes My Way

5.1 Introduction and Aims

Prior to the chapters detailing the research carried out for this PhD, this chapter

describes the requirements gathering and technical design carried out by the

author during the creation of the My Diabetes My Way (MDMW) electronic

personal health record (ePHR). It explains the work that was required to enable

the system to be developed, from initial project proposal, through the system

design and to final implementation. It explores the considerations and

approaches used to deliver industry-standard security, to define a usable clinical

dataset and to define the data flows and interfacing that produced a manageable

and maintainable technical infrastructure.

The MDMW ePHR aims to build on some of the previous information technology

successes within NHS Scotland described in Chapter 2: Long-term Conditions

and Government Strategy. It explains how patients can be enabled to become

participants in their own care by providing access to a novel, focused, information

resource for diabetes. Data are captured from the national 'shared diabetes

record' and its multiple feeding systems, rather than one distinct silo residing in a

particular care setting. This allows patients access to all of their diabetes information, regardless of the source in which it was originally recorded. This chapter explains the new work leading up to the subsequent evaluation that was completed to enable the research into electronic records access for this thesis.

5.2   Methodology

This chapter explains the requirements capture methods performed by the author to define the key components of the MDMW ePHR. It begins by explaining how funding was acquired and how relevant stakeholders were consulted to produce an initial set of functional system requirements. Non-functional requirements are then specified, along with an explanation of the information governance obligations and how these have been met.

Following on from the requirements capture, the system design explains how the technical infrastructure was implemented to create the ePHR intervention upon which this PhD is based. It also explains the administrative workflow processes set up to manage user enrolment and to ensure that sufficient technical support is available to deal with any issues or queries that may arise.

5.3   Requirements Capture

This section describes the work carried out by the author to capture system requirements prior to the development of the system. It explains the government

strategy that led to the request for funding that enabled the creation of the

MDMW ePHR. It outlines the stakeholder consultation that led to the creation of

functional and non-functional requirements, before concluding with a discussion

around the relevant information governance obligations.

5.3.1 Acquisition of Funding

The 2006 Scottish Diabetes Framework Action Plan (Scottish Executive, 2006)

stated *"that improvements are required to allow all patients' access to their own*

electronic medical records" (Scottish Government, 2006). Following the

publication of this ambition, the author of this thesis submitted a proposal to the

Scottish Diabetes Group to obtain modest funding to develop and deliver a pilot

system to meet this aim. At this time, it was planned that a limited number of

patients (~50) across Scotland would be given the opportunity to gain access and

view their records. By the time the system went live, more than 100 registrants

had engaged. After completion of successful pilot, running from December 2010

to March 2011, and acceptance of the design based on initial anecdotal user

feedback, the project was in a position to roll out more widely, allowing all

patients with Diabetes in Scotland access to their own information. This

anecdotal feedback was expanded upon more systematically using the survey

which evaluates the first year of user activity, detailed in Chapter 8.

In 2010, the Scottish Diabetes Action Plan (Scottish Government, 2010a),

expanded on previous objectives by aiming to achieve *"optimal use of*

information technology" to *"enhance self management and improve*

patient/professional communication" by increasing *"the number of patients directly accessing their own data electronically".* Further Scottish Diabetes Group funding was then obtained in early 2011 to increase the uptake of the system and to expand the functionality, offering more features to assist self-management, enhance user experience and incorporate more automated processes to speed up the registration procedures. This funding, due to run until the end of 2013, enables the aim to engage with 5000 individuals by the end of 2013. In addition to a review from the Scottish Diabetes Group, both funding proposals were discussed in collaboration with strategic planners within the Scottish Government.

5.3.2 Stakeholder Involvement

Throughout the requirements capture process and continuing throughout the system's further evolution, various stakeholders have been engaged to ensure the acceptability of the system amongst patients and healthcare professionals. Key to this engagement was the formation of a project board, involving patients (Ross Kerr, Marilyn Jackson, Andy McQueen, Bruce Knight), healthcare professionals from both primary and secondary care (Dr Debbie Wake, Dr James Walker, Dr Alistair Emslie-Smith, Dr Ian Dickson, Lyn Wilson) and IT professionals (Scott Cunningham, Massimo Brillante, Brian Allardice, Allen Marr), led by the author of this thesis. The project board meets approximately every 3 months and oversees the strategic objectives and management of the services provided.
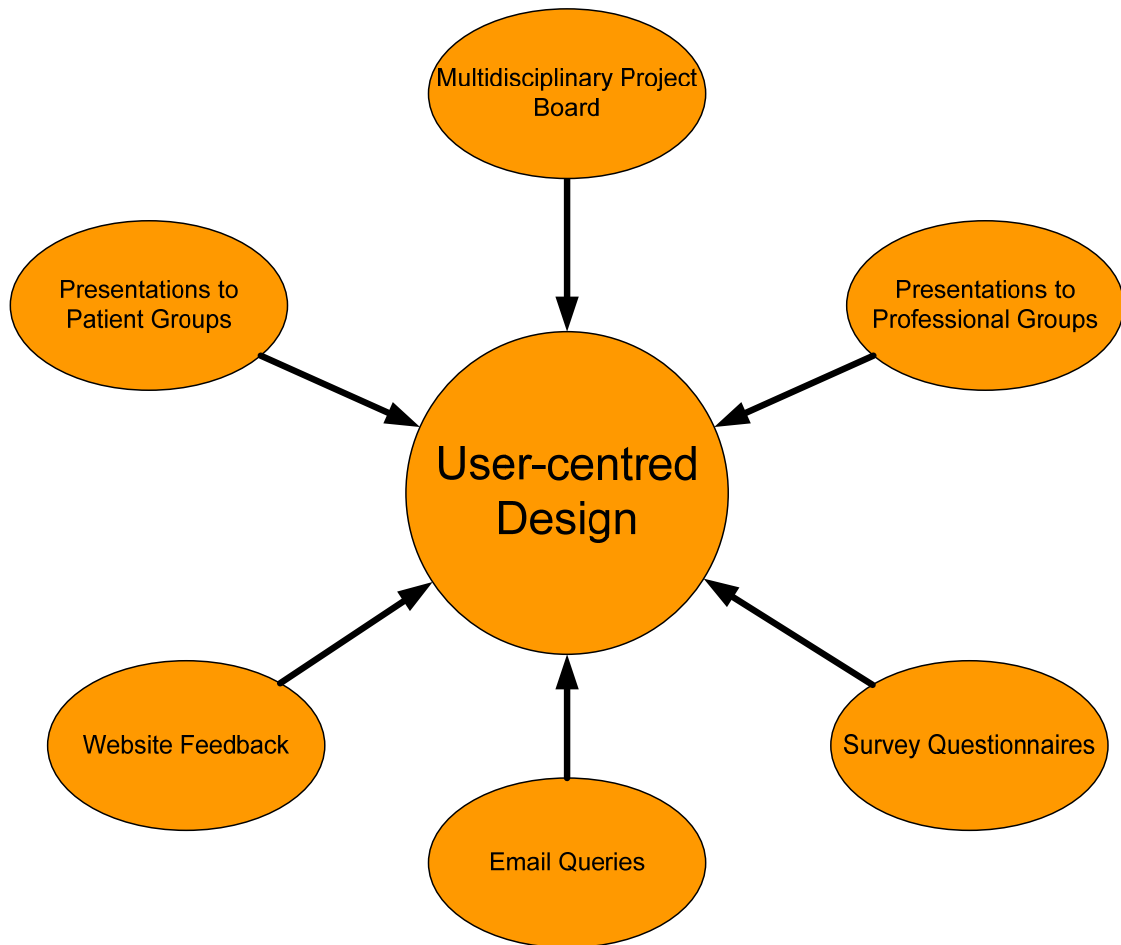
Figure 7: Diagram of stakeholder involvement

In addition to the project board and in order to engage with the wider clinical and patient community, project status is reported at the quarterly SCI-DC Implementation Group, members of which cover all health boards and diabetes Managed Clinical Networks (MCNs). Information and awareness materials are sent directly to diabetes MCN managers and lead clinicians to disseminate more widely within each health board. The SCI-DC Steering Group and Product Development Group receive regular updates and presentations have been delivered by the author directly to the Scottish Diabetes Group.

The author has also taken considerable time to engage beyond these organisational structures to deliver overview and awareness presentations at local Diabetes UK patient groups (Lothian, Fife, Greater Glasgow & Clyde, Lanarkshire) and professional events in Tayside, Fife, Lothian, Greater Glasgow & Clyde, Grampian and Ayrshire & Arran). These awareness presentations showed example Microsoft PowerPoint screens depicting a system demonstration at various stages in the system development, and allowed participants to feed back their opinions, and in some cases their experiences, so that enhancements could be documented. A summary of awareness events is shown in Appendix A: Awareness Presentations Delivered. Each of these methods of stakeholder engagement has also assisted in the assessment of usability and accessibility using feedback received. Based on the discussion following these presentations and anecdotal feedback received from the participants, comments were noted for further discussion and in some cases, development. One example of this came as a result of feedback from a patient who had used the system, explaining that one of their graphs contained skewed data. On investigation, it was found that a value outwith acceptable upper and lower boundary limits was being plotted in error. This resulted in an update to all graphs and tables to exclude data that was clearly erroneous.
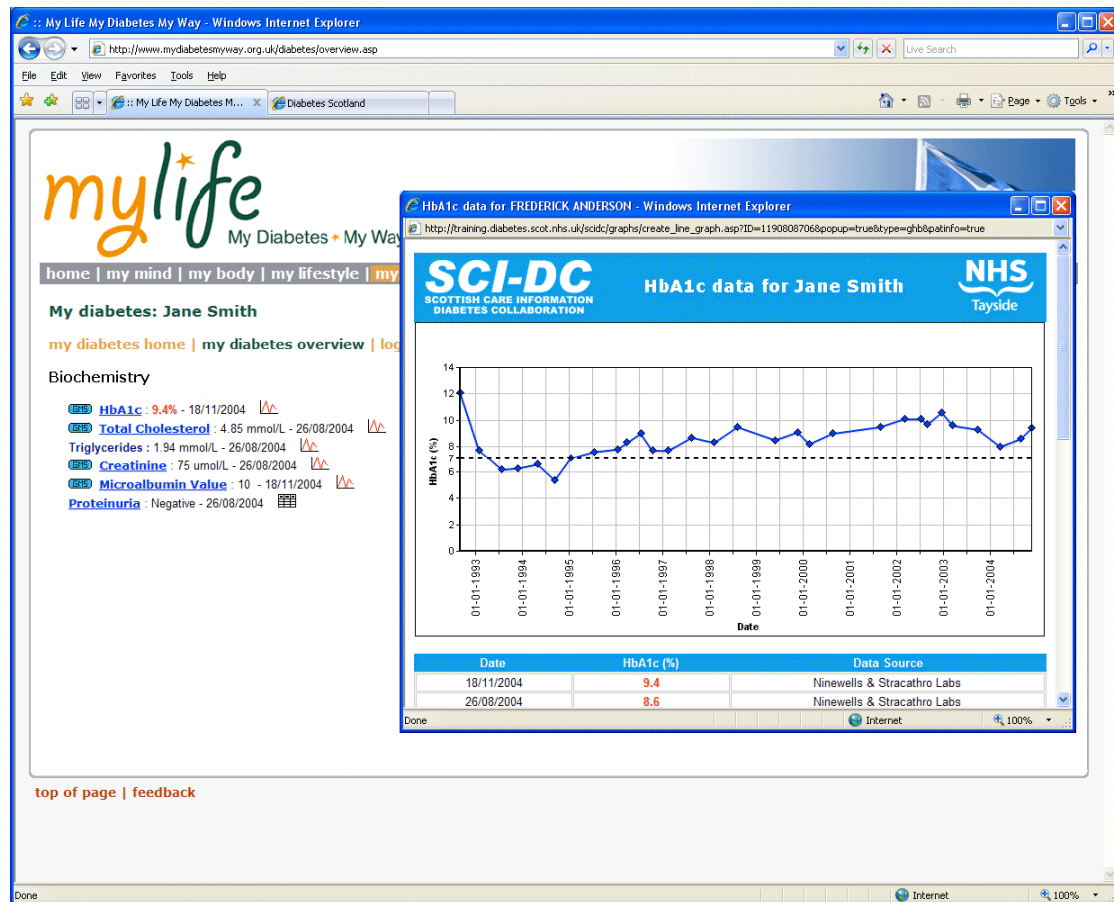
Figure 8: An early non-functional prototype of the MDMW ePHR (anonymised data shown)

Part of the review process involved stakeholder feedback on early prototypes and mock-ups produced by the author. Figure 8 above shows an early non-functional prototype showing the types of data that would be made available, with the possibility to drill-down to view longitudinal changes in line graph format. The prototype was based around the look and feel of the MDMW website at that stage in its development (April 2008, six months prior to the launch of the general information site), and biochemistry results and graphs as they are found in SCI-DC. It was explained that alterations would be made to ensure that the data was displayed in a more 'patient-friendly' format. This concept is discussed in more detail later in this chapter.

Finally, throughout the development and design process, guidance was sought from experts in this field, many of whom had been co-ordinating some of the established systems described in the Literature Review. In particular, early guidance was provided by the pioneers of records access in Scotland who manage Renal PatientView and primary care access at Townhead Surgery in Irvine. Meetings were arranged with key stakeholders, who passed on information regarding their experiences as well as guidance regarding lessons that had been learned. These insights provided essential information for the requirements capture and design of the MDMW ePHR. In particular the information received from Renal PatientView, whose enrolment documentation and patient and staff leaflets were used as the basis of those created for MDMW following rework by the author. This support was complemented along with guidance and support from Scottish Government eHealth Department who continue to monitor the effectiveness of PHRs.

A more formal structured stakeholder consultation was completed at Forresterhill Hospital in Aberdeen in May 2012. During this workshop session, an overview presentation was delivered by the author, prior to workshop activities where the audience, consisting of 16 healthcare professionals, patients and researchers, were asked to complete a structured questionnaire in five groups of three or four individuals. The questionnaire is shown in Appendix B: Structured Evaluation Questionnaire. A discussion of the responses is outlined below.

When asked what may encourage an individual to register for records access, participants stated the ability to track results, improve control, knowledge and self-management would be influencing factors. An interactive, up-to-date record was seen as essential to monitor status, with the ability to check accuracy. Functionality recorded as appealing included access using other technologies, such as phones & apps and the ability to backup and export the data available. The user must be confident with the security of the website and the NHS branding was seen as providing a level of trust. Strategically, the system was expected to offer *"better symmetry of information between doctor and patient"*. Participants believed that showing examples of functionality or supplying training, perhaps facilitated by a 'buddy', would be beneficial so that potential users can see what is on offer before registering.

When asked what barriers may prevent registration, the most common themes surrounded security and privacy and the potential for the system to be "hacked". Two of the groups felt that patients may be deterred by potentially seeing things they don't want to know or that are negative regarding their condition. Reports of negative feedback from other users would discourage potential registrants, as would the potential for the user to spend *"too much time in front of the computer"*. Poor design suggesting a "dull/old fashioned NHS" would be a barrier, as would general apathy, lack of numeracy skills and low IT literacy. Respondents felt that

a multi-staged enrolment process would cause problems and that languages other than English should be supported.

When asked what potential harm could be caused by changing or removing system features, three groups of respondents explained that it may cause worry or concern that something is wrong, particularly a the reason for removal is not understood. It could also make the system confusing and potentially lead to a loss of control if the user was reliant on the withdrawn feature. Others felt that if data were to be lost and/or trend data were to be compromised, it could have an adverse effect on the patient's condition.

Users were asked to consider how benefits could be tracked and measured. Many methodologies were highlighted, including direct feedback on the website, extending to a "Facebook-style" interaction where the user could can like or dislike a feature. A "personal progress score" was seen as being a useful self-assessment tool, where users could track their own learning. An outcomes analysis based on longitudinal data was seen as the most convincing method of proving benefits.

When asked to consider what new and previously unconsidered functionality would be useful, three of the five groups indicated that an online forum or community interaction area would be extremely useful and provide flexibility in

sharing information. Smartphone apps and versions in different languages were also seen as being useful.

These responses provided some useful insights and assisted in the prioritisation of developments. Security and confidentiality were obvious priorities, but smart phone apps and an online forum were both seen as being outwith the scope of the current development, particularly as there are existing systems providing these functions. Management of user expectations are essential and any planned changes must be clearly reported so as not to cause worry. Acceptance of the system amongst clinical teams will ultimately come down to its effect on clinical outcomes.

5.3.3 Functional Requirements

The first requirement for the MDMW ePHR was to allow potential users to register their interest in accessing their data online. This was necessary to collect the minimum amount of personal information required to match the individual to their diabetes records. The current registration form (figure 9) collects name, address, email address, date of birth and CHI number (National Services Scotland, 2013), if known.

Figure 9: The MDMW secure online registration form

All data collected using this form is captured securely and none of it is made available to any third-parties. The form uses industry standard security to maintain the secure transfer, further details of which are available later in this chapter.

SCI-DC contains a wide and varied clinical dataset for the care of people with diabetes. For the design of the MDMW PHR, a subset of data was selected based on core diabetes process outcomes and data which are believed to be most robust and reliable. The initial dataset consisted of:

- Basic demographics (e.g. name, address, post code, CHI, date of birth)

- Diagnosis details (e.g. diabetes type, date of diagnosis)

- Routine measurements (e.g. BP, height, weight, BMI, smoking status)

- Laboratory tests (e.g. HbA1c, cholesterol, creatinine)

- Eye screening

- Foot screening

- Prescribed medication

- Letters and comments

- Appointments

Since the initial implementation, the following data items have been added:

- Laboratory tests (HDL, LDL, eGFR)

- Flu vaccination status

- GP demographics (registered GP, registered practice)

All data items listed in history graphs and/or tables are shown alongside their contributing data source to enhance visibility of where they originated. The dataset will continue to be extended as required following continuing stakeholder discussions. This is likely in future to include long-term outcomes such as cardiovascular and renal status. Patients have expressed an interest in seeing data related to intercurrent illnesses and diagnoses, and this will be explored in future one suitable data sources are identified or become available.

Figure 10: "my lifestyle" summary page (anonymised data shown)

Clinical data are split into manageable sections based on the dataset, such as 'my personal details', 'my lifestyle' (figure 10), 'my foot screening' and 'my medication'. Within these sections, key diabetes data are displayed alongside supporting text, avoiding clinical jargon. These explanations of clinical information are available for all data items and explain why they are necessary, and what normal range values are. For example, the explanatory text for blood pressure is shown below:

"The top value is called the systolic pressure and is the pressure generated in the blood vessels when the heart pumps. This value should be under 130. The bottom value is called the diastolic pressure and is the pressure in the blood

vessels when the heart is relaxing and filling with blood. This value should be

under 80. High blood pressure levels damage the blood vessels"

Alongside the clinical information are links 'tailored' to the individual. Evidence

suggests that by providing tailored information, a patient will be more likely to

absorb the advice given and act upon it (Revere and Dunbar, 2001, Edwards et

al., 2003). This leads to better educated and informed individuals. The example

below (figure 11) shows an example of links tailored to a patient who has a high

risk of foot related complications. The links refer the user to information on how

to look after and monitor their feet in order to prevent or delay the onset of

diabetes-related foot complications.

Figure 11: Information tailored to a patient with high risk feet (anonymised data shown)

The final functional requirement specified was to allow users to enter home-recorded data. At the time of requirements capture during the final months of 2012, devices were available for patients to take reliable home readings of the following measurements:

- Blood glucose

- Blood pressure

- Weight

- Total cholesterol

In addition, following requests from patients to correct their smoking status, this outcome was identified as a candidate for update.

5.3.4 Non-functional Requirements

In addition to the functional requirements of the system, several non-functional requirements were identified. Firstly, the MDMW ePHR was required to build upon the existing look and feel of the general information website to maintain consistency and branding. This was essential from a user experience perspective so that the

Usability and accessibility were highlighted as key areas to focus on, particularly as the specification and design aimed to follow user-centred processes. Usable websites can typically be utilised with the minimum amount of training, are intuitive and do not contain elements unfamiliar from previous computing

experience, leading to increased user satisfaction, vital for the success of any system. Similarly, accessibility is a great determinant of a system's ability to succeed or ultimately fail. Accessibility means a website is designed in such a way that all members of the target community will be able to view its information regardless of physical ability. For diabetic patients with visual impairment, this is extremely important. For this example, it may be as simple as offering enlarged text options and the ability to "save" settings for future use, providing audio versions of content or structure it to support "screen readers".

The security and confidentiality of identifiable patient data are of paramount importance. Requirements were specified regarding the measures of acceptable data transfer and user access to the system. Models were required to follow similar standards to those employed in online banking, using features such as transport layer security and online authentication requiring a username and password combination. In addition, a system audit trail is required to log all access attempts and actions performed when the system is in use. These quantitative data have been used for a considerable portion of the analysis documented later in this thesis.

Finally, in order to maintain user engagement beyond the system launch, a series of newsletters were planned to pass on information regarding new features, known issues and general information that may of interest to participants. While this was not a requirement for the system development as

such, it was necessary to identify an appropriate method of distribution. Following on from this, and to encourage two-way communication with participants, a series of support processes were also required to deal with user feedback, problems and queries.

5.3.5 Information Governance Requirements

This section describes how the MDMW ePHR meets the Caldicott Principles which were described earlier in this thesis (see Information Security and Governance).

1. Justify the purpose: The purpose of the system is to give patients access to their own clinical information, currently held within the confines of the NHS intranet (N3) and inaccessible via the internet. Record access for the diabetes community is a strategic government objective.

2. Don't use patient-identifiable information unless it is absolutely necessary: This is records access for the patient at their explicit requestallowing them to review and report anomalies with their clinical and demographic data held on NHS records.

3. Use the minimum necessary patient-identifiable information: Patient access to records means that CHI, name, address, contact and diagnosis data are all necessary. Identifiable demographics are required to contact the patient and explicit consent is obtained for this. Diagnostic details are required to allow

tailored information to be presented to the patient based on, for example, duration of disease.

4. Access to patient-identifiable information should be on a strict need to know basis: Only those patients who have signed up to the project and those staff maintaining and supporting the system will be permitted to access the information held.

5. Everyone should be aware of their responsibilities: All NHS and University staff employed within the departments processing these data have a duty to maintain their knowledge of current Information Governance standards. The two main departments involved, the Clinical Technology Centre at Ninewells Hospital and the Health Informatics Centre at the University of Dundee, have many years of experience in dealing with sensitive information electronically.

6. Understand and comply with the law: The data transfer processes described in this proposal have been reviewed and approved by the SCI-DC Steering Group. The SCI-DC Operations Manager is responsible for ensuring that legal requirements are met when transferring data from SCI-DC. The SCI-DC Technical Consultant (the author of this thesis) is responsible for ensuring that legal requirements are met once data are transferred beyond SCI-DC and on to the patient-accessible system. The University of Dundee acts as data controller.

5.4 System Design

Designing commenced following the successful attainment of funding, and has continued to evolve during the course of the project. As this project built on the existing My Diabetes My Way website, it was possible to reuse certain elements that had been previously assessed for usability and accessibility. This allowed the layout, navigation and style of the website, which had previously been validated with non-expert focus groups, to be reused for this new component. The following sections describe the system design, where appropriate linking back to the original requirements.

5.4.1 Technical Design and Architecture

This section explains the technical architecture design and outline of the system based on experiences from relevant industries handling sensitive personal data. It explains the security considerations and technical infrastructure that has been implemented.

5.4.1.1 Authentication and User Access

The Improvement Service (Improvement Service, 2013) was established in 2005 to support councils in improving the health, quality of life and opportunities of citizens in Scotland. It offers a national online Citizen Account Service (CAS) with the aim of maintaining accurate, up to date records for people living in Scotland.

Residents with an account can view their own demographic information and keep their personal details up to date. The system allows consumers to consent to share changes to their demographic data through a secure messaging system. For example, when they change address, it enables data to be passed on to other public service providers, therefore removing any administrative burden on the individual.

The key component of the CAS infrastructure that can be reused by any public service partner is its secure authentication platform that can be embedded within any web application requiring strong security. The MDMW ePHR has been designed to utilise this infrastructure to manage user login credentials. The Citizen Account supplies and manages the user authentication details required for each user to log in, supported by secure printing facilities allowing usernames and passwords to be generated and posted separately to the patient.

With this approach, MDMW doesn't need to have any information about the user credentials, increasing the availability and security of this information. The trust relationship between the systems means that successfully authenticated users are simply redirected to MDMW along with a unique citizen identifier. This delegation of user provisioning removes considerable administrative overhead for MDMW and other services making use of the infrastructure. A single, centrally managed user account also makes it easier for the citizen as they do not have

multiple user accounts to remember, while potentially accessing multiple public

services from the CAS portal.

There are two distinct stages in the authentication process once a user has been

sent their login credentials. Firstly, the user accesses the 'My Diabetes' section of

MDMW where they are redirected to the Citizen's Account portal in order to

validate the details they supply. When successfully authenticated, a unique

identifier is directed back to MDMW which is in turn passed back to the Citizen's

Account portal in a secure certificated web service request. This second request

returns the patients authentication level and Unique Citizen Reference Number

(UCRN), which is then used to map to the patient's NHS identifier, the

Community Health Index (CHI). The CHI number is then used to locate the

relevant patient data within the records access database, ensuring that a patient

can only access their own information. Only once fully authenticated will a user

be able to access any screens under the 'My Diabetes' hierarchy. A token is

maintained during the login session which will expire on user logout, or after a

period of 15 minutes of inactivity.

5.4.1.2   User Audit Trail

Every user action on the main MDMW website and the records access module is

logged in the system audit trail log. This allows quantitative data to be gathered

which can subsequently be used to report on user activity, to monitor trends and

to provide feedback on usage patterns. Much of the analysis in Chapter 7: What

People Do with Access to their Electronic Records is based on this audit log. For

example, it is possible to identify what educational materials a user accesses alongside their clinical information. From an administrative point of view, these data are useful to capture information on system usage, numbers of concurrent users, to log potential attacks or to identify users who may be using the system inappropriately.

5.4.1.3 Security

As with any Internet resource containing sensitive information, it is imperative that any data are transferred safely and securely. Experience can be gained by examining industry, and in particular banking, which has been allowing consumers' online access to financial information for many years.

Web Services Enhancements (WSE) for Microsoft.Net (Microsoft Corporation, 2013b) allows the development of secure, interoperable Web Services that are based on open industry specifications, providing end-to-end message level security. Messages exchanged for the integration with the CAS are for user authentication, authorisation and automated registration and subscription. These XML messages are secured using digital certificates and are based on the Security Assertion Markup Language (SAML) standards (OASIS, 2013b). They support single sign-on systems and are designed by OASIS (Organization for the Advancement of Structured Information Standards) (OASIS, 2013a).

All transport-level communications between the users browser, the MDMW web server, SCI-DC systems and the CAS Portal are encrypted using Secure Sockets

Layer (SSL) encryption meaning that information transmitted cannot be intercepted. All security considerations for this project are designed to meet, or exceed industry standards and independent penetration testing of the integration of both the CAS and MDMW infrastructure has been completed.

5.4.1.4   Data Activation

Once a patient has fully registered and has consented for records access, their request is manually activated on the central SCI-DC server. In future, this task will be automated from within SCI-DC and MDMW web applications. Once active, data are transferred securely each night to the patient access database hosted by the University of Dundee Health Informatics Centre (HIC) (University of Dundee, 2013a). Ensuring that servers are secure is a full-time job due to the large number of threats on the Internet such as spyware, viruses and hackers amongst many others. HIC have considerable experience in handling clinical information and securing servers for similar purposes.
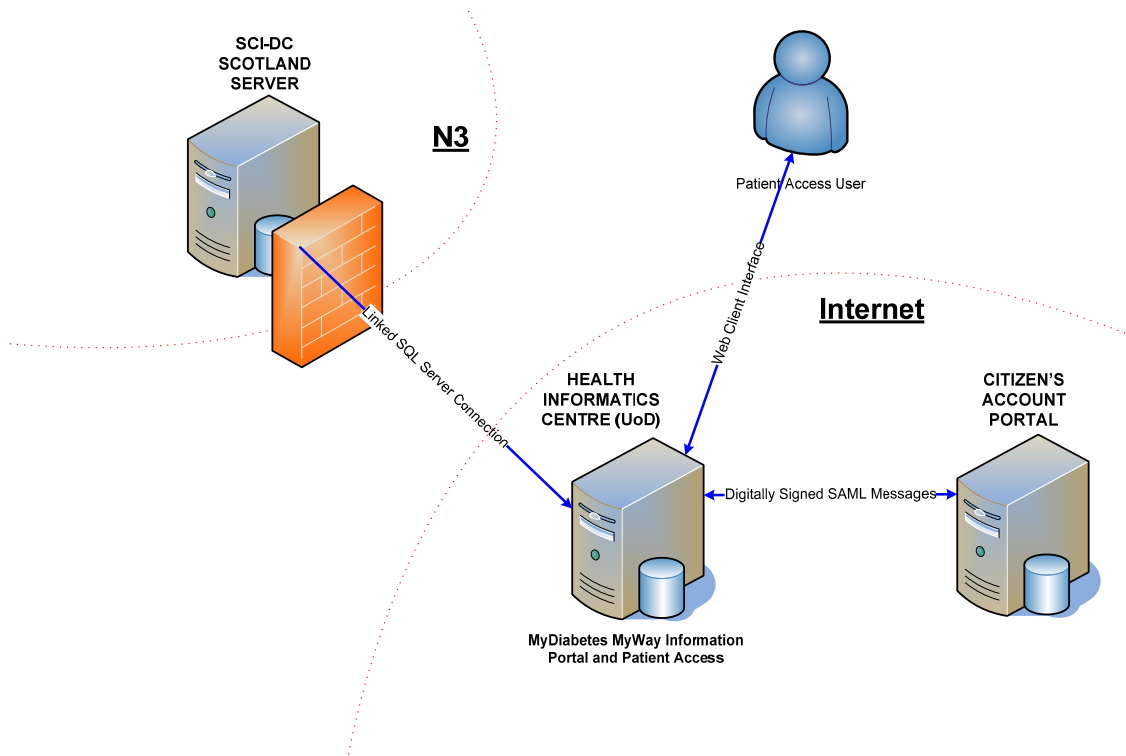
Figure 12: Server infrastructure

Data access is not provided as a default and patients are required to consent and specifically request access for its availability on the Internet, before it can be transferred and it becomes available.

5.4.1.5 Data Management

This section explains the data flows required to allow data from SCI-DC to be made accessible on the internet via My Diabetes My Way after all signup criteria have been fulfilled and enrolment with the Citizen Account is complete.

The main SCI-DC infrastructure consists of multiple database instances covering all fourteen NHS Scotland health boards. Data for the patients involved may be held on more than one server due to cross-boundary migration and the

availability of health service provision, meaning that all necessary information must be pulled and merged from those that are relevant.

On a batch schedule, data for activated patients is passed from each SCI-DC server to a central SCI-DC server for consolidation.
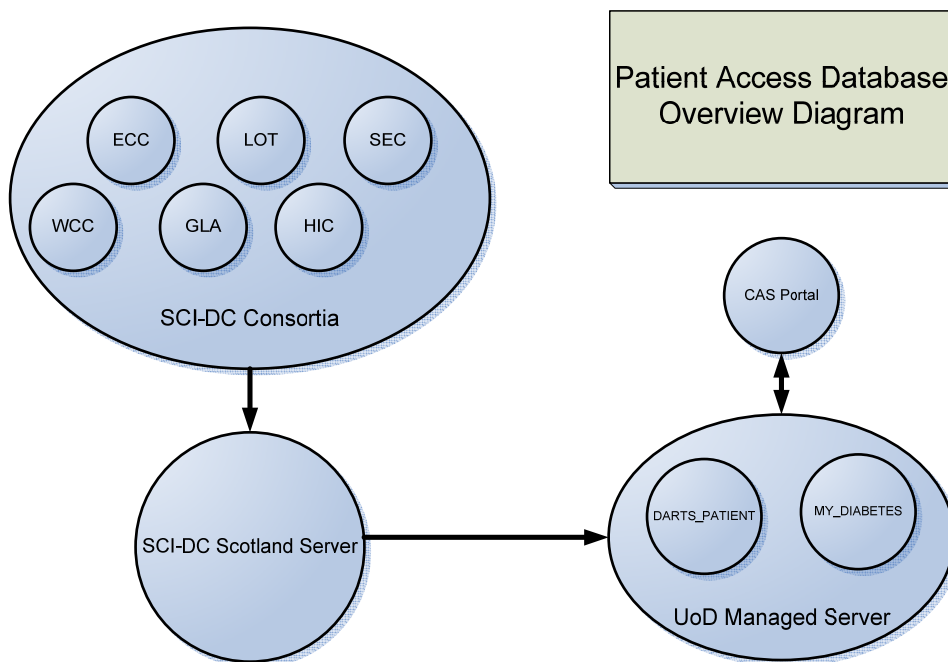
Figure 13: Data flow model

Once consolidated, the patient data are ready for transfer to the secure managed server environment hosted by the University of Dundee Health Informatics Centre. A secure linked server connection has been configured and firewall rules applied to allow the transfer of data from the NHS intranet (N3) to a dedicated managed server. IP Address restrictions and digital certificates are in place, ensuring that the transfer of all clinical data is managed securely.

The services hosted by the University of Dundee consist of a web (IIS 7.5) and database (SQL Server 2005) server. The web server handles the processing of authentication requests, while the database stores the clinical data and all information materials currently available on the My Diabetes My Way Website.

In order to keep these data separated, two distinct MDMW databases are required, one which contains data **ONLY** for the storage of personal identifiable clinical data made available for to the patient. The other hosts all the public information content required by the information website. This is used for the 'tailored' web links made available to the patient based on their current condition. Access requests to these databases are validated using Windows authentication, which is more secure than built-in SQL Server authentication.

5.4.2 Patient-recorded Data

The personal information available on the MDMW ePHR was, until January 2013, collected from NHS systems alone. Since then, it has been possible for patients to enter their own home monitoring results (blood glucose, blood pressure, cholesterol, weight and smoking status), allowing them to contribute to a truly 'shared' electronic record. Further information is likely to be available for entry in the near future, including personal details (mobile phone, email), waist circumference, alcohol consumption, and other patient reportable outcomes. At the present time, these home recordings are not yet transferred back to SCI-DC systems, but this is currently under consideration. Challenges to overcome

include the way in which SCI-DC presents these results to healthcare

professionals and whether it is suitable for transfer back to primary care systems.

5.4.3 Project Newsletters

On a periodic basis, newsletters were sent to the to project participants to pass

on useful information regarding the system. Thee types of information included

details of new features and functionality, explanations of known issues, offers of

support to those who may be struggling with access and references to

background materials and new information content on the general information

website. As all participants had a registered email address when signing up, the

most suitable and cost-effective method of distribution was by email. This was

however not simply a case of sending these messages in to every patient in one

batch. Although MDMW has a registered NHS email address

(mydiabetesmyway@nhs.net), it is not a simple case of drafting the email, then

copying all email addresses in the carbon copy (CC) section. Firstly, NHS email

has a restriction of 1000 recipients, which means that later newsletters have had

to be sent in batches of less than 1000. Furthermore, governance rules regarding

information disclosure prevent the distribution of emails to patients using the CC

field as this would effectively let all recipients know the email addresses of

approximately 999 people with diabetes. Therefore, all emails are sent out with

the MDMW email address in the "To" field and the remaining recipients in the

blind carbon copy section (BCC) so that they are masked.

5.4.4 User Feedback

Users are provided with a feedback mechanism to report errors or anomalies when using the system, while additional requests may be submitted via email. Users are requested not to contact MDMW regarding clinical queries. Instead, if they have questions about their data, they are directed back to their main care provider for further discussion. Patient feedback regarding technical issues has been handled in the majority of occasions by the author of this thesis. In certain scenarios it has been necessary to involve local SCI-DC support teams to resolve data quality and completeness issues. Figure 14 outlines the support process that was defined following the initial three month pilot.
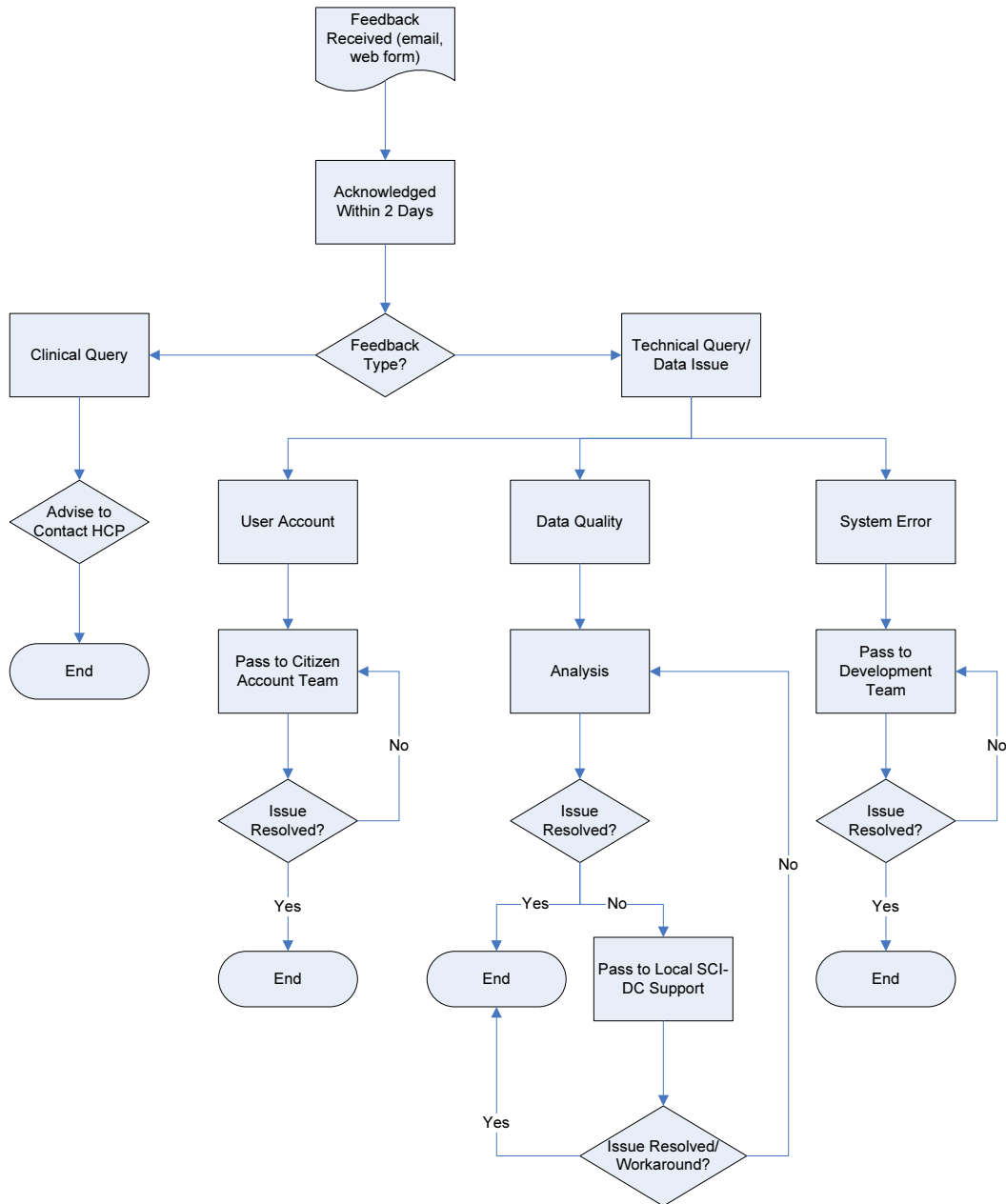
Figure 14: MDMW support flowchart

This explains that an acknowledgement of the receipt of feedback should be sent

back to the patient within 2 working days. Depending on the type of feedback

(clinical query, technical query/issue), the data flow splits. Clinical queries are

referred on as discussed earlier, while technical issues are split into one of three

categories. The most common feedback is in relation to user account and access

problems. These are referred on to the Citizen Account team to deal with.

System errors are passed on to the development team to investigate and

resolve, while data quality issues are assessed in the first instance by the author.

Depending on the complexity of the potential resolution, the issue is either

referred back to the local support teams with guidance, or logged under existing

SCI-DC call logging processes and is treated as an escalation.

5.5 Administrative Workflow

The transition of patients as they work towards access to their own records is

facilitated by an administrative workflow process which is described in this

section.

5.5.1 Enrolment Process

This MDMW ePHR is available to every individual with diabetes in Scotland aged

14 or older, regardless of their geographical location or demography. The

enrolment process required for the patient to register and gain access to their

diabetes record consists of 4 main steps:

Step 1: The patient initiates the process by entering their demographic

information and email address using the secure registration form on the MDMW

website.

Step 2: An enrolment pack is sent to the patient containing further information

leaflets (see section 5.5.2) and a form (Appendix C) which must be completed

and signed, consenting for data to be made available online. This form must be

countersigned by a member of their healthcare team to verify their identity before

it is returned.

Step 3: User credentials are generated, securely printed and posted to the

patient.

Step 4: Patient uses authentication details received to access their diabetes

record via MDMW.
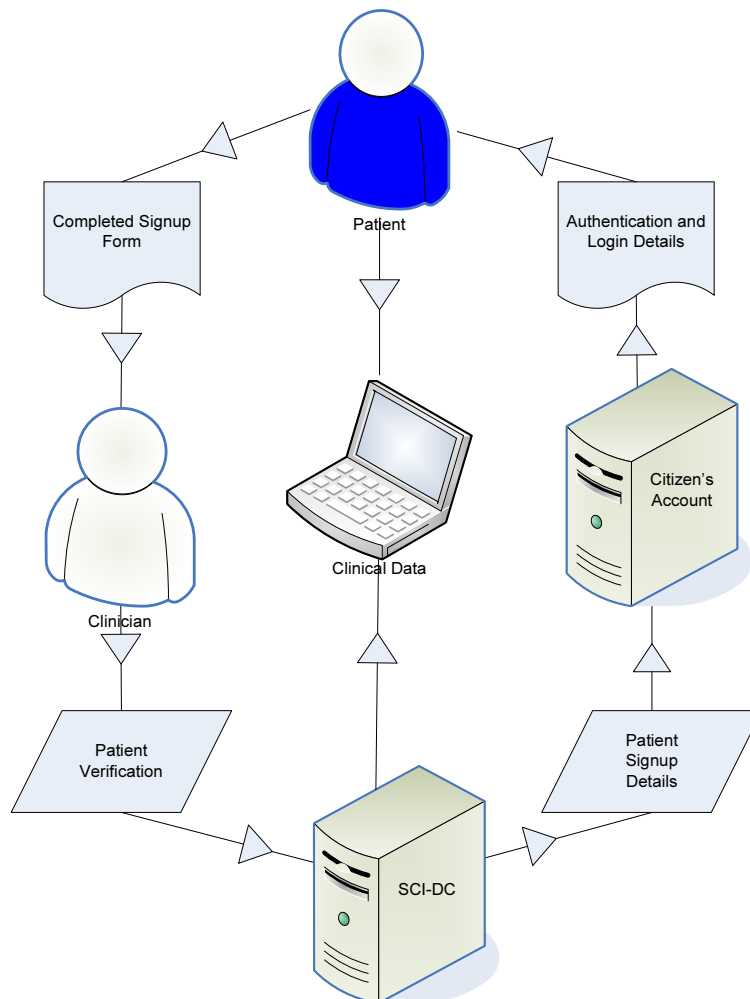
Figure 15: High-level enrolment Process

Streamlining of the registration process means that enrolment can now also be initiated by the patient completing an enrolment form with their healthcare team during a routine appointment. The diagram above (figure 15) shows the high level data flows.

Once the patient has filled in their enrolment form and received verification, the form is returned to the project team for processing. Data matching is then completed and login credentials are generated by the Citizen Account team. These are securely printed and sent to the patient, at which point then can log in to the system.

5.5.2 Information Materials

Information leaflets for both patients and staff have been devised to explain more about the system and what it offers. The leaflet for patients explains the functionality of the system and shows examples of the types of data offered. It also explains where the data are sourced from and how it is handled and made available securely on completion of the enrolment process.

The staff leaflet is intended for use by members of the healthcare team who may not have heard of the system and who may have been asked to verify a patient's identity. This leaflet was particularly useful in the early stages of the project, where awareness of the system was low, particularly in health board areas which had not disseminated information materials beyond the boundaries of their local

diabetes Managed Clinical Network. Both of these leaflets are included in the

enrolment pack sent to patients who register online.

5.5.3 Workflow Staging

At any time during the registration and enrolment process, patients may be at

many varying phases through the process. It was necessary therefore to define a

series of workflow steps, so that it was immediately possible to identify where an

individual had reached from initial registration, through to active system use. The

table below (table 1) outlines the sequential stages defined:

Workflow Stage	Description
Pending	A new registration submitted using the secure web form
Enrolment Sent	An enrolment pack has been sent to the new registrant
Enrolment Received	A signed enrolment form has been received for a patient
Enrolled	The registrant and their address has been identified on the CAS and is ready for registration completion
Address Mismatch	During the matching with the CAS, an address mismatch has been identified for resolution
Matching in Progress	A registration issue has been identified by CAS for resolution
Matched	The registration issue has been resolved by CAS and the user is ready to be subscribed
Pending Activation	The registration process has completed successfully, pending confirmation of user details being sent
Complete	The registration process has completed successfully and letters containing user details have been issued
Cancelled	The user registration has been cancelled.
Underage	The user is under the age of 14

Table 1: MDMW workflow stages

The 'Pending' stage is the initial holding area for new registrations made via the

website. Automated processes use the data supplied to match the patient to the

SCI-DC record, therefore validating patient demographics and ensuring that an

enrolment pack is posted to the correct address. Once the enrolment pack is

sent, the patient is moved to the stage 'Enrolment Sent'. Once the signed and verified enrolment form is received back, patient status is marked as 'Enrolment Received'. At this point enrolment forms may be received from patients who had not previously registered on the website. These are individuals who have either printed the enrolment form from the MDMW website, or those who have signed up at their diabetes clinic.

Once the enrolment form has been received and demographics validated, it is necessary to look up the individual on the Citizen Account system in order to find their Unique Citizen Reference Number (UCRN) and Unique Property Reference Number (UPRN). This lookup now runs automatically, but occasionally requires manual intervention to match address details, particularly for those living in blocks of flats. When both identifiers are found, the patient is moved to the 'Enrolled' stage where they are ready for registration on the Citizen Account System (CAS) system.

The next step is to initiate the registration. In most cases, the registration will complete successfully ('Pending Activation'), but on the occasions where the NHS address doesn't match the address on CAS, the patient is moved to the 'Address Mismatch' stage while this is resolved. For any other issues or delays in the process (e.g. UCRN or UPRN issues), the patient is temporarily moved to the 'Matching in Progress' stage. Once resolved, the patient is moved to 'Matched' and manually subscribed to the MDMW service. Once a registrant reaches the

'Pending Activation' stage, the last remaining stage until the registration is 'Complete' is to receive confirmation from CAS that authentication details have been securely generated and mailed to the patient.

Many of the transitions throughout the process are processed manually (e.g. when letters are posted and UCRN/UPRN details are matched), but the aim is to automate processes wherever possible to do so, to minimise manual intervention. For example, when a registration and subscription request is made to CAS using the web interface, the outcome of that request will appropriately move the individual to 'Address Mismatch' or 'Pending Activation' depending on the response from the web service.

This process was an essential part of the system design as it provides clarity on the current status of each registrant. This is particularly relevant when considered alongside the information governance obligations described earlier in this chapter. It ensures that patient data are not made available for access until all necessary steps in the enrolment have been completed. To make this easier for the project team to manage, these data are now clearly detailed and managed using the MDMW "Administrative Dashboard".

5.5.4 Administrative Dashboard

A key development in support of workflow management is the administrative dashboard. This area is only available to the administrative and development teams to assist in the support of the system. The main page of the dashboard is

shown in figure 13, providing a high-level overview of the total number of patients at each stage in the enrolment process. This is useful to highlight when backlogs in processing occur and ensures they are resolved quickly.
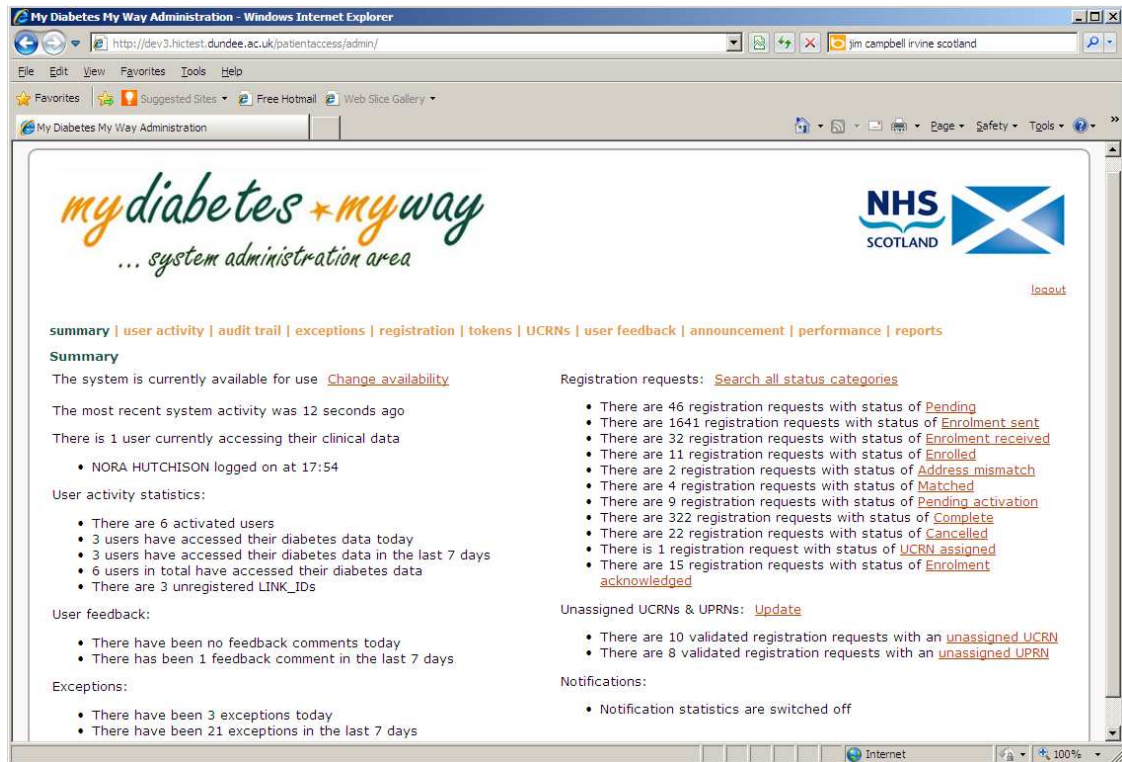
Figure 16: MDMW Administrative Dashboard (example from test system)

This screen also provides information on system utility, showing when there are patients currently using the system and when the last activity occurred. In addition, there are running totals highlighting the number of users active during the current day, over the last 7 days and those who have ever accessed it. The total number of system exceptions (errors) highlights any trends regarding issues with system performance and the feedback figures let administrators know when there are questions to address. All of these features ensure that queries are responded to in a timely manner, and that if there are any issues with performance or reliability, they are spotted early.

Most of the other features available within the administrative area are there to support this high-level overview. For example, "user activity" tells administrators when each user last logged in and the number of times they have accessed the system. The "audit trail" shows who has accessed the system each day and which areas of the system they have used. The "exceptions" link provides the low level detail of every system error generated each day since the system was launched. The "registration" page provides a detailed list of each registrant, filtered by workflow stage and the "user feedback" section allows user-submitted comments to be managed. Management "reports" can also be generated based on a variety of criteria including aggregate totals of registration figures by health board and number of logins each month.

5.6   Summary

This chapter has described the design, workflow and technical outline implemented in support of this project, which ultimately enabled the research documented in the next chapters to occur. It has explained the design methodology used, involving stakeholders from all specialties at each stage of the design, development and review. It also explained how feedback was obtained from individuals who were not directly involved in the project and outlined the system requirements as they came to be implemented.

The technical outline covers some of the architectural and security decisions that were applied to ensure the security of the sensitive clinical information that has been made available to patients online. The interaction with the Citizen Account is explained in more detail, before the chapter ends by showing how MDMW meets the Caldicott Principles.

The administrative workflow is a key component in the throughput of patients, and it will become even more important as uptake increases. The enrolment process has been described along with the supporting materials available for patients and staff. A clearly defined process has been implemented, alongside an administrative dashboard, which allows much of the processing that was originally handled manually, to be automated.

The MDMW ePHR was launched in December 2010 and fully integrated under the 'my diabetes' section of the MDMW website. A three-month pilot phase completed in March 2011 and the system has continued to roll out more widely since then. While the system was under development, and during the pilot period, those signing up for records access on MDMW were asked to complete a survey explaining their reasons and expectations for the system. This was so that benefits and potential risks from a user perspective could be highlighted. This survey provides the data for the first piece of research contributing to this thesis, in Chapter 6: Patient Expectations of Records Access.

Chapter 6:   Patient Expectations of Records Access

"reading it in black & white will give me more incentive to make positive changes"

A registered user of My Diabetes My Way

6.1   Introduction and Aims

The Department of Health in England recently published its information strategy (Department of Health, 2012b) which states its objective to make the general practice record available to all by 2015, with a clear emphasis on patient ownership (Wyatt, 2012). The strategy outlines that patients should be assisted to better understand their clinical results, but what do the patients themselves want or need from access to this information?

This chapter presents the analysis a study which aims to capture patient views regarding access to their electronic record. It aims to highlight the demographic characteristics of those registering for records access (age distribution, type of diabetes) and their degree of computer literacy based on their current internet use and previous experiences with online services, such as shopping and banking. This analysis also aims to capture patients' expectations in terms of the benefits they perceive and concerns they anticipate and provides the opportunity to raise further comments for discussion.

6.2 Methodology

6.2.1 Recruitment

When the My Diabetes My Way website was launched in October 2008, people with diabetes from across Scotland were given the ability to express an interest in accessing their own diabetes information online using a website 'registration of interest' form. In the initial stages, this self-selecting population of 'early adopters' are most likely to have learned about the system via web search engines or through communication via their local managed clinical network and patient groups.

Those individuals were then followed-up by email in order to match details to their NHS records. At this stage, it was necessary to obtain name, address, post code, date of birth and their personal identifier, the Community Health Index (CHI) number (National Services Scotland, 2013), if known. The request for a patient's demographic information was a key step in the identification process to ensure that each patient gained access to their own data, but is likely to have led to the high drop off rate, due to the two-stage information acquisition process that was deployed until November 2010. The registration process has since been changed to capture all necessary identification information at one stage via a secure web form, therefore streamlining the enrolment process.

6.2.2 Survey Design and Data Capture

Alongside the request for demographic information during this pre-live time period, a survey form (Appendix D: Patient Expectations Survey) was issued electronically as a Microsoft Word attachment to capture patient views and expectations regarding access to personal clinical data. The survey was completed prior to the patient learning more about the system and gaining access, while the results formed the basis of this study and informed future functionality.

The survey was designed for potential users of the system and was based around the objectives of the NHS Scotland self-management strategy (Long Term Conditions Alliance Scotland, 2008). Questions were incorporated following input from the project steering group covering features that the team and the strategy highlighted as being relevant in this area. The project group piloted the survey internally before further comments were obtained from two expert evaluators. Face validity of the questionnaire was assessed by independent reviewers to determine its ability to measure patient expectations of records access. This review process led to the addition of an extra 'high impact' question focusing on the potential improvements for diabetes self-management in Scotland.

The survey explained that all results would be handled securely and analysed anonymously. It captures basic demographics (gender and age range), before splitting into 3 main sections. The first of these captures details of the individuals' current computer use and the frequency in which they access online services for information related to their diabetes, or for services such as online shopping and banking. The second section aims to capture opinions regarding patient expectations of record access using 12 closed questions with the options indicating a level of agreement or disagreement. These questions included educational and motivational factors, ability to check for and correct errors, security issues and consultation reminders. The final section consisted of 4 open-ended questions which allowed the participant to provide further information regarding their responses to previous sections, highlight areas that were not covered and explain what their main motivational factors are.

6.2.3 Statistical Analysis

The survey responses were anonymised and analysed using a mixed methods approach. Percentage levels of agreement and disagreement with the closed questions in the second section were collated by combining the results of those who "strongly agree" or "agree" with each question in to the former category and those who "strongly disagree" or "disagree" into the latter.

A multivariate analysis was then carried out using IBM SPSS Statistics 21.0, incorporating age, gender, type and duration of diabetes on the closed questions.

The "Descriptive statistics" option in the software was used to generate cross-tabulations and run linear regressions against the variables in order to assess confidence intervals.

The open-ended free-text questions in the final section were analysed using grounded theory approach for qualitative analysis. The responses were carefully analysed using a two-stage process. The first stage involved line-by-line coding of the responses to the second, third and fourth open ended questions in the final section of the survey. These questions aimed to highlight users' anticipated motivation, benefits and concerns, to identify the key themes emerging from the data. The second stage involved a review to improve the coding on categories to avoid any duplication and overlap. The occurrence of these coded data by distinct individual were counted and summed up into tabular and graphical formats.

6.3   Results

6.3.1 Demographics and Response Rate

At the time of the analysis, the 2010 Scottish Diabetes Survey (Scottish Diabetes Group, 2011) reported that there were 237,468 people with known, diagnosed diabetes in Scotland. Table 2 shows how this figure is broken down by each of the fourteen health board areas.

Region	MDMW Population	Diabetes Population	Recruitment/100,000 Diabetes Patients	General Population	Recruitment/ 100,000 Population
Ayrshire & Arran	5	19,075	26	367,160	1
Borders	0	5,355	0	112,680	0
Fife	17	17,467	97	363,385	5
Greater Glasgow & Clyde	24	54,470	44	1,199,026	2
Highland	7	13,914	50	310,530	2
Lanarkshire	11	27,450	40	562,215	2
Grampian	34	23,357	146	544,980	6
Orkney	0	923	0	19,960	0
Lothian	44	32,717	134	826,231	5
Tayside	19	19,223	99	399,550	5
Forth Valley	5	13,618	37	291,383	2
Western Isles	3	1,170	256	26,180	11
Dumfries & Galloway	4	7,771	51	148,510	3
Shetland	3	958	313	22,210	14
SCOTLAND	**176**	**237468**	**74**	**5194000**	**3**

Table 2: Recruitment by health board prior to launch

In this background population, 11.8% had type 1 diabetes, compared to 35% (61) in the study population. In Scotland, 87.7% have type 2 diabetes, compared to 65% (115) in this self-selecting group. It is theorised that as type 1 diabetes requires more intensive management, people in this group may more likely to seek interventions that can assist them and make their lives easier. The age distribution of the respondents showed that those signing up for records access were, in general, younger than the overall diabetes population in Scotland (see figure 17). This is likely to be due to the higher uptake from type 1 patients who are typically diagnosed under the age of 35, but also because those in the younger age group are perhaps more comfortable with technology and used to accessing online services.
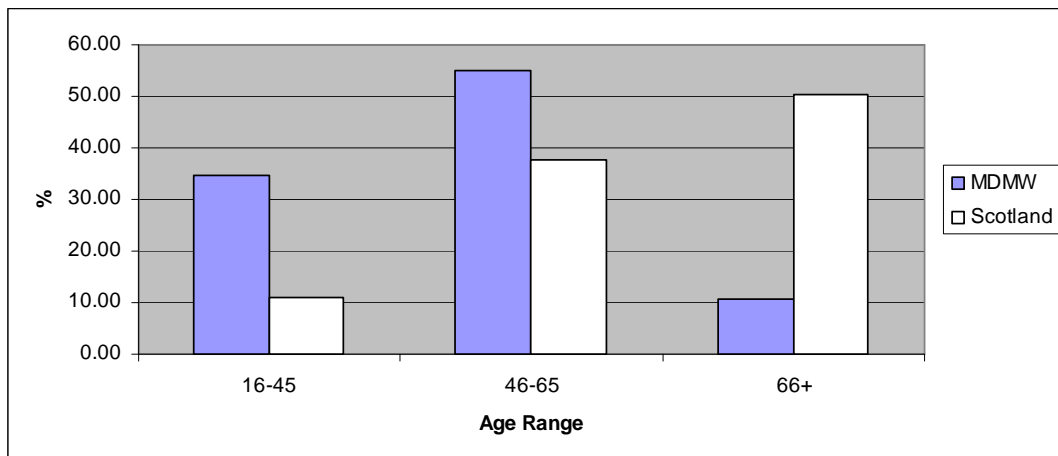
Figure 17: Patient population comparison: MDMW users v Scotland's diabetes population

By February 2011, 356 individuals had registered an interest in accessing their diabetes information. Of these registrants, 176 responded to the initial follow-up email requesting completion of the survey and further identifiable information in order to match their details to the NHS record. This gave a high drop-off rate as only 50.6% of the initial registrants continued beyond this stage. 144 (81.8%) of the 176 who completed this stage submitted a completed pre-project evaluation survey, with 142 of these forms returned electronically by email, while 2 were returned as paper copies through traditional mail.

A very high proportion of participants (145 – 83%) were aware of and able to supply their valid CHI number. 11 (6 %) were able to supply closely approximating their CHI number, while the remaining 20 (11%) did not know what this was.

The results of the survey concluded that 57% of respondents were male, which is consistent with the general diabetic population, where a greater proportion of those with diagnosed diabetes are men. All 144 respondents were interested in viewing their information online and indicated that the data should be shown alongside information materials that are tailored to their diabetes.

6.3.2 Current Internet Use

Individuals requesting access to their diabetes information were experienced in the use of other online services. 98% owned a computer with internet access and 90% look for information about diabetes at least once a month. 67% use internet banking at least once a week and 55% shop online at least once a week. These results indicate that respondents are potentially a more affluent and motivated subset of the wider diabetic population. More detailed analysis identified that those in the younger age group were more likely to shop online (p=.017), validating the assumption that younger users may already use internet services more often. In addition, those who banked online were significantly more willing to upload their own home-recorded results (see table 3 below).

Variables	Method & p value	Comment
Age vs. Time spent online shopping	Chi squared .090 Linear by Linear .017	Younger users currently shop more frequently online
Age vs. Time spent online looking up Information on diabetes	Chi Squared .017 Likelihood ratio- .018	Younger users are likely to spend more time looking up information on diabetes
Age vs. MDMW improving diabetes management in Scotland	Chi squared .013 Likelihood ratio .71	Users aged 31 and above are in 100% agreement that MDMW will improve the management of diabetes in Scotland, compared to 66% in the 25-30 age group
Any online banking vs. willingness to transfer data	Chi squared 0.048 Linear by linear 0.032	Users are more willing to transfer data when already banking online: 96% vs. 82%
Duration of diabetes vs. Desire to ask questions regarding personal diabetes	Chi squared .063 Likelihood ratio-.016 Linear by linear- .002	Those who have had diabetes longer are more likely to wish to ask questions about their diabetes. Agreement is 100% in the

issues		group where duration has been greater than 10 years, compared to 80-96% in those groups of duration under 10 years
Age vs. Time spent online shopping	Chi squared .012 Likelihood ratio .023 LbL .048	Younger users currently shop more frequently online

Table 3: Summary of positive associations

6.3.3 Patient Expectations

The main area of interest expressed was, by a clear margin, the ability to check up on diabetes control. A total of 99% of respondents expressed this as an important factor. 83% wanted to remind themselves about their medication. 95% wanted to check the accuracy of their diabetes record, have the facility to report errors and be able to ask questions about their information. All of those who had diabetes for more than 10 years wanted to ask questions about their diabetes, compared to 80-96% for the remaining age groups. This was quite a surprising finding, as the author expected that those that were more recently diagnosed would have more questions to ask. Due to the small sample size however, this finding cannot seen as reliable at this stage.

94% wanted to be able to transfer their own home recorded readings to the system, believed online record access would improve their knowledge of diabetes and believed MDMW would assist them in meeting their goals. However, 26% stated that they were worried about the security of their online record. This was quite a startling response as those responding were effectively requesting access to a service that could potentially expose this sensitive data to unauthorised third-parties if it were not handled apprpriately. The author

theorises that those who had these security concerns believed that accessing their medical information was more important than any potential risk.

99% agreed that record access is an excellent innovation that will significantly improve diabetes care across Scotland. The two individuals who disagreed with this statement were in the 25-30 age group (66%), meaning that it was the only group without 100% agreement.

6.3.4 General Feedback

Analysis of the free-text comments showed that the areas of most interest were to see HbA1c (22%) and history graphs (20%) tracking changes over time (figure 18). This result is not surprising, given that HbA1c is the main indicator of diabetes control and monitoring change could act as a motivator for improvement. 33 (23%) users reported that improved management of their diabetes was the most important potential benefit (figure 19). 70 (49%) did not anticipate any problems with record access at all (figure 20).
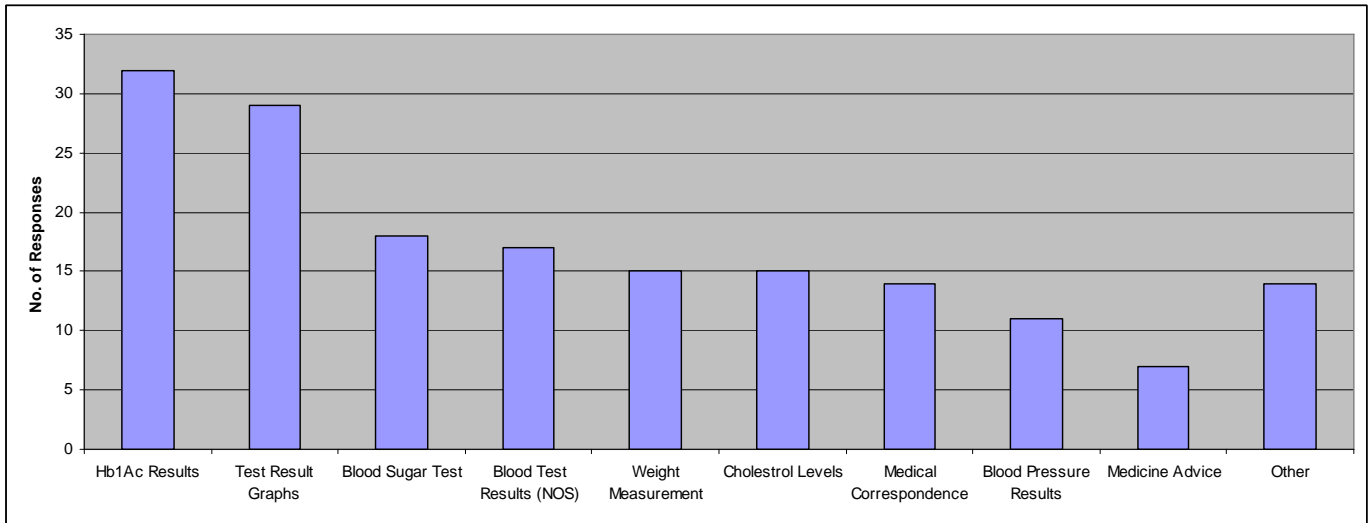
Figure 18: Information of most interest
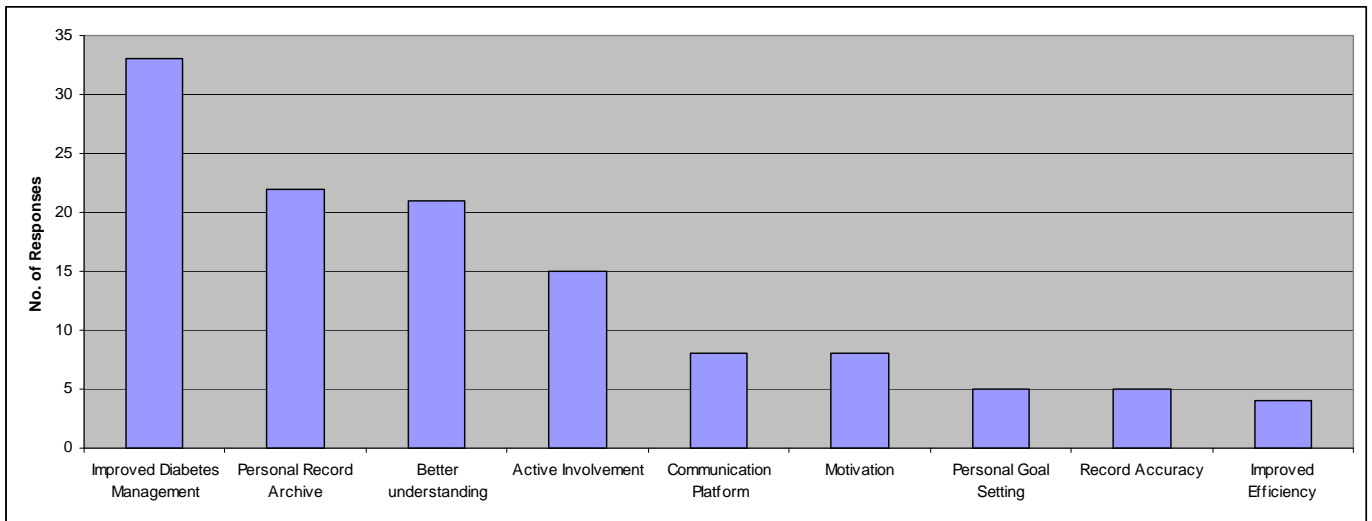
Figure 19: Perceived benefits
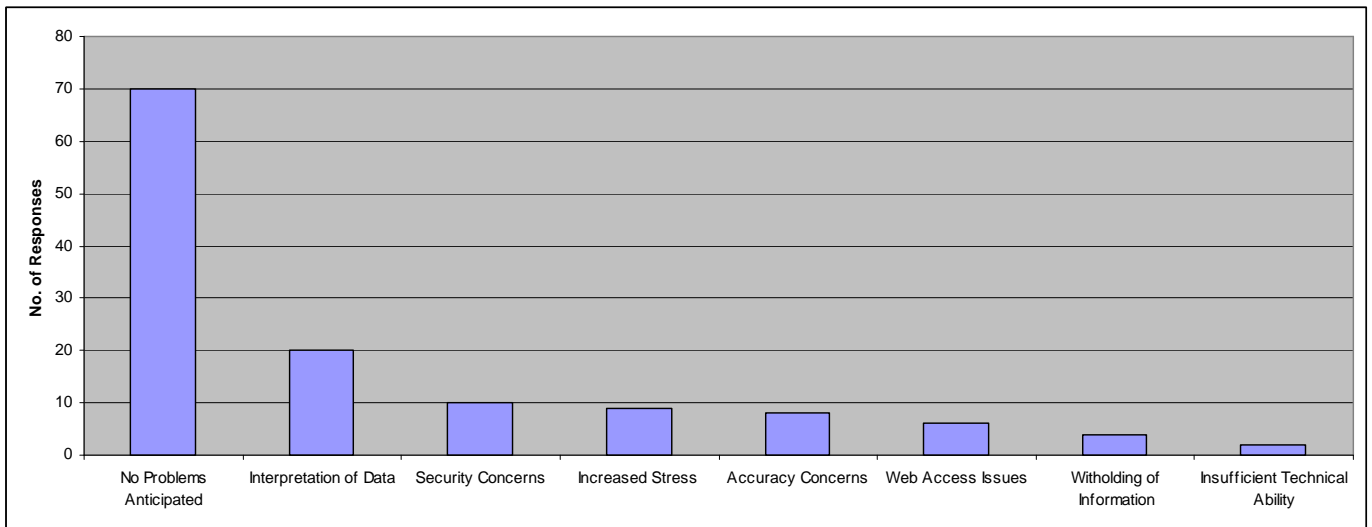
Figure 20: Anticipated problems with record access

6.3.5 Multivariate Correlation

Further multivariate analysis of positive associations can be found in table 3. The key findings showed that the younger age group shop more frequently online. Age groups above 31 are in 100% agreement that the system would improve diabetes self-management, compared to 66% in the (25-30) age group. Users are more willing to transfer data to their electronic record when already banking online: 96% vs. 82% indicating a level of comfort with existing online transactions.

6.3.6 Further Findings

Unexpected benefits extended from the idea of reminders of information discussed during consultations. Respondents said that the system would mean that they no longer had to maintain their own paper record or phone their health care team for updates on recent results. In addition, many wanted to use the system take a more active role in their diabetes management and to be able to

set their own goals. There were however concerns that too much information may be displayed in a way that is difficult to understand.

Notable feedback comments included:

- *"reading it in black & white will give me more incentive to make positive changes.".*
- *"it will be an invaluable tool for me and also will encourage me to be more positive about my diabetes.".*
- *"essential to helping to modernise diabetes hospital care".*
- *"I believe this innovative idea of online record access is extremely useful to both patient and doctor".*

6.4   Discussion

6.4.1 Limitations

The survey was essential in order to gather information regarding patient expectations, but this may have deterred potential users from proceeding due to a lack of motivation to complete it. Concerns about privacy may also have contributed, even though all users were informed that their responses would be analysed anonymously. Some may also have been deterred from proceeding if they encountered problems in completing the survey, or didn't have the time or inclination to finish it. The fact that it was distributed as a Microsoft Word document is acknowledged a being less than ideal, and if the survey was to be

run again, an online web survey would be used. Some registrants highlighted the fact that there was no "Neither agree nor disagree" option available within the closed questions. If the analysis were to be repeated, five-level Likert items would be presented, using the original four categories with the addition of this neutral option. Completion of the survey was only requested during the pilot period and its withdrawal also contributed to the registration process being streamlined.

A small number did respond with valid reasons for their failure or delay in responding. Firstly, the initial project email, despite being a genuine NHS address was in some cases blocked by spam-filters from certain email providers. As the final stage in the enrolment process involves the posting of an enrolment form to sign, the project team can now pass on information regarding potential 'spam-filter' issues via traditional mail that may affect the transmission of follow-up emails. Some of those who did not complete the survey indicated that they believed they had completed it, or that they had been unable to complete it due to technical problems or lack of necessary skills.

Some potential users did not realise that the system was only available within NHS Scotland, when they were resident within other parts of the UK, or in some cases overseas. Other responses were parents of children with diabetes. Although at the time of the pilot, support for this kind of access was not available, it will soon be possible for 'proxy' accounts to be created for parents and carers.

This patient group is acknowledged as likely to be a highly motivated 'early adopting' cohort of the diabetes population. In recent months, recruitment has been pushed through primary and secondary care clinics, ensuring a more representative sample of the wider diabetes population for future studies.

6.4.2 Principal Results

Of the 176 individuals who did complete the registration process following the initial drop-off, 82% submitted the survey form. This high level of return was achieved despite the fact that there were no reminders sent to the patients after the survey was issued, there was no financial or other incentive and it was not mandatory to complete it. It is believed that this high response is because the survey was embedded within the enrolment process and motivation to gain access ensured that all steps were completed fully. This would therefore be a key recommendation for those implementing similar surveys in future. Despite the limitations highlighted, the survey is accessible as it can be completed in the comfort of the patient's home, regardless of their age, gender, socioeconomic status. The anonymous analysis avoids potential social response bias.

Registrants stated clearly that their main incentive for using a record access system was the ability to check their diabetes control and believed it would help them, and other users, improve their knowledge of the condition. This clearly shows that their expectations meet the objectives of the strategic government literature. Patients also want to be able to interact with their record and take

control by checking the accuracy of their information, reporting errors, entering their own results and to be able to ask questions.

The results indicate that there is a high level of awareness of the master patient index (CHI) used in NHS Scotland. In one instance during the record matching process, one individual was flagged as having two separate, unlinked identifiers on NHS systems. This process enabled these records to be successfully linked, the complete historical record was merged and a hospital clinic is now using the correct identifier after using a legacy number for several years.

Levels of patient representation varied across the fourteen health boards in NHS Scotland (table 2). In some of the more rural areas (NHS Grampian, NHS Western Isles, NHS Shetland), uptake was higher (per 100,000 of the population) in proportion to the general diabetic population, as it was in areas where awareness presentations were delivered during the course of the project development and pilot. The author is based within NHS Tayside and has presented at various local events, while in NHS Lothian where one of the project board are based, a patient-event presentation was delivered and one hospital diabetes clinic actively encourages its patients to sign-up. One of the patient representatives on the project board reside in NHS Fife which may also explain the higher than average uptake there. In Western Isles and Shetland where there were no exceptional circumstances and low general population, it is understood that word of mouth has had a major contributing factor to the high levels of

uptake. However, these users may have had more exposure to technology, and in particular video consultations, as part of their routine care.

The results show that the individuals completing the survey were relatively computer-literate due to their existing online activities. Furthermore, all registered online, almost all owned a computer with internet access and a high percentage completed and returned the survey electronically. Computer literacy is further demonstrated by the fact that most of those who did complete it did so electronically, so they were able to download the survey, complete and save their responses, attach the survey to an email and then send it back to the administration centre. This further highlights bias and limitations in reaching a representative cross-section of people with diabetes in Scotland.

6.4.3 Accessibility

Although most of the project group owned a computer with internet access, an individual's ability to gain access to the necessary technology in the UK is now very high. The Office for National Statistics reported in 2011 that 85% of UK individuals now have access to the Internet (Office for National Statistics, 2011). While a good level of computer experience was acceptable for the pilot phase, the main objective of which was to prove the concept worked, it is clear that people with diabetes who do not have these skills must be encouraged to interact. This will be a significant challenge as the project expands, but is likely to become less of a factor as time progresses as the demographic of the population changes and society's experience of technology interactions increases. For those

without the necessary skills, most public libraries now have facilities to train individuals on computer basics and allow access to the internet for all those who wish to participate. Patients are also encouraged to speak to family members to gain the necessary skills required in order to "go online".

Although 26% of respondents stated that were worried about the security of their record, this did not prevent them from continuing with the enrolment process, indicating that any perceived risks were believed to be worth undertaking. Respondents in younger age groups reported slightly more concerns about security.

6.4.4 Lessons Learnt

The author used the evaluation results to influence and prioritise the second phase of development following an initial three month pilot period. The online registration process has been streamlined by capturing all required patient information using a secure online form. The initial system was designed to be read-only but the desire from patients to enter their own home-recorded results led to the development of a data entry mechanism. In addition, users can now ask non-urgent questions about their data and the development of a 'personal goals' module is planned. Initially, a limited subset of process outcomes history (e.g. 18 months history of blood pressure, HbA1c) was to be available, but as expectations indicated the full history was required, it was provided in its entirety when the system launched.

The results of this analysis contributed significantly towards the design a usable system that would meet most users needs, ensuring that the eventual launch was much less painful than it may have otherwise have been.

6.4.5 Comparisons with Previous Work

The results led to similar outcomes to those identified by previous similar studies (Pyper et al., 2004, Ross et al., 2005) in that possible problems were believed to be considerably outweighed by the potential benefits. This study shows that patients are now ready to take a more active role in accessing their own information and are not simply content to have read-only access. They wish to be able to contribute to their clinical data and interact with a truly 'shared' electronic record. There is also evidence from these results that the cyber-divide between younger and older age groups is rapidly diminishing.

6.5   Conclusions and Summary

The results show that patients see the system as having the potential to be an essential tool in the self-management of diabetes. Not only would it allow them to review their historical data but it would act as a reminder system after each clinical contact. Respondents report that they believed the system would help them to become better informed and make their consultation time more productive, particularly when armed with more relevant questions and queries. It was also described as being an essential way to self-motivate when results are available to review in "black and white".

A revised Scottish Diabetes Action Plan was published in 2010 (Scottish Government, 2010a). This outlines the desire to "maximise the use of the diabetes care system by patients to enhance self management and improve patient/professional communication" by increasing "the number of patients directly accessing their own data electronically."

Following the launch of the system in December 2010, usage was logged and monitored prior to further analysis. The first of these analyses was to find out what patients did when accessing their electronic records. The finding of this analysis can be found in Chapter 7: What People Do with Access to their Electronic Records. In order to investigate barriers to use, a further qualitative analysis is explained in Chapter 8: Survey of User Experiences.

Chapter 7: What People Do with Access to their Electronic Records

"It is great to be able to view all of my results so that I can be more in charge of my diabetes"

A respondent to the survey questionnaire.

7.1 Introduction and Aims

At the end of both the first and second years of system use, quantitative analyses were designed to identify areas in which the MDMW PHR was most and least commonly used. The aims were to interrogate system activity to highlight usage patterns, ensure that the system was being used to its full potential and to highlight areas for review and possible training. To do this, the following objectives were defined:

- Identify demographic characteristics of registrants: to highlight which groups of patients were signing up to access their records and whether there were any groups that were not engaging.
- Identify levels of user disengagement following registration and enrolment
- Identify which pages were most commonly accessed: to find out which areas were proving to be most useful to see if lessons could be learned for less popular sections.

- Identify which areas of functionality were not routinely used: to highlight areas in need of improvement.

- Highlight future training needs: to ensure optimal use of the functionality provided.

- Inform future development work: based on the most and least popular sections, areas for enhancement can be highlighted.

This chapter explains the methodology used and outlines the results and conclusions drawn.

7.2   *Methodology*

An anonymised extract of demographic characteristics, such as age, gender, ethnic group, registered NHS health board, type of diabetes and date of diabetes diagnosis were sourced from SCI-DC. These data were captured for all registrants to the system, regardless of whether they had gone on to access their records at the time of data extraction (December 2012). The rationale was that this study should highlight the demographic profile of those who have expressed an interest in accessing their records, as specified in the aims of this chapter. Aggregate summary data highlighting levels of registration by each demographic characteristic listed above were validated in comparison with the background data published in the 2011 Scottish Diabetes Survey (Scottish Diabetes Group, 2012).

A retrospective extract was taken from the system audit trail from the launch date of 15th December 2010 until 14th December 2012 (inclusive), covering the first two years of live use. The primary use of the audit trail is to trap system errors, log successful and unsuccessful access attempts and to monitor each page that is viewed while the system is in use. This was used in conjunction with the latest administrative workflow status of each registered user to highlight the total number of patients who had registered for records access, completed the enrolment process and finally logged in at various time points during the project (December 2011, December 2012 and April 2013). This data were essential in highlighting levels of user disengagement and drop-off at each stage.

Further analysis of the system audit trail allowed the anonymous collection of statistics on usage patterns for those users who finally logged on to access their records. Each distinct page within the system was highlighted, along with the number of number of users who had accessed it and the total number of times it had been accessed. This allowed conclusions to be drawn on those sections that were commonly and less frequently used. Aggregate figures were collected showing the number of distinct users and total pages accessed each month during the first two years of activity. These results were tabulated and graphed to show a more visual representation of trends within the data. User logins were then aggregated by hour of the day and day of the week to show when high and low periods of activity had occurred.

In May 2013, a new extract of system audit trail data was obtained to assess some additional characteristics. During the course of the project, the author had observed periods of high activity following the distribution of the periodic project newsletter to all registered users. In order to quantify the effect of this mailout, login patterns for 7 days before and after each transmission were assessed. The final assessment based on the system audit trail was to show levels of ongoing engagement. This showed the total number of distinct users who had accessed the system with 3, 6, 9, 12 and 15 month periods, along with those who had ever accessed the system. This data could then be used to assess whether or not users continue to use the system following their first login, indicating a level of acceptance and value.

7.3 Results

After the first year of system usage, 361 individuals had registered, 216 (59.8%) had completed the enrolment process and 160 (44.3% registrants; 74.1% enrolled) had logged in to access their diabetes information. By the end of the second year, the number of registrants had increased to 2601, 1183 (45.4%) had completed the enrolment process and 625 (24% registrants; 52.8% enrolled) had successfully accessed their data. Table 4 shows that these figures have since progressed to 3696 registrants, 2355 enrolled (63.7%) and 1038 active users (28.1% registrants; 44.1% enrolled) at the end of April 2013.

NHS Region	Registrants	Enrolled	% of Registrants	Active	% of Registrants	% of Enrolled
Ayrshire & Arran	149	71	47.7%	39	26.2%	54.9%
Borders	43	22	51.2%	11	25.6%	50.0%
Dumfries & Galloway	93	47	50.5%	27	29.0%	57.4%
Fife	383	236	61.6%	144	37.6%	61.0%
Forth Valley	256	195	76.2%	58	22.7%	29.7%
Grampian	265	126	47.5%	86	32.5%	68.3%
Greater Glasgow & Clyde	489	218	44.6%	129	26.4%	59.2%
Highland	193	103	53.4%	63	32.6%	61.2%
Lanarkshire	339	224	66.1%	88	26.0%	39.3%
Lothian	1095	847	77.4%	223	20.4%	26.3%
Orkney	7	4	57.1%	4	57.1%	100.0%
Shetland	43	29	67.4%	21	48.8%	72.4%
Tayside	335	228	68.1%	141	42.1%	61.8%
Western Isles	6	5	83.3%	4	66.7%	80.0%
Total	**3696**	**2355**	**63.7%**	**1038**	**28.1%**	**44.1%**

Table 4: Registration status at end of April 2013

These figures show that there are 2 main areas in which potential users may disengage and drop off. Firstly, there is the enrolment process to negotiate following the initial registration, requiring a form to be completed and returned by the patient, giving their consent for their data to be made available to them online. This form must also be signed by a member of the healthcare team to verify the patient's identity. Chapter 8 explains some of the reasons reported for disengagement at this point. The second stage occurs following the completion of the enrolment process and the provisioning of user account details. Again the figures above show that by the end of April 2013, only 44.1% of those who had completed the process had subsequently gone on to access their data, dropping from 74.1% at the end of year one and 52.8% at the end of year two. During the second year of usage, several clinics in Forth Valley, Lothian and Lanarkshire began proactively recruiting patients as they attended for appointments. While

this increased the number of patients who were registered and fully enrolled, it is startling that these boards have the lowest percentages of active users. This indicates that those signing up in this way may not be as motivated to login to their records in support of their self-management.

In comparison, the Ayrshire and Arran record access pilot (Axiom Consultancy, 2011) reported that 49.6% registrants (194 of 391) went on to use this system, with these figures similar to My Diabetes My way at the end of its first year. The author theorises that the patients signing up for access during these "pilot" periods are likely to be more motivated than those signing up during the wider rollout stages.

7.3.1 High-level Demographics

The following sections are based on data analysed at the end of the first and second full years of use.

NHS Region	Patients	Diabetes Population	% of Diabetes Population
Ayrshire & Arran	113	19,075	0.6%
Borders	31	5,355	0.6%
Dumfries & Galloway	75	7,771	1%
Fife	242	17,467	1.4%
Forth Valley	140	13,618	1%
Grampian	220	23,357	0.9%
Greater Glasgow & Clyde	389	54,470	0.7%
Highland	160	13,914	1.1%
Lanarkshire	263	27,450	1%
Lothian	661	32,717	2%
Orkney	7	923	0.8%
Shetland	34	958	3.5%
Tayside	260	19,223	1.4%
Western Isles	6	1,170	0.5%
Total	**2,601**	**237,468**	**1.1%**

Table 5: Year 2 registrants by NHS Health Board

During the first two years of system use, all 14 NHS Health Boards had representation in the form of registrants to the system. Levels of regional uptake were quantified as a percentage of the local diabetes population with contrasting results. Health boards exceeding the national average included NHS Lothian, who actively promoted signup at secondary care clinics and NHS Fife who have an active and vibrant patient support network involving one of the project board. The author is unaware of any unusual circumstances related to NHS Shetland, however the uptake of 3.5% may be due to awareness through word-of-and mouth the island's familiarity with telehealth technologies. This does not however appear to have been the case in the Western Isles or Orkney where the geographical landscapes are similar. The disappointing figures in NHS Greater Glasgow and Clyde are further compounded by the fact that this is the largest health board in Scotland, meaning that awareness activities must be targeted here in the future.

Gender	N	%
Male	1578	60.7%
Female	1023	39.3%
Total	**2601**	**100%**

Table 6: Year 2 breakdown of registrants by gender

These figures for gender are consistent with the general diabetic population in 2011 (Scottish Diabetes Group, 2012), where a greater proportion of those with diagnosed diabetes are men.

Diabetes Type	N	%
Type 1	791	30.4%
Type 2	1781	68.5%
Other Types	11	0.4%
Type Unknown	18	0.7%
Total	**2601**	**100%**

Table 7: Year 2 breakdown of registrants by type of diabetes

Table 7 shows a higher proportion of people with type 1 diabetes in the project

group, compared to the diabetic population of Scotland where type 1's account

for only 11.8% of the total number. This may be due to the fact that type 1

diabetes requires more intensive management and people in this group may

more likely to seek interventions that can assist them and make their lives easier.

People with type 1 diabetes are diagnosed younger and may be more likely to

use technology to learn more about their diabetes. They are also more likely to

be treated in secondary care, where MDMW awareness materials are more

readily available than they may be in primary care where most people with type 2

diabetes receive the majority, if not all of their care.

7.3.2 Ethnicity Profile

The following table and figure shows the ethnic grouping category of registrants:

Ethnic Group	N	%
African, Caribbean or Black	1	0.0%
Asian, Asian Scottish or Asian British	29	1.1%
Mixed or multiple ethnic groups	41	1.6%
White	2093	80.5%
Other Ethnic Group	5	0.2%
Refused/Not provided by patient	36	1.4%
Not Known	396	15.2%
Total	**2601**	**100.0%**

Table 8: Ethnicity of registrants
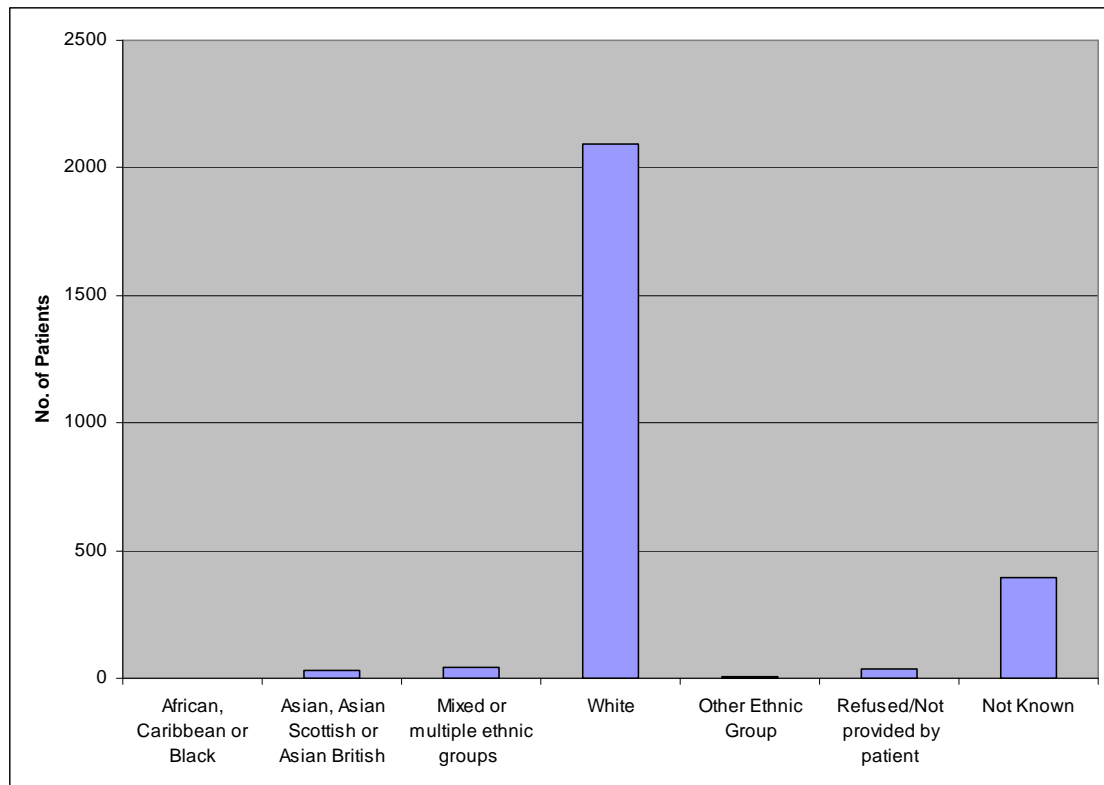
Figure 21: Ethnicity of registrants

Registration is clearly skewed towards white Caucasians based on these data although the reliability of the source data has been queried as will be discussed later in this chapter. At this stage, the author is not convinced that the data are reliable due to legacy systems supplying "default" values in some cases.

Remaining figures in this chapter analyse data only on those with type 1 and type 2 diabetes to enable comparisons with the background national data published in the Scottish Diabetes Survey (Scottish Diabetes Group, 2012).

7.3.3 Age Distribution

Age	Type 1	%	Type 2	%	All	%
0-4	0	0.0%	0	0.0%	0	0.0%
5-14	9	1.1%	0	0.0%	9	0.3%
15-24	79	10.0%	3	0.2%	82	3.2%
25-34	174	22.0%	39	2.2%	213	8.3%
35-44	204	25.8%	157	8.8%	361	14.0%
45-54	171	21.6%	444	24.9%	615	23.9%
55-64	104	13.1%	587	33.0%	691	26.9%
65-74	43	5.4%	457	25.7%	500	19.4%
75-84	7	0.9%	89	5.0%	96	3.7%
>=85	0	0.0%	5	0.3%	5	0.2%
Total	**791**	**100%**	**1781**	**100%**	**2572**	**100%**

Table 9: Year 2 age distribution of registrants

The graphs below show how the age distribution of registrants compared with the general diabetic population for both type 1 and type 2 diabetes.
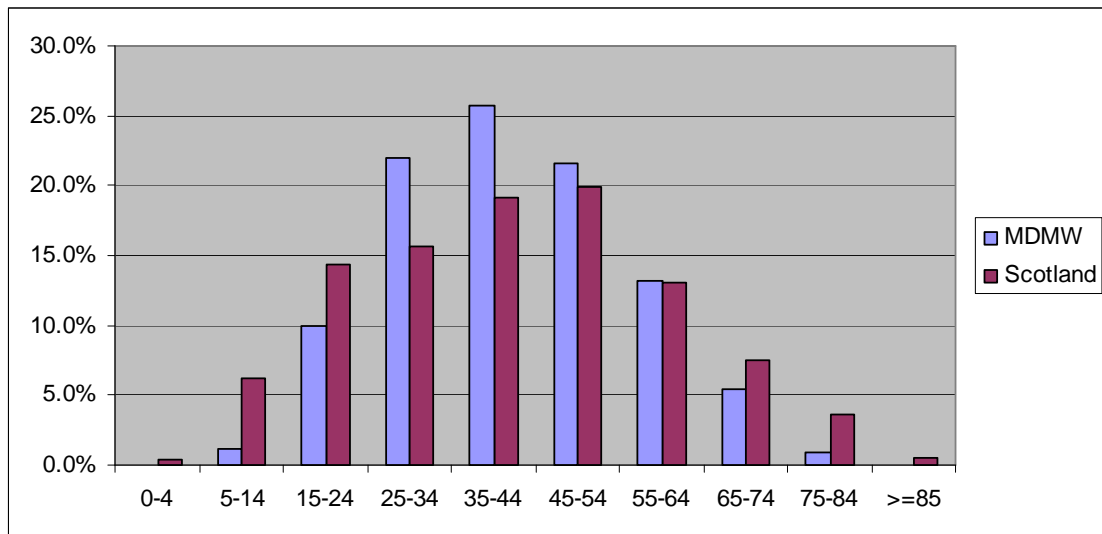
Figure 22: Year 2 age distribution comparison - Type 1 diabetes
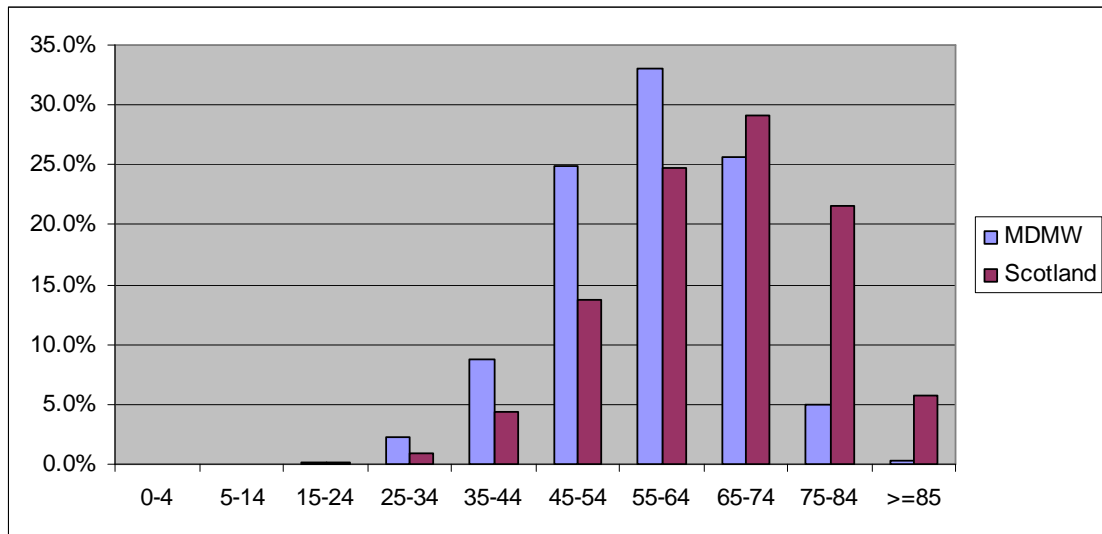
Figure 23: Year 2 age distribution comparison - Type 2 diabetes

The age distribution of the registrants showed that those signing up for patient access were, in general, younger than the overall diabetes population in Scotland. The age range, however, is still wide with even those over the age of 85 signing up to use the system. This is an important point to stress at awareness sessions, particularly with patient groups as many may think they are "too old" or unable to use systems such as the MDMW PHR.

7.3.4 Duration of Diabetes

Duration (Years)	Type 1	%	Type 2	%	All	%
<1	39	4.9%	235	13.2%	274	10.7%
1-4	91	11.5%	593	33.3%	684	26.6%
5-9	118	14.9%	442	24.8%	560	21.8%
10-14	122	15.4%	298	16.7%	420	16.3%
15-19	101	12.8%	147	8.3%	248	9.6%
20-24	93	11.8%	39	2.2%	132	5.1%
25-29	69	8.7%	15	0.8%	84	3.3%
30-34	57	7.2%	7	0.4%	64	2.5%
35-39	41	5.2%	3	0.2%	44	1.7%
40-44	31	3.9%	1	0.1%	32	1.2%
45-49	11	1.4%	0	0.0%	11	0.4%
>=50	12	1.5%	0	0.0%	12	0.5%
Unknown	6	0.8%	1	0.1%	7	0.3%
Total	**791**	**100%**	**1781**	**100%**	**2572**	**100%**

Table 10: Year 2 duration of diabetes by type

The graphs below show how the duration of diabetes of registrants compared

with the general diabetic population for both type 1 and type 2 diabetes.
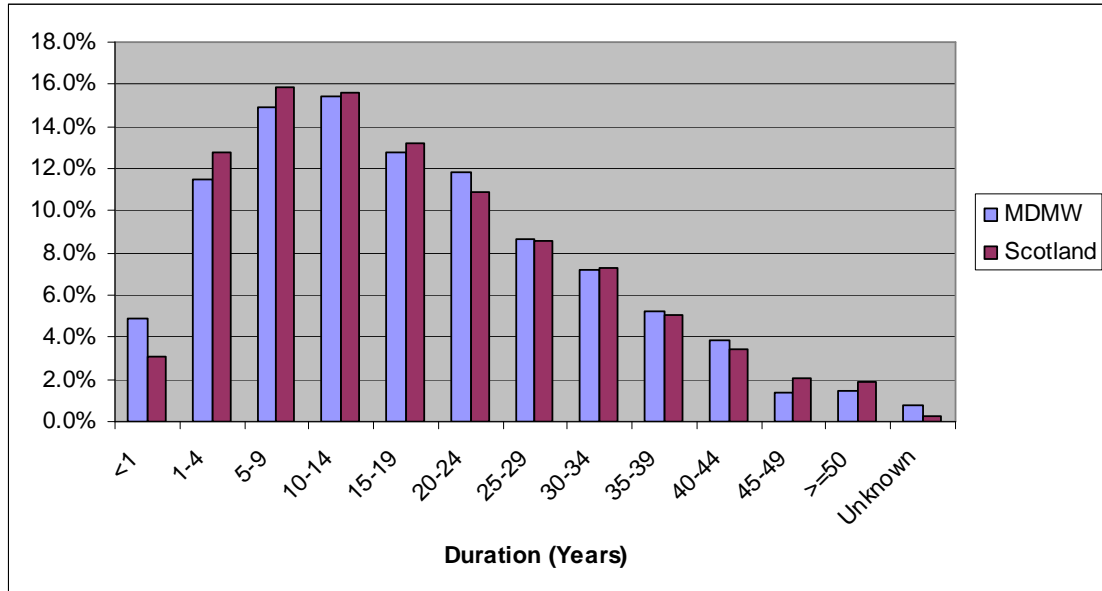
Figure 24: Year 2 diabetes duration comparison - Type 1 diabetes
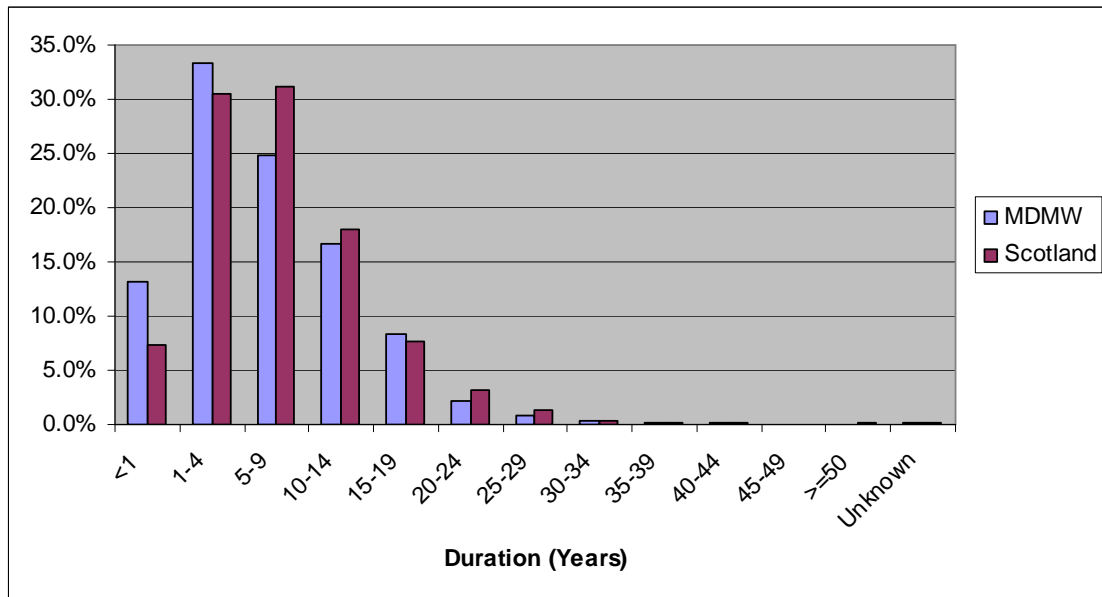
Figure 25: Year 2 diabetes duration comparison - Type 2 diabetes

The duration of diabetes of registrants showed that a significant number were signing up within their first year following diagnosis. The duration of disease for type 1 patients for the remaining age groups remains largely comparable with the background population, but those with type 2 diabetes are also signing up in a higher proportion within 1 to 4 years of diagnosis. The author expects that this is in many cases due to newly diagnosed patients searching online for more information about diabetes shortly after diagnosis and coming across the website.

7.4   Analysis of System Usage

The following section presents measures of user activity and system use during the first two years of activity. The following table shows the number of times that each page on the system was viewed and the number of patients who viewed

them. "Overview" pages contain summaries of the latest data in each category,

while history line graphs allow individuals to track changes over time for the full

duration of their electronic clinical record.

Page	Distinct Users	%	Total Accesses	Total / User
Personal Details Overview	625	100.0%	6943	11.1
Test Results Overview	618	98.9%	11818	19.1
Eye Screening Overview	593	94.9%	3590	6.1
Medication Overview	589	94.2%	3028	5.1
Foot Screening Overview	583	93.3%	3390	5.8
Lifestyle Overview	572	91.5%	4757	8.3
Patient Diary	550	88.0%	2386	4.3
HbA1c History	477	76.3%	2866	6.0
External, Tailored Links	436	69.8%	2044	4.7
Blood Pressure History	430	68.8%	1637	3.8
Cholesterol History	405	64.8%	1756	4.3
Creatinine History	392	62.7%	1630	4.2
Any Data Item Definition	353	56.5%	3550	10.1
Weight History	332	53.1%	995	3.0
BMI History	328	52.5%	834	2.5
Retinopathy History	272	43.5%	643	2.4
Visual Acuity History	227	36.3%	471	2.1
Target Chart	212	33.9%	692	3.3
Foot Risk History	208	33.3%	452	2.2
Foot Pulses History	197	31.5%	387	2.0
Maculopathy History	182	29.1%	382	2.1
HDL Cholesterol History	180	28.8%	438	2.4
User Feedback	178	28.5%	673	3.8
eGFR History*	176	28.2%	441	2.5
Medication Information Links	168	26.9%	519	3.1
Flu Vaccination History*	168	26.9%	311	1.9
Correspondence Page	134	21.4%	1134	8.5
Foot Sensation History	131	21.0%	274	2.1
Triglycerides History	130	20.8%	314	2.4
Monofilament Testing History	119	19.0%	240	2.0
Vibration Testing History	90	14.4%	175	1.9
LDL Cholesterol History	74	11.8%	165	2.2
Correspondence Item	61	9.8%	664	10.9

Table 11: First 2 years system usage by page

During the first two years, 625 users accessed the system (most logins=346),

with 5158 logins in total (average=8.3/patient; median=3). Audit trails show

59599 page views (95/patient), with 'test results' proving the most popular (11818 accesses; 19/patient). The most utilised history graph was HbA1c (2866 accesses, 5/patient), which is not surprising given that this is the most important measure of diabetes control. The personal details page is the first page shown when the user logs on, so as expected, every activated user had seen this. Other popular overview pages included those for eye and foot screening and medication, although repeat use was around a third of that shown for test results. This indicates that biochemistry tests are a key component of the system and its continued use. Clinical correspondence is currently only available to those patients who have attended secondary care and whose clinics have consented to sharing letters with the patient. This explains the relatively limited use, however those who have been permitted access to letters have one of the highest repeated use levels. Data item definitions have also proven popular for those who have accessed them, indicating that these users have found the explanatory text and reference materials a useful aid to learning. Many of those screens least commonly used are for data items that are not regularly recorded, such as LDL cholesterol and foot vibration testing. eGFR and influenza vaccination histories were new pages added during the second year of active use, explaining the relatively low access rates.

Tables 12 and 13 show the breakdown of usage for each month since the project launched in December 2010.

Month	1	2	3	4	5	6	7	8	9	10	11	12	Overall
Distinct Users	60	42	25	20	24	41	30	23	49	51	50	58	**159**
Total Pages	3525	1455	656	851	966	1340	921	703	1737	1843	1806	1942	**17745**

Table 12: Distinct users and total page accesses by month – Year 1

Month	13	14	15	16	17	18	19	20	21	22	23	24	Overall
Distinct Users	56	70	83	89	116	105	98	118	139	97	177	279	**579**
Total Pages	1439	2156	2597	2467	3886	3291	3264	3053	3931	2292	5104	8375	**41855**

Table 13: Distinct users and total page accesses by month – Year 2

These tables outline the number of distinct users and page accesses during these periods. In year 1, 159 unique users logged in to access their data, while in year 2, the number increased to 579. Over the course of the two years of activity, a total of 625 distinct users logged in. Table 13 shows in the last month of this two year period that 44.6% of these ever active users had logged in. At this time, there were 1183 enrolled users, meaning that 23.6% of those who could have logged in actually did during this final month. The author does not expect that every user will log in every month due to a number of possible factors, including:

1. Type 2 diabetes progresses relatively slowly (especially when compared with type 1 diabetes), meaning that these users may not have new assessments available to access regularly.

2. Intercurrent illness or hospital admission may restrict the patient's access to technology, and as a result, their clinical results.

3. Records access may take a lower priority when competing against the other aspects of day-to-day life.

Further analysis of ongoing user engagement is detailed later in this chapter.

7.4.1 Usage Trends – Year 1

Figures 26 and 27 show data access trends during the first year of system use, based on both distinct users and total pages accessed.
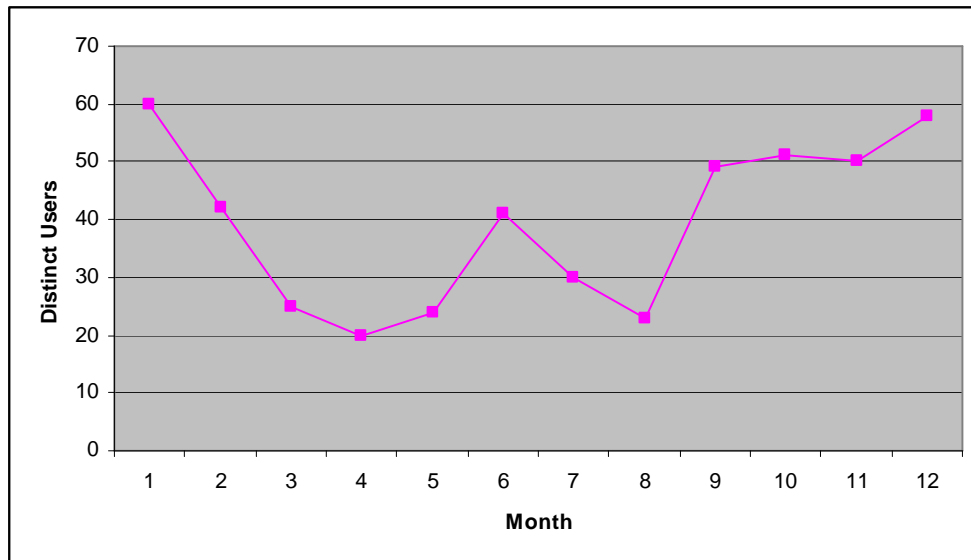
Figure 26: Distinct users by month – Year 1
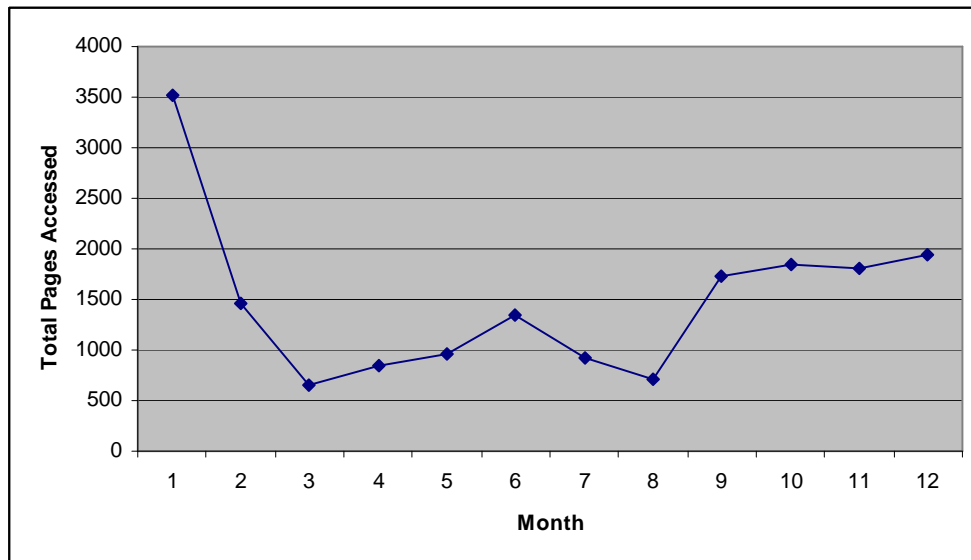
Figure 27: Page accesses by month – Year 1

These graphs show that at project launch there was a peak in activity as users logged in for the first time. Monthly usage dropped in subsequent months, before

finally rising to initial levels by the end of year 1 as more people gained access.

Despite the return to initial user levels, the number of page accesses remained

around half of the initial level. The author believes that this is due to the way in

which people use the system initially, compared to ongoing review. For example,

on first access, the user may be likely to review all data, whereas subsequent

visits may be to focus on a new blood test result or screening following an

appointment, meaning more focused use.

7.4.2 Usage Trends – Year 2

Figures 28 and 29 extend the data access trends displayed in section 7.4.1 to

cover the first and second years of activity.
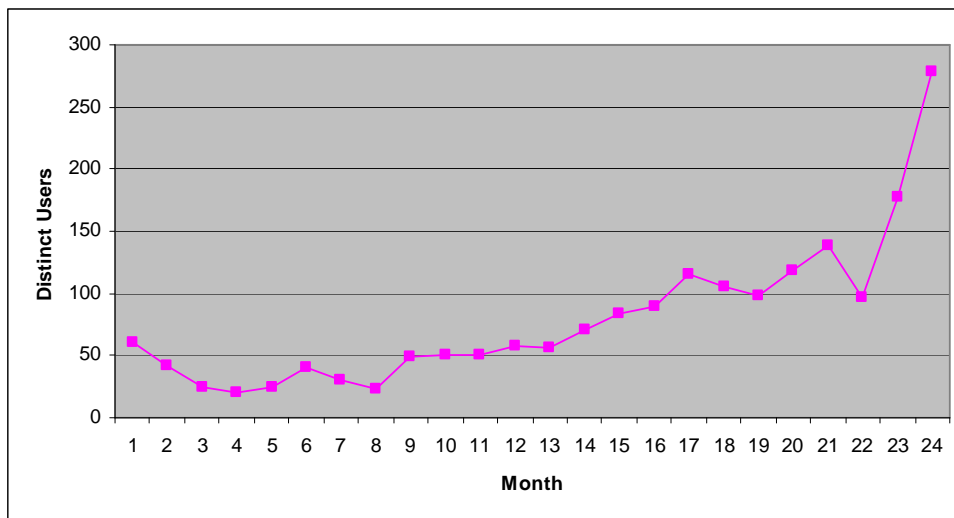
Figure 28: Distinct users by month – Years 1 and 2
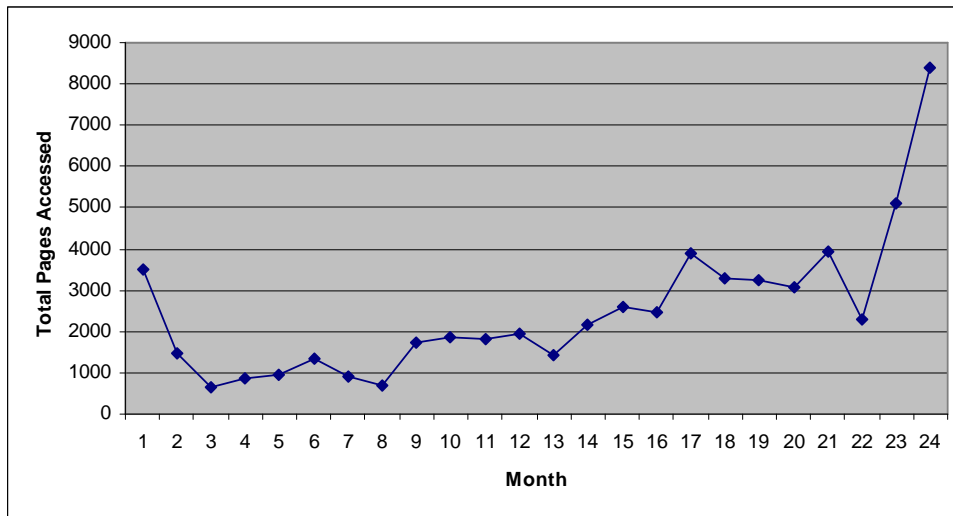
Figure 29: Page accesses by month – Years 1 and 2

These graphs show a gradual increase in both distinct users and total pages accessed before a dramatic rise towards the end of 2012. Continued recruitment activities, including a Scottish Government diabetes awareness campaign in August 2012 (Diabetes UK, 2012a) helped contribute to this rise and peak of activity.

7.4.3 Access by Hour of Day

As reported earlier in this chapter, there were 5158 logins in total during the first two years. The following table and graph show the time of day (rounded down to the nearest hour) when these logins occurred:

Hour of Day	00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00
No. of Logins	80	44	16	13	9	6	16	71	161	281	350	349

Hour of Day	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00
No. of Logins	357	385	326	327	335	284	308	331	367	323	228	191

Table 14: User access by hour of day
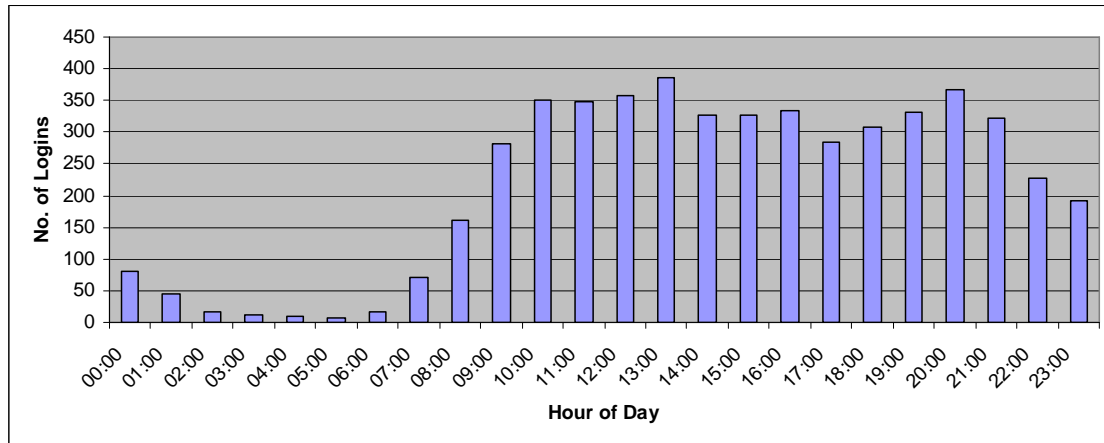
Figure 30: User access by hour of day

Unsurprisingly, these data show limited usage during the course of the night and most use during the day, particularly around the lunchtime period and early evening when users may have more free time outwith work.

7.4.4 Access by Day of Week

This following table and graph breaks down logins by day of the week:

Day of Week	No. of Logins
Sunday	379
Monday	793
Tuesday	814
Wednesday	905
Thursday	881
Friday	857
Saturday	529

Table 15: User access by day of week
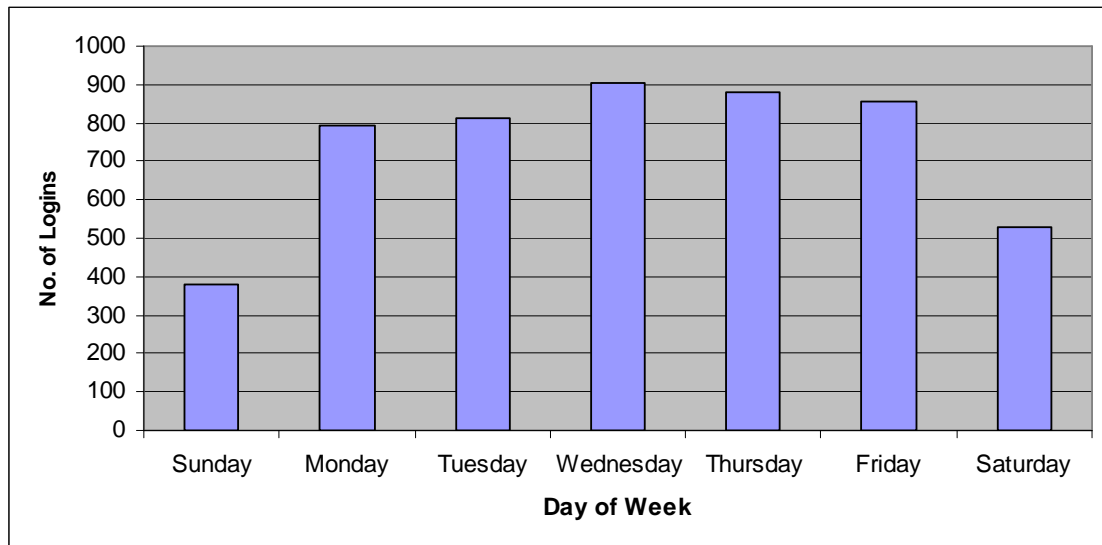
Figure 31: User access by day of week

These data show that usage rises during the course of the week, peaking on

Wednesday, before dropping down again towards the end of the week. Weekend

days, and in particular Sunday, show significant reductions in activity, which may

be due to the availability of internet access outwith the working environment, or

due to social commitments taking priority at the weekend. By combining these

last two analyses it can be extrapolated that Sunday's around 5am are likely to

show least user activity, while Wednesday's around 1pm are likely to be most

busy. These data are useful for scheduling periods of maintenance and ensuring

high availability during peak periods.

7.4.5 Accesses Following Newsletter

In May 2013, a new extract of system audit trail data was acquired to provide

data for the remaining analyses in this chapter. The following graph shows the

number of logins prior to and following the mailing of the MDMW newsletter. This

is emailed out to registrants on a periodic basis to pass on information regarding

new system features, developments and scheduled downtime. Day 0 is the day

of the mailout, with usage shown on this day and the seven days before and

after.
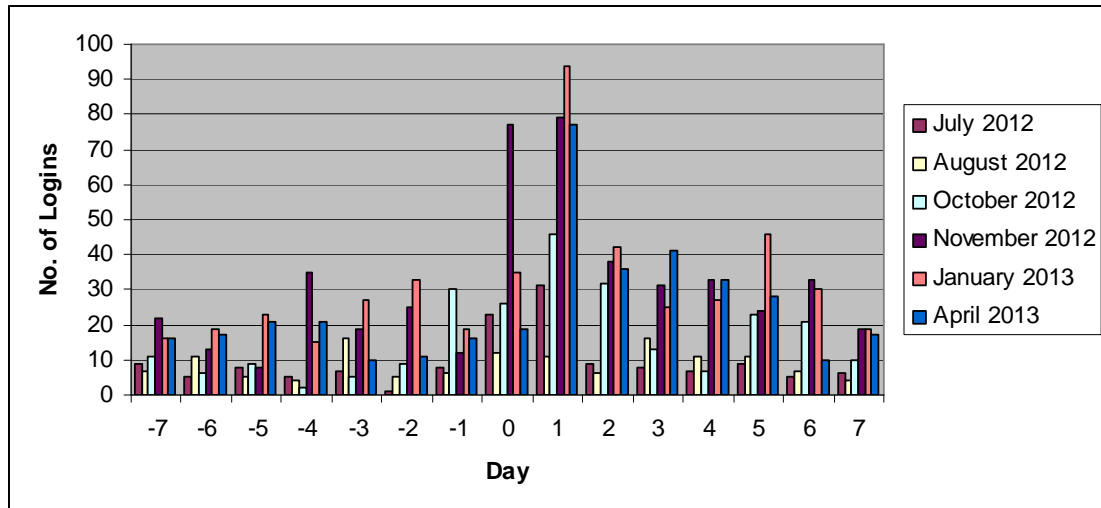
Figure 32: User access following newsletter

These figures show how the newsletter mailing results in a flurry of user activity

for the days following it, before returning to the previous levels by the end of the

next week.

7.4.6 Assessment of Ongoing User Engagement

The following table and graph compare the total number of users who have ever

logged on to the system with those who have logged in within defined finite time

periods from three to fifteen months.

Time Period	N	%
Within 3 Months	601	55.3%
Within 6 Months	858	78.9%
Within 9 Months	953	87.7%
Within 12 Months	994	91.4%
Within 15 Months	1031	94.8%
Ever	**1087**	**100.0%**

Table 16: User engagement – all patients
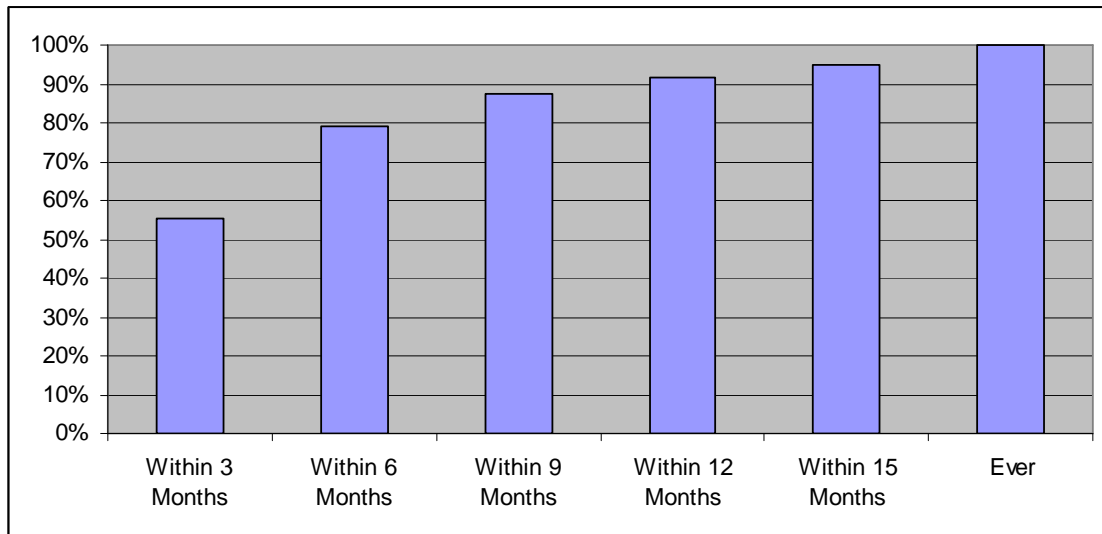
Figure 33: Analysis of user engagement

These figures show that over 50% of users who have ever accessed the system, have done so within the last 3 months and nearly 80% have accessed it within the last 6 month. This is not adjusted for the small number of deaths (n=4) amongst the previously active user population.

The following table breaks down activity by type 1 and type 2 diabetes to highlight any potential difference in usage amongst these groups.

Time Period	Type 1	%	Type 2	%
Within 3 Months	157	51.6%	428	55.7%
Within 6 Months	231	76.0%	612	79.6%
Within 9 Months	254	83.6%	683	88.8%
Within 12 Months	276	90.8%	703	91.4%
Within 15 Months	289	95.1%	727	94.5%
Ever	**304**	100.0%	**769**	100.0%

Table 17: User engagement – type 1 and type 2 diabetes

This table shows that the usage patterns amongst patients with type 1 and type 2 diabetes are fairly consistent. Recent activity is slightly lower within the type 1

group, which is surprising to the author as it was expected that these patients may use the system most often due to the high levels of management required.

7.5   Discussion

The following section discusses the results reported above, providing insights into the data and delving deeper into its interpretation. The reason for the percentage reduction in active users towards the end of year two can be attributed to two issues. Firstly, the Citizen Account team were in the process of implementing new automated processed towards the end of 2012, which delayed the provisioning of user account details at this time. Indeed, a batch of over 400 user accounts was delayed due to this service update and release.

Secondly, due to an awareness campaign launched by the Scottish Government in collaboration with Diabetes UK (Diabetes UK, 2012a), requests for access spiked towards the end of 2012. This meant that many more users were in the process of acquiring the necessary verification signature to complete their enrolment. This meant that there were many patients in various stages of workflow following receipt of their signed enrolment form, but still prior to completion and with that, the provisioning of usernames and password. It is believed that these will be more representative figures than those reported earlier in the project, based on a much slower influx of registrations and patients who were, perhaps, more enthusiastic early adopters. The overall effect of these two issues resulted in a jump in registration requests, a percentage reduction in

completed enrolments and a similar reduction in those who received login

credentials and therefore accessed their data.

An interesting observation was made on the data from NHS Lothian. They were

the first health board to enhance their recruitment by offering access to patients

as they attended appointments in secondary care clinics. As a result, Lothian has

the highest number of registered users and the highest percentage of users who

have completed the enrolment process and therefore access to their data.

Despite these figures, they also have the lowest percentage of users who have

actually logged in to the system, a trend which can also be observed in

Lanarkshire and Forth Valley who have similar processes. This indicates that

there may be usability issues with the login process, or that users signing up in

this way completed enrolment without the necessary intention or motivation to

login once they received their username and password.

Analysis of ethnicity shows that there are extremely low numbers of minority

ethnic groups registering to access their data, with registrants in these groups

totalling only 2.9%, compared to 80.5% classed as 'White'. At the time of writing,

there are no comparable national data for the diabetes population, although

these data are expected to be available in future Scottish Diabetes Surveys. The

author theorises that this may be due to a lack of completeness and quality in the

background data from SCI-DC. 15.2% of registrants are shown as having an

ethnic group classification of 'Not Known', many of which may fall in to one of the

minority categories. This is further supported by the author's domain knowledge, where at one point, a default value of 'White Scottish' was applied to records sourced from secondary care. This is likely to have left legacy misclassification prevalent throughout records. It is believed that the publication of the national survey data will provide a benchmark for future improvements in this area.

Reasons for a higher proportion of type 1 patients recruited, when compared to the background diabetes population (30.4% vs 11.8%), may include the fact that people with type 1 diabetes are generally diagnosed at a younger age, suggesting an ongoing digital divide. My Diabetes My Way also engages better with hospital diabetes clinics where a higher proportion of people with type 1 diabetes attend, rather than primary care, which covers the general population.

It is clear that those signing up for access are on average younger than the background diabetes population of NHS Scotland. This is clearly shown for both type 1 and type 2 diabetes groups. Although it was explained to new users that the system was only initially accessible to those aged 16 and older, there were registrations made by the parents of young children. The implementation of 'proxy access' is soon to be made available via the Citizen Account, while the minimum age of direct access will be dropped to 14 by mid-2013.

Analysis of registrant's duration of diabetes shows that a large proportion of users are registering with MDMW within the first year of their diagnosis. This

indicates that newly diagnosed patients actively look for resources online to enhance their self-management and education regarding their condition.

All patients who logged on to the system gained access to the 'Personal Details' page, which contains high-level demographic and diagnosis information. Interestingly however, no other pages were viewed by 100% of users. This indicates a potential training need or usability issue. The 7 users who did not make it beyond this page may have simply logged in once with the intention of investigating the system further later, but then experienced subsequent login problems, or may not have had the inclination to try again. Users who have had the opportunity to access their clinical letters have made significant use of this functionality, with nearly 11 accesses per patient. This makes it one of the most popular pages based on the total number of accesses by the relatively small number of patients who have had this functionality available to them. This shows that it is important to make this function available to as many users as possible moving forward.

The table and graphs showing usage trends (number of distinct users and page accesses) present some interesting data. At the beginning of the project there was a clear spike as user accounts were activated and those involved in the initial pilot were clearly curious to see what the system offered and the data it presented. Since that initial flurry of activity, usage and user numbers clearly dipped, likely due to the slow-moving and relatively infrequently assessed

parameters of type 2 diabetes in particular, before increasing towards the end of year 1. Although new users were continually being added throughout the course of the year, there is a clear change in the way that users are now accessing the system. The number of monthly users recovered to the same level at initial launch, but the total page accesses remain at around a half of that first month. There may be several reasons for this:

- On first login, users are likely to want to see every feature offered, explaining the spike in month 1.

- Once a user has read supporting material on a particular data item (which contributed to the audit trail), they may be unlikely to read it again.

- Frequent users are more familiar with the system and now have more focused activity after logging in. e.g. looking for test results after an appointment.

As the analysis continued into year two figures continued to increase, with a clear spike at the end of the second full year of usage. This is the culmination of continual recruitment and enrolment process that has been ongoing since the project launched.

Although the number of monthly users continues to rise, with 44.6% of active users logging in during the final month of year two, many issues remain to be assessed and evaluated:

- o What issues prevent users from completing registration?

o   What are the reasons for users not logging in?

o   Why have some users from year 1 not logged in during year 2?

These issues are discussed following the qualitative analysis in Chapter 8: Survey of User Experiences.

The analysis of usage by hour of the day did not throw up any particular surprises, with minimal usage during the course of the night, before beginning to pick up from approximately 7am. The main hours of usage (over 200 logins recorded) are between 9am and 11pm. Most usage appears to occur during the working day and early evening, with a slight dip between 5 and 6pm. The author theorises that this may be attributed to users accessing the system while at work during the day, and after their return from work.

Analysis of usage by day of the week also presented some interesting findings. Daily usage increases each day until its peak on a Wednesday, following which it continues to drop until the weekend. Again the author theorises, that usage at work may be an influencing factor, while the weekend may be seen as 'time off' from diabetes management given the comparatively low number of logins. Both analyses by day and by time may also be attributed by the availability of access to internet accessible computers, something which users may not have at home. These data are useful to show high and low periods of activity which provide essential insights when scheduling system maintenance, etc.

The periodic newsletter mailing can be shown to result in a flurry of user activity immediately following its transmission. This continues for the days following it, before returning to the previous levels by the end of the next week. Periodic mailings are clearly an effective way of ensuring that users remain engaged. Indeed, not only does usage increase immediately, but in many cases it prompts users to reply in order to follow up lost, forgotten or delayed user credentials.

Finally, the analysis of ongoing user engagement shows that over 50% of users who have ever accessed the system, have done so within the last 3 months, while nearly 80% have accessed it within the last 6 months. Given that interaction with healthcare providers is relatively infrequent within the type 2 diabetes population, and that type 2 diabetes accounts for around two-thirds of the user base, these figures provide much encouragement for the realisation of benefits to users. Despite the initial thoughts that type 1 patients may log in to the system more regularly, analysis of these data by type 1 and type 2 diabetes showed no such trends. Given that new users are constantly being added to the system, these figures may not tell the whole story due to potential recruitment bias, but nonetheless they appear to suggest that users will continue to use the system following their first access.

7.6   Conclusions and Summary

This chapter highlights the demographic profiles of system registrants and usage trends of those who have successfully logged in during the first two years of

system availability. It provides an outline of access patterns, showing the most popular pages and areas of functionality that were most commonly used.

The analysis provides some essential insights into the current users of the system. They have traditionally been a largely self-selecting group who are younger, more recently diagnosed and more proportionally focused on those with type 1 patients when compared to the background diabetes population of NHS Scotland. The bias in this group is likely to change following more active recruitment activity in hospital and general practice diabetes clinics.

Study of the system audit trails, showed that users are most interested in viewing their biochemical tests over any other clinical area, and of these tests, HbA1c was the most commonly expanded to show the full history of how it changed over time. This conclusion was not entirely surprising as HbA1c is the key marker for diabetic control.

Definitions for each clinical data item are shown within the system, and these were expanded less often than expected, highlighting a potential training need to encourage people to use these more often with the aim to aid understanding. Although it is clear that if an experienced patient were to look at their own results, they may not require this information. Usually, however, curiosity may be expected to intervene.

As users become more familiar with the system, patterns of usage appear to change. On initial use, users have been seen to view most clinical data items as both summary and longitudinal history items, whereas subsequent accesses appear to be more focused, with fewer system operations performed. This is believed to be because users know what tests they have had recorded at recent appointments and look specifically for them. This can be seen, particularly when comparing the initial usage statistics at launch against those at the end of year 1, where distinct logins were similar, but page accesses significantly reduced.

As the analysis of usage extended into its second year, a clear upward trend in both distinct monthly users and pages accessed is visible, before spiking towards the end of year two as a large batch of new registrants came online. These encouraging data show that those who find the system useful remain engaged, while new users continue to come on board.

Usage patterns by hour of day and by day of the week have presented some interesting figures, indicating that users may find that using the system while at work is the most effective route, however this assumption requires further analysis that is beyond the scope of this thesis. Engagement can clearly be retained by appropriate marketing strategies. MDMW has only scratched the surface in this area with its periodic newsletters, but initial analysis proves that this is an area worth further investigation, with more frequent mailing recommended. These will undoubtedly contribute to the ability of MDMW to keep

users involved beyond their initial login, as shown in the final analysis in this chapter.

This quantitative analysis highlights the usage of the system and the general demographics of the user base, but it does not tell the whole story. A quantitative analysis is reported in Chapter 8: Survey of User Experiences, which aims to dig into these raw data to explain reasons for the popularity of certain sections, and why some areas were less well-accepted. It was also necessary to highlight reasons for disengagement and pinpoint reasons for documented trends.

Chapter 8:   Survey of User Experiences

"The doctor has told me that patients don't have the knowledge to interpret their results and it "only causes them to worry". The exact opposite is true. This service solves this problem."

A respondent to the survey questionnaire.

8.1   Introduction and Aims

Following the first year of usage of the My Diabetes My Way records access system, a qualitative analysis was performed. The aims were to capture user experience and identify any areas that would cause potential users to disengage. Further objectives were to capture:

- Thoughts on current processes and suggestions for improvement.

- Key successes and reasons for using system.

- Barriers to use.

- Recommendations for the future.

These findings help to explain the reasons behind some of the trends highlighted in Chapter 7. This chapter explains the methodology used and outlines the results and conclusion drawn.

8.2 Methodology

A survey questionnaire (Appendix E: User Experience Survey) was created and emailed as a Microsoft Word document to participants who had engaged with the system during the first year to capture details of their experiences. This included patients who had submitted their initial registration but had not completed the enrolment process, those who had completed the enrolment process and who had not logged on and those who had successfully used the system.

The survey was based around the questionnaire designed for the pre-project expectations analysis described in Chapter 6 so that comparisons could be drawn along with new data. As such, it aimed to tie in with the objectives of the NHS Scotland self-management strategy (Long Term Conditions Alliance Scotland, 2008). Further questions were added following input from the project steering group covering features that the team highlighted as being relevant following patient feedback during the first year. This feedback was based on email and web communications regarding enrolment and login issues, data quality and system availability. Questions were included to cover experiences of the support process and user satisfaction with responses received. The project group piloted the survey internally before further comments were obtained from one expert evaluator. The methodology used to provide this feedback was based on 'face validity', where the third-parties assessing the questionnaire provided their opinions on face-value as to the appropriateness to accurately measure

patient experiences of records access. There were no additional questions added following this review.

As with the pre-project questionnaire, the survey explained that all results would be handled securely and analysed anonymously. The first page of the survey aimed to capture experiences of the registration and enrolment processes to highlight barriers, before moving on to gauge opinions on actual experiences or records access. Those who submitted feedback or comments were asked to describe their experiences regarding speed of response and the final outcomes to their enquiries. The final page contained open-ended questions aimed to summarise the best and worst parts of the system and allow suggestions for new functionality. The full analysis of the survey was published online as part of the My Diabetes My Way Year 1 Evaluation report (Cunningham, 2012).

8.3 Results and Discussion

In this chapter, results and discussion have been merged to provide immediate feedback on each section of the questionnaire. This includes details on factors that were deemed to be enablers, and conversely, those that were seen as barriers to use.

There were 55 respondents to the survey, 53 (33.1% of active users at this time) had successfully logged in to access their diabetes information at least once. This low response rate was disappointing, but not entirely surprising as there was

no incentive to do so, other than to assist in improving the system for future use. As previously discussed, the patients signing up for records access are a highly motivated, self-selecting cohort of individuals, which leads to selection bias. The author speculates that those completing the survey are likely to be some of the most motivated and technologically proficient and this will add further to the selection bias within the results. The data are however still likely to contain useful insights, so it was considered worthwhile to see the process through to completion. The analysis focused on their experiences and to identify factors which enhanced the process, as well as those that caused barriers that could be addressed when moving forward. These analyses were based on groupings of the most common feedback.

8.3.1 Enrolment Process

Participants were asked if they had any comments about the enrolment process, or if they experienced difficulties in obtaining a signature to verify their identity from a member of their healthcare team.

Enablers

- The staff information leaflet was very useful to educate uninformed healthcare professionals

Barriers

Although most users experienced no problems, the three main issues raised are highlighted below:

- Doctor refused to sign the form

- Doctor requested a fee for signature

- HCP did not feel authorised to countersign the enrolment form.

Solutions Implemented

As a result of occasional difficulties in obtaining verification signatures, MDMW now encourages users not to give up and approach another member of their healthcare team in these situations. The form is not to provide 'permission' for access, but is purely to confirm that the patient is who they say they are. As a result, the author has engaged with the national Diabetic Retinopathy Screening Programme which has issued guidance to eye screeners to participate in the process. The patient should not be expected to pay a fee for this service.

Discussion

It is likely that many of those refusing to verify the enrolment form were doing so because they had not heard of the service or were unwilling to share data with patients. Although an information leaflet for staff was sent out with each enrolment form with the intention to persuade healthcare professionals of the benefits, it is not possible to quantify how frequently this occurred. As the project becomes more established and awareness activities continue to filter down to all involved with diabetes care, these instances are likely to continue to occur on occasion.

8.3.2 Login Process

Users were asked to provide information regarding any problems they had experienced while attempting to access their data.

Barriers

The main issues are highlighted below:

- Username and password:
    - o Font size and type difficult to interpret (1 or l, 0 or O, etc).
    - o The username is far too large and complicated.
    - o Username cannot be remembered unless written down.
    - o Most other systems you access comprise your name/initials as a user id and a password of 8 characters or more.
- Password updates:
    - o Obtaining a password was difficult.
    - o Password took a long time to arrive.
    - o 'Captcha' used when updating password difficult to read and interpret for those with visual impairment.
- Length of time from enrolment to gaining access.
- Consent for data sharing with other agencies:
    - o Uncertainty over who get access, what information they have access to and how they secure the information.
    - o Actual enrolment should just be via a single form containing all authorisations required.

- General feedback:

    o Login process is cumbersome, particularly for the elderly.

Solutions Implemented

The feedback raised via the survey, and anecdotally from other forms of feedback such as email and website feedback, highlighted that the 'Password Reset' option on the Citizen Account System portal did not generate or send out new details. This is now routinely checked to ensure that no users are left in this situation.

Length of time for access is dependent on the time taken to obtain a signature from a member of the healthcare team. MDMW currently processes new registrations and marks enrolled patients for activation every 2 weeks. This time period will be considerably reduced once automated processes are in place.

Discussion

There are many benefits in using the Citizen Account portal as the authentication component for MDMW. Firstly, the ultimate aim is to have everyone in Scotland accessing all of their public services using this one system, rather than having to remember numerous usernames and passwords for each. Secondly, MDMW have been able to delegate responsibility for user account provisioning, relieving the core team of a considerable administrative overhead which would have been difficult to maintain otherwise.

Some solutions to the issues raised have already been implemented and the record matching and user detail provisioning is now much smoother, completing in around 1 week. Users can now update their username to their email address for ease of access and password resets can automatically be sent to their email if forgotten. In order to aid the login process, users can now also contact the CAS team directly using the email address provided on the MDMW website. The CAS project team will continue to improve these and other areas via a technology infrastructure refresh which is currently in development and due for release by early 2014.

8.3.3 Opinions of My Diabetes My Way

Section B of the survey questionnaire contained 17 structured questions which aimed to capture the opinions of those who logged in and accessed their data. Reponses were counted and tallied to produce a percentage agreement score. The results are shown below:

- 89% believed the system contained all the features they expected.
- 83% said that the system helped to remind them of information discussed during consultations.
- 98% believed the system would help them make better use of their consultation time.
- 73% said that the system means that they do not need to keep paper records.
- 73% said the system means that they do not need to phone their doctor for new results.

- 77% said the system was up-to-date.

- 96% said the system was easy to use.

- 89% said that the explanatory information helped them to understand their results better.

- 90% said the tailored links helped them to find further information relevant to their diabetes.

- 93% said that the graphs of information were helpful to monitor changes over time.

- 100% were confident that their information was secure when using the system.

- 81% said that the system has helped them manage their diabetes better.

- 79% said that accessing their information has helped to improve their knowledge of diabetes.

- 89% said that accessing their information has made them more motivated about their diabetes.

- 79% said that accessing their information has helped them to meet their diabetes goals.

- 89% said the system would help them to set their own diabetes goals.

- 96% said that online access to diabetes information will significantly improve diabetes self-care across Scotland.

At the end of the structured section, a free-text box was available to allow the patient to explain any of the statements they agreed or disagreed with.

Enablers

Patients expressed an improvement in self-management outcomes, such as awareness, better information and satisfaction.

Described as "*a great resource for the newly diagnosed*", with resources "*of a very good quality and easy to understand.*"

Barriers

Some patients indicated that although they had access to a subset of their diabetes data, they didn't have access to all, or a sufficient amount of it. This includes information on more complex biochemistry tests and clinical outcomes.

One particular area of concern was from those who, during the initial three month pilot, had access to the letters sent from hospital clinicians to the patient's GP. These were withdrawn due to concerns expressed regarding the potential content. Particularly:

- Possible third-party references.
- Possible information that may cause concern or harm to the patient.
- Information written in a way that is not appropriate for patient review.

Patients, however, expressed the importance for this information:

"Needs to have the written notes available as this is where 'objectives' are detailed"

Some patients indicated that they have other long-term conditions where additional tests are required and it would be useful to make these available.

Some members of the clinical community are still to be convinced that records access will provide any benefit. One patient's response was:

"My DM consultant does not see the need for patient access, a shortsighted view in my opinion."

Although in most cases, patient data was current and correct, several users expressed problems with data completeness for recent tests and data accuracy for others. In particular, some of the graphs were initially skewed by out-of range results and in many cases, smoking status was inaccurate.

'Tailored' information resources were provided to the patient as external links, and while users indicated that this information was useful, some indicated that the links did not contain sufficient detail.

Solutions Implemented

The available dataset has been expanded to include an extended lipid profile including HDL and LDL cholesterol and triglycerides. Latest Flu Vaccination status, eGFR, registered GP and surgery details have also been added. MDMW will continue to add relevant data items as the project progresses,

A process has been defined to allow hospital diabetes clinics to sign off clinical letters en-masse from a date that they specify. This ensures that they have the opportunity to train staff on what is, and what is not acceptable content for these letters. St. John's Hospital in Livingston approved the reintroduction of letters in May 2012, back-dating those available to 01/01/2000 as they had experienced successful correspondence sharing by paper means for many years. The objective is now to encourage the remaining clinics to follow this example.

The system was originally designed to be read-only, with a view to implementing direct data entry at a future stage. Not only are patients recording their own weight, blood pressure and some biochemistry tests using home recording devices, but when patients obtain results from their healthcare team, patients require the facility to enter the results. Implementing data entry was always planned for future phases, and was prioritised based on this feedback.

While data accuracy is of critical importance in a record access system, some issues were raised as detailed above. To combat the effects of out-of-range values skewing historical graphs of data, MDMW has implemented a boundary value check, where obviously wrong values are filtered out. These results are also logged in the user audit trail so that they can be investigated at a later date by a member of the technical team. In addition, there were several reports of inaccurate smoking status, particularly those who proudly expressed the fact that

they had given up smoking for several years. On investigation, it became clear that the date shown next to "Ex-smoker" was in fact the date on which this status had last been recorded. The date was corrected and users now have the opportunity to update the information themselves, the first of many data entry sections planned for MDMW.

Data currency is also an issue as some patients may still obtain results from their healthcare provider before it reaches the system. Due to the complex interfacing and batch processing implemented, it may take up to three days from the point a result is entered in a GP or hospital system before it appears on MDMW. SCI-DC and MDMW are looking at ways to speed up this process and incorporate more 'real-time' processing. Unfortunately, there is always likely to be some delay due to technical and data entry factors.

Several reports were received from users who indicated that their registered GP was incorrect. After investigating this further, it has become clear that some practices allocate patients equally between all of their registered doctors. This means that the GP associated on the system may not necessarily be the GP that the patient regularly sees. As GP registration details are provided to us by the national master patient index (CHI) there is, unfortunately, nothing that can be done by MDMW to change this. To change the 'official' registration, the patient must raise this with their doctor during their next visit to their health centre or surgery.

While the tailored links were designed to be most appropriate for general information on relevant diagnoses, the project team acknowledge that they may not be suitable for all and this section of the resource will be reviewed to provide more dynamic and detailed links based on usage and duration of diabetes. Target charts will be tailored to patients' current condition based on their process outcomes, rather than potentially unachievable 'gold-standard' target.

Discussion

The tallied agreements shown in response to the closed questions provided considerable encouragement for the general usefulness of the system. Users stated that the system is feature-rich, a useful memory aide and allows them to make better use of consultation time by giving time to formulate appropriate questions prior to appointment. 3/4 responded that the system means they no longer need to keep paper notes or call their doctor for results. 77% said the system was up-to-date, showing that there is room for improvement, and as a result improved interfacing with NHS systems will be prioritised. 96% said the system was easy to use, which was particularly reassuring given the efforts to incorporate user-centred design approaches and maximise usability. Most said that the explanatory information and tailored web links were effective and history graphs helped to monitor change over time. Every patient said they were confident that their data were secure when using the system, which is especially reassuring when it is considered that 74% had concerns about security during

the initial pre-project expectations analysis. Patients agreed that the system

helps improve diabetes management, knowledge and motivation while allowing

them to meet and set their own goals. Finally, 96% agreed that online access will

significantly improve diabetes self-care in Scotland, which was only slightly down

from the 99% agreement reported prior to the project implementation.

Some patients expressed the opinion that they still need more help managing

their medications and weight, particularly when starting new drugs. This is

entirely understandable as MDMW is not intended, or expected to provide the

complete solution for diabetes management. There will always be the need for

clinical discussion, although MDMW can provide considerable assistance during

the time periods between appointments and lead to more productive

consultations as the results above confirm.

The project team are currently investigating ways in which personalised goals

can be included in the system and if this proves successful it may help to support

successful weight management, amongst other metrics.

MDMW only presently provides data on diabetes, but along with Renal

PatientView with its focus on kidney disease, these systems can effectively be

viewed as proofs of concept for further developments in support of a wider range

of long-term conditions and multiple morbidities. Other conditions are however

beyond the remit of the current project, as acknowledged by those who raised the possibility of including non-diabetes data.

8.3.4 User Guide

The next survey question aimed to identify what proportion of users reviewed the user guide before their period of access. Around 4/5 of users indicated that they had reviewed the user guide before they used the system, indicating that it was a worthwhile training resource. No other training resources are currently planned in addition to this guide other than a 'screen-cast' version explaining the user guide in the form of short videos.

8.3.5 User Feedback and Issue Reporting

The following three questions aimed to identify what proportion of users submitted feedback and whether or not this was responded to quickly enough and to the patient's satisfaction. While a large proportion (roughly 2/3) of patients' submitted feedback either via the website or email, feedback indicates that this was responded to, in the main (over 80%) quickly, and to the satisfaction of the individual. The project team acknowledges that there is scope for improvements to be made and this will be alleviated with the appointment of a new administrative resource to triage and manage any feedback. To date, the core project team has dealt with all feedback and as the project rolls out towards its target of 5000 registrants by the end of 2013, continuing the current approach is not sustainable.

Most issues highlighted were in relation to login problems and some users indicated that as the system has evolved, issues have been resolved more quickly and efficiently. Mid-way through the project, the Citizen Account team appointed a dedicated administrative resource to deal with these issues and provided a contact email address. These developments have clearly made a considerable improvement.

Most acknowledged that issues were addressed quickly although feedback indicates that some issues remain unresolved. The project team will investigate these issues as a priority to ensure all users are provided with a suitable response.

8.3.6 Best Features

The remaining four questions in the survey were open-ended and allowed the patient to express their opinions in their own words. The first of these aimed to identify what the users felt were the best features of the system.

The presentation of clinical results not only provides traditional line graphs, but also the target chart described earlier. Patients report that they have taken this to appointments and have received favourable feedback from the healthcare team. The ability to track progress against guidelines is seen as an essential reminder of the history of the diabetes journey.

The full prescribing record containing all drugs going back several years was described as helpful to track progress and useful to identify when other illnesses were being treated.

Many users particularly liked the monthly email updates. These provide an update on the project status, detailing known issues and new developments. System usage around these mailings has proven interesting to observe as usage spikes significantly around these times as explained in Chapter 7. It is now seen as an essential awareness tool in encouraging repeat usage.

Patients appreciate the ability to have instant, hassle-free access to the data, where the traditional approach to diabetes care has been dictated by the healthcare team. The development has broken down barriers to access where there is often reluctance to share data. This has led to reports of fewer phone calls to NHS establishments, indicating a reduction in time and financial costs to both the patient and the NHS. Users preferred access to "hard data" rather than hearing terms such as "within acceptable limits". There is a strong belief that efficient and secure access leads to more involved and responsible patients aiming to benefit from improved outcomes.

"I firmly believe that I am part of the system that manages my healthcare. This facility encourages – and reinforces – that belief."

Patients like having the results at hand alongside easy to understand information so that they can discuss them with their healthcare providers. It also means that patients no longer need to write down their results and keep paper records. Users like being able to spend time interrogating their data, without any pressure. This led to reports of "less worry" and greater understanding, which will ultimately lead to better results and subsequently a reduction in diabetes complications and inpatient admissions.

> *"…this has had a positive influence on my control/results already."*

Discussion

Many of the positive features highlighted were expected by the project team, but there were notable exceptions. While the process outcome histories were expected to be useful to track changes over time, the ability to track conditions using the medication history was not anticipated.

There was an expectation that the system would break down some traditional barriers to record access from clinical staff, but there were more reports of reluctance to share data by the healthcare teams than were anticipated.

The project team were interested in how patients deal with record access and whether it may cause "harm" in some cases. Clearly, this is not the case for the majority, with reports of less worry and a positive impact on control and outcomes.

While the site was described as easy to navigate, suggestions have been made

to improve the layout to make it less text-based and incorporating more graphical

displays. This is an area that the project team are already investigating.

8.3.7 Worst Features

The next question aimed to identify what the users felt were the worst features of

the system.

As described previously, some issues with the login process and username

format remain, but these are currently in the process of resolution so that the

user details are more memorable. Some would like the ability for the site to

remember login credentials so that they do not have to be entered each time.

Unfortunately, this would be in breach of security protocol so this suggestion

cannot be progressed,

Data issues were mentioned by several respondents who said that some results

were either missing, out of date, wrong or duplicated. Due to the nature of the

system collecting information from all diabetes-related sources, duplication is

likely. However, work will continue to improve data accuracy and completeness,

led by the wider SCI-DC team to ensure that all stakeholders using the results,

including the healthcare team, may benefit.

One user indicated that the significance of the tests was not explained well enough. This is believed to be a training issue as all clinical tests are displayed alongside "?" links which, when clicked, provide more information on the test, why it is recorded and what normal ranges are.

Finally, the time taken from original registration to initial access is in some cases too long. While the improvements described earlier will enhance the process, the time taken for doctors to sign forms is outwith the control of MDMW.

Solutions Implemented

Data issues have been addressed where possible to do so. One significant area of "missing" information is eye data after patients are referred to the ophthalmology clinic with diabetes-related complications. This is a failing of the healthcare infrastructure generally as these results are not currently shared electronically outwith these silos. This is an area the project team is actively pursuing to obtain these results and provide a more complete, integrated record. In addition, where erroneous data are found outwith defined ranges, they are now filtered from display on the history graphs and tables and logged in the system audit trail for further investigation.

Those users involved in the early stages of the project who had access to the clinical correspondence expressed their dismay at the fact they were removed. The solution to this problem is described earlier in this chapter, but

correspondence will remain inactive at the present time until a hospital clinic explicitly opts-in to data sharing.

Early in the project, there were reports of system failures and downtime. While the system is now far more resilient, exception logs are also maintained and monitored daily.

The signup process clearly has scope for improvement in order to speed it up. One amendment is to allow diabetes clinics anywhere in the health service to provide information and enrolment forms directly to the patient while they are in the waiting area. This means that the patient can sign up immediately without the current paper trail, therefore reducing costs and improving the user experience.

Discussion

All issues raised were deemed to be manageable within the scope of the project and several improvements have already been implemented, with others in development. The system is far more resilient that when it was first implemented and more centralised resources are in place to deal with problems.

8.3.8 New Features

The next question aimed to identify what new features the project group wished to see implemented to assist in their self-management. The author has divided these into two sections to distinguish between those anticipated, and those that were not expected.

Anticipated Requests

Many patients expressed their desire to enter their own home recorded results. In particular weight, blood glucose and blood pressure. They also asked to record related medical conditions, family history and any other issues. They also want to record details of their next appointments, all of these data cumulating as an aide memoire. This is already part of the plan for the next stage of development. Patients will also be given the option to decide whether or not they want to share self-recorded data with health care team electronically via SCI-DC, ensuring they remain in full control *their* data.

Users expressed their interest in additional results and data. The system was designed with a "minimum dataset" with the scope to expand as required. Results explicitly mentioned that are yet to be added include ACR, HDL:LDL ratio and dates of future appointments. Patients also want to know about how certain drugs can affect their diabetes. While the medication section shows external links explaining diabetes-related drugs, this section will be expanded to include other relevant medications such as steroids. Some asked for results not directly related to their diabetes, but this is currently outwith the scope of the system. There is no reason why, in future, other NHS system could not expand on the MDMW infrastructure, and this approach would be actively encouraged. Furthermore, patients want to be able to edit obviously erroneous results and become active

participants in their data validation. These functions will be assessed for feasibility at a future date.

Users would like the ability print their own results to take for discussion at appointments. While the web pages are printable individually, the project team plan to provide focused PDF files for download and printing. These will include latest results and charts as appropriate and will be available in a variety of options including a complete summary and patient-recorded "my home results" to pass to the healthcare team. These can then be interpreted and discussed appropriately with the healthcare team.

Some respondents wished to have the ability to book appointments using the system. This has been discussed previously with the Diabetic Retinopathy Screening service and may be possible in future. Existing record access systems provide "appointment request" functionality due to the difficulty in directly interrogating hospital and GP systems. It should be possible to do the same for MDMW.

Enhanced online communication with the healthcare team is seen as being essential. The system is currently only resourced to deal with technical and non-urgent queries. Patients with urgent queries are advised to contact a member of their diabetes team directly. In future, the project plans to incorporate a real-time communication 'hub' where patients can ask questions during defined "surgery"

hours to a helpdesk manned by a trained specialist nurse or consultant. The author expects that this will cut down on phone calls and non-emergency appointments.

Patients said it would be nice have a goals section for discussion with the healthcare team describing objectives for the next review. The patients could then go on to the system to review and amend accurately what has, or has not gone well.

Finally, the project team are developing an alert system to advise when results are updated. This will avoid users having to go in and out of the system frequently as they await new reading. The project team will be implementing this functionality using SMS and email. Further consideration will be given to how patients are advised to act upon new results once they appear.

Unexpected Requests

Some patients expressed the desire to see all of their results since diagnosis, some even going as far back as 1966. Unfortunately, the system is restricted to data recorded electronically in NHS systems, so unless retrospective data are entered, this will not be possible until the patients can directly add information they may have recovered from previous personal notes.

Some patients wish to have the ability to view their eye photographs on screen. While this is possible, the project team are interested in knowing how these will be interpreted. It is likely that this will be taken forward in pilot to assess the implications prior to a wider rollout.

In addition to the presentation of results, patients would also like to see what in effect constitutes decision-support functionality. Respondents asked for a summary page showing "alerts" for out-of-range values for prioritisation.

Discussion

The requests listed above provide considerable scope for expanding the remit of the project. While many requests are already part of the plan, those that were not anticipated will be reviewed and prioritised appropriately. The user group will be informed as these developments progress.

8.3.9 Any Final Comments?

The final section of the survey allowed the respondents a final opportunity to express any opinions not previously articulated.

Generally, final comments were very positive, complimenting the team on developing the resource and indicating that several users were doing their best to promote it amongst their peers. Despite that, it is acknowledged that the project is currently only interacting with a relatively small cohort of the wider diabetic population, many of whom would benefit greatly from the initiative. The

awareness campaign (Diabetes UK, 2012a) is discussed in the final sections of this report.

"I cannot tell you how much of a psychological boost this system has given me. I am suffering great pain and every day is a struggle to exist. This site and the information on it is like a lifeline for me. Thank you so much."

There seemed to be general understanding that this was a new system and the 'odd difficulty' is hard to avoid, although these are now known to be fewer and further between. The final request was to include links to more relevant websites such as NHS Inform. Closer collaboration with other NHS websites is currently under discussion.

8.4   Further Discussion

Despite the acknowledged low response rate and the subsequent selection bias, the feedback from the surveys provided some essential insights into the current usage of the system, its benefits and where it can be improved. The main barriers would appear to be around the usability and accessibility of the infrastructure offered by the Citizen Account, with users highlighting problems with the font used in letters, the length of the username, logging in or when requesting password updates. It is also known that several user credential letters appear not to have reached their destination, a process that the Citizen Account continues to monitor. Many of these issues have now been addressed, but if the

user's first experience with the system was negative, it is very likely that they would be put off trying again permanently.

It is known from the qualitative evaluation that some potential users felt it was "too much hassle" or had experienced difficulties in obtaining a signed verification form – some of whom had been asked for payment from their GP. At the time of writing, five reports of payment requests had been reported to the project email address and via website feedback, ranging from a cost of £15 to £65. Although the verification step remains in place, closer engagement with healthcare teams via general practice and hospital clinics is expected to reduce these barriers. Feedback also reported that in most cases the information materials for staff that were included in the enrolment packs assisted the process.

It was highlighted that the process from initial registration until receipt of user credentials takes a considerable length of time in some cases. During the initial stages of the project, all patient management and workflow was handled manually. This did however offer the opportunity to define an optimal process that has now been implemented into the automated workflow management tool described in Chapter 5. Although new registrations are still managed in batches, the processing of signed enrolment forms now occurs twice a month, reducing the length of time it takes to provision user account. Work will continue to further enhance this process.

Another issue that has been raised since this evaluation has been with the use of the Safari web browser on certain models of iMac. It was reported that in some cases a security digital certificate error is raised. Since then, as a workaround, users affected have been advised via the periodic newsletter to download the Chrome web browser which operates as expected. Work continues to pinpoint the specific fault.

The closed questions within the survey provided considerable encouragement, with the system scoring highly overall with ease of use (96%), understanding of results (89%), motivation (89%) and better use of consultation time (98%). Another interesting finding was around the issue of security. In the 'patient expectations' analysis, 26% stated that they were worried about the security of their record if it was to be made available online. After using the system, 100% were happy that the system was secure and their data was protected.

Further feedback highlighted that newly diagnosed patients found the system useful in order to learn more about diabetes. This aligns with the registrants' duration of diabetes analysis in Chapter 7, in which a large proportion of people with newly diagnosed diabetes had registered to use the system. This would indicate that when patients are diagnosed with the condition, they actively look on the internet for information that could help them.

Another area that users reported they liked was the periodic newsletters. Again, linking back to the analysis of usage in Chapter 7, where these can be seen to result in a sharp rise in logins and activity.

During the first year of use, a considerable amount of anecdotal feedback has been captured by email and website feedback functions. This has not yet been catalogued and analysed to its full potential, so the author aims to arrange for further analysis at a future stage in the project rollout. These messages are likely to provide further useful insights not captured within the survey questionnaire detailed. It would also be appropriate to allow the assessment of these data to be carried out by an independent analyst so that the results can be viewed as genuinely objective.

8.5   Conclusion and Summary

This chapter explains the findings of the qualitative analysis, highlighting user experiences and areas for improvement that the project team, and other developers of records access systems, can use to inform future work.

While some concerns were raised with the usability of the login process via the Citizen Account, the overall usability of the system scored highly at 96%. The author has recommended to the Citizen Account team that a formal usability assessment exercise must be performed on their web interface. This has been approved and once re-worked, a follow-up analysis will be performed.

Despite these issues, a high level of user acceptance and continued use shows that the system worked well within its first year, and with some additional enhancements, would provide an even more valuable and usable service. The overall conclusion is that the system is now a useful additional component for the care of people with diabetes in Scotland. Users report that it helps them in their self-efficacy and self-management, with 98% also indicating that it leads to a more productive consultation with healthcare professionals.

Chapter 9:   Analysis of Impact on Patient Outcomes

"Quite funny, I was able to see my latest blood test results the day

before I went to see my GP, so ended up being the shortest consult

I've ever had.

Yup, ok, liver ok, hba1c ok, see you."

http://www.diabetessupport.co.uk/boards/showthread.php?t=25740

9.1   Introduction and Aims

At the end of May 2013, during the final days of this PhD, the author analysed

the impact on clinical outcomes for those participants who had used the system

for at least a year. The reason for the delay in performing this analysis was to

maximise the data collection window, from project launch in December 2010, to

the date of analysis. This would therefore ensure that the most complete amount

of user data could be analysed, maximising the potential statistical power

available for this research.

The aims were to assess the impact on key clinical outcome variables to identify

whether or not the MDMW PHR produced tangible benefits that could be

advertised to stakeholders to increase awareness and uptake, and to the wider

informatics community to support the benefits of PHRs. This chapter explains the

methodologies used and details the results and conclusions gained.

9.2 Methodology

A retrospective before-and-after comparison of clinical process outcome data was undertaken to study the effects of the personal health record intervention on each system user. This was based on their latest result (e.g. HbA1c) prior to first login and their first equivalent test result following one year of live use.

On 31st May 2013, an anonymised extract of patient data was taken from the MDMW PHR, following appropriate ethical approval, for all patients who had completed the enrolment process and who would therefore have had the opportunity to access the system. This retrospective analysis focused on the following key clinical process outcomes:

- HbA1c.
- Creatinine.
- Total cholesterol.
- HDL cholesterol.
- LDL cholesterol.
- Triglycerides.
- Body Mass Index.
- Weight.
- Systolic blood pressure.
- Diastolic blood pressure.

These data items were chosen as they are available to view on the system and are some of the most routinely recorded, maximising the potential for comparison. More slowly changing assessments such as eye and foot screening results were not deemed by the author to be suitable for analysis at this stage. In an ideal scenario data would be captured at the intervention date, defined as the date of first logon, with subsequent results for comparison captured exactly one year later. This was not possible given the constraints of the project, so the following modified methodology was defined. Firstly, the 'intervention date' marker was defined as being the last recorded result on or before the date of first login. The comparison data was defined as being the first result of the same type recorded, on or after the intervention date + 1 year. No limitations were specified on the source of the data in either group.

For each patient whose data were analysed, key demographic profiling data were available as part of the multivariate analysis, including:

- Date of birth.
- Gender.
- Type of diabetes.
- Date of diabetes diagnosis.
- Number of logins.

From the datasets detailed above a before-and-after methodology was used to analyse the intervention and comparison data. Results could then be drawn from

the overall cohort and the various patient groups based on their demographics. The main demographic factor analysed in detail and referenced below along with the process outcomes was for type of diabetes. Where results are worthy of mention, they are referenced in the discussion.

Mean and median results were compared at intervention (Year 0) and one year later (Year 1). A Mann-Whitney U test was then performed using IBM SPSS Statistics 21.0 on the two groups of data to identify changes of a statistical significance. These data were used to highlight whether or not the MDMW PHR had any observable impact on clinical process outcomes.

The non-parametric Mann-Whitney U test was selected for the investigation as it allows analysis of two groups of data against an alternative hypothesis that one group may have larger values than another. For the purpose of this analysis, the author hypothesised that those who had used the system for one year may have improved clinical outcome results after exposure to the system. The null hypothesis would therefore be that the two groups of data remain unchanged.

The author completed the analysis by using the results captured to calculate the total number of patients required to achieve 80% statistical power for each data item at normal levels of significance ($p \leq .05$). This analysis was assisted using a web-based Statistical Power Calculator (DSS Research, 2013) and required the

entry of the Y0 and Y1 means and standard deviations calculated from the initial

results.

9.3   Results

The following section shows the high-level results of this analysis at intervention

(Year 0) and one year later (Year 1) for the number of patients who had data

suitable for comparison (N). Data are shown in two sections, separating

laboratory results and lifestyle factors into distinct sections.

9.3.1 Laboratory Test Results

Test (units)	Sample	N	Mean Rank	Mean	Median	Normal
HbA1c **(mmol/mol)**	Year 0	188	189.19	59.3 (ST Dev = 17.9)	56	48 – 58
	Year 1	188	187.81	58.1 (ST Dev = 15.5)	56	
Creatinine **(μmol/L)**	Year 0	198	207.01	82.8 (ST Dev = 27.1)	76.5	60 – 120
	Year 1	198	189.99	79.9 (ST Dev = 24.8)	74	
Total Cholesterol **(mmol/L)**	Year 0	183	183.68	4.4 (ST Dev = 1.0)	4.2	< 4
	Year 1	183	183.32	4.4 (ST Dev = 1.0)	4.3	
HDL Cholesterol **(mmol/L)**	Year 0	167	164.97	1.3 (ST Dev = 0.4)	1.2	> 1
	Year 1	167	170.03	1.3 (ST Dev = 0.4)	1.3	
LDL Cholesterol **(mmol/L)**	Year 0	52	53.01	2.3 (ST Dev = 1.0)	2.1	< 2
	Year 1	52	51.99	2.2 (ST Dev = 0.9)	2.1	
Triglycerides **(mmol/L)**	Year 0	137	139.59	1.8 (ST Dev = 1.2)	1.4	<= 1.7
	Year 1	137	135.41	1.7 (ST Dev = 1.3)	1.4	

Table 18: Laboratory result analysis – total population

For the 188 patients whose HbA1c was compared a mean reduction of

1.2mmol/mol was observed. Median values remained static at 56mmol/mol. The

Mann-Whitney U test reported $p = .902$ (asymptotic significance (2-tailed)) for the

total population. The value for type 1 diabetes alone was $p = .789$ and for type 2

diabetes $p = .803$.

For 198 patients whose creatinine was compared, an average drop of nearly 3µmol/Lwas observed. Median values dropped from 76.5µmol/Lto 74µmol/L. The Mann-Whitney U test reported p = .139 (asymptotic significance (2-tailed)) for the total population. The value for type 1 diabetes alone was p = .146 and for type 2 diabetes p = .296. For males, p = .272 and females, p = .197. Type 1 females had p = .168 using 2 tailed asymptotic significance and p = .086 using one-tailed exact significance.

For 183 patients whose total cholesterol was compared, there was no change in mean value, although median values increased from 4.2mmol/L to 4.3mmol/L. The Mann-Whitney U test reported p = .974 (asymptotic significance (2-tailed)) for the total population. The value for type 1 diabetes alone was p = .505 and for type 2 diabetes p = .627.

For 167 patients whose HDL cholesterol was compared, there was no change in mean value, although median values increased from 1.2mmol/L to 1.3mmol/L. The Mann-Whitney U test reported p = .631 (asymptotic significance (2-tailed)) for the total population. The value for type 1 diabetes alone was p = .347 and for type 2 diabetes p = .783.

For 52 patients whose LDL cholesterol was compared, there was slight reduction of 0.1mmol/L in mean value, while the median values remained identical. The Mann-Whitney U test reported p = .863 (asymptotic significance (2-tailed)) for the

total population. The value for type 1 diabetes alone was p = .665 and for type 2 diabetes p = .602.

For 137 patients whose triglycerides were compared, there was slight reduction of 0.1mmol/L in mean value, while the median values remained identical. The Mann-Whitney U test reported p = .663 (asymptotic significance (2-tailed)) for the total population. The value for type 1 diabetes alone was p = .834 and for type 2 diabetes p = .742.

9.3.2 Lifestyle Factor Results

Test (units)	Sample	N	Mean Rank	Mean	Median	Normal
Body Mass Index (kg/m^2)	Year 0	179	182.2	30.3 (ST Dev = 6.6)	29.2	18.5 – 25
	Year 1	179	176.8	30.1 (ST Dev = 6.8)	28.87	
Weight (kg)	Year 0	167	169.26	88.6 (ST Dev = 19.5)	87	Varies by height
	Year 1	167	165.74	88.1 (ST Dev = 20.1)	86	
Systolic BP (mmHg)	Year 0	206	205.61	131 (ST Dev = 15.6)	132	< 130
	Year 1	206	207.39	131 (ST Dev = 14.7)	132	
Diastolic BP (mmHg)	Year 0	206	206.65	76 (ST Dev = 9.3)	77	< 80
	Year 1	206	206.35	76 (ST Dev = 10.5)	77	

Table 19: Lifestyle factor result analysis – total population

For 179 patients whose body mass index results were compared, an average drop of 0.2kg/m^2 was observed. Median values dropped from 29.2kg/m^2 to 28.9kg/m^2. The Mann-Whitney U test reported p = .621 (asymptotic significance (2-tailed)) for the total population. The value for type 1 diabetes was p = .792 and for type 2 diabetes p = .608.

For 167 patients whose weights were compared, an average drop of 0.5kg was observed. Median values dropped from 87kg to 86kg. The Mann-Whitney U test

reported p = .739 (asymptotic significance (2-tailed)) for the total population. The value for type 1 diabetes was p = .857 and for type 2 diabetes p = .773. At year 0 total weight was 14790.7kg, compared to 14716.4kg at the end of year 1, resulting in a total weight loss of 74.3kg or 11st 9.8lb.

For 206 patients whose systolic blood pressures were compared, mean and median values remained the same. The Mann-Whitney U test reported p = .879 (asymptotic significance (2-tailed)) for the total population. The value for type 1 diabetes was p = .206 and for type 2 diabetes p = .483.

For 206 patients whose diastolic blood pressures were compared, mean and median values remained the same. The Mann-Whitney U test reported p = .979 (asymptotic significance (2-tailed)) for the total population. The value for type 1 diabetes was p = .572 and for type 2 diabetes p = .651.

9.4   Discussion

Despite the fact that none of the analyses resulted in changes of statistical significance either positively or negatively, there were reasons for encouragement. None of the results were significantly affected negatively, while most showed slight improvements in mean and/or median.

At this stage, creatinine was the test result that showed most statistical improvement in both type 1 and type 2 diabetes groups, with type 1 slightly

better. This led to the author drilling down further and extending the analysis for showing that females appeared to show slightly better results than men. A final comparison of before and after results in female type 1 patients were not statistically significant (p = .168 using 2 tailed asymptotic significance) but one-tailed exact significance reported p = .086, approaching levels of significance.

9.4.1 Samples Sizes Required

The patient samples available for this study were clearly not large enough to achieve significant results. However, using these data as a baseline, the author can project the number of patients required for each data item to achieve 80% statistical power at normal levels of significance (p ≤ .05). The following table shows the number of required patients calculated for each of the data items above:

Data Item	N
HbA1c	1374
Creatinine	540
Total Cholesterol	N/A
HDL Cholesterol	N/A
LDL Cholesterol	618
Triglycerides	890
Body Mass Index	6725
Weight	9391
Systolic Blood Pressure	N/A
Diastolic Blood Pressure	N/A

Table 20: N patients required to achieve statistical significance

As expected based on the p-values shown in the previous section, creatinine shows the lowest number of patients required to achieve statistical significance if the current mean and standard deviations are maintained for a wider cohort. LDL cholesterol and triglycerides also show targets within the three-figure range with

HbA1c requiring 1374 patients. The author believes that appropriate levels of data will be exceeded during the fourth year of live use, mainly due to the increased number of users recruited towards the end of 2012. The target values for body mass index and weight remain out of reach for the foreseeable future. Total cholesterol, HDL cholesterol and blood pressure could not be calculated using these data as the mean values before and after the intervention remained identical. Work will continue during 2014 to re-analyse these outcomes and reassess the potential for significant changes.

9.4.2 Limitations

As discussed, the main limitations of this analysis was that despite the fact that 1087 patients had accessed the system at the time of the extract, comparatively small numbers had used the system for long enough to capture the necessary amount of data spanning one calendar year. Even amongst those who had used the system for the requisite amount of time, not everyone had enough complete data to contribute to the analysis. For example, some subjects had intervention data, but no data at the end of the first year, and vice-versa. It is also not possible to attribute these modest improvements only to the MDMW PHR, as other competing initiatives and routine care will also be contributing. This group are also likely to consist of a large proportion of 'diabetes enthusiasts' who may already be 'medically compliant', reporting optimum levels in their process outcomes.

While this was an extract of data for patients who had ever used the system, analysis did not explore in detail the correlation between improved outcomes and frequency of use. This therefore provides scope for future research.

9.5 Conclusion and Summary

The findings of this analysis, while not statistically significant, do show scope for optimism. The majority of the process outcomes analysed appear to be moving in the right direction, although perhaps not as quickly as had originally been hoped.

Further work is required to analyse the data at a later date when more significant number of patients meet the necessary criteria, thereby increasing the power of the analyses. Further profiling, perhaps using randomised controlled trial methodology, will allow more robust analyses on impact, particularly for newly diagnosed groups and a more representative 'general' population. Retrospective analysis would also benefit through comparisons with background data matched on diabetes type, age and duration of diabetes.

This analysis sets an early baseline marker for MDMW, upon which further research can be based. It is still very early in the use of this PHR as an intervention and more work is required to extend beyond these process markers to longer-term outcomes that are beyond the scope of this thesis.

Chapter 10: Recommendations and Conclusions

"I find this method extremely helpful as our results are never communicated to us unless there is something wrong by which time it is too late to try to rectify things. For example today I've discovered that my HBA1C is creeping up which probably means that I need to be a bit more vigilant. I do appreciate Diabetes is a progressive illness but the more I know about my results the more I can try to help myself."

A My Diabetes My Way system user

10.1 Introduction

This final chapter of the thesis aims to highlight key findings of the research performed for this PhD, the limitations and bias associated and a set of recommendations for existing and future PHR projects. As the MDMW PHR is now an established service for people with diabetes in NHS Scotland, there are no plans to end this work following the completion of the PhD. Instead, there are plans to extend the scope and functionality available to users to further enhance the available features in order to maximise its potential. An outline of proposed next steps and developments describes some of the potential routes that may be followed, depending on the identification of suitable funding. The overall conclusion provides the author's opinion on the overall success of this work, its impact and its potential for moving forward.

10.2 *Discussion of this Research*

In 2012, Pagliari stated that there were several unanswered research questions including the profiling of patients using PHRs and the effectiveness of public awareness (Pagliari et al., 2012). This section aims to highlight the answers to these and other questions based on the experiences of MDMW. It also highlights the accepted limitations of the studies performed by the author and proposes approaches to avoid them in future.

10.2.1 Limitations

The outstanding limitation across all of the research presented in this thesis is that the patient populations involved are not representative of the wider diabetes population. It is known that they are younger, more recently diagnosed and have a heavy bias towards type 1 diabetes when compared to the background population. They are also likely to be a more highly motivated 'early adopting', self-selecting cohort. However, although this results in selection bias and affects the general applicability of the results, particularly as more motivated individuals may have optimal clinical measurements already, there are many benefits from engaging with this group. These individuals may be more likely to provide feedback on issues and make constructive suggestions that others may choose to ignore, thereby affecting their ongoing engagement. This is particularly important during early stages when usability and functionality issues are likely to require resolution.

Analysis was performed on data regarding the ethnic group of patients signing up for access. This reported that 80.5% were classed as 'White', while only 2.9% were from a minority group. Although the numbers categorised in minority groups are smaller than in the general diabetic population, the author believes that this may be due, in part, to recording bias. Firstly, a high proportion had no data available (15.2%), and from the authors domain knowledge it is known that systemic default values may be misclassifying some as 'White' when this may not in fact be the case. There are currently no comparable data for the NHS Scotland diabetes population, but it is expected that this will be published for the first time in 2014. This will be a useful benchmark, but in order to address this issue now, the author is in discussion with the national Diabetes Minority Ethnic Group (DMEG) to work on approaches to engage with these hard-to-reach groups.

Early survey responses indicated that those signing up for records access were more computer-literate than the general population, and with concerns about a widening 'digital-divide', it is essential that new developments to not stretch this further. There is an indication from the pre-project evaluation that this divide may in fact be diminishing, due to the wide age range of respondents. It is anticipated by the author that this gap will in fact shrink during the coming years, due to the ubiquity of electronic technologies in all aspects of daily life.

The integration with the Citizen Account has proven to be one of the most challenging aspects of this intervention. While the system removes a significant administrative overhead by providing the provisioning and secure transmission of user account details, several barriers have been highlighted. Firstly, the login process has been described as 'cumbersome' with usernames being long and difficult to remember and password replacement taking some time. There were issues reported with the delivery of username and password letters towards the end of 2012 following the implementation of new automated processes. This resulted in considerable feedback to the Citizen Account team, but with this feedback came the necessary improvements that have subsequently improved the transmission and password reset processes. Despite these issues, the author remains supportive of the engagement with the Citizen Account due to the benefits provided to the project and their intentions to continue to work towards a more usable and accessible interface. In broader terms, the Citizen Account portal also offers benefits to the patient beyond just diabetes, as they will only have one username and password to remember to allow them to access the various public services, planned for future development.

Although the system had been active for two and a half years there were limited data to compare pre- and post-intervention when analysing the clinical process outcome figures. These meant that results of statistical significance were not achieved, however there are grounds for encouragement as reported in the next section.

10.2.2   Key Findings

User feedback indicates that despite the limitations highlighted earlier in this

chapter, the system remains usable, with 96% of users in agreement. The author

believes that much of this is due to the user-centred design approach applied.

Users find it useful to monitor diabetes control (93%), improve knowledge (89%)

and enhance motivation (89%). This would appear to be particularly important for

newly diagnosed patients who are keen to learn more about their new condition.

Patients appreciate the opportunity to check and report on the accuracy of their

records and find that it is a useful reminder system, leading to more productive

consultations with the clinical team (98%).

While in the pre-project analysis, 26% of individual expressed concerns about the

security of their information when it is made available online, those who actually

went on to use it reported 100% satisfaction that their data were safe. This initial

figure did not prove to be a deterrent, backing the finding of previous studies that

stated that potential problems can be outweighed by potential benefits (Pyper et

al., 2004, Ross et al., 2005).

When it came to actually using the system, the author has observed some

changes in utility following first login. In the initial phases, it is clear that users

want to see everything that the system offers and will access most data pages

and explanatory links. However following familiarisation and, the author

assumes, greater understanding of the clinical tests presented, activity following

each login drops. This is believed to be because the user knows where to find the information they desire, for example new results following appointments, meaning that they quickly access the required section before logging off. Further analysis of user patterns and survey evaluations are required to confirm this assumption.

The use of appropriate awareness raising and marketing can dramatically increase the interest in PHRs. The campaign launched by the Scottish Government in collaboration with Diabetes UK and MDMW is testament to this (Diabetes UK, 2012a). Following the campaign launch in August 2012, user requests increased to more than 200 in one single day while healthcare professionals also became more engaged when previously they had not been. Previous approaches had involved the dissemination of information via diabetes Managed Clinical Networks, and while these had proved effective in small pockets, they failed to reach broad engagement universally. Engaging users as they attend for appointments has also highlighted some interesting trends. One clinic in NHS Lothian has been a key promoter of the system, enrolling patients as they attend routine appointments. While this had dramatically increased the number of registrations, the percentage of users who have been sent user details and then actually logged in to the system is one of the lowest. This indicates potential issues with usability, although it may be due in some part to patients feeling obliged to register, without any real intention or motivation to go on to use the system. Further analysis is required to confirm whether or not this is the case.

Access to clinical letters has proven to be one of the main areas for debate during the development of the MDMW PHR. While access across Scotland was available for an initial 3-month pilot and no issues were reported, at the request of the lead diabetes clinician for NHS Scotland this access was withdrawn following concerns from the clinical community regarding the possible contents of these letters. These concerns mainly focused on the possibility of third-party references, information that may cause harm or upset to the patient, or information that they wouldn't understand. The author has worked hard to reintroduce this access, backed by feedback from users and projects such as Renal PatientView which has reported no significant negative response from users. At present, only 4 clinics across NHS Scotland have agreed to reactivate these letters, but it is hoped that this number will continue to rise as clinicians become more aware of ways in which information can be communicated without falling foul of these concerns. A positive point to note is that this project has raised awareness of legal obligations in relation to the Data Protection act, something that clinicians should be more fully aware of as part of their information governance training. For those who do have access to these letters, they remain one of the most useful and commonly accessed sections. In addition to clinical letters, the main area of user access has been around laboratory tests. Of these, the most commonly accessed for historical comparison via table and graph is, unsurprisingly, HbA1c – the key marker for diabetes control.

The author has noted that engagement with the system remains high with 91.4% of those who have ever used the system doing so within the previous year. Given the relatively infrequent access to services for type 2 diabetes in particular, and the fact that most of these patients will be assessed annually, the figures show encouragement for continued engagement. Further work is required to assess why some have never logged on, and why some may have logged on once, but never again.

The author has noted some interesting trends in the day and time of system access. As would be expected, there is light use during the course of the night, with most use occurring during 'normal' office hours and into the early evening. The day of the week also provides some interesting trends, with usage rising from Sunday to Wednesday, before dropping again towards the weekend. This indicates that many users may use the system while at work, perhaps if it is the only place where they have internet access, and then when they return home in the evening. Further analysis is required to investigate why usage drops significantly at the weekend, although the author theorises that this may be similar to users taking the weekend off work, and with it their diabetes. More research is required to investigate this theory.

The mailing of the periodic project newsletter has resulted in some observable trends, with activity rising significantly following the transmission of information regarding new features and reports based on user feedback. This has proven to

be a highly effective user engagement tool, perhaps acting as a reminder to

users who have not logged on for some time. It is also useful to prompt those

who may be experiencing access issues to get in touch so that their problems

can be resolved.

The final analysis performed for this thesis was a comparison of patient clinical

outcomes. While these did not report any improvements of statistical

significance, there were reasons for encouragement. Creatinine tests in particular

improved with type 1 females faring better than those in other groups. For other

clinical tests such as HbA1c, triglycerides, weight and body mass index

improvements were shown in mean and/or median values. Further analyses will

continue as the number of patients meeting the criteria of this before-and-after

study continues to rise towards the target recruitment figures required to achieve

statistical significance shown in Chapter 9.

10.3 Next Steps

The project will continue to evolve in order to meet strategic requirements and

achieved its target to achieve an uptake of 5000 individuals by the end of 2013

during August 2013. Recent enhancements have incorporated user data entry

(since January 2013) of home-recorded results, encouraging further ownership of

the clinical record. It is known that many patients keep their own home paper

records, spreadsheets or databases and the ability to store these online would be

more secure and sustainable. It would also allow these records to be shared with

the wider diabetes and healthcare teams in between appointments, providing

essential insights. Alerts and recommendations may then be built in to highlight

any potential areas of concern. At the time of writing (May 2013), data entry has

been activated for the following measurements:

- Blood Glucose.

- Blood Pressure.

- Cholesterol.

- Weight.

- Smoking Status.

These measurements were selected as smoking status data from SCI-DC was

not found to be as robust as initially expected and users had asked to be able to

change it, while devices are freely available in the domestic market for the

remainder. Waist circumference and alcohol intake are also being considered as

additional parameters. At this stage, it is too early to report reliably on the impact

as a direct result of adding this feature, but it has been observed that many users

are now entering their own home-recorded results.

Further development and expansion of the system is dependent on additional

funding, but a proposal was submitted to Scottish Government eHealth in May

2013 reporting the findings of this thesis and proposing several new features. Up

until the end of its second year of live usage, the MDMW PHR has contained

limited interactive functionality that can be initiated by the end user. Its main

offering has been the ability to review current and historical clinical results

alongside information resources tailored to help users manage their condition better. The system therefore has the potential to be expanded to offer more features that would encourage current users and potential future users to either remain engaged, or to sign up for access.

Data input may not necessarily be limited to single data entry items. There are several validated instruments used to collect scores for anxiety and depression, and to provide details of current dietary intake and exercise, for example. These tools could potentially be incorporated to delegate responsibility for routine recording to the patient, rather than the care provider. Manual data entry is acknowledged as not being the most ideal solution and plans are underway to integrate more closely with home-recording devices to allow patients to electronically upload their results.

One potential obstacle that would have to be overcome is how the expectations of the patients were then managed. Some patients may expect any results entered or uploaded to be routinely checked by healthcare teams and that if there are any problems then they may expect to be contacted to discuss them. This is clearly unfeasible at present, but two potential ways to negotiate the problem would be via online decision support advising on next steps, or through the use of printable summaries.

A printable summary is a proposed area of functionality that will allow the patient to print of details of their clinical record. While there may be summaries available allowing the patient to print out their information for a specific clinical area (e.g. foot screening), an overall summary may be produced containing only results that the patient has recorded at home. This report may then be printed and taken along to appointments for the interest of the patient's care provider during an appointment, particularly where it provides additional information that may enhance the discussion during consultation.

A similar summary is proposed outlining the measurements and services patients should expect to receive each year. Using the data within the system, it is possible to reliably identify which tests and assessments are overdue. These will be highlighted, alongside those within and outwith acceptable range, so that the patient can request any missing measurement to be recorded at their next review and prompt discussion regarding the outliers. This development should not only empower patients to become more active participants, but aims to meet the strategic objective of putting them at the centre of their own care.

A summary of proposed enhancements are listed below, much of which has been based on user requests and feedback:

10.3.1 Enhanced Communication

- Additional home recorded data (e.g. waist circumference, alcohol intake) and home self-assessments that can contribute to appointments e.g. PHQ-9 standard depression screening.

- Genuine two-way communication of data with patient-recorded information transferring in to SCI-Diabetes (clearly marked as patient recorded).

- Patient agenda-setting, based on issues that are important to the individual, rather than dictated by the HCP.

- Asynchronous messaging where patients can "ask a specialist nurse" for non-urgent queries.

- Monthly, real-time, group "drop-in" clinics using live chat messaging, facilitated by a specialist.

- Video-linked 'virtual clinics' using technology such as Skype or WebEx.

- Patient dashboard, where patients can compare their data with the aggregated data of their peers (based on the Scottish Diabetes Survey, for example).

- Extension of MDMW onto social media websites (e.g. Facebook and Twitter).

10.3.2 Further Developments

- Enhanced tailored content, signposting patients to information that is relevant to their condition.

- Personal goal setting: the ability to set realistic, modifiable targets that are achievable, rather than relying on 'hard' clinical guidelines.

- Extension of goal setting functionality to automatically create a customised training package (from MDMW resources) based on the patient's priorities.

- Enhanced patient diary, allowing users to document information that is of interest to them as an aide memoir. This may also include the ability to log details of future appointments, linking to the 'agenda setting' functionality described earlier.

- Extended dataset following further assessment of available SCI-Diabetes data.

- Enhanced messaging to support email newsletters. Newsletters are currently emailed manually, but result in a dramatic increase in system usage following transmission. Automated processes will enable these to be sent more frequently.

- Patient notifications via SMS or email to alert the arrival of new clinical data for review. Again, this is expected to enhance user activity.

10.3.3   Strategic

- Links to existing systems: where possible, enhance links to local patient-portal sites currently under development and continue discussions with Renal PatientView.

- Continue to work with the Citizen Account to enhance the usability and accessibility of their system in order to remove potential barriers to use and streamline access procedures.

- Continue to raise awareness via local diabetes managed clinical networks, patient and professional events and by targeted signup in primary and secondary care clinics.

- Development of a generic framework that can be reused for another disease area. Aim to implement beyond diabetes, once a suitable data source has been identified.

- Aim to reach 25,000 patients (10% of current population) by the end of 2015.

10.3.4 Reusable Services

MDMW has developed a technical infrastructure that supports the needs of people with diabetes across NHS Scotland. In order to prove the wider applicability of the system and components that have been developed, the author presents a set of reusable components that may be applied generically beyond this disease area. Any new system may be able make use of the following additional reusable services within NHS Scotland:

- Synchronous and asynchronous interfacing framework allowing patients to view clinical results and communicate their own home-recorded results as necessary. This may be extended to provide real-time integration with hospital patient administration systems for appointment management.

- Quality-assured data presentation framework positively evaluated by system users. This has been assessed for accessibility and usability.

- Managed server environment: This is used by patients as the internet facing window in to the exposed data for all those who have subscribed.

- Administrative dashboard, used to monitor service access and manage registration and enrolment workflow processes.

10.4 Further Research

The research documented in this thesis is by no means the end of the potential studies that may be performed against MDMW. Indeed it is ripe for future many quasi-experimental analyses and assessment.

As part of the ongoing evaluation of the system and the functionality it provides, patient experience must continue to be assessed using a variety of quantitative and qualitative methods in order to document the system's impact on self-management and satisfaction. This is particularly relevant for the novel communication methodology proposals, where sessions can be followed up immediately with satisfaction questionnaires to assess their usefulness and future viability.

Quantitative data can be derived from system audit trail to assess the features of the system that are most commonly used. Further analysis of usage patterns may confirm the assumption that more focused access follows initial use. Moving in to this next phase, following two and a half years of activity, it will be possible to assess in more detail the impact on key process outcomes such as HbA1c, Cholesterol, Blood Pressure and Body Mass Index. Preliminary findings have shown improvements in several process outcomes one year following first login.

Qualitative data from patients should be collected using a combination of methods, including structured interviews, survey questionnaires, focus groups and direct user feedback.

The expectations and experiences of clinical staff and the impact on the care they provide must also be assessed. A survey has been created to assess the expectations of health care professionals when dealing with patients who have received access to their information. Another approach would be to arrange structured interviews with those who have dealt with patients who have access to their data to evaluate whether this intervention has helped, or hindered the clinical encounter.

A considerable amount of user feedback has been received via website comments for logged in users since the initiation of the project and this may be analysed in more detail to highlight common themes. The author believes that examples may include data errors (e.g. types of diabetes), data completeness (e.g. missing results from recent appointments) and suggestions for further enhancements. These anecdotal responses may be catalogued and analysed to provide further useful insights not captured within the survey questionnaires detailed within this thesis.

As mentioned earlier in this thesis, one clinic in NHS Lothian has been a key promoter of the system, enrolling patients as they attend routine appointments.

While this had dramatically increased the number of registrations, the percentage of users who have been sent user details and actually logged in to the system remains one of the lowest. Further analysis is required to identify whether this is down to users feeling obliged to complete the forms when they visit or whether there remains underlying usability problems. Following on from this, there remains a gap across the country between those who have been sent user details and those who have actually logged in. Follow-up of users will be progressed during 2013 to address this issue and to identify why some have not proceeded beyond the signup stage.

Analysis is required to investigate why usage drops significantly at the weekend. While the author has theorised that access to the internet may be a factor, there may be wider issues regarding perspectives on diabetes management during the weekend. More research is required to investigate this.

Further areas of research will continue to focus on patient satisfaction, usability and demography profiles. One area not assessed to date is around the economic impact and cost-effectiveness of such systems. The author has been informed informally by the podiatry diabetes lead for NHS Scotland that a diabetes-related amputation may cost as much as £40,000 when surgery, follow-up treatments and rehabilitation are included. If MDMW can be shown to suppress the progression of disease then it will be possible to extrapolate potential savings.

The initial analysis of diabetes process outcomes has placed a benchmark for the impact of the MDMW PHR, but this is just the beginning. Further interrogation of diabetes outcomes, particularly in relation to the frequency of use and based on a larger volume of patients are likely to provide more meaningful and statistically significant data as the project progresses. One approach would be to devise a randomised controlled trial for newly diagnosed patients, with one arm gaining access to the system and the other receiving regular care. The outcome would be likely to provide robust and reliable evidence in this area. A similar approach may also be applied to a general practice population to identify what demographic of patients go on to use such a system.

Furthermore, a retrospective comparison of background data may provide an alternative approach. This would rely and the analysis of data based on matching patient cohorts on diabetes type, age and duration of disease in order to provide meaningful outcomes. It would be appropriate to allow the analysis in any future studies to be carried out by an independent analyst so that the results can be viewed as genuinely objective, rather than biased by contact from the project team.

10.5 Recommendations

This section highlights a series of recommendations that can be used as learning points for other PHR projects, based on the experiences of MDMW. These are drawn from the lessons learnt during the development, implementation,

evolution, evaluation and research performed by the author and resulting in this thesis.

10.5.1   Health Service/Voluntary Sector Ownership

It is one significant task to develop a PHR that can be used and be found of benefit, but it is another significant undertaking to gain buy-in from the entire clinical and patient communities. Many examples of good practice tend to operate in distinct silos, with wider communities in each domain remaining disengaged. It is therefore necessary to encourage participation, when benefits can be demonstrated, particularly when objectives meet key national strategies. The author proposes a tiered approach to disseminate knowledge and educate professionals and patients on the benefits:

1. Healthcare organisations must actively commit investment in training to promote PHRs to their healthcare teams when they are of good quality, meet strategy objectives and are backed by appropriate evidence.

2. These healthcare team members should pass on information to their patients regarding the availability and benefits of these PHRs. They should also encourage them to register and become active participants and ease the path to enrolment by supporting the process within their areas.

3. Patient groups consisting of active enthusiasts who can extol the benefits of records access must be encouraged to disseminate their experiences with their peers and with their healthcare teams. In many cases, 'patient-power'

can be seen as a positive driving force to ensure that a bottom-up approach is in synchronicity with the top-down objectives.

10.5.2 Patient Involvement

As outlined in earlier sections of this thesis, user engagement is essential in the evolution of any new computer-based system and health informatics and PHRs in particular are no different. MDMW has adopted a user-centred design approach with its developments and this is reflected in the following recommendations:

1. Involve your users in every stage of the development and evaluation process so that you can deal with problems and usability and accessibility issues early.

2. Data access alone is not enough. Users demand to become genuinely involved. PHRs must contain functionality that allow them to become active participants in their care, for example, by recording home-recorded results and allowing them to prepare materials for discussion during clinical consultations.

3. Beyond engaging with individuals, it is essential to discuss new systems with patient groups to encourage further involvement. Following awareness presentations to patient groups, delivered by the author in specific localities, uptake had been seen to increase.

10.5.3   Administrative Processes

Once buy-in has been received, it is necessary to ensure that those who request an account are given access as quickly as possible to ensure that engagement and enthusiasm are not lost. Although workflow processes may vary by clinical domain, it is essential to ensure that the optimal approach is identified early in the development of any new system. With MDMW, this was refined by the author by directly managing patients through the process. Once the most efficient approach has been identified, automated processes must be implemented to streamline this further. Security considerations are essential, but they must not be overly cumbersome as to disengage potential users:

1. Identify administrative processes and enrolment workflow to ensure that patients can move swiftly from initial registration, on to receiving their user credentials.

2. Automate administrative workflow processes once a clear strategy has been defined to further enhance this approach and minimise any delays in users receiving access to their data.

3. Ensure the security of the record, but do not make it overly complex or cumbersome. Lessons can be learnt from the banking industry, where good user-interface design and efficient provisioning of user account details reduces the potential for user disengagement.

10.5.4   Research Activities

While research is essential to prove the concept of any new intervention, it is not necessarily a high priority objective for the end-user of any system. Approaches

must therefore be taken to minimise the impact on the user, and if possible link the research to direct user benefit:

1. User audit trails: a simple way of analysing user engagement, with no impact on the user is via the use of system audit trails. These log areas of user activity, frequency of login and provide useful insights into the utility and preferences of an individual. These must be a key component of any PHR, while also being useful to address potential breaches in security.

2. While research may not be of interest to all users, there remain individuals who are keen to stay involved and contribute to future developments. Enthusiasts must be encouraged comment openly and provide their valuable insights. Their input must not be underestimated.

3. Where possible, it may be useful to embed research into access processes. MDMW has shown that by including the survey of patient expectations into the enrolment process, an 82% response rate was received. Access may have been seen as the 'carrot' in this instance, but other projects may find this approach helpful, rather than including it as an extra step.

10.5.5   Communication

Communication with users is an essential process to retain engagement. While many PHR projects, such as MDMW, may not have the necessary experience to produce sophisticated marketing strategies, several approaches have proved effective in retaining user involvement:

1. Keep users informed: it is important to manage the expectations of users in any eHealth environment and patients are no different. If they are made

aware in advance of potential downtime, for example, they are likely to remain committed to a system when they know when they will and will not be able to access it. Communications of this type are essential in order to avoid user apathy.

2. The analysis of MDMW newsletters has shown that these result in an immediate increase in user activity that, in some cases, lasts for several days. It is important to ensure that any messages communicated via these newsletters are both appropriate and relevant for the target user group, and many have reported that they contain very useful information.

3. As with any computer-based system, user feedback is highly effective. It is important to respond to user feedback quickly to put users at ease, particularly when concerns are raised. It is also important to take constructive criticism well so that lessons can be learnt. Microsoft's Bill Gates was once quoted as saying that *"your most unhappy customers are your greatest source of learning"* and this is no different in the field of PHRs. If someone has taken time to express their displeasure it means that they are engaged and a resolution will, in the majority of cases, prove to be of benefit to the wider user group.

10.6 Conclusions and Summary

The current project funding ensures that the system will continue to evolve, providing new resources to further enhance the self-management of diabetes in NHS Scotland. The project team are due to employ a new administrative

resource to deal with user feedback, further enhancing the sustainability of the system. The fact that it is centrally managed means that there is minimal impact on front-line services. Work will continue to evaluate and report on the system both via the MDMW website and via peer-reviewed literature.

This thesis has brought new material to the field of electronic personal health records based on the experiences of a subset of the NHS Scotland diabetes population. This local and domain-specific knowledge has much wider applicability as outlined in the recommendations above, particularly around health service and voluntary sector ownership, patient involvement, administrative processes, research activities and communication. Some legacy PHRs have failed due to lack of uptake and deficiencies in usability, so as new systems progress, it is essential not to repeat the mistakes of the past.

This thesis has assessed the expectations of a subset of the Scottish diabetes population regarding access to records and has reported on the effectiveness of this intervention. It is seen as usable and effective in many areas, with users remaining engaged beyond initial login. The analysis of user experiences has provided some valuable insights to inform future developments and enhance access and these activities will continue to provide additional refinements. In summary, the author believes that the system developed has proven to a highly effective method of engaging people with diabetes in their self-management.

MDMW has a proven track record of delivering it's objectives to a high quality based on total funding of only £256,068 to date. This covers both public and private areas of the MDMW website. The project received an NHS Tayside Quality Award in December 2012 and a UK-wide Quality in Care Diabetes Award as the "Best initiative supporting self-care" in 2013.

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Appendix A: Awareness Presentations Delivered

Date	Location	Description
13/08/2009	Dundee	Meeting with eHealth leads to present the proposed system.
11/02/2010	Glasgow	Diabetes UK Scottish Advisory Council (patients and HCPs).
23/04/2010	Glasgow	Diabetes Care Focus Group (national patient group)
26/04/2010	Glasgow	Glasgow MCN Executive Group meeting (HCPs).
17/06/2010	Edinburgh	Meeting with national eHealth and stakeholders from Renal PatientView and the Ayrshire & Arran GP pilot
09/09/2010	Dunfermline	HCP awareness session and presentation: all practice staff
30/10/2010	Edinburgh	Lothian Patient Conference workshop presentation
16/02/2011	Dundee	Dundee Diabetes Forum presentation to diabetes MCN staff
05/03/2011	Edinburgh	Diabetes UK Patient Seminar presentation
13/04/2011	Kilmarnock	Presentation to Ayrshire & Arran HCP IT users group
30/04/2011	Dunfermline	Diabetes UK Fife West patient group presentation
05/05/2011	Dundee	Rehabilitation & Particpation conference presentation
13/07/2011	Edinburgh	Meeting with national eHealth and stakeholders from Renal PatientView
12/09/2011	Edinburgh	BCS Health Informatics Conference presentation
21/09/2011	Glasgow	Diabetes UK Glasgow South patient group presentation
04/10/2011	Glasgow	Patient information Forum Conference presentation
29/10/2011	Edinburgh	Lothian Patient Conference workshop presentation
03/03/2011	Edinburgh	Diabetes UK Patient Seminar presentation
05/12/2011	Dubai	International Diabetes Federation Conference
13/12/2011	Edinburgh	Presentation to Lothian Data Sharing group
07/03/2012	Wishaw	Diabetes UK Wishaw patient group presentation
26/04/2012	Dundee	Tayside Patient Participation Group
15/05/2012	Internet	WebEx webinar for interested parties across the NHS (UK)
16/05/2012	Aberdeen	Informatics seminar presentation for researchers and clinicians
06/06/2012	Dundee	Health Informatics seminar presentation for researchers
17/07/2012	Leeds	Yorkshire and Humber Clinical Innovators group presentation
21/09/2012	Edinburgh	BCS Health Informatics Conference presentation
03/10/2012	Berlin	European Association for the Study of Diabetes presentation
19/10/2012	Kirkcaldy	Overview presentation to HCPs
26/10/2012	Edinburgh	Diabetes Care Focus Group (national patient group)
06/12/2012	Internet	Outpatient services group WebEx presentation
23/01/2013	Dundee	Overview presentation to HCPs
07/02/2013	Dundee	Meeting with Tayside eHealth leads to present the system
27/02/2013	Edinburgh	Lothian Lead Clinicians meeting presentation
06/03/2013	Edinburgh	Scottish Diabetes Industry Group (pharmaceutical reps)
26/04/2013	Edinburgh	Minority & Ethnic Group presentation (multidisciplinary)
30/05/2013	Kilmarnock/Ayr	Ayrshire & Arran showcase day for HCPs.

Appendix B: Structured Evaluation Questionnaire

What would encourage you to register for a record access system?

What would put you off registering for a record access system?

What harm could be caused by withdrawing a feature from a record access system?

What methodology could be used to measure and track benefits?

If you could develop a new module within the My Diabetes My Way system, what would it be?

Appendix C: Patient Enrolment Form

my diabetes ★ my way
...the interactive diabetes website

NHS SCOTLAND

Enrolment Form

By completing this form you are asking us to make your information from your diabetes records available to you securely on the Internet via the mydiabetes*myway website. This information may come from:

- Your GP computer record
- Your hospital clinic computer record
- Other computer systems relevant to diabetes, such as the national retinopathy screening system

We will pass your details securely to the 'Citizen's Account' who will issue your username and password. You will then be able to access your information from any Internet-connected computer. This is your personal diabetes information and you should treat it as if it were your bank details.

Your information will not be made available to you on mydiabetes*myway without your permission. If you decide not to join, or wish to withdraw, it will in no way affect your treatment.

I understand the information I have been given about the management of my computer-held clinical information. I would like to securely access my information on the mydiabetes*myway website and am happy to be contacted further.

Signed: _____   **Date:** _____

Print Name: _____   **Date of Birth:** _____

Email: _____ (Please print clearly)

Verified By
This should be completed by a staff member. You should know or be able to confirm the identity of the patient.

It is helpful to check that the name, contact details and GP are correctly recorded on SCI-DC before anyone joins mydiabetes*myway. We may contact you to confirm the details and verification outlined in this form.

I confirm the identity of the patient detailed above:

Signed: _____   **Date:** _____

Print Name: _____   **Position:** _____

Email: _____

I confirm the patient CHI as: _____

(NB: All fields required)

Please return to:
mydiabetes*myway, Clinical Technology Centre, Level 7, Ninewells Hospital, Dundee, DD1 9SY

Appendix D: Patient Expectations Survey

We are about to launch a new feature that will allow you to securely view your own diabetes information online. In order to complete these developments, we need to ask you a few questions about your expectations and concerns about the new service. It will only take 5 minutes to do this. Please answer the questions as honestly as you can. There are no right or wrong answers. All responses will be stored securely and the analysis will be carried out to conceal the identity of respondents. Please mark one answer for each question with a cross.

Are you male or female?

Male	Female

How old are you?

Under 16	16-25	26-35	36-45	46-55	56-65	66-75	Over 75

Section A. The following questions aim to identify how often you use existing online services related to your personal circumstances.

Do you own a computer that has internet access?

Yes	No

How often do you refer to the Internet for information about your diabetes?

About once a week	About once a month	Never

What other online services do you use?
Internet banking

More than once a week	About once a week	About once a month	About once every 6 months	Never

Price comparison sites (e.g. to get quotes for insurance or choose utility providers)

More than once a week	About once a week	About once a month	About once every 6 months	Never

Shopping for goods **(e.g. Tesco, Amazon, eBay)**

More than once a week	About once a week	About once a month	About once every 6 months	Never

Continued overleaf…

Section B: The following questions aim to identify your opinions on having your personal information available online.

Please mark one answer for each of the following statements with a cross, depending on how much you agree or disagree with them:

	Agree strongly	Agree	Disagree	Disagree strongly
1. I would be interested in looking at my diabetes information online				
2. I would like to check how I am doing with my diabetes control				
3. I would like to remind myself of my medications				
4. I would like to see information materials tailored to my diabetes				
5. I would like to check the accuracy of my electronic diabetes information				
6. I would like to have the facility to report errors in my electronic diabetes information				
7. I would like to ask questions about my electronic diabetes information online				
8. I would like to be able to transfer home-recorded readings into my record (e.g. blood sugars, weight)				
9. I have no concerns over the online security of my diabetes information				
10. I think accessing my information will help to improve my knowledge of diabetes				
11. I think accessing my diabetes information will help me to meet goals set by my doctor				
12. I think that providing patients with online access to their diabetes information is an excellent innovation that will significantly improve diabetes care across Scotland				

Continued overleaf…

Please answer the final questions in your own words:

If you would like to add anything that has not been covered so far in the questionnaire, or if you disagree strongly with any of the statements above, please explain your reasons why here:

What information in your record are you <u>most</u> interested in viewing, and why?

What are the most important benefits you expect from viewing your diabetes information?

What problems do you anticipate from viewing your diabetes record?

Thank you for taking the time to complete this questionnaire.

Appendix E: User Experience Survey

We will soon be writing our project evaluation which we will make available for you to review on the My Diabetes My Way website. In order to do this thoroughly we would very much appreciate your help. In order to gain your feedback on this service, we need to ask you a few questions about your experiences so far. It should only take about 5 minutes to do this.

We would like to know what you liked about the system and what could be improved. Please answer the questions as honestly as you can. There are no right or wrong answers. All responses will be stored securely and our analysis will conceal the identity of respondents. Please mark one answer for each question with a cross and return the completed form to mydiabetesmyway@nhs.net

Section A. The following questions aim to identify how you found the enrolment process.

Did you receive information leaflets and an enrolment form to sign through the post?

Yes	No

Did you complete and return your enrolment form, signed by a member of your health care team to verify your identity?

Yes	No

Did you gain access to your personal diabetes information?

Yes	No

If you have any comments about any part of the enrolment process or experienced any difficulties in obtaining a signature from a member of your health care team, please explain below:

Continued overleaf…

Section B: Please only answer this section if you were able to get online and access your information. The following questions are about your opinions of the My Diabetes My Way system.

Please mark one answer for each of the following statements with a cross, depending on how much you agree or disagree with them:

	Agree strongly	Agree	Disagree	Disagree strongly
1. The system contained all the features that I expected				
2. The system helped to remind me of information discussed during consultations				
3. The system will help me make better use of my consultation time				
4. The system means I do not need to keep my own paper records				
5. The system means I do not need to phone my doctor for new results				
6. The system was up-to-date				
7. The system was easy to use				
8. The explanatory information helped me understand my results better				
9. The links helped me to find further information relevant to my diabetes				
10. The graphs of information were helpful to monitor changes over time				
11. I was confident that my information was secure when using the system				
12. The system has helped me manage my diabetes better				
13. Accessing my information has helped to improve my knowledge of diabetes				
14. Accessing my information has made me more motivated about my diabetes				

Continued overleaf…

	Agree strongly	Agree	Disagree	Disagree strongly
15. Accessing my information has helped me to meet my diabetes goals				
16. The system will help me to set my own diabetes goals				
17. Online access to diabetes information will significantly improve diabetes self-care across Scotland				

If you disagree with any of the statements above, explain why below:

Did you review the user guide before you accessed your personal information?

Yes	No

Did you raise feedback about any problems you had when using the system?

Yes	No

If so, was your issue responded to quickly enough?

Yes	No

Did you receive a resolution to your issue that was to your satisfaction?

Yes	No

If you have any comments to make about any feedback you submitted and responses you received, please enter them below:

Please answer the final questions in your own words:

What was the best part of the system, and why?

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What was the worst part of the system, and why?

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What new features would you like to see added to the system?

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If you would like to add anything that has not been covered so far in the questionnaire, please use the space below:

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Thank you for taking the time to complete this questionnaire. Please return the completed form to mydiabetesmyway@nhs.net