

**DEVELOPING AND EVALUATING A PLAN TO IMPLEMENT AN ONLINE
SELF-MANAGEMENT PROGRAMME FOR PEOPLE WITH TYPE 2 DIABETES WITHIN
ROUTINE HEALTHCARE**

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Thesis submitted for the degree of PhD

DECLARATION

I Jamie Anne Dolan Ross confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Jamie Anne Dolan Ross

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ABSTRACT

Background

Internet interventions have the potential to provide self-management support to patients with type 2 diabetes. However, little is known about the adoption and use of internet interventions within routine healthcare by services and patients. Available data on the reach and use of such interventions has been collected in the context of research which may not generalise to routine practice. Implementation of e-health into healthcare settings is frequently described as challenging, and concerns about a digital divide are reported.

Aim

To employ implementation science methods to investigate the implementation of HeLP-Diabetes, an internet based self-management intervention for people with type 2 diabetes into routine healthcare.

Methods

A theoretically informed implementation plan was developed and applied to the implementation of HeLP-Diabetes within routine healthcare. A mixed methods case study in one National Health Service (NHS) Clinical Commissioning Group evaluated the implementation. Data were collected to describe: the adoption and implementation by NHS services, uptake and use by patients, and barriers and facilitators to implementation and use.

Results

Adoption was high but relatively few NHS services actually implemented HeLP-Diabetes. Barriers included the current NHS context with limited time and resources to undertake the work of implementation and the prioritisation of incentivised tasks over HeLP-Diabetes. A wide range of patients registered to use HeLP-Diabetes including those with basic computer skills and no education. Over half of registered patients made some use of HeLP-Diabetes. Staff facilitation of access and the accessibility of HeLP-Diabetes promoted uptake and use.

Conclusion

In the context of diabetes self-management there seems to be good potential for internet based interventions. Staff facilitation of access has the potential to provide access to patients with lower education and basic computer skills. However, to become part of routine practice resources need to be allocated and the work has to be prioritised by staff.

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Figure key: The first number refers to the chapter, the second number refers to the order within the chapter (e.g. Figure 8-7= Chapter 8, Figure 7).

GLOSSARY

Adoption	A decision to make full use of an innovation as the best course of action available.
Assimilation	In the organisational context adoption may also be referred to as assimilation.
Complex intervention (intervention)	Interventions with several interacting components
Diffusion	The process by which an innovation is communicated through certain channels over time among the members of a social system.
Dissemination	An active approach of spreading evidence-based interventions to the target audience via determined channels using planned strategies.
Embedding	The innovation becoming routinely incorporated in everyday work of individuals and groups.
Implementation	The active process of putting to use or integrating evidence-based interventions within a setting.
Innovation	An idea, practice or object that is perceived as new by an individual or other unit of adoption.
Normalization	The point at which the innovation becomes so embedded into routine practice that it disappears from view.
Routinized	The innovation becoming an ongoing element in the organisations activities.
Uptake	The action of taking up something that is available.
Use	The action of or making use of something that is available.

STATEMENT OF INTELLECTUAL PROPERTY/CONTRIBUTION

This PhD has been conducted as part of a wider National Institute for Health Research (NIHR) funded project to develop, evaluate and implement a web-based self-management programme (HeLP-Diabetes). The programme grant was divided into five work packages, with the final two work packages (WPD and WPE) evaluating and implementing HeLP-Diabetes. I began working on this project as a Research Associate (in September 2011) to help develop the HeLP-Diabetes intervention, and later registered for my PhD (May 2012).

Although initial objectives had been set for the implementation work package (WPE) in the original grant application, no protocol for this work package had been devised so that a PhD student could use this work package as the basis for their PhD. The original objectives of WPE were to: implement the computer-based self-management programme in two Primary Care Trusts and to determine the uptake, use and effects of the intervention in an unselected population in routine care; determine factors that inhibit or facilitate integration into existing services and utilisation of the intervention and determine the resources needed for effective implementation.

Once registered for my PhD I developed the protocol for the WPE work package supported by members of the team and my PhD supervisors. Based on my reading in the subject area and understanding of the intervention I devised a protocol of how to implement HeLP-Diabetes into the National Health Service (NHS). This included creating the implementation plan, choosing the setting, deciding upon the outcomes, creating a data collection and analysis plan and devising timelines for the work.

I appointed a steering group for the implementation study in September 2012 who comprised experts in diabetes, research methods, statistics, health economics, implementation and psychology as well as patient and public (PPI) representatives to advise on the protocol, research methodology and study conduct. Throughout the study they have advised on issues such as suggestions for settings to offer HeLP-Diabetes, strategies to engage staff and patients, statistics, data needed for health economic analysis, strategies to improve recruitment and the content of interview topic guides.

This thesis is a subset of work which contributes to the overall programme grant. My PhD addresses the objectives set out in the original programme grant through a protocol I devised and have implemented. There are also data that I have collected as part of my work developing, evaluating and implementing HeLP-Diabetes that are not part of my PhD including health economic data and patient self-report measures. These data are of great value to the overall findings of the programme grant, however are not within the scope of this thesis, the main focus of which is the evaluation of the implementation.

THESIS AIMS AND OBJECTIVES

The aim of the research presented in this thesis was to employ implementation science methods to explore the implementation of HeLP-Diabetes, an internet based self-management intervention for people with type 2 diabetes into routine NHS care.

Specific objectives were to:

- Design a theoretically informed implementation plan that reflected best practice according to the available literature
- Evaluate the effectiveness of the implementation plan, including identifying and describing barriers and facilitators to implementation
- Identify modifications and improvements to the implementation plan in light of the barriers and facilitators identified
- Draw generalizable inferences to inform future implementations of similar interventions in similar contexts.

This PhD thesis explored the implementation of HeLP-Diabetes within the National Health Service (NHS). It provides data on what happens in practice, and what actions and resources are needed to successfully implement and realise the potential benefits of HeLP-Diabetes. To the best of my knowledge, no other research has addressed the implementation of an e-health initiative within routine care in as much detail or with as much intellectual rigour. As a result of the work in this thesis, HeLP-Diabetes is now the only International example (again, to the best of my knowledge) of an internet based self-management service for people with type 2 diabetes in use in routine healthcare. Five inter-related pieces of intellectual property contribute to this thesis. These are:

- An update of a systematic review of reviews, with a new approach to data extraction, coding, analysis and synthesis;
- The design of an implementation plan, based on my understanding of the theoretical and empirical literature;
- A quantitative study, looking at adoption, uptake and use of HeLP-Diabetes by NHS services and patients;
- A qualitative study, determining staff perspectives on the implementation of HeLP-Diabetes;
- A qualitative study, determining patient perspectives on reasons for observed use of HeLP-Diabetes.

THESIS STRUCTURE

Chapter 1 presents background information on key areas pertinent to this thesis including, diabetes, self-management, e-health and implementation.

Chapter 2 provides a description of the HeLP-Diabetes intervention including a description of its development and content.

Chapter 3 presents a systematic review of the literature exploring factors that are important for the implementation of e-health within health services.

Chapter 4 discusses and describes implementation theories, frameworks and models. It provides a rationale for the selection of the framework and model selected to inform the development of a theoretically informed implementation plan to implement the HeLP-Diabetes intervention into routine practice.

Chapter 5 describes the original, theoretically informed implementation plan, including details of how the selected theory and model were operationalised.

Chapter 6 presents the mixed methods selected to evaluate the implementation plan. The specific research questions addressed with these methods were:

- To what extent was HeLP-Diabetes adopted by NHS services?
- To what extent was HeLP-Diabetes implemented within NHS services?
- What was the uptake of HeLP-Diabetes by patients?
- How was HeLP-Diabetes used by patients?
- Were there any factors that predicted patient use of HeLP-Diabetes?
- Were there any factors that predicted HeLP-Diabetes registration method?
- What barriers and facilitators did staff identify to the adoption and implementation of HeLP-Diabetes by NHS services?
- What barriers and facilitators did patients identify to the uptake and use of HeLP-Diabetes?

Chapter 7 describes the implementation plan that was actually implemented in the case study Clinical Commissioning Group (CCG). A description of the case study CCG (Islington), the changes that occurred to the original implementation plan and the final plan to implement HeLP-Diabetes are described.

Chapter 8 is the first of three results chapters. This chapter describes the adoption and implementation of HeLP-Diabetes by NHS services and the uptake and use of HeLP-Diabetes by patients.

Chapter 9 is the second of the three results chapters. It presents the results from interviews with staff, which explored the implementation of HeLP-Diabetes within practice and the barriers and facilitators to adoption and use.

Chapter 10 is the third of three results chapters. It presents the results from interviews with patients, which explored the uptake and use of the HeLP-Diabetes intervention and barriers and facilitators to use.

Chapter 11 brings together the findings of the results chapters (chapters 7, 8 and 9) and discusses them in relation to the literature. Overall methodological strengths and weaknesses are considered, together with implications for policy, research and future practice.

1 CHAPTER 1: BACKGROUND

1.1 Chapter summary

In this chapter key background information to the thesis is presented. Diabetes is a long term condition which, if poorly managed, can lead to a range of health complications which in turn may have a significant impact on quality and longevity of life. A description of this condition is presented in order to give the reader an understanding of the growing problems of diabetes faced by populations and health services and to set the scene for how a self-management intervention such as HeLP-Diabetes may support living with this condition. The concept of self-management, the current dominant paradigm for managing long term conditions in many countries, is described in order to illustrate the work involved for patients in living with a long term condition and the potential of internet interventions to support this. The use of e-health is presented as a promising method for delivering and supporting healthcare. Given the focus of this thesis on implementation, background information on e-health, the adoption and assimilation of e-health interventions into healthcare and factors that have been found to influence individuals' adoption and continued use of e-health are presented.

1.2 Definitions

Within this thesis many terms referring to the adoption and use of new innovations are used. One challenge in implementation research as a whole is the lack of standardised terminology which is partly explained by the numerous different fields of research that contribute to this research area (1), the variation in thinking in scientific circles and the range of policies that cover this subject (2). Rabin and colleagues attempted to clarify the most commonly used terms and their definitions by synthesising the most frequently cited manuscripts on dissemination and implementation research in health (1). These definitions along with other key definitions in the field are presented here to aid the reading and understanding of this thesis. A glossary of terms can be found on page 13 for reference.

An **innovation** is “*an idea, practice or object that is perceived as new by an individual or other unit of adoption*” (3). Most innovations investigated in diffusion and implementation research have been technological innovations and the term ‘technology’ is often used in the literature as a synonym for innovation.

Diffusion, a term coined by researcher Everett M. Rogers is described by him as: “*The process by which an innovation is communicated through certain channels over time among the members of a social system*” (3). In other definitions, diffusion is described as being at the beginning of a continuum characterised by the intensity of the approaches used to spread new innovations (4). The continuum ranges from ‘let it happen’ to ‘make it happen’ with diffusion being a process of ‘let it happen’ or a “*passive, untargeted, unplanned, and uncontrolled spread of new interventions*” (1).

Dissemination, “an active approach of spreading evidence-based interventions to the target audience via determined channels using planned strategies” (1) falls in the middle of diffusion and implementation on the continuum. It is a “planned and active process intended to increase the rate and level of adoption above which might have been achieved by diffusion alone” (4).

At the other end of this continuum (‘make it happen’) is **implementation** which is described as “the process of putting to use or integrating evidence-based interventions within a setting” (1). Implementation encompasses all the activities that take place “between making an adoption commitment and the time that an innovation either becomes part of the organizational routine, ceases to be new, or is abandoned” (5). Implementation is a much more active process than diffusion and has been described as “dissemination plus action to actively encourage the adoption recommendations contained in a message” (6)

Adoption is defined by Rogers as the “decision to make full use of the innovation as the best course of action available” (3). This definition applies to decisions at the individual level, however quite often, especially in healthcare settings, the adoption decision “to commit to and initiate an evidence-based intervention” (1) is a group or organisational one. In the organisational context adoption may also be referred to as ‘assimilation’ which highlights “the long and complex processes involved, with multiple decisions made by multiple agents” (4).

The following terms are used to describe what may (or may not) happen to an innovation once a decision to adopt it has occurred. The innovation may be embedded into routine practice which refers to the innovation becoming “routinely incorporated in everyday work of individuals and groups” (7). It may become routinized which refers to the innovation becoming an “ongoing element in the organisations activities and [the point at which the innovation] loses its distinct identity” (4). Routinization is similar to the innovation becoming normalized which refers to the point at which the innovation “becomes so embedded into routine practice that it ‘disappears’ from view” (8). Innovations, once adopted, may also become rejected, denormalized or discontinued if they fail to bring about desired change or if they are replaced by newer, more advantageous innovations.

1.3 Diabetes

The focus of this thesis is on the implementation of a self-management intervention for people with type 2 diabetes within the NHS. Diabetes mellitus (diabetes) is one of the most prevalent long term conditions globally, with current estimates suggesting that 347 million people worldwide have diabetes (9) and the WHO predict that by 2030 diabetes will be the 7th leading cause of death worldwide (10). In England, approximately 4.5% of the population are affected by diabetes (11), however, there are also an estimated 822,000 people aged 16 and over in England who have diabetes but have not yet been diagnosed which increases prevalence estimates to 7.4% of the population (12). In real terms these statistics equate to more than 400 adults in England being diagnosed with diabetes every day (11). Diabetes poses a tangible

threat to the health of the nation. In 2004, an estimated 3.4 million people globally died from consequences of high fasting blood sugar (13) and this figure is set to increase.

Diabetes is a long term disorder of metabolism, resulting from a diminished ability to use insulin and / or defective insulin secretion (14). According to the International Classification of Diseases there are several different forms of diabetes (15). Diabetes is not a single condition; rather there are different types with differences in pathophysiology, presentations and treatments (16). All however, are characterised by a raised blood glucose level (17). The most predominant types of diabetes are type 1 diabetes mellitus and type 2 diabetes mellitus (16). Type 2 diabetes is the most common type of diabetes globally, representing 85-90% of all diabetes cases in the UK and its prevalence is increasing across all groups, including children and young people, and particularly among black and minority ethnic groups (17). It is characterized by disorders of insulin action and insulin secretion, either of which may be the predominant feature. The exact cause is not fully understood although it is believed there are probably several different mechanisms which result in this form of diabetes (14).

Significant inequalities exist in the risk of developing type 2 diabetes. Its frequency varies in different racial and ethnic subgroups. In the UK it is up to six times more common in people of South Asian descent and three times more common in those of African and African Caribbean descent compared with the white population. It is also more common in people of Chinese descent and other non-white groups (17). It is often associated with strong familial, likely genetic predisposition, however, the genetics of this form of diabetes are complex and not clearly defined (14). There are also links between type 2 diabetes and socio-economic status with diabetes more prevalent among less affluent populations in the UK. Those in the most deprived fifth of the population are one-and-a-half times more likely than average to have diabetes at any given age (17). The majority of patients with type 2 diabetes are obese; those who are not obese by traditional weight criteria may have an increased percentage of body fat distributed predominantly in the abdominal region (14). The risk increases with age; type 2 diabetes is most commonly diagnosed in adults over the age of 40, although increasingly it is appearing in young people and young adults (17).

The long-term effects of diabetes mellitus are generally categorised as microvascular and macrovascular, referring to the damage it can cause to small and large blood vessels respectively. Microvascular complications include; retinopathy (disease of the retina of the eye) with potential blindness; nephropathy (kidney damage or disease) that may lead to renal (kidney) failure; neuropathy (nerve damage); neuropathic arthropathy (bone and joint changes); and, sexual dysfunction. Macrovascular complications include; cardiovascular, peripheral vascular and cerebrovascular disease (14) which can lead to heart attacks, stroke and circulation problems. People with diabetes are also at risk of mental health problems, including depression and eating disorders (17).

In addition to the potential impact on physical and mental health, diabetes can also result in significant financial burden. It is estimated that people with diabetes in the UK are spending around £500m per year on coping with their condition due to missing work, the cost of travel for medical treatment, and, loss of employment or early retirement because of ill health (18). The presence of diabetes related complications increases personal expenditure three-fold, and doubles the chance of needing a carer. As well as personal cost, the financial burden of diabetes to health services is great. As diabetes increases globally so does the need to provide health services to meet the needs of people with the condition. As such, associated costs have risen, particularly those related to the treatment of complications (19). The Department of Health (20) report that diabetes related spending accounts for between 5% and 10% of the total health budget in England, with the total direct cost of diabetes in the UK estimated at £13.8 billion annually with a spend of £3,717 per person with type 2 diabetes (19).

As discussed, type 2 diabetes can have a major impact on the physical, psychological and material well-being of individuals as well as being a serious financial burden to health services. Management of type 2 diabetes is complex; it requires lifelong attention to lifestyle routines, particularly adjustments to diet and physical activity patterns, self-monitoring of blood glucose, medication management, and attendance at numerous screening tests and appointments to monitor for complications associated with having diabetes. However, evidence shows that with successful management life expectancy can increase and the risk of complications can decrease (17). Meeting the demands of successful management requires support from a team of healthcare professionals, although as most management tasks occur on a daily basis and health services often struggle to give the recommended level of diabetes care within the constraints of time limited appointments (21), responsibility for management lies primarily with the individual with diabetes.

1.4 Self-management

Traditionally, healthcare systems dealt predominantly with acute illness and the role of the healthcare professional was to diagnose and treat. This traditional model of care is not well suited to long term conditions as the emphasis shifts from treatment to management. An ageing population, increased sedentary lifestyles and the successful treatment of many acute conditions have made long term illness the main challenge to Western 21st Century healthcare systems (22). In managing a long term illness, the role of the healthcare provider becomes that of teacher and partner (23) and the responsibility is placed on the patient to care for themselves on a daily basis. The Chronic Care Model developed in the 1990's and based on literature of strategies to manage chronic conditions (24), emphasised the role of the patient in the care of long term illnesses, with self-management the cornerstone of this.

Self-management has been defined by Barlow and colleagues as *“the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition”*. Barlow further states that self-management also incorporates the psychological and social management of living with a chronic condition

and encompasses the *“ability to monitor one’s condition and to effect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life”* (25).

Self-management in long term illness has been conceptualised by Corbin and Strauss as the “work” involved in living with a long term condition (26). From qualitative work with patients with long term conditions they identified three major tasks that people living with a long term condition must undertake: medical and behavioural management; role management; and, emotional management. For people living with diabetes, medical management may relate to tasks such as; taking medications; attending appointments; and modifying behaviours around eating and physical activity. Role management may involve learning to adjust to the ‘patient’ role, managing the impact of diabetes on relationships with others, and adjusting to the disruption of one’s biographical narrative. Emotional management involves learning to manage the emotions associated with having a long term condition such as anger, fear, frustration, and depression.

In order to achieve the tasks required for successful self-management of a long term condition, patients need to acquire the necessary skills. A common classification in the literature of the core self-management skills needed to achieve successful self-management comes from Lorig and Holman (23) who describe the five core self-management skills as: problem solving, decision making, resource utilization, forming of a patient/healthcare provider partnership, and taking action. These skills describe the medical, behavioural and role management aspect of self-management but skills to deal with the emotional burden of a long term illness are also needed. In the UK, current policy states that people with diabetes should be offered access to educational programmes which teach the skills necessary for self-management. Diabetes self-management education (DSME) in which the knowledge and skills necessary for self-management are taught, has been found to have beneficial effects on health and psychosocial outcomes (27, 28), including reducing the risk of diabetes related complications developing (29) and improving patient glycaemic control in the short term (30). DSME programmes are thought to work by changing patients’ knowledge and attitudes, and the role of self-efficacy in achieving desired self-care behaviours is becoming increasingly recognised (31).

DSME programmes are widely used in the UK. The National Institute for Health and Care Excellence (NICE) recommend structured education at diagnosis with annual reinforcement for all people with type 2 diabetes. Current diabetes education programmes offered through the NHS include; the diabetes education and self-management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes (32); the 'Diabetes X-PERT Programme' (33) for people with type 2 diabetes; and the dose adjustment for normal eating (DAFNE) for people with type 1 diabetes (34). Despite being recommended by NICE and free for patients to attend in the UK, uptake of such educational programmes is low. Only 5.3% of those newly diagnosed with type 2 diabetes in England were recorded as having attended structured education in the National Diabetes Audit published in 2016 (35).

Non-uptake of DSME by patients is associated with poorer health outcomes (36) and as these programmes are of considerable cost to the NHS (37), non-uptake by patients reduces the cost-effectiveness for health services. The reasons for DSME non-attendance among patients with type 2 diabetes are not well understood and this represents an understudied research area (37). Depression, self-efficacy and readiness to change may influence self-management in general (38), however, little research has been conducted into the reasons for non-attendance at DSME when it is made available as part of routine diabetes care. The predominant mode of delivery of DSME in the UK is through group based sessions and several qualitative studies with non-attenders at group based DSME report that barriers include: healthcare professional factors (a lack of information about DSME from healthcare professionals, lack of healthcare professional support for attendance, satisfaction with current care); cognitive factors (patients not perceiving the benefit of attendance, the timing of the referral with patients not feeling ready to attend, satisfaction with current knowledge and current diabetes management activities); emotional factors (shame and stigma of diabetes); health factors (absence of diabetes complications and comorbidity impeding attendance, feeling well or not feeling sick enough, low perceived concern for the disease); accessibility factors (being unable to take time off work or unable to afford time off work, being unable to attend because of caring responsibilities, transportation or distance difficulties); mode of delivery factors (a dislike of groups, a preference for alternative sources of help, particularly the internet) (36, 37, 39-41). Associations between female gender, non-smoking status and better glycaemic control and attendance at structured education have been reported, as have associations between performance of general practices on diabetes clinical outcomes and attendance at education (42). Several studies of patient reported barriers to attendance at diabetes education also suggest that healthcare professionals may play an important role in patient attendance (37, 40-42).

With NHS resources unlikely to increase for such education and the poor referral and uptake of existing programmes there is an urgent need for new cost effective ways of delivering self-management education which are acceptable to patients and healthcare professionals.

1.5 e-health

e-health, defined as *'the use of emerging information and communications technology, especially the Internet, to improve or enable health and healthcare'* (43), is providing new, promising and potentially cost effective ways for delivering healthcare to patients.

This broad definition of e-health encompasses other terms often used to describe the application of information, computer, or communication technology to some aspect of health or healthcare. These other terms include; medical informatics, consumer health informatics, public health informatics, telemedicine, telehealth, and interactive health communication. Specific examples of e-health technologies becoming widely used include; management systems, such as the electronic health records (EHR) that allow the acquisition, transmission and storage of patient data; computerised decision support systems including diagnostic support, alerts and

reminder systems; communication systems such as telecommunication that act as an intermediary between users; and information resources such as the internet.

In industrialised countries the use of the internet is rapidly growing. One of the most common reasons that people use the internet is to access information about health (44). In the first quarter of 2015, 86% of adults (44.7 million) in the UK had used the internet in the last three months and 49% reported using the internet to look for health related information, up from 18% in 2007 (45). An abundance of health related websites exist and entering the search terms 'health information' into Google returns approximately 344,000,000 results (as of 05.05.2016). As spending on health continues to rise, many governments and medical health agencies, such as the NHS, are also using the internet as a cost effective way to distribute health information (46). The interactive nature of the internet, combined with the potential to store large volumes of information, provides a unique opportunity to offer high-quality interactive evidence-based information to consumers (47) .

Health consumers are accessing internet based health information for a number of reasons including to: educate themselves; gather information before visiting a doctor; gain a second opinion; become more actively involved in decisions relating to their health; inform lifestyle choices and to participate in virtual healthcare activities (48). Consumers access health information in a number of ways including searching directly, by participating in online support groups and by consulting with healthcare professionals online (49). The Pew Social Life survey (44) reported that 27% of internet users have tracked their weight, diet, exercise routine or some other health indicators or symptoms online; 6% have posted comments, questions or information about health or medical issues online; 4% have posted a review of a doctor and 3% have posted a review of a hospital.

From the inception of the internet healthcare has thought to be a 'major potential beneficiary' (50). Benefits of the internet in the healthcare setting may include: enabling more informed decision making; remote consultations; and more accessible, convenient and efficient service delivery. Studies have shown that accessing online health information can have significant effects on consumer health behaviours and interactions between patients and healthcare providers with internet users more likely to ask more detailed questions, make self-diagnoses, or ask for specific treatments (47, 51, 52). The internet has the potential to be empowering for health consumers and may be particularly beneficial for those with long term conditions as interactive components, such as self-assessment tools, permit the provision of personalized tailored information to users and provide decision support, peer support, and behaviour change support (47). One in four internet users living with high blood pressure, diabetes, heart conditions, lung conditions, cancer, or some other long term ailment say they have used the internet as a form of peer support by finding others with similar health concerns (53).

The use of new information and communication technologies to improve health and healthcare is now a central part of NHS policy (54) and NHS Choices is already delivering a number of

websites to patients, although many of these have yet to be evaluated. The internet offers huge potential for delivering public health interventions (55) offering convenience, accessibility, and anonymity as well as potential cost effectiveness in delivering education to large numbers of people.

Although the current evidence on the use of new technology in diabetes care is still evolving, positive effects of such interventions have been demonstrated in several studies. A Cochrane systematic review of interactive healthcare applications looked at 24 randomised controlled trials in a range of long term diseases including diabetes. It found mostly positive effects, with users tending to become more knowledgeable, feel better supported, with possible improved behavioural and clinical outcomes compared with non-users (56). Another systematic review produced a narrative report of interactive computer-assisted technology in diabetes care (57). It identified 14 studies that looked at HbA1c levels (a measure of glucose metabolism which reflects average blood glucose levels over six to eight weeks) and found that 6 of the 14 studies demonstrated significant improvements in HbA1c. Evidence from a systematic review of 16 randomised control trials suggests internet-based self-management programmes for people with type 2 diabetes can improve HbA1c (58), but that this positive effect may decrease over time. This is similar to the effect of more traditional group-based self-management education which also shows a similar decline in improved HbA1c over time (28, 59, 60). The American Diabetes Association's standards for self-management education recognise the need for both initial training and subsequent on-going support to try and maintain the benefits of educational interventions (61), something the internet is suited to do.

As well as improving HbA1c, internet based interventions for type 2 diabetes have been shown to have the potential to improve, behavioural, psychological, emotional, and psychosocial outcomes. Systematic reviews have reported improvements in, healthcare utilisation, physical activity, dietary changes, medication use, smoking, knowledge, self-efficacy, stress, diabetes distress, psychological well-being and communication (57, 62-65). Internet-based interventions are ideally suited to providing ongoing self-management support that could promote sustained improvements and long term improvements in outcomes.

Despite the potential of the internet to deliver accessible, convenient and anonymous DSME to patients, and to address some of the identified barriers to group based education (38, 39), an area of concern for delivering DSME through the internet is the issue of the digital divide. The digital divide refers to the gap between those who have access to information technologies such as the internet and those who do not (66). For people with diabetes, it is often those who experience the burden of diabetes the most who are also most likely to lack access to the internet, as older age, lower educational status and income are negative predictors of diabetes outcomes and internet use (62). However, a study to explore engagement with an internet DSME intervention indicated that patients with a variety of education, age, income levels, ethnic backgrounds, socio-demographic, psychosocial, and clinical characteristics were able to use the intervention. Moreover, older, ethnic minority patients as well as those with a higher risk of

diabetes complications, lower health literacy, and little experience of computers were equally as engaged with the intervention (38).

Although research has been conducted to establish that internet DSME interventions can be beneficial for people with type 2 diabetes; less is known about how they are perceived and used by patients. Internet interventions show promise in meeting many of the barriers that have been identified to patient attendance at group based DSME, and evidence demonstrates that they can impact positively on patient outcomes. However, the majority of research into internet interventions for self-management has been undertaken in controlled research with a focus on the efficacy outcomes of the intervention. What is lacking from the literature is an insight into patients' experiences of using internet interventions that gauges whether these interventions meet user needs of people with type 2 diabetes. If internet interventions are to become part of routine care for people with type 2 diabetes, as an alternative or adjunct to group based DSME, it is particularly important to understand how these interventions are perceived and used by patients as patient uptake, use, and attrition become of central importance in order for the potential benefits to be realised. Low levels of engagement with and attrition (discontinued usage) from internet interventions in general is common (38), suggesting that users may not use them as intended (55, 67). This may be particularly true when interventions are implemented into 'real life' settings where there are complex, unmotivated patients; practitioners who have many competing demands; and systems which have few resources (68).

1.6 Patient engagement with e-health

In order to actualise the potential of e-health interventions, intended users must engage with them. Studies of e-health interventions often report that the frequency and intensity of intervention use is important in achieving desired outcomes (68, 69). Understanding factors that influence user engagement with e-health interventions is therefore an important consideration for those developing and implementing e-health. A systematic literature review of factors that influence public engagement with e-health, (including health information on the internet; custom made online information such as kiosks and CDs; online support and telehealth) (70) suggests that socio-demographic characteristics (including; age, ethnicity economic status, educational attainment and literacy levels); interest in one's health; openness to experience and; belief in the efficacy and trustworthiness of information, are important factors in e-health use.

Technological issues such as: access to computers, internet connection, support in using the technologies, accuracy of information, and security and privacy concerns, also proved important. Characteristics of the e-health services including: the content of the information, the way the information is delivered, anonymity and trustworthiness, influenced use as did the ease of use of a system, usability, and fit with everyday life (cost and time). Social aspects of e-health proved important for users including the ability to connect with others (peers and professionals) and share experiences. However, one study reported in the review found that online support was not always received favourably, with the sharing of experiences and receiving alternative points of view a barrier to on-going participation in a support group.

The above factors have been found to influence whether users will engage with e-health. Another important issue, particularly for internet interventions, concerns factors that keep users coming back. Many research studies of e-health interventions have reported that participants' use of the interventions decrease over time (68, 71, 72). Eysenbach (67) labels this phenomena as the 'law of attrition', and states that the law of attrition is one of the "fundamental characteristics" of e-health applications. He describes the usage patterns of e-health in research studies as a curve; at the beginning participants have agreed to adopt the intervention as part of the study and therefore usage is high, but over time participants discontinue their use or drop out of the research study all together. He cites losing interest as the underlying variable to explain this curve. Several strategies have been proposed to protect against attrition including the use of push reminders; incentive programmes; self-monitoring systems; tailored messaging; and social networking (55). A systematic review of factors that promote engagement with interactive internet-based interventions for long term illness self-management (73) found that interventions with the lowest attrition rates (ranging from between 0% to 8%) included features such as tailored information, professional feedback, social networking, dynamic content (new content added weekly), rewards for logging in, the function to add self-monitoring data and the ability to make contact with a healthcare professional.

Much has been written of the potential of e-health to improve medical practices. E-health may improve healthcare through assisting decision-making processes by facilitating access to guidelines; simplifying the prescription of diagnostic procedures; producing alerts and reminders; producing lower rates of medication errors and preventing adverse drug events; increasing productivity among professionals; and, lowering costs (74-81). In order to actualise this potential within healthcare systems, the adoption and use of e-health by healthcare professionals is pivotal. In particular, General Practitioners (hereafter GPs), because of their links to all tiers of the healthcare system, and between healthcare and social care have been described as being potential catalysts or bottlenecks for e-health innovation (82).

A survey of over 9000 GPs was conducted in 31 countries (including 27 EU countries) to measure e-health availability and adoption (82). The findings suggest that the use of basic e-health by GPs is now universal, however, there is still much more progress needed in providing access to, and promoting use of, more complex e-health systems. For example, internet use by GPs is now widespread, with 97% of all GPs surveyed reporting having access to and using the internet in consultations. However, figures for GPs access to advanced internet based technologies such as mobile devices (including smartphones, laptops and tablets), broadband, and high-speed internet are not as impressive: 13%, 65% and 9% respectively. This study suggested that in the UK there are variable rates of adoption and use of e-health by GPs. Whilst 99% (n=482) of GPs from the UK (surveyed between November 2012 and March 2013) stated that they used aspects of the electronic health record (EHR), availability (43%) and use (21%) of telemedicine and health information exchange (HIE) technologies were much lower. In the qualitative data from this report, GPs highlighted the main barriers to adoption as financial, concerns about security, lack of regulatory frameworks and strains on the doctor-patient

relationship. The most important impact of e-health adoption that GPs hoped for was the possibility to access structured and up to date clinical data. They were more sceptical about the possibility of e-health increasing efficiency or enhancing doctor-patient relationships. Issues of barriers and facilitators to the adoption and use of e-health by health services and healthcare professionals are explored in depth in Chapter 3.

1.7 Evaluating and implementing e-health

Many e-health interventions have been studied in the context of randomized controlled trials (RCTs), which are designed as experiments with high internal validity - the ability to determine cause-effect relationships. The same characteristics that contribute to the high internal validity of a trial (well-defined inclusion and exclusion criteria, blinding, controlled environment) can potentially hamper its external validity, the ability to generalize the results in an extended population and clinical setting (83). As such the need for high-quality, widely applicable evidence is gaining momentum, especially amidst health care policy makers (84-86). The increased costs of interventions and health care in a resource-limited environment have fuelled the demand for clinically effective and applicable evidence and over the last several years, there has been a substantial movement toward practical, pragmatic implementation research that will translate into usable health-related policies, programs and practices (87).

Implementation science is a relatively new field which is concerned with "*the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice*" (88). It seeks to understand the behaviour of healthcare professionals and other stakeholders as a key variable in the sustainable uptake, adoption, and implementation of evidence-based interventions. The study of implementing innovations into routine practice is a growing area of interest; the Medical Research Council framework (89) recommends that the implementation of interventions should be considered from the early stages of intervention development and researched alongside the efficacy of interventions. A continuum of implementation research in healthcare with certain research activities being *implementation-light* and others *implementation heavy* has been proposed (90).

Pragmatic trials fall in the middle of this continuum and seek to provide proof of implementation and are designed to increase the generalisability of findings from trials. In contrast to explanatory trials which seek to address the question *if and how an intervention works* (and are situated towards the implementation light end of the continuum), pragmatic trials seek to address *whether an intervention actually works in real life* (83). Explanatory trials are undertaken in an idealised setting to give the innovation under evaluation the best chance of demonstrating beneficial effect whereas pragmatic trials are undertaken in 'real world' settings where the innovation is intended to be used and aim to maximise the applicability of the intervention to usual care (91). The PRECIS-2 tool (91) highlights specific domains which are likely to vary depending on where a trial falls on the continuum between 'explanatory' or 'pragmatic' and include participant eligibility criteria, recruitment, setting, flexibility in delivery

and adherence, follow up and outcomes, with pragmatic trials reflecting a closer match between trial and usual care than explanatory trials.

Problems with implementing evidence based interventions, even ones that have been positively evaluated in pragmatic trials, are reported widely in the literature (92). Many promising health interventions, when implemented, fail to achieve their maximum potential and/or reach those most in need (92). Even in the most pragmatic trials the constraints required to achieve internal validity may affect external validity (93). For example, often pragmatic trials rely on controlling/ensuring the delivery of the clinical intervention, albeit in a less restrictive setting (94) and targets for recruitment must still be met in order to produce robust statistical outcomes. As such, other types of implementation studies at the implementation-heavy end of the implementation research continuum may be particularly useful to better understand implementation successes and failures, informing scale-up of interventions, informing how to integrate interventions into health systems and to make interventions sustainable (90). Study designs at this end of the continuum include mixed methods and quasi-experimental studies to determine the changes in delivery or acceptability of an intervention, cluster RCTs to evaluate the effects of implementation strategies and observational studies on adaptation, learning, and scaling-up of interventions. Studies of this type are used to explore implementation related barriers and facilitators to routine use and sustainability of “effective” practices, test implementation strategies to support uptake of interventions in routine practice and focuses on the adoption or uptake of clinical interventions by providers and/or systems of care (2, 95, 96).

These studies are likely to add valuable data to that provided by pragmatic trials which will be necessary for commissioners of care. By identifying the barriers and facilitators and trying to address them in the design of strategies, implementation research of this type increases the chances of producing positive outcomes and can help to; map the political and institutional context in which policies will be implemented, identify barriers to implementation and the determinants which prevent effective access to interventions, develop practical solutions and monitor and evaluate new implementation strategies, introduce evidence-informed implementation strategies in health systems and facilitate full scale implementation (92).

1.8 Summary

Diabetes is a long term condition which, if poorly managed, can lead to a range of health complications which in turn may have a significant impact on quality and longevity of life. Self-management is the current dominant paradigm for managing type 2 diabetes in many countries and internet interventions have great potential to support patients in this. The research in this thesis will use a case study design to explore the implementation of HeLP-Diabetes, an online self-management programme for people with type 2 diabetes within routine NHS care. The focus is on evaluating the implementation, including the uptake and use by services and patients and will provide an assessment of barriers and facilitators to use. Research of this kind has the potential to characterise population based reach and adoption of internet based

interventions designed to be delivered through health services. The next chapter presents the HeLP-Diabetes intervention.

2 CHAPTER 2: THE HELP-DIABETES INTERVENTION

2.1 Chapter summary

Although the development of the HeLP-Diabetes intervention is not the focus of this thesis, this chapter briefly describes the theoretical underpinning and the development process as well as giving an overview of the content of the intervention in order to provide context to the thesis.

2.2 Grant and team

As part of a National Institute for Health Research (NIHR) grant (Grant Reference Number RP-PG-0609-10135), I was part of a team of researchers and general practitioners (GPs), with support and input from; psychologists, dieticians, consultants, nurses and patients with type 2 diabetes who developed an internet based self-management programme for people with type 2 diabetes; HeLP- Diabetes (which stands for: Healthy Living for People with Diabetes). My role in developing HeLP-Diabetes included writing content, creating video content, assisting with the design, managing the Web Designer and facilitating the collaborative design with patients with type 2 diabetes.

2.3 Theoretical underpinnings

The Medical Research Council, in their guidance on developing complex interventions (89), recommends that development, evaluation and implementation of healthcare interventions requires a strong theoretical foundation. The HeLP-Diabetes intervention was informed by several theories described briefly below.

Corbin and Strauss' theory of the work involved in living with a chronic condition (26), provided a guide to the nature of the content of HeLP-Diabetes. As described in Chapter 1, this model states that patients living with long term conditions face three tasks: medical management; emotional management; and role management. The three tasks outlined by this theory guided the content of HeLP-Diabetes.

Individual theories of behaviour change underpinned the behaviour change tools in HeLP-Diabetes; and Normalisation Process Theory (NPT) (7, 97), which offers an explanatory framework of why interventions work in practice (or fail to) was also drawn upon. Qualitative development work including focus groups and interviews with staff and patients was guided by NPT in order to determine the needs and preferences of these key stakeholders with regard to an internet-based self-management programme for type two 2 diabetes, as well as to understand factors that might promote or inhibit implementation and use.

2.4 Description of HeLP-Diabetes

HeLP-Diabetes takes a holistic view of self-management and addresses a wide range of patient needs including; education, lifestyle changes, medicine management, emotional management, social and peer support and also addresses how patients interact and work with healthcare

professionals. A facility to interface with patients' electronic medical records had been designed to provide patients access to self-management metrics recorded by GP surgeries. The information provided on HeLP-Diabetes is evidenced based and compliant with National Institute for Health and Care Excellence (NICE) guidelines.

Guided by the Corbin and Strauss model, HeLP-Diabetes content was divided into eight sections, available from the homepage (see Figure 2-1).

- Understanding diabetes (explaining what type 2 diabetes is and how it can affect patients)
- Staying healthy (focusing on what patients can do to help themselves)
- Treating diabetes (about treatments for diabetes)
- Living and working with diabetes (food, socialising, shift work, travel, impact on relationships, driving, financial issues)
- Managing my feelings (managing emotions experienced by people with diabetes)
- My health record (personal information about medications, care plan, results of self-monitoring and tests)
- News and research (new research, stories behind the headlines, information for healthcare professionals)
- Getting help (useful resources, online forum, ask the expert function, personal stories).

Medical management tools include information, behaviour change tools, self-monitoring tools and care planning. Emotional management tools include information, computerised cognitive behavioural therapy (CBT), mindfulness, journaling, a forum, and personal stories. Role management tools included information, Cognitive Behavioural Theory (CBT), personal stories and the forum.

A range of resources are available on HeLP-Diabetes including behaviour change tools, such as decision support to help users determine what they most want to do, goal setting, action planning, self-monitoring, feedback and email and text message reminders. There are also a large number of videos and animations on HeLP-Diabetes, presenting the core information in an accessible format.

Behaviour change modules for individual behaviours were both developed by the HeLP-Diabetes team and licensed from collaborators. Down Your Drink (University College London) (98) addresses drinking alcohol in moderation, POWeR (University of Southampton) (99) targets weight loss, Stop Advisor (University College London) (100) tackles smoking cessation, Living Life to the Full is an online CBT course (University of Glasgow) (101) that was adapted specifically for people with type 2 diabetes and Health Talk Online (previously DIPEX) (University of Oxford) (102) is a repository of personal stories of which all those related to type 2 diabetes were imported into HeLP-Diabetes.

Figure 2-1 The HeLP-Diabetes homepage



2.5 Promoting engagement with HeLP-Diabetes

HeLP-Diabetes employed a number of strategies to promote patient use. The use of technology-based reminders or prompts has been found to promote engagement with digital interventions (69). As such patients who were registered to use HeLP-Diabetes were sent regular emails and newsletters from November 2013 and text message prompts were introduced in October 2014. The prompts were sent at a frequency of three a month and contained topical and seasonal information as well as links to HeLP-Diabetes content. The prompts were developed by a PhD student (Ghadah Alkhalidi) and were then sent to members of our Patient and Public Involvement in research (PPI) group for comments and feedback. Following this the prompts were sent to members of the research team for further comments

and proof reading. The effects of the prompts on patient engagement with HeLP-Diabetes are being evaluated as part of Ghadah Alkhaldi's PhD.

2.6 Access to HeLP-Diabetes

HeLP-Diabetes was designed to be an online diabetes education service that could be offered by healthcare professionals to patients alongside existing group based structured education programmes. HeLP-Diabetes was not meant to replace group based education but rather become one of a menu of options that healthcare professionals can offer to their patients.

As described in Chapter 1, healthcare professionals' engagement with and promotion of with diabetes self-management education may be important in patient uptake of the education (37, 40, 41) and the ability to make contact with a healthcare professionals may be important to reduce attrition to e-health interventions (73). As such, HeLP-Diabetes was designed to be delivered to patients through the NHS.

For the duration of this implementation study (July 2013-August 2015), access to HeLP-Diabetes was restricted to those who had access to the URL, and it was not searchable on any internet search engines. This was in order to protect HeLP-Diabetes access as it was also being evaluated in a randomised control trial. Further, in order to access the content of HeLP-Diabetes, patients had to register to use it by completing an online registration form (described in Chapter 6) and creating a username and password which had to be entered on each visit to the site. As discussed in Chapter 5, it was planned that staff would assist patients in completing the online registration form.

2.7 The HeLP-Diabetes Randomised Control Trial

In parallel to the implementation study reported in this thesis, as part of the wider NIHR funded program grant, the HeLP-Diabetes intervention was evaluated in a randomised control trial (RCT). The RCT is described here in order to provide additional context to this study in relation to the overall programme grant and to highlight the additional contribution to understanding that undertaking an implementation study in routine practice adds to the data provided by the RCT.

2.7.1 Aim

This RCT aimed to determine:

1. The effect of HeLP-Diabetes on clinical outcomes and health related quality of life in people with T2DM;
2. The incremental cost-effectiveness of the intervention compared to usual care from the perspectives of health and personal social services and wider public sector resources.

2.7.2 Design

This was a multi-centre, two-arm individually randomised controlled trial in primary care.

2.7.3 Participants

Participants were adults, aged 18 or over, with type 2 diabetes, registered with participating general practices. In order to maximise the generalisability of this pragmatic trial, exclusion criteria were kept to a minimum. People were excluded who were: unable to provide informed consent, e.g. due to psychosis, dementia or severe learning difficulties; terminally ill with less than 12 months life expectancy; unable to use a computer due to severe mental or physical impairment; unable to use the intervention due to insufficient mastery of spoken or written English; and those who were currently participating in a trial of an alternative self-management programme. Participants did not have to have home internet access or prior experience of using the internet to participate. Participants with previous or current experience of self-management education were eligible to participate.

2.7.4 Setting

The RCT was undertaken in General Practices in the UK. Practices were recruited with assistance from the Primary Care Research Network (PCRN). In order to maintain staff blinding to the intervention that each patient received, participating practices were required to have two nurses to participate in the RCT, one nurse to act as a practice nurse (training participants in use of the intervention, providing routine clinical care) and one to act as a research nurse (blind to allocated intervention, collecting follow-up data). In some areas the PCRN had employed and trained research nurses.

Service support costs were provided to all practices for their participation in the RCT to reimburse staff time.

2.7.5 Procedure

Recruitment

Recruitment took place in two stages: first practices were recruited through the research networks including the Primary Care Research Network (PCRN) and the North Central London Research Consortium (NoCLOR). Once a practice had agreed to participate, and completed set up procedures, patient recruitment started.

Patient recruitment followed standard opt-in procedures. Each practice had a register of patients with type 2 diabetes as they needed it for the Quality and Outcomes Framework. A nurse or other qualified health professional reviewed the electronic medical record of each of the patients on this register with a view to screening out ineligible patients. All remaining, potentially eligible patients were sent a letter from their GP inviting them to participate in the study. A participant information sheet, consent form, expression of interest and stamped addressed envelope was included. Patients who were interested in participating were asked to return the expression of interest form to the trial manager.

On receipt of the expression of interest form, the trial manager contacted the practice research nurse who offered the patient an appointment at the practice. This appointment provided patients with an opportunity to discuss the pros and cons of participation, and if they wished to proceed, sign the consent form.

Baseline clinical data were obtained either at this appointment or a subsequent one. After signing the consent form, patients were asked to complete the self-report baseline data, and only once all baseline data were complete were patients randomised. Randomisation marked the point of study entry.

Randomisation

Randomisation was performed centrally using a web-based randomisation system provided by Sealed Envelope. Randomisation was at the level of the individual participant, and conducted using random permuted blocks of sizes 2, 4 and 6, stratified by recruitment centre. The practice nurse was informed which arm the participant had been randomised to, so that those in the intervention arm could be offered the training appointment.

Intervention

The intervention consisted of facilitated and supported access to HeLP-Diabetes. There were three components to the supported access: first an introductory training session, secondly supportive follow-up phone calls, and thirdly, on-going discussion of patient's self-management goals in routine appointments for diabetes-related matters.

In the training session, practice nurses gave the patient a booklet containing the url for the programme, the participant's log in details, and information about the content of the website and how best to use it. Nurses showed the patient how to access the website, and introduced them to the main content areas. The nurse was asked to discuss with the patient what the patient's most pressing needs are and use this to guide the patient toward certain sections (for example, improving diet, being more physically active, or managing emotions).

Follow-up phone calls were offered to support the patient in use of the programme. Nurses and doctors in participating practices were asked to refer to the programme in consultations with participating patients and to integrate information from the programme into management plans.

Comparator

From an NHS perspective, the important research question was whether HeLP-Diabetes could improve health outcomes when compared to current practice. However, to improve acceptability to participants and help maintain blinding, all participants had access to a website. Participants in the control arm were given access to a simple information website, based on the information available on the Diabetes UK and NHS choices websites. These participants were

also given a booklet with the URL and user log in details, but did not have the introductory session with the nurses.

2.7.6 Outcomes

Primary outcomes.

The outcomes reflected the aims of improving clinical outcomes and health related quality of life. Two joint primary outcomes were selected: glycated haemoglobin (HbA1c) and health related quality of life, measured by the Problem Areas in Diabetes (PAID) scale (103, 104). PAID has 20 items focusing on areas that cause difficulty for people living with diabetes, including social situations, food, friends and family, diabetes treatment, relationships with health care professionals and social support.

Secondary outcomes

Secondary outcomes were selected to reflect the proposed pathway of action of HeLP-Diabetes and allow health economic analysis and can be categorised as clinical, patient-reported, or economic.

Clinical outcomes include:

- Systolic and diastolic blood pressure;
- Body mass index;
- Total cholesterol and HDL (not fasting);
- Completion of “9 essential processes” (= weight, BP, smoking status, measurement of serum creatinine, cholesterol and HbA1c, urinary albumen and assessment of eyes and feet). Data were obtained from notes for the 12 months prior to randomisation and the 12 months after randomisation at the 12 month follow-up point.

Patient-reported outcomes:

- Depression and anxiety, measured using the Hospital Anxiety and Depression Scale (HADS) (13);
- Diabetes-related self-efficacy measured using the Diabetes Management Self-Efficacy Scale (DMSES) (105);
- Satisfaction with treatment, measures using the Diabetes Satisfaction with Treatment Questionnaire status and change version (DTSQs & DTSQc) (15).

Economic outcomes:

- Cost of developing the intervention;
- Cost of supported access;
- Costs of training NHS staff both in using the intervention and training patients to use the intervention;
- Costs of maintaining and updating the intervention;
- Health service utilisation during the study period;

- EQ-5D to calculate QALYs (106);
- Clinical parameters required for modelling long term cost-effectiveness of the intervention (detailed below).

In addition automated software was used to automatically record each participant's use of the intervention (date and time of log-ins, pages visited).

2.7.7 Data collection

Each practice provided information on the number of invitation letters sent out, and the age and gender of the patients invited.

Data to describe participants were collected at baseline and included demographic and clinical data. Demographic data collected consisted of: age, gender, highest educational attainment, ethnicity, current employment status, presence or absence of home internet access, level of expertise in computer use, current or previous participation in diabetes self-management education.

Baseline clinical data obtained from the medical record included:

- date of diagnosis of diabetes;
- HbA1c, blood pressure, total cholesterol, HDL cholesterol and smoking status at time of diagnosis;
- presence or absence and date of diagnosis of complications of diabetes including ischaemic heart disease, myocardial infarction, congestive cardiac failure, atrial fibrillation, peripheral vascular disease, amputation, cerebro-vascular disease, retinopathy, renal failure and neuropathy;
- a list of current medications.
- Additional clinical data on height (cm), weight (kg), systolic and diastolic blood pressure, current smoking status, and current levels of HbA1c, total cholesterol and HDL cholesterol will also be obtained during the baseline visit

Baseline patient reported outcomes include:

- PAID,
- HADS,
- DTSQ,
- EQ-5D,
- DMSES

Baseline health economic data includes:

- Clinical data as above;
- Health service utilisation in 12 months prior to baseline visit.

Follow up data were collected at 3 and 12 months, with 12 months as the primary outcome point. The 'window' for 3 month data was 60 – 120 days post randomisation (90 days +/- 30 days), while that for the 12 month data was 305 – 425 days (365 days +/- 60 days).

Data on health service utilisation were collected for the past 6 months at baseline, the past 3 months at 3 month follow-up and the past 9 months at 12 month follow-up. Data on completion of the "9 essential processes" were collected from the GP record for the 12 months prior to randomisation and the 12 months after randomisation at the 12 month follow-up point to avoid triggering behaviour change amongst the study nurses.

Standard operating procedures (SOPs) covered every aspect of data collection and nurses were trained in these procedures. Adherence to SOP was monitored. Participants completed self-reported questionnaires (demographics, PAID, HADS, DMSES, DTSQ and EQ-5D) online, prior to the nurse recording clinical outcomes and taking blood for HbA1c and lipids. Clinical data were entered directly into the online database by the nurse. Health service utilisation data were extracted from the clinical record by the nurse.

2.7.8 Summary of results

Of the 374 participants randomised between September 2013 and December 2014, 185 were allocated to the intervention and 189 to the control.

Final (12 month) follow up data for HbA1c were available for 318 (85%) and for PAID 337 (90%) of participants. Of these, 291 (78%) and 321 (86%) responses were recorded within the pre-defined "window" of 10-14 months.

The mean age of participants was nearly 65 years, over two-thirds (n = 258, 69%) were male, and most were White British (n = 300, 80%). Just over half (n = 210, 56%) rated themselves as experienced computer users. Around one-third (n = 134; 36%) had been diagnosed for less than 5 years, with a further third (n = 115, 31%) having been diagnosed between 5 and 9 years ago. Overall, this was a population with well-controlled diabetes at baseline: mean HbA1c was 7.3% (56 mmol / mol), mean systolic (SBP) and diastolic (DBP) blood pressures were 135 and 78 mm Hg respectively. Self-reported levels of distress were low, with mean PAID score of 19

Participants in the intervention group had lower HbA1c than those in the control (mean difference -0.24%; 95% Confidence Interval -0.44 to -0.049; p=0.014). There was no significant overall difference between groups in the mean PAID score (p=0.21), but pre-specified subgroup analysis of participants who had had diabetes for less than 7 years showed that a beneficial impact of the intervention in this group (p = 0.004). There were no reported harms.

Economic data were still being analyzed at the time that this thesis was submitted for examination.

2.8 Rationale for an implementation study

The decision to undertake an RCT and an implementation study was made by the programme grant team as it was believed that even in the most pragmatic of trials, the constraints to achieve internal validity can affect external validity so that benefits demonstrated in trials can be hard to achieve in routine practice. Evidence of effectiveness derived from randomised controlled trials does not always transfer to “real world” use. By their nature, trials such as the HeLP-Diabetes trial described above, involve selected participants, whose characteristics may differ substantially from non-trial participants; and tightly controlled procedures. Trial methodology emphasizes the importance of fidelity of the intervention, and these types of trials of complex interventions may devote considerable resource to ensuring that the intervention is delivered as intended. However, once the intervention becomes approved for routine use, these resources are often not available, and the emphasis often changes from ensuring fidelity to the original intervention to enabling adaptations which improve local uptake and use. This combination of changes in the population using the intervention and changes to the intervention mean that the effects seen in trials may not be replicated in routine use. Implementation studies can help researchers to better understand the uptake and adherence to an intervention in more relevant populations.

Even though the HeLP-Diabetes RCT was designed as a pragmatic trial, delivered in the intended setting to patients who are likely to use HeLP-Diabetes in the real world, constraints of the research design limited how pragmatic the trial could actually be.

Table 2.1 presents a summary, using the PRECIS-2 framework (91) of study designs of the RCT and the implementation study to highlight the differences between them with specific attention given to the pragmatic and explanatory nature of both (please see Chapter 6 for full details of the implementation study design). Each PRECIS-2 domain can be attributed a score from 1 to 5 according to how pragmatic or explanatory it is for a given trial (1=Very explanatory, 2=Rather explanatory, 3=Equally pragmatic and explanatory, 4=Rather pragmatic, 5=Very pragmatic). These scores can be plotted onto a wheel to visualise how pragmatic or explanatory a given study is. Scores have been attributed to the PRECIS-2 domains for both the HeLP-Diabetes RCT and implementation study and Figure 2-2 and Figure 2-3 present wheels for both studies to highlight the differences in the pragmatic/explanatory nature of them (it must be noted that the applicability of the PRECIS-2 is usually to RCTs only and thus may not transfer to the consideration of an implementation study as readily).

Table 2-1 Summary of the HeLP-Diabetes RCT and implementation according to domains of the PRECIS-2 framework

PRECIS-2 Domain	Definition	HeLP-Diabetes RCT	HeLP-Diabetes implementation study
Eligibility	<p>The extent that the participants in the trial/study are similar to those who would receive the intervention if it was part of usual care.</p>	<p>Eligibility criteria for patients were kept to a minimum in order to maximise generalisability. Participants were adults, aged 18 or over, with type 2 diabetes, registered with participating general practices. People were excluded who were: unable to provide informed consent, e.g. due to psychosis, dementia or severe learning difficulties; terminally ill with less than 12 months life expectancy; unable to use a computer due to severe mental or physical impairment; unable to use the intervention due to insufficient mastery of spoken or written English; and those who were currently participating in a trial of an alternative self-management programme. Participants did not have to have home internet access or prior experience of using the internet to participate. Participants with previous or current experience of self-management education were eligible to participate.</p> <p>Eligibility criteria for general practices included the practices having two nurses, the practice being interested in research, and committed to complex recruitment, data collection, and intervention delivery procedures.</p>	<p>All patients over 18 who had type 2 diabetes were eligible to use HeLP-Diabetes. There were no exclusion criteria for use and staff at participating sites used their judgment to discern which patients to offer HeLP-Diabetes to.</p> <p>There were however exclusion criteria for patients taking part in the research to evaluate the implementation (see Chapter 6).</p> <p>There were no eligibility criteria for general practices other than the practices having to be part of the case study CCG.</p>

Recruitment	How much extra effort is made to recruit participants over and above what that would be used in the usual care setting to engage with patients?	A largely explanatory approach to patient recruitment was taken with registers of patients with type 2 diabetes screened, invitation letters sent to eligible patients, patients returning expression of interest forms, additional appointment at the practice with a research nurse.	A very pragmatic approach was taken with patients offered use of HeLP-Diabetes within routine appointments. In a few practices a mail out was conducted to all patients with type 2 diabetes with an information leaflet (see chapter 7).
Setting	How different is the setting of the trial/study and the usual care setting?	Same as usual care	Same as usual care
Organisation	How different are the resources, provider expertise and the organisation of care delivery in the intervention arm of the trial and those available in usual	In order to maintain staff blinding to the intervention that each patient received, participating practices were required to have two nurses to participate in the RCT, one nurse to act as a practice nurse (training participants in use of the intervention, providing routine clinical care) and one to act as a research nurse (blind to allocated intervention, collecting follow-up data). In some areas the PCRN had employed and trained research nurses. Service support costs were provided to all practices for their	The delivery of HeLP-Diabetes relied on the resources and expertise of those available in routine care. It had been planned that I would assist practices to offer the intervention to patients, however this only happened in two practices (see chapter 7). Staff were provided with training on offering HeLP-Diabetes to patients.

	care?	<p>participation in the RCT to reimburse staff time.</p> <p>Training was provided to practices nurses to deliver the intervention and to research nurses on the research procedures.</p>	
Flexibility (delivery)	How different is the flexibility in how the intervention is delivered and the flexibility likely in usual care?	A detailed protocol for the delivery of HeLP-Diabetes was provided to practices. Patients had to be offered the intervention within a specific time period following randomisation. A training session was provided to patients which was a core part of the protocol.	The details of how to implement HeLP-Diabetes was left up to individual practices/clinics to decide. Although the facilitation of patient use was encouraged this was left to practices to deliver or not.
Flexibility (adherence)	How different is the flexibility in how participants must adhere to the intervention and the flexibility likely in usual care?	Follow-up phone calls were offered to support the patient in use of the programme. Nurses and doctors in participating practices were asked to refer to the programme in consultations with participating patients and to integrate information from the programme into management plans. There were no measures in place to monitor patient adherence to HeLP-Diabetes.	Although staff were encouraged to provide patients with ongoing encouragement to use HeLP-Diabetes within routine appointments this was left up to practices and clinics to implement or not. There were no measures in place to monitor patient adherence to HeLP-Diabetes.
Followup	How different is the intensity of measurement and follow-up of	<p>Fairly intense follow up according to a strict protocol.</p> <p>Follow up data were collected at 3 and 12 months</p> <p>Standard operating procedures (SOPs) covered every aspect of</p>	No follow up

	participants in the trial and the likely follow-up in usual care?	data collection and nurses were trained in these procedures. Adherence to SOP was monitored. Participants completed self-reported questionnaires . The nurse recorded clinical outcomes and took blood for HbA1c and lipids..	
Primary outcome	To what extent is the trial's primary outcome relevant to participants?	HbA1C and diabetes related distress as measured by the PAID are of great relevance to patients.	Uptake and use of HeLP-Diabetes were judged to be of less relevance to patients than the primary outcomes of the trial.
Primary analysis	To what extent are all data included in the analysis of the primary outcome?	Pragmatic approach to the analysis using an intention-to-treat analysis using all available data.	Data from all sites and registered patients included

Figure 2-2 PRECIS-2 scores and wheel for the HeLP-Diabetes RCT

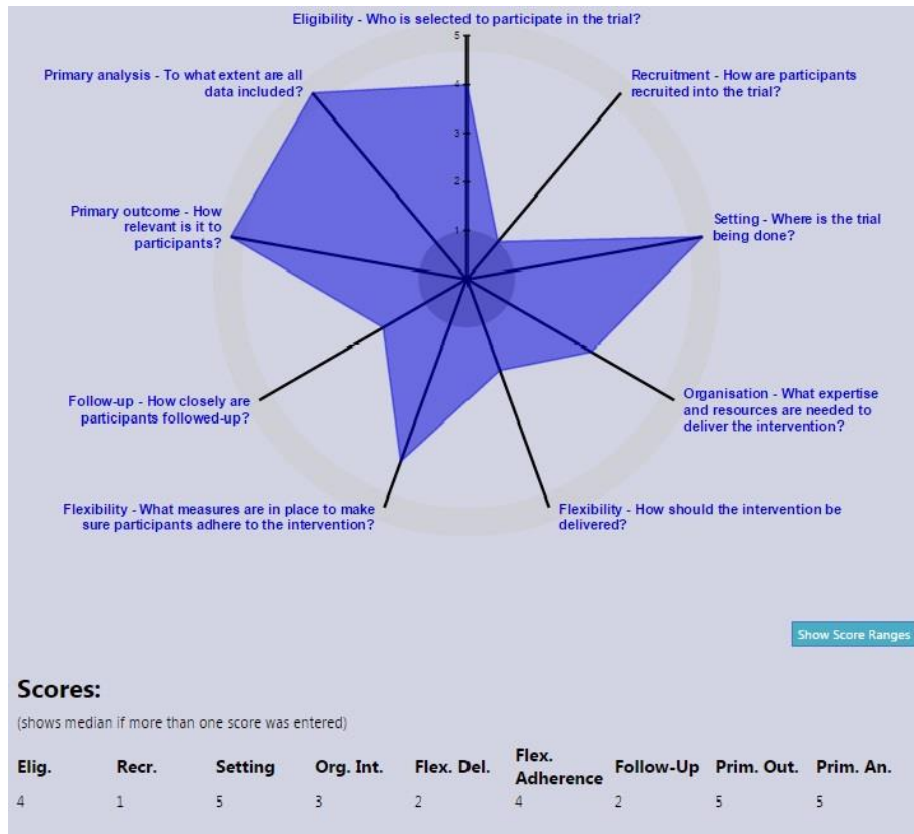
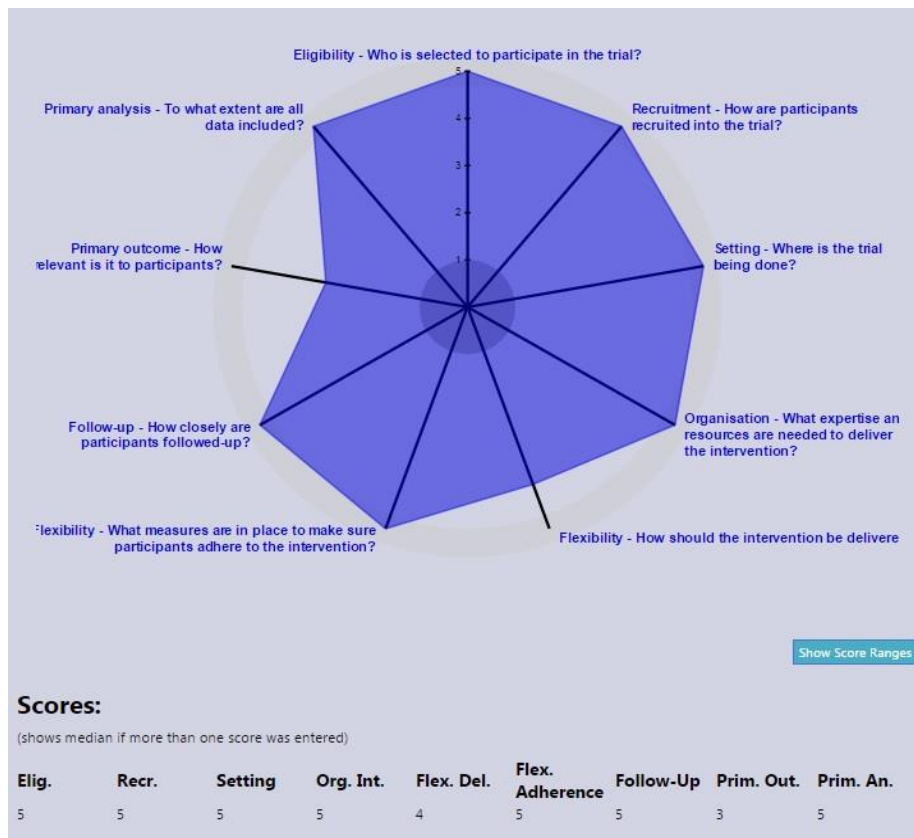


Figure 2-3 PRECIS-2 scores and wheel for the HeLP-Diabetes implementation study



In addition, the rationale for including an implementation study was that whether or not HeLP-Diabetes itself proved effective in a trial, the policy and financial imperatives for introducing e-health interventions to help patients improve their health are overwhelming; hence producing knowledge about how best to implement such interventions is useful for the NHS and other health care systems internationally.

Finally, one of the over-arching aims of the NIHR Programme of Applied Health Research is for funded work to achieve benefits for the NHS. Hence it was important to ensure that the programme of research generated all the data required to inform future implementation and use of HeLP-Diabetes throughout the NHS. As part of the planning for this programme grant, the programme grant team thought about long term sustainability and maintenance. It was clear that a revenue stream would be required for this, and that the most likely source of such revenue would be commissioning by NHS commissioners. Commissioners need more information about a service than can be provided from trial data, including information about likely uptake and use, and the resources required for effective implementation. This study was designed to address these needs as well as providing generalizable data of international relevance.

3 CHAPTER 3: FACTORS THAT INFLUENCE THE IMPLEMENTATION OF E-HEALTH: AN UPDATE OF A SYSTEMATIC REVIEW OF REVIEWS

3.1 Chapter Summary

This chapter presents a systematic literature review, which summarises and synthesises data from published reviews on the implementation of e-health in health services. A focus is placed on identifying factors that facilitate or hinder the implementation of e-health and strategies that promote implementation.

3.2 Background

As described in Chapter 1, the use of technology in providing and delivering healthcare is pervasive worldwide (107, 108). The use of e-health, a term that describes the application of information, computer, or communication technology to some aspect of health or healthcare, is viewed as integral to solving problems facing healthcare systems(109) . Despite potential benefits of e-health, implementation of these systems is often reported as problematic (110). Barriers to implementation may arise at the individual, organisational and wider levels of the healthcare systems and interact in complex and variable ways (111, 112). Barriers may also be innovation- and context- specific. Recognising and understanding factors that influence implementation is crucial for devising strategies and interventions to improve the widespread, effective use of e-health and addressing blockages to implementation.

However, as the e-health implementation literature is fragmented across multiple subspecialty areas, with a plethora of reviews on the implementation of different e-health technologies available, it may be difficult for anyone involved in implementing e-health systems to locate an appropriate body of evidence and to determine the relevance of that evidence to their specific circumstances (113).

A systematic review of reviews by Mair *et al.* (113) synthesised the literature on the implementation of e-health interventions in healthcare settings published up until 2009. An update of this review was deemed timely given three factors: the increasing emphasis on e-health solutions for healthcare services worldwide and the persistent problems with implementation; the changing context of e-health with more ubiquitous use and increased spending on e-health services and implementation; and the development of new e-health technologies.

Since the reviews included in the first review were published, e-health has become increasingly viewed as essential for solving problems facing healthcare systems of increasing demand, due in part to an ageing population and improved treatments, and limited resources (114). Furthermore, the need to understand problems with implementation of e-health in healthcare settings has grown markedly. There is an ongoing tension between the need to use health technologies to good effect and difficulties with implementation. For example, in the UK, the recent National Health Service (NHS) Five Year Forward View (54) states the need to make

better use of available health technologies and acknowledges that the NHS has previously failed to make best use of these because of difficulties in understanding how best to adopt and implement them. High profile implementation failures continue to be reported, such as the failure of implementation of an e-health system in a major UK teaching hospital leading to reduced performance, demoralised staff, costs of £200 million and the Trust being put into special measures (115). This highlights the strong need for those undertaking the implementation of e-health within health systems to understand factors that influence implementation and be well equipped to devise strategies and interventions to improve the widespread effective use of e-health and address blockages to implementation.

e-health, is emerging as one of the most rapidly growing areas in healthcare today (116) with the period since the last review seeing a rapid increase in the types, use and spending on e-health. For example, in 2009, only 12 percent of U.S. acute care hospitals had adopted the Electronic Health Record, however by 2014 this had increased to 75% (117). More and more money is also being provided by healthcare services to facilitate the adoption of these technologies within healthcare systems. For example, NHS England has funded several schemes to support e-health implementation including The Integrated Digital Care Fund to facilitate the adoption of modern, safe standards of electronic record-keeping, the Nursing Technology Fund which provides grants to Trusts to buy digital services for nurses, and the NHS Innovation Accelerator scheme which funds fellows who have worked with industry and the third sector to develop health technologies (118).

New e-health technologies and platforms have developed and been put into use in healthcare settings since the last review including smartphones, tablets, wireless technologies, wearable technologies, Apps, fibre optic broadband and Cloud computing technologies. Technologies such as websites and telemedicine that existed at the time of the first review but have evolved significantly in functional capabilities and scope of applicability (119). Therefore, given that: the use of e-health is rapidly growing and changing, the investments made by healthcare systems in e-health are increasing, and the importance of updating systematic reviews has been stressed (120), an update of the original review was deemed timely.

As the focus of this review was to determine factors that are important to the implementation of e-health across multiple healthcare settings, I deemed a systematic review of reviews to be the most appropriate method, rather than a systematic review of the primary literature as the huge number of primary studies in the area would make synthesis potentially unworkable and very time consuming. A systematic review of reviews provides a summary of evidence from a variety of different levels, including the combination of different interventions, different populations and different settings (121) in a coherent and economical way (113). Conducting a systematic review of reviews allowed the findings of separate reviews to be brought together, compared and contrasted, with the aim of providing a comprehensive overview of factors that influence the implementation of e-health across settings and allowed factors common to all types of e-health interventions to be identified.

One criticism of implementation research is a lack of consistent terminology and definitions to describe factors that may impede or facilitate implementation of innovations (122). The use of a framework can facilitate the identification and understanding of the myriad of potentially relevant factors and how they may apply in a particular context. Normalisation Process Theory (NPT) (7, 97) was employed by the Mair *et al.* review as a framework to code the data, and has been used in other sections of this thesis to understand the implementation of HeLP-Diabetes, it was not however deemed the most appropriate framework to use here. NPT focuses on social processes involved in the operationalization of new innovations within healthcare. However, many studies included in this review deal with factors that are important to implementation but are not directly related to social processes such as national and international policies and financial factors. Furthermore the authors of the original review stated that there were data within their review that could not be included in the analysis because it lay outside of the NPT framework, including data related to technical and attitudinal issues.

For these reasons the Consolidated Framework for Integrating Research (CFIR) (122), which consolidates constructs from a broad array of theories and includes both process and non-process factors, was selected as the framework to guide the coding of the data in this review. The CFIR is a meta-theory of implementation which was developed from a review and synthesis of existing implementation theories and offers a pragmatic organisation of constructs that are believed to (positively or negatively) influence implementation. The CFIR is composed of five major constructs (intervention characteristics, outer setting, inner setting, characteristics of individuals and process) that influence the implementation of innovations into practice (see Table 3-2).

The intervention characteristics construct captures whether an innovation is simple or complex and its adaptability. The implementation setting is described as comprising an “outer context” that includes economic, political and social factors, and an “inner context”, including the organisational structure, culture and resources. The individuals involved in implementation include the various stakeholders (e.g., administrators, healthcare professionals, patients, etc.) and their characteristics, including attitudes about implementation (e.g., readiness/buy-in) and their roles in the organisational structure. Finally, the process of implementation addresses the stages in moving an innovation into full practice, including exploration/planning, installation/educating, initial/limited implementation, full implementation, innovation, and sustainability (including policy change) (122). One of the strengths of selecting this particular framework which has been used in many previous implementation studies is that it provides a consistent taxonomy, terminology, and definitions on which a knowledge base of findings across multiple contexts can be built and allows comparisons with other research.

3.3 Aim

The aim of this review was to update a systematic review of reviews in order to summarise and synthesise published reviews on the implementation of e-health in health services. A focus was

placed on identifying factors that facilitate or hinder the implementation of e-health and strategies that promote implementation.

This review was conducted, in part, to inform the fieldwork components of this thesis. It was hoped that the findings from this review would provide guidance for the implementation of the HeLP-Diabetes intervention into NHS services and that the factors important for implementation reported by this review would provide a sensitising tool for potential barriers and facilitators to the adoption and use of HeLP-Diabetes. However, as I was conducting my PhD part time alongside my full time job to implement HeLP-Diabetes, the time scales were dictated by the needs of the wider programme grant. Therefore, the initial screening and reading of the literature was conducted while designing the implementation plan to implement HeLP-Diabetes into routine practice, however I was only able to update the citation search and systematically analyse the data after the fieldwork began. Therefore the learning from my reading of the reviews was applied to the development of the HeLP-Diabetes implementation plan, but the formal recommendations that arose from the results of this review were not available. The findings from this review are used to inform the discussion of the findings of this thesis (chapter 11).

3.4 Methods/ Design

The protocol for this systematic review has been published (123) and registered with the Prospective Register of Systematic Reviews (registration number CRD42015017661).

This is a systematic review of reviews which includes data collected from both qualitative and quantitative reviews. It largely replicates the methods for identifying and selecting studies described in the original review (113), but, as detailed, differs in the methods of data analysis. For reader clarity, henceforth the following terms shall be used to describe the reviews referred to:

- Review: the current systematic review of reviews
- Original review: the systematic review of reviews conducted by Mair *et al.* (113)
- Studies/papers: the systematic reviews identified and synthesised in this review

3.4.1 Reporting

This systematic review is reported following the ENTREQ statement guidelines to enhance transparency in reporting qualitative evidence synthesis (124).

3.4.2 Inclusion and exclusion criteria

The eligibility criteria for study inclusion (replicated from the Mair review) were developed using the acronym PICOS (see Table 3-1)

Table 3-1 Eligibility criteria for study inclusion

Criterion	Description
Population	<ul style="list-style-type: none"> Healthcare settings (including but not limited to: primary, intermediate, secondary, homecare). All healthcare settings were considered. Not limited by: clinical area, health concern; the type of patient receiving the e-health technology; the type of healthcare professional delivering care or country.
Intervention	e-health technologies (including: management systems, such as electronic health records that allow the acquisition, transmission and storage of patient data; computerised decision support systems including diagnostic support, alerts and reminder systems; communication systems such as telecommunication that act as an intermediary between users; and information resources such as the internet)
Comparator	This review was not limited to comparator studies.
Outcomes	Qualitative data on factors that inhibit or promote implementation of e-health.
Study type	<p>Papers were included if they were:</p> <ul style="list-style-type: none"> Systematic reviews: where relevant literature had been identified by means of structured search of bibliographic and other databases; where transparent methodological criteria were used to exclude papers that did not meet an explicit methodological benchmark, and which presented rigorous conclusions about outcomes. Narrative reviews: where relevant literature had been purposively sampled from a field of research; where theoretical or topical criteria were used to include papers on the grounds of type, relevance, and perceived significance; with the aim of summarising, discussing, and critiquing conclusions. Qualitative meta-syntheses or meta-ethnographies, where relevant literature was identified by means of a structured search of bibliographic and other databases, where transparent methods had been used to draw together theoretical products, with the aim of elaborating and extending theory. <p>And were excluded if they were;</p> <ul style="list-style-type: none"> Secondary analyses (including qualitative meta-syntheses or meta-ethnographies) of existing data-sets for the purposes of presenting cumulative outcomes from personal research programmes. Secondary analyses (including qualitative meta-syntheses or meta-ethnographies) of existing data-sets for the purposes of presenting

integrative outcomes from different research programmes.

- Discussions of literature included in contributions to theory building or critique.
- Summaries of literature for the purposes of information or commentary.
- Editorial discussions that argue the case for a field of research or a course of action.

Where an abstract stated it was a review, but there was no supporting evidence in the main paper, such as details of databases searched or criteria for selection of papers (either on methodological or theoretical grounds), the paper was excluded.

3.4.3 Search strategy for identification of studies

Comprehensive electronic searches of MEDLINE, EMBASE, CINAHL, PSYCINFO and The Cochrane Library (which include Cochrane Database of Systematic reviews, Cochrane Central Register of Controlled Trials, DARE, NHSEED (NHS Economic Evaluation Database), Health Technology Assessment Database) were conducted.

The search strategy, which was replicated from the original review, was based on the following two concepts: e-health and implementation. The search strategy included a combination of medical subject headings and free-text words. The MEDLINE (Ovid) search strategy that was used to identify papers is presented in Appendix A. The two concepts of implementation and e-health were combined, and then the search was limited by study type and date (up to 1.1.14). There was no limitation of language. Citation searches were carried out in ISI Web of Science in September 2015 and results were limited, in line with the search strategy, to studies published up until 1st January 2014. Reference lists of all included studies were also screened for additional literature.

The original review (113) was based on 37 papers published between 1995 and 31st July 2009. The search strategy used in the original review was replicated to identify additional literature published from the 1st August 2009 until 1st January 2014. The 37 papers identified by the original review were also screened for inclusion in the current review.

3.4.4 Selection of studies

Search results were imported into EndNote reference management software and duplicates were removed automatically and manually double-checked. Titles and abstracts of all identified records were independently assessed by me and a second reviewer (Rosa Lau). Full text papers of references that were deemed potentially eligible were obtained and assessed for eligibility against the pre-specified inclusion and exclusion criteria. Any discrepancies between reviewers were resolved through discussion. Reasons for exclusion at this stage were recorded and are detailed in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram (125) (see Figure 3-1).

3.4.5 Study quality assessment

Because the aim was to describe and synthesise a body of qualitative literature, and not determine an effect size, a formal quality appraisal of the included studies was not conducted as it would not affect the interpretive synthesis. However, an attempt to describe the quality of the reviews by focusing on certain key elements, such as searching methods and use or consideration of theory was made using items described in the PRISMA checklist as a guide (125).

3.4.6 Data extraction

All included studies were critically appraised during the data extraction stage. An Excel spreadsheet was created for the purposes of data extraction. This contained a row for each

included study and columns to describe the studies and classify the extracted data related to the implementation of e-health. I extracted data from the included studies and this data extraction and coding was checked by a third reviewer (Elizabeth Murray).

3.4.7 Data synthesis

The original review had used a thematic approach to analysing and synthesising the data, together with an analysis based on the NPT. In view of the large amount of new data, and the subsequent development of the CFIR, I decided to update the analytic approach to use meta-ethnography for data synthesis, with the CFIR as an organising framework.

As described in the background section, the CFIR is composed of five major constructs that influence the implementation of innovations into practice which comprise a number of components (see Table 3-2). The use of the constructs from the CFIR to organise data within the review provided a clear way to facilitate data synthesis from such a large data set. The use of the CFIR constructs also aided the transferability of the findings from this review to other implementation studies.

Table 3-2 Constructs and components of the CFIR

Constructs	Components
Intervention characteristics	<ul style="list-style-type: none"> • Intervention source • Evidence strength and quality • Relative advantage • Adaptability • Trialability • Complexity • Design quality and packaging • Cost
Outer setting	<ul style="list-style-type: none"> • Patient needs and resources • Cosmopolitanism • Peer pressure • External policy and incentives
Inner setting	<ul style="list-style-type: none"> • Structural characteristics • Networks and communications • Culture • Implementation climate (tension for change, compatibility, relative priority, organisational incentives and rewards, goals and feedback, learning climate, readiness for implementation, leadership engagement, available resources, access to knowledge and information)
Characteristics of individuals	<ul style="list-style-type: none"> • Knowledge and beliefs about the intervention • Self-efficacy • Individual stage of change • Individual identification with organisation • Other personal attributes
Process	<ul style="list-style-type: none"> • Planning • Engaging (opinion leaders, formally appointed internal implementation leaders, champions, external change agents, key stakeholders, innovation participants) • Executing • Reflecting and evaluating

Meta-ethnography, as described in depth by Noblit and Hare (126), focusses on interpretation and tries to 'synthesise understanding', unlike other approaches to qualitative synthesis, such as thematic analysis, which seek to summarise data (127). The phases involved in conducting a meta-ethnography described by Noblit and Hare were applied here in order to bring about new interpretations from the data within the studies. They were not used prescriptively, but rather as a systematic guide to the stages that can be considered in the synthesis of qualitative data. The following phases proposed by Noblit and Hare (126) to synthesising qualitative data informed the synthesis:

Determining how studies are related

This phase seeks to determine the relationships between the studies to be synthesized. Noblit and Hare suggest creating a list of the key concepts used in each account (126). For this review, I developed a data extraction form to extract key information and concepts from the included studies and to ease comparison between them. Data were firstly extracted to describe the type of study, including: publication date, e-health domain, healthcare setting, inclusion and exclusion criteria and methods used. Secondly, the main themes from each review relating to factors that influence implementation of e-health were extracted from both results and discussion sections of the included papers. Data from discussions were included as they often contained further interpretations from the authors, which offered important insights and enhanced the richness of the findings. A summary table created from this matrix, which includes key study details and the summaries of the main findings from each review, is presented in Appendix B.

Translating the studies into one another

This stage requires that the relationships between themes or concepts arising from the different studies are considered. I extracted detailed data related to the implementation of e-health from the studies into some initial broad codes, informed by the summary of main findings from each paper. These codes formed columns of the data extraction matrix, and a row for each study was created. The completion of this matrix for each study established that each concept in each paper was encompassed by one of the codes in the matrix and allowed the relationships between themes to be explored between studies. Cells within the matrix remained empty in cases where there were no relevant data in the paper concerned. As a way of remaining faithful to the meanings and concepts of each study, the terminology used in the original paper was preserved within the matrix.

Next, after careful further reading, I decided that these broad codes, although useful for providing a sense of the themes within the papers, were not adequate for representing the nuances of the data within them. There was a considerable amount of data within each broad code that could be further explored. As such, data within the broad codes were extracted into further codes that were guided by the constructs of the CFIR (see Table 3-2). A category for data that did not fit into one of these constructs, or for data that warranted further discussion between reviewers was created. This ensured that data were not being forced into the

constructs where there was not a good fit, and allowed for the CFIR to be evaluated as to how well the constructs could account for the data from this review. A category was also created for the main explanations or theories arising from the authors' interpretations that were relevant to the research question. Data were re-categorised from one construct to another and discussions about these categorisations continued between me and my supervisors (Professor Elizabeth Murray and Dr Fiona Stevenson) until I was confident that all data were coded into appropriate constructs or categories.

Synthesising translations

Noblit and Hare describe synthesis as making a whole into something more than the parts alone by analysing types of competing interpretations and translating them into each other. They identify three forms of synthesis: reciprocal, where concepts of one study encompass another; refutational, where concepts are contested across papers; and line of argument, where an overarching narrative is developed that summarises and represents the key findings of the papers. By reading the concepts and interpretations off the matrix, it was possible to establish a sense of the relationships between the studies. It became clear that the studies were not refutations of one another even when a particular concept was not identified in a particular paper (empty cells). Many themes occurred across studies from which a line of argument could be developed. Guided by the CFIR constructs, I constructed a narrative about the factors that are important for the implementation of e-health.

Communicating the findings

This thesis is one attempt to communicate the findings of the synthesis. The line of argument synthesis is described next in the results section, but also in the discussion section where the interpretations of the data are discussed.

3.5 Results

3.5.1 Search results

In total 2812 unique citations were identified (see Figure 3-1). Of these, 2694 could be excluded on the basis of the title or abstract, leaving 118 citations where the full paper was needed before a decision could be made. Of the 118 full papers assessed, forty-four (128-171) met the criteria for inclusion and were included in this review (Appendix B gives details of all included reviews).

3.5.2 Description of the included reviews

All studies were published between 2003 and 2014. Fifteen studies originated from Canada (129, 138-142, 144-146, 149, 152, 154, 155, 157, 166), fourteen from the USA (130, 135-137, 143, 148, 151, 153, 162, 165, 167-170), three from the Netherlands (130, 133, 147), three from the UK (150, 159, 164), two from Australia (128, 156), and one each from Germany (160), Sweden (163), Mexico (134), Malaysia (171), Kenya (158) and Israel (161). All papers were written in English.

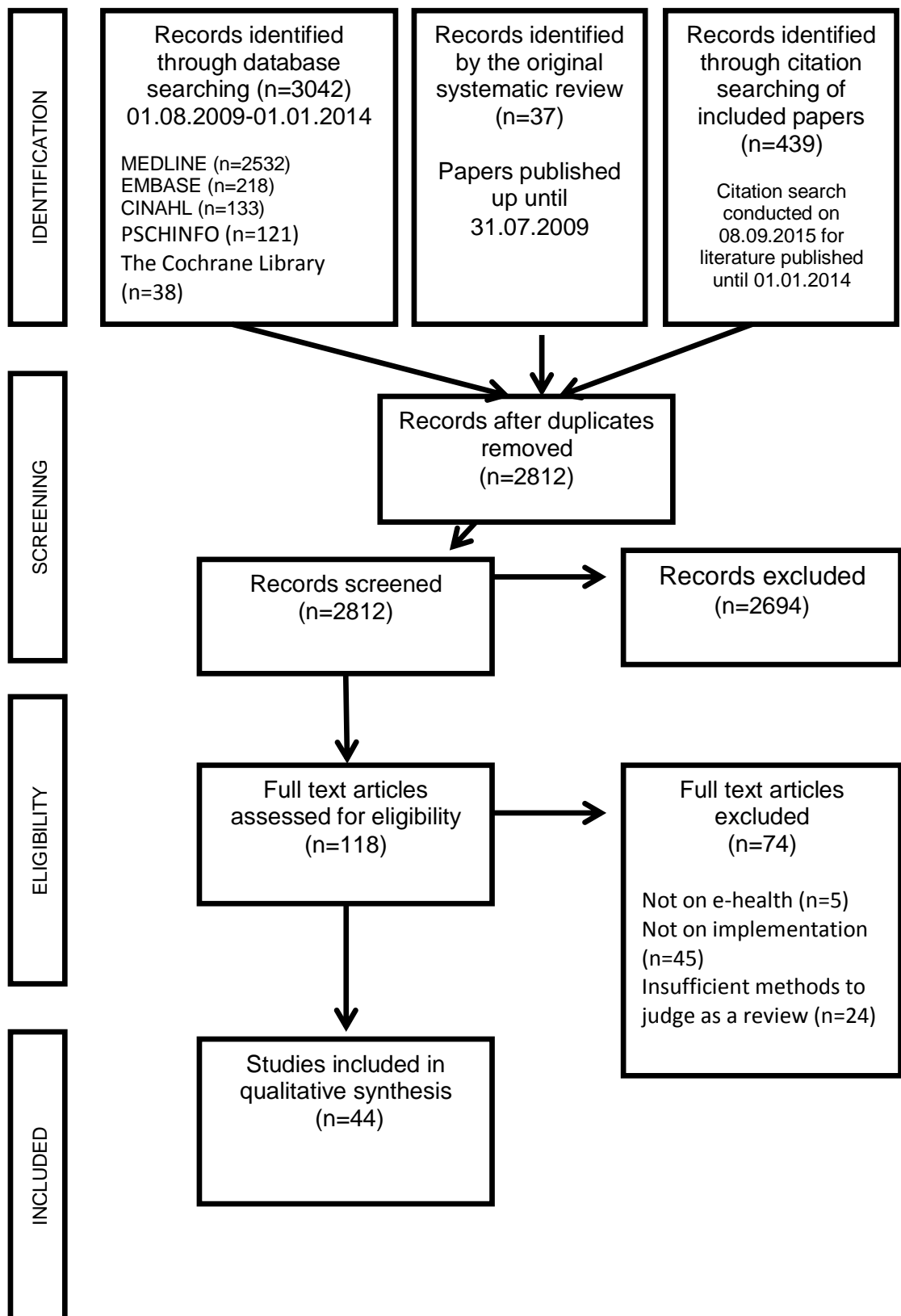
Of the forty-four studies, twenty-five focussed specifically on one type of e-health technology. Five of these were concerned with electronic medical records (EMR) (131, 141, 149, 167, 168), six with clinical decision support systems (CDSS) (147, 153, 155, 156, 158, 161), five with telemedicine (133, 135, 144, 157, 164), and three with telehealth (130, 145, 146). Other studies focussed on electronic health records (EHR) (154), electronic personal health record systems (PHRs) (129), e-prescribing (140), handheld computers and personal digital assistants (PDAs) (151), and home telecare systems (132). Nineteen studies focussed on a collection of e-health technologies described as; information and communication technologies (ICT) (128, 136, 138, 139, 148, 165), health information technologies (HITs) (150, 162, 169), healthcare information systems (HISs) (134, 143, 163, 171), information systems (159, 170), clinical information systems (CISs) (142), electronic health information systems (EHIS) (166) and health information exchange (HIE) (137).

Twelve studies were focussed on one particularly type of healthcare setting including primary / ambulatory care (128, 137, 140, 141, 149, 152), hospital/inpatient/acute care (135, 142, 153, 159) and homecare (132, 166). Twenty one studies focussed on the implementation of e-health in to two or more types of healthcare setting (134, 136, 138, 139, 143, 144, 146, 148, 150, 154-158, 160, 162, 163, 165, 167-169). The remainder of the studies did not define a specific healthcare setting (129, 131, 133, 141, 147, 151, 161, 170, 171).

Fifteen studies explicitly referenced and/or discussed a guiding theory or conceptual model for the categorisation of the data. There was a wide range of frameworks or existing classifications called upon including: The Clinical Adoption framework (CA) (149); human, organisation and technology-fit framework (HOT-fit) (147, 154); Technology Acceptance Model (TAM) (140, 154, 170); Diffusion of Innovations Theory (140, 154); Promoting Action on Research in Health Services theoretical framework (PARiHS) (166); Expanded Systems Life Cycle framework (ESLC) (142); and the PRECEDE and PROCEED conceptual framework (148).

When judged against the PRISMA checklist for reporting systematic reviews (125), many studies were methodologically poor. For example, three (143, 146, 171) did not give details of databases searched and seven searched only one database or source, such as the proceedings of a particular conference (132, 133, 140, 151, 157, 161, 167). Information about study selection criteria was also inadequate: Sixteen of the forty-nine studies did not specify the criteria for inclusion or exclusion (129, 130, 133, 135, 143, 145-149, 151-153, 161, 166, 169). Five did not detail the number of primary studies included in the review (135, 145, 153, 157, 161). As this review was not concerned with numeric outcome measures, the PRISMA checklists for summary measures and result synthesis were not applicable.

Figure 3-1 PRISMA flow diagram of study selection



3.6 Factors that influence implementation

By using the concepts of the CFIR to examine the data from within the reviews I developed a conceptual model specific to the implementation of e-health based on the most prominent constructs to arise from the synthesis of the studies. In developing this model I have moved the synthesis beyond just describing the data present in the reviews related to the constructs of the CFIR and have produced further interpretation from the data as to the factors that are important for the implementation of e-health. This conceptual model is presented in Figure 3-2 and described next.

Figure 3-2 Conceptual model of factors that influence the implementation of e-health



3.6.1 *Innovation Characteristics*

Adaptability

An important factor in vendor and technology selection is the ability of the technology to be adapted to fit the local context (147, 152). Technologies that can have technical adjustments made to them to suit the constant modifications of the environment may have greater acceptance and adoption (131, 148, 154, 163, 171). End user input in the design and development of e-health technologies should be considered as a way of overcoming barriers of adaptability (141).

Related to adaptability is the importance of the interoperability of systems (129, 131, 134, 135, 137, 138, 141, 151, 161-163, 165, 166). To promote their acceptance and use, systems must be able to adequately interface with other IT systems and exchange information (131, 140, 162).

Complexity

Complexity factors such as slow system performance (168), software and hardware problems (140), the need for extensive software modifications (165), the work involved in transferring records between two systems (131), the inability to provide real-time access (151), data handling, reliability, slow speed, unplanned downtime (154) and connectivity issues (162) influence implementation of systems in healthcare settings. Often issues of complexity are linked to health professionals being unable to master the technologies that are implemented (131, 141). Vendors of e-health systems should aim to make systems as user friendly as possible, involving end users in the design and development (166), providing guides to their use (147) and providing technical assistance (156).

Cost

The cost of e-health system and the costs associated with their implementation are extremely important for implementation success (128-132, 135-138, 140, 141, 143-146, 149, 151, 152, 154, 156, 160, 162, 164-167, 170). Cost factors can relate to start-up costs, ongoing costs, costs related to a loss of revenue and savings. High set-up costs including purchasing and installation costs may act as barriers to the initial adoption of e-health systems (162) whereas financial incentives to adopt e-health systems from insurers and government agencies can facilitate adoption decisions (137, 150, 162).

Concerns about ongoing costs act as barriers to adoption (130, 162). Evidence of cost-saving and returns on investment may be important for ongoing use of technologies (149, 152). Establishing cost-effectiveness through formal evaluations, financing of services on a bigger scale, redesigning business models and incentives are strategies that may help to overcome cost related barriers (133, 137, 164).

3.6.2 *Outer Setting*

External policy and incentives

An absence or inadequacy of legislation and policies and liability concerns may hamper the implementation of e-health systems at the organisational and health professional level (130, 131, 133, 164). There is a strong need for recognised standards for the provision of e-health systems (129, 131, 133, 141, 146, 149, 161, 162, 164). The creation of standards may serve to reduce health professionals' concerns over patient data safety, professional liability (130, 146), and facilitate the exchange of electronic health information between systems (129) and organisations while maintaining data integrity (162).

Incentives by government organisations and other external stakeholders may facilitate adoption by healthcare organisations (130, 131, 152, 161, 162). Financial incentives include the provision of initial funds to cover upfront costs (162), financial sponsorship (152), reimbursements for adoption (132, 143, 144, 149) as well as pay-for-performance initiatives (137, 149, 150, 162).

3.6.3 *Inner Setting*

Implementation climate

Implementation climate includes the *compatibility* or general fit between the e-health intervention and the organisation (129, 136, 144, 146, 150, 159, 162, 172). The fit between e-health systems and workflows seems particularly important for implementation success (128, 129, 131, 134, 136, 138, 140, 141, 149, 153, 154, 156, 160-163, 165, 168-171) with implementation failures occurring when systems do not fit well with work practices or daily clinical work (138). Health professionals' perceptions that e-health systems disrupt workflows, and the delivery of care, are barriers to both the implementation and use of these systems (136, 162, 165, 169, 170). When there is a good fit, or perceived fit, between e-health systems and workflows, and when systems positively influence workplace efficiency, this facilitates use (128, 153, 154). Incorporating workflow analysis into system design (161, 168), the integration of systems into the usual process of care (128), user-friendly systems (153) and minimizing workflow interruptions during implementation (130) may minimise disruptions to workflow.

Alterations to workflows created by the introduction of e-health systems may also disrupt established professional roles, responsibilities (129, 133, 138, 149, 168) and working styles (131). Physician resistance to e-health implementation may be related to fear of (131), dissatisfaction with (131), and uncertainty over (156, 160), new roles and responsibilities, created by the introduction of e-health systems (131). The quality of project management during the implementation period (131), careful study of the downstream effects of implementation on workflow (168), additional training (144, 168), the adaptability of technologies to fit with roles, tasks and workflows (150) and dedicated technical support staff (144) are strategies that may reduce barriers related to disruptions to workflow, roles and responsibilities that e-health implementation may bring.

Readiness for implementation

Leadership engagement at all stages of the development and implementation processes can help improve the effective implementation of e-health systems (156, 167, 169, 171) and a lack

of involvement can be a barrier to implementation (131, 166). Management support is also important for implementation success (138, 150, 163, 167).

Available resources including the availability of suitable infrastructure are important for implementation success. Infrastructure features include electricity supply (164), available bandwidth (144, 164), access to reliable internet connectivity (158, 164), access to computers (147), electrical power (158), access to phone lines and mobile phones (158). The availability or lack thereof, of time to learn new e-health systems, implement them (138, 150, 166) and train staff to use them (162) is important for implementation, as is providing a period of transition in which end-users can become familiar with and learn how to use new systems (152, 163).

Access to knowledge and information is also important for the implementation of systems across all e-health domains. Education increases staff acceptance of e-health systems (129, 138, 154, 158) including education around anticipated benefits and when those benefits could be expected (167). A lack of knowledge and a limited understanding of benefits afforded by the systems can act as a barrier to implementation (162, 165, 166). Training and support in relation to implementation and acceptance of e-health systems is of particular importance. Generally, access to appropriate, high quality, well-funded, and easily available training acts as a facilitator to implementation, whereas it is a barrier when it is non-existent, or existent but inadequate (128, 129, 131, 133, 136, 138, 141, 144, 150, 156, 158, 163, 164, 166-171). Similarly, access to ongoing support to use systems is important for system use (134, 138, 141, 144, 150, 152, 156, 167) and a barrier to implementation when it is lacking (134).

3.6.4 *Individual Characteristics*

3.6.4.1 **Knowledge and Beliefs**

Attitudes and beliefs act as both facilitators and barriers to implementation and acceptance of e-health systems. Positive attitudes of practitioners toward e-health systems and their implementation increase acceptance and implementation (133, 134, 154, 157, 159, 162) whereas negative attitudes and staff resistance act as barriers (162, 165). Positive staff attitudes include beliefs that new systems will benefit patients (169), interest in the technologies, perceived usefulness, and motivation in working with the systems (134). Negative perceptions include beliefs that electronic systems disrupt the delivery of care (162), doubts that systems can improve patient care, clinical outcomes or improve the quality of medical practices (156), distrust in systems (150) and more general staff resistance to change (141, 145, 152, 154, 162, 164-166). Strategies to challenge negative attitudes include fostering a culture of communication and cooperation, involving the eventual users of systems in the development and implementation (133, 162), leadership (169), friendly and context-aware user interfaces which promote perceived ease of use and usefulness (134), better education (160), and clearly and prospectively communicating intended benefits and realistic expectations for the system (167). The attitudes of colleagues (138, 154), and patients (138, 140, 154) also influence staff attitudes with regard to e-health acceptance as do staff demographic factors (136, 159, 169).

Specifically, fears over a loss of autonomy, (129, 131, 140, 147, 150, 152, 156) concerns about liability (129, 131, 135, 150, 156, 164), concerns over patient privacy and security being compromised (129, 131, 133, 136, 137, 140, 141, 143, 144, 146, 152, 154, 156, 158, 160, 162, 164-166, 169, 170) and perceived threats to patient and health professional relationships (131, 138, 140, 141, 144, 147, 150-152, 154, 156, 167, 170) through the introduction of e-health systems are barriers to use.

3.6.4.1.1 Other Personal Attributes

Healthcare professionals' computer skills, abilities and experience influence implementation and acceptance of e-health systems (129, 131, 138, 141, 147, 149, 150, 154, 156, 165, 170).

Training (138, 150, 156) and financial incentives (150) are strategies that can overcome skill-related barriers. Demographic factors such as age, education, sex, nationality, and clinical experience may influence healthcare professionals' attitudes towards e-health systems (136, 141, 159, 169, 170), however, no clear relationships between these characteristics and attitudes has been established (159, 169, 170).

3.6.5 Process

Planning

Planning for implementation is important for success, whereas the lack of a strategic plan may be a barrier to e-health implementation (137, 140, 144, 157, 163). The work of planning includes the delineation of roles and responsibilities (156), securing time to invest system selection and procurement (131), evaluating other concomitant policy and process changes (153), needs assessment and analysis, development of a business plan (157), early identification and engagement of champions (144), involving end users (129, 140, 154, 164) establishing a guiding philosophy (146), testing organisational readiness (140, 145), development of incentive and innovation structures (140), communication of the strategy to all staff (163), development of protocols for using the system and for provision of training (144). Incremental implementation strategies where features are made available to users according to a plan are preferable to 'big bang' approaches to implementation within complex organisations (152, 162).

Engaging

The designation of *champions* (131, 133, 138, 142, 144, 145, 149, 150, 152, 164, 167, 171) and engagement of *key stakeholders* in the development and selection of e-health systems, and in the planning and execution of implementation processes may be important for implementation success (129, 133, 141, 142, 147, 154, 157, 162-164, 166-169, 171) by fostering a sense of ownership (133, 157, 164), confidence (141), acceptance (147), enjoyment and self-pride (133) towards the e-health system and increasing buy-in (167).

Reflecting and Evaluating

Evaluation is important to ensure system benefits (142, 161), to increase health professional acceptance through demonstration of benefits (144, 147, 154, 156) and to secure ongoing

funding (166), whereas a lack of evaluation and evidence may act as a barrier to implementation (166).

3.7 Discussion

This systematic review of reviews sought to synthesis available literature on factors that influence the implementation of e-health systems across a range of healthcare settings.

By using the CFIR to examine the data within the systematic reviews included in this study, it was possible to develop a new conceptual model of the factors that are of most importance for the implementation of e-health within health systems. This model stresses: the importance of the selection of an appropriate e-health system with the need for careful consideration taking into account system complexity, adaptability, compatibility with existing systems and work practices and costs; the importance of inclusion of key stakeholders and implementation champions as early as possible in the implementation process; the need for sufficient financial and legislative support in place to support implementation; that standards for technology may greatly improve acceptability and implementation of e-health systems and that planning implementation is a critical step which includes ensuring organisations are in a state of readiness.

Using rigorous methods for the identification and selection of studies, this review identified forty-four systematic reviews which met the inclusion criteria. These studies were focussed on a range of e-health systems including electronic health and medical records, clinical decision support systems, telemedicine and telehealth with several studies focussed on health information technologies in general. Twenty studies were published in the five years since the original search (1st August 2009 until 1st January 2014) reflecting a growing interest in the implementation of e-health.

The findings suggest that issues around implementation are multi-level and complex. All the included reviews reported multiple factors that were important for implementation and no single factor could be identified as a key barrier or facilitator. Although different types of e-health systems have certain unique implementation factors, they nevertheless share many common factors. The factors that seem to have an important impact for all types of e-health systems, which were discussed by the majority of reviews are; evidence, strength and quality; relative advantage; complexity; cost; external policies and incentives (legislation, standards for technology and incentives); organisational culture; implementation climate (compatibility and goals and feedback); readiness for implementation (leadership engagement, available resources and access to knowledge and information); individuals' knowledge and beliefs; planning; engaging (opinion leaders, formally appointed leaders, champions and key stakeholders); and reflecting and evaluating. Technological, external, organisational, individual and process factors were all important, and it appears to be the fit between these factors which is of critical importance for successful implementation.

The Consolidated Framework for Implementation Research (CFIR) (122) provided a framework to guide the categorisation of data within the identified reviews. The CFIR accounted very well for the data within the reviews; there were no data that could not be coded to one of the constructs. There were however, constructs of the CFIR for which little or no data in the included reviews was identified, suggesting either that these factors may not be as crucial for the implementation of e-health as they may be for other innovations, or that they have had insufficient attention paid to them in existing reviews. These were; trialability, patient needs, cosmopolitanism, peer pressure, implementation climate (tension for change, relative priority, learning climate), self-efficacy, stage of change, identification with organisation, engaging (external change agent, patients) and executing. This lack of data may also be a reflection of the type of data reported in systematic reviews as opposed to primary studies. For example, data on how implementation plans are executed would likely be described in individual primary studies, but would less likely to be synthesised in a systematic review that summarises barriers and facilitators from a number of studies.

In comparing the findings of this review with the one it updates (113), it appears that many implementation factors are consistent over time, such as the prevailing focus on organisational issues including the way a new technology impacts on work practices, the need for adequate resources, particularly financial, training, policy support, standards and interoperability. Similar findings were also noted between the reviews in terms of the importance given to getting users engaged with new technologies and the recruitment of champions in order to legitimize participation in the implementation process. Both reviews highlighted the importance of the ease of use of new technologies for health professionals and note a distinct absence of data on the ease of use for patients or other service users. These similarities suggest that although e-health may be a rapidly changing field, many of the challenges of implementing systems within organisations remain constant over time. However, some notable differences exist between the findings of the two reviews. The original review reported a concentration on organisational issues within the literature. Although also strongly present in this review, the use of the CFIR sensitised the focus of analysis to other factors as well including factors related to the innovation, outer context, individuals and the process of implementation. The original authors reported that very little attention had been paid to ensuring that the potential benefits of new technologies are made transparent through ongoing evaluation and feedback. In this review, there was focus given to the role of reflecting and evaluating which may represent an increased awareness of their importance in implementation. The original review reported that there was little coverage given to the 'sense-making work' undertaken when new e-health technologies are implemented (e.g. to determine whether users see it as differing from existing practice, have a shared view of its purpose, understand how it will affect them personally and grasp its potential benefits). In contrast one of the main factors to influence implementation in this review was the knowledge and beliefs that individuals held towards the new technology, particularly around the beliefs they had about potential benefits and the understanding of how technologies are likely to affect work practices. Finally, the original review reported that six percent of issues were unable to be coded because they fell outside of the coding framework used (NPT), this

means that issues that related to technical issues and attitudinal issues were not analysed and reported in the original review, whereas the more inclusive nature of the CRIF meant that all the data within the current review could be attributed to a CFIR construct.

The results from this review are comparable to another large systematic review of reviews by Lau et al. which synthesised the literature on the barriers and facilitators to the implementation of complex innovations within primary care settings (173). Both reviews highlighted the importance of policies and incentives; adequate infrastructure and resources; engagement of key personnel; organisational readiness; individuals' knowledge and beliefs; and the fit of innovations with workflows, processes and systems. As such it seems these factors are important for implementation across interventions and health care settings. Lau's review found that the perceived benefits or harm of implementation such as expectations of more efficient workflow or lower productivity were only an important factor for the implementation of e-health interventions and was not present in the data for other types of interventions (guidelines or evidence-based practice, management of care, public health or preventative medicine, integration of new role or collaborative working). Adaptability and cost were only present in the data for e-health interventions and one other type of intervention. These factors were given a lot of focus in the current review thus suggesting that these factors may be unique or particularly relevant to e-health implementation.

Conducting a systematic review of reviews, given the enormous literature reporting on the implementation of e-health, provided a useful and economical way to manage evidence across a broad topic area. The use of the constructs from the CFIR to organise data within the review provided me with a clear way to facilitate the data synthesis from such a large data set. This review allowed the findings of many separate reviews to be compared and contrasted and provided a summary of evidence from reviews which focussed on different e-health interventions and different healthcare settings. Although this review was rigorous, carefully executed and employed a robust methodological approach and guiding framework, it has limitations which require addressing. Systematic reviews, and also the studies included in them, may be subject to publication bias. This review was limited to reviewing what was published and in the public domain. It is possible, therefore, that some reviews were missed. There is the possibility that not all relevant primary research studies were captured by included reviews, so some findings may be missed by concentrating on reviews. Moreover, by only focusing on reviews, there is an inevitable time lag, with recent studies less likely to be reported in reviews. Other limitations include the fact that this review was dependent on the interpretations of primary data provided by the authors of included reviews. It was often not clear whether the data came from the primary studies or were subsequent interpretations by the authors of included reviews. Many reviews did not specify whether the data came from clinicians, nurses, other primary care healthcare professional or multidisciplinary teams, therefore it was not possible to differentiate the perspectives of specific roles (e.g. nurses).

3.7.1 Application of the findings

The findings from this review were used to inform the implementation plan to implement HeLP-Diabetes within routine practice (described in Chapter 5). Although as discussed earlier in this chapter the timing of the completion of this review and the development of the implementation plan did not fully align, the learning gained from undertaking the review was still able to be applied to the development of the plan (and the HeLP-Diabetes intervention). Table 3-3 presents a summary of how the findings of this review were applied to the development of the HeLP-Diabetes implementation plan, which is described in detail in Chapter 5.

Table 3-3 A summary of how the findings of the systematic review were applied to the development and implementation of HeLP-Diabetes

Factors important for e-health implementation	Application of findings to the HeLP-Diabetes implementation
<p>Innovation characteristics</p> <ul style="list-style-type: none"> • Adaptability • Complexity • Cost 	<p>Throughout the development phase of the HeLP-Diabetes intervention issues of adaptability and complexity were considered carefully. HeLP-Diabetes was designed to be user led so that there was great flexibility in the content that was accessed and the content was constantly being updated. A feedback button on the Homepage allowed any comments or suggestions to be sent to the research team in real time in response to any issues that might be encountered in practice. In addition, when HeLP-Diabetes was implemented within the case study CCG staff requested additional content and resources to be added to HeLP-Diabetes which I was able to do.</p> <p>Similarly, through the feedback function and the close contact that I had with practices in the implementation study, any issues related to complexity of HeLP-Diabetes could be dealt with quickly. Early development work with health professionals and patients ensured that HeLP-Diabetes was as user friendly as possible. In the implementation study guides were also provided to health professionals and patients on how to use HeLP-Diabetes. As part of a research study there were no financial costs to practices to implement and use HeLP-Diabetes. Practices were also informed that HeLP-Diabetes had the potential to be cost-effective in the long term and that this was being established through the parallel RCT. Costs to practices in terms of staff time were considered and discussed with practices, and practices were reimbursed for staff time spent on research activities (as opposed to implementation activities), through Service Support Costs.</p>
<p>Outer setting</p> <ul style="list-style-type: none"> • External policies and incentives 	<p>The use of NPT in the development phase of the HeLP-Diabetes intervention alerted the programme grant team to the importance of aligning HeLP-Diabetes with external policies and incentives. In the implementation study the presentation that I delivered to practices highlighted how HeLP-Diabetes aligned with external policies including the self-management agenda in the CCG, diabetes as an NHS priority area and the use of health technologies as an NHS priority area. During this talk, the potential of HeLP-Diabetes aligned with the Quality and Outcome</p>

	<p>Framework (QOF) for diabetes education was also highlighted.</p> <p>The sponsorship of HeLP-Diabetes by the NHS was discussed in order to allay any fears about data safety or professional liability.</p>
<p>Inner setting</p> <ul style="list-style-type: none"> • Implementation climate <ul style="list-style-type: none"> ○ Compatibility • Readiness for implementation <ul style="list-style-type: none"> ○ Leadership engagement ○ Available resources ○ Access to knowledge and information 	<p>The implementation plan aimed to be tested in a few pilot practices first in order to determine the fit between HeLP-Diabetes and work practices and that learning could be generalised from. It was initially thought that the use of HeLP-Diabetes within practices would be most compatible with the work of nurses and as such the training package was tailored to this group of professionals.</p> <p>Training aimed to allay fears over the disruption of workflows and highlight how HeLP-Diabetes could fit well into existing appointments and consultations.</p> <p>In order to assess readiness and to develop strategies to increase this I aimed to begin the implementation in a few practices which I thought, based on conversations with the CCG, would be good to use as pilot sites. The aim was to try out the implementation plan within these practices and learn from the experience, and respond to challenges that arose in these practices before moving on to more widespread implementation..</p> <p>The importance of leadership engagement led to me firstly trying to engage the GPs at each practice first by attending clinical meetings and presenting HeLP-Diabetes to them before asking them to suggest who else in the practices might be involved with implementing HeLP-Diabetes.</p> <p>I was sensitised to the fact that there would be limited resources within practices to implement HeLP-Diabetes and therefore as part of the implementation plan I worked with practices to determine what available resources they had and how they thought we could be apply them to the implementation of HeLP-Diabetes. I also offered my time to practices to help them initially set up HeLP-Diabetes and to assist them with registering patients to use it.</p> <p>Access to knowledge and information about HeLP-Diabetes was incorporated into the implementation plan through the initial presentation to staff within practices, training session and materials provided to support staff with using it.</p>

<p>Individual characteristics</p> <ul style="list-style-type: none"> • Knowledge and beliefs • Other personal attributes 	<p>The presentation delivered in practices was specifically designed to align with core medical values and emphasis that HeLP-Diabetes was designed to help patients. The presentation also emphasised that the development of HeLP-Diabetes had involved a large amount of input from health professionals and patients in order to ensure that it would fit well in routine practice, be easy to deliver and be useful to patients. Emphasising the evidence based nature of the content was also a priority of the presentation.</p>
<p>Process</p> <ul style="list-style-type: none"> • Planning • Engaging • Reflecting and evaluating 	<p>The importance of planning the implementation of HeLP-Diabetes was highlighted by this review and considerable time and attention was devoted to developing a theoretically informed implementation plan (see Chapter 5).</p> <p>As part of the implementation plan I engaged commissioning officers, the CCG diabetes steering group, and patients in order to get the word out about HeLP-Diabetes and identify champions within the CCG who could help promote it. I gave talks at the CCG headquarters, the CCGs' long term conditions group and patient involvement groups. I also engaged PPI members to spread the word about HeLP-Diabetes through patient networks.</p> <p>To promote positive reflection and evaluation of HeLP-Diabetes I planned to provide feedback to practices about the adoption rates within the CCG by services and by patients. The presentation given to practices also evolved during the study period to include quotes from health professionals and patients using HeLP-Diabetes in order to disseminate the benefits that were being experienced through using HeLP-Diabetes.</p>

4 CHAPTER 4: MODELS OF IMPLEMENTATION

4.1 Chapter summary

This chapter discusses and describes implementation theories, frameworks and models and presents the rationale for the selection of two of these to inform an implementation plan to implement HeLP-Diabetes into routine practice.

4.2 Introduction

Chapter 3 identified factors that can hinder or promote the implementation of e-health, and the synthesised reviews highlighted many examples of problematic implementation of health innovations into routine practice. The review findings suggest that well planned implementation may be crucial for implementation success. It is also understood that it may be important to use a theoretical and evidenced based approach to developing and operationalising implementation strategies to integrate interventions within their target settings (122, 174-177).

There is now widespread recognition that implementation requires whole system change (178), implicating both the individual and organisation. However, despite a growing awareness that implementing innovations into routine practice is a complex, multi-faceted process, there remains a lack of knowledge about what methods and approaches are effective, for whom and in what contexts. The use of theory has been presented as a promising way to understand the 'black box' of implementation, the premise being that if there is a better understanding of what happens when implementation activities are undertaken, then implementation will be more effective in the future (177). A greater use of explicit theory in order to understand barriers, design interventions, and explore mediating pathways and moderators has been advocated to advance of the science of implementation research (179). A systematic review of the use of theory in 235 evaluations of guideline dissemination and implementation (179) found that theories had been applied to the following areas of implementation research: guiding the choice of intervention; process assessment; exploring mediators and/or moderators of behaviour; exploring the effects of interventions; explaining the results of research and stimulating further discussion. Frameworks and models of implementation can be used as references to highlight the things to think about and pay attention to when undertaking implementation activities. The use of theory in implementation attempts also allows for easier replication of successfully implemented interventions.

There are many theories of implementation in the literature and there is a lack of agreement on terminology, with the terms model, framework, and theory often used interchangeably. For the purpose of this thesis, Table 4-1, derived from work by Rycroft-Malone and Bucknall and Kitson *et al.* (177, 178), presents definitions for these three terms, draws distinctions between them, and highlights their applicability to implementation, although it is acknowledged that others may employ different definitions for these terms.

Table 4-1 Definitions of implementation theories, frameworks and models

Term	Definitions	How it may be applied to implementation
Theory	<p>A theory is made up of concepts that characterise a particular phenomenon. Concepts are mental images of phenomena and propositions are statements about the concepts.</p> <p>A theory provides a logically coherent set of relationships. Theories can offer views on the causal relationships and seek to explain the phenomena, although from an interpretative perspective theories also play a vital role in offering explanations rather than causal relationships. Numerous theories may be consistent within the same framework.</p>	<p>Theories can be used to describe, explain and predict implementation phenomenon.</p> <p>They can provide a guide to planning, intervention development, measurement/evaluation and for facilitating theory development</p>
Frameworks	<p>A framework identifies a set of variables and relationships that should be examined in order to explain the phenomena.</p> <p>A conceptual framework is made up of sets of concepts and the propositions that integrate them into meaningful propositions. A conceptual framework need not specify the direction of relationships or identify critical hypotheses.</p>	<p>Frameworks provide a heuristic for organising implementation efforts: what should be paid attention to, assessing barriers and facilitators, generating propositions, developing theory-based interventions, and facilitate a better understanding of what occurred during implementation</p>
Models	<p>Models represent a specific situation, are narrower in scope and more precise than a conceptual framework.</p> <p>The concepts within a model should be well defined, and the relationship between them specific.</p> <p>Models are representations of the real thing; they attempt to objectify the concept they represent.</p>	<p>Models have much the same applicability to implementation as conceptual frameworks but are narrower in scope and situation and offer more precise representations and are more prescriptive.</p>

A review by Tabak *et al.* (176) highlights the number and variety of implementation models (a term used by these authors to encompass both theories, frameworks and models) available. In their review they identified 61 models of implementation that have been designed specifically for use by researchers excluding models that are only focussed at national level implementation, or that apply only to individual behaviour change with no application to community or organisational levels.

4.3 Selecting a theory, model or framework

Given the large number of implementation theories, models and frameworks, it was important to articulate the rationale for the selection of one or more models to inform the implementation plan which was developed to implement the HeLP-Diabetes intervention into routine practice.

It has been suggested that theory selection could be based upon whether a theory is robust, generalizable, stable, useful and appropriate (180, 181). However, in the implementation of complex interventions such as HeLP-Diabetes, it is likely that more than one theory will be required. Often the application of an overarching theoretical framework or model which encompasses more than one theory and often more than one model may be needed (177). For example a process model can be applied to how the implementation should be planned, organized and scheduled and impact models can be applied to hypotheses and assumptions about how implementation activities will facilitate a desired change, as well as the facilitators and barriers for success (182).

In their review, Tabak and colleagues categorised implementation models by their construct flexibility, their focus on dissemination or implementation and their socioecological framework. Construct flexibility refers to whether the model is broad or operational in focus or somewhere in between. Broad models containing less well defined constructs allow greater flexibility in their application to an array of implementation activities and contexts. Operational models, on the other hand, provide more detailed and step-by-step constructs which are defined for particular activities and contexts. Models were also classified by where they fit on the continuum between dissemination and implementation (discussed in Chapter 1). The models were also categorised by the level at which they operate, for example, individual, organisation, community, systems and/ or policy levels.

I used this categorisation as a tool for considering the selection of theories, frameworks and/or models to inform the HeLP-Diabetes implementation plan. The categories of construct flexibility, dissemination/implementation and socioecological framework were applied in turn to the context of the HeLP-Diabetes intervention and the implementation setting in order to select a theory, framework or model that was fit for purpose.

Firstly, taking the category of construct flexibility, as this was the first time I had undertaken the task of implementing a new innovation I felt I needed to select a model that would help me to

consider the steps that needed to be thought through in order to successfully implement HeLP-Diabetes. Therefore I selected an operational, step-by step model to assist me in the planning of the implementation plan. I also selected a broader theory of implementation that could be applied to the work of operationalising the plan, which helped with hypothesising about which implementation strategies might be effective in bringing about change and why, and to also provide an explanatory framework to consider barriers and facilitators that may arise.

Secondly, applying the construct of dissemination vs. implementation led me to choose theories, frameworks and models that apply to implementation, rather than dissemination, as HeLP-Diabetes was a new intervention which was to be actively introduced into a specific setting.

Thirdly, as the implementation of HeLP-Diabetes would involve changes in behaviour and practice at more than one socioecological level, including individual and organisational levels, theories, frameworks and models that applied at several levels were considered.

As theories, frameworks and models of dissemination and implementation are derived from many disciplines including management, education and psychology, an additional criterion I included was that the selected theory, framework or model had previously been successfully applied to implementation planning in the healthcare setting.

4.4 The selected model and theory

Based on these criteria, I selected a model and a theory of implementation to inform the HeLP-Diabetes implementation plan. Appendix D provides details of theories, frameworks and models which were not selected and the primary reasons for this.

4.4.1 Effective Implementation: A Model

Based on the above criteria the first model that I selected to guide the implementation of HeLP-Diabetes was Grol, Wensing and Eccles's model which they call "Effective implementation: a model" (2). This operational model has been developed to assist the implementation of change in healthcare and is applicable for planning change at several socioecological levels. This model provides a stepwise approach to guide the user through a series of deliberate steps in order to accomplish healthcare practice improvement.

It provides a methodical process starting with the description of operational-change objectives and a thorough analysis of current practice, the target group, and the context where change should take place. The crucial step in the model, the development or selection of strategies, is facilitated by the previous steps. In this way, the model prevents the selection of standard but inappropriate solutions and facilitates better choices. Finally steps include operationalizing an implementation plan and the evaluation of both process and outcomes. The analytical approach to deliver a clear rationale for implementation is an essential feature of this model allowing it to be applied in a variety of settings.

This model describes the importance of selecting strategies to target change based on evidence or theory and urges the user to decide upon these through careful consideration of the target group, context, innovation and by using relevant evidence on barriers and facilitators and/or the selection of a suitable theory. As such, in order to hypothesize and make assumptions about how implementation activities facilitate the desired change, as well as the facilitators and barriers for success, I selected a theory of implementation (Normalisation Process Theory) to guide the choice of strategies to effect change and to understand arising barriers.

4.4.2 Normalisation Process Theory

Normalisation Process Theory (NPT) (7, 97) can be used to explain the processes by which an innovation becomes, or indeed fails to become, normalised into routine practice and offers a framework for assessing the conditions in which interventions become practically workable in healthcare. Normalization is defined as the embedding of a technology as a routine and taken-for-granted element of clinical practice (183). This is different from decisions about diffusion or adoption as it focuses on the conditions of use and the behaviour of everyday users. Therefore this theory helps predict not only factors that may lead to an adoption decision, but what factors are important for something like HeLP-Diabetes to become sustained within the NHS. NPT may be operationalised at multiple socioecological levels including the individual, the organisation, the system and community. NPT has been applied as a theoretical framework in healthcare settings by several authors (184-187) and to the implementation of e-health (113, 188, 189).

NPT, developed out of the Normalisation Process Model (190) is an action theory concerned with explaining what people do rather than their attitudes or beliefs. Action is categorised into four constructs representing the work that people do when they work around a new innovation, the four constructs, each of which comprise four sub-constructs are: Coherence, Cognitive Participation, Collective Action, and Reflexive Monitoring. Coherence is the sense-making work that people do individually and collectively when they are faced with operationalizing a new innovation. Cognitive participation is the relational work that people do to build and sustain a community of practice around a new technology. Collective Action is the operational work that people do to enact a new technology. Reflexive Monitoring is the appraisal work that people do to assess and understand the ways that a new innovation or set of practices affect them and others around them. Table 4-2 presents a description of NPT constructs and sub-constructs provided by the NPT online manual and toolkit (191).

Table 4-2 Constructs of Normalization Process Theory

Construct	Coherence	Cognitive participation	Collective action	Reflexive monitoring
Definition	The sense-making work that people do individually and collectively when they are faced with the problem of operationalizing some set of practices.	The relational work that people do to build and sustain a community of practice around a new technology or complex intervention.	The operational work that people do to enact a set of practices.	The appraisal work that people do to assess and understand the ways that a new set of practices affect them and others around them.
Sub-construct	<i>Differentiation</i>	<i>Initiation</i>	<i>Interactional workability</i>	<i>Systematization</i>
Definition	Sense-making work to understand how a set of practices and their objects are different from each other.	Relational work to drive a set of practices forward.	The interactional work that people do with each other, with artefacts, and with other elements of a set of practices, when they seek to operationalize them in everyday settings.	Appraisal work to determine how effective and useful a set of practices are. This involves the work of collecting information in a variety of ways.
Sub-construct	<i>Communal specification</i>	<i>Enrolment</i>	<i>Relational Integration</i>	<i>Communal appraisal</i>
Definition	Sense-making work to build a shared understanding of the aims, objectives, and expected benefits of a set of practices.	Relational work involved in collectively contributing to the work involved in new practices.	The knowledge work that people do to build accountability and maintain confidence in a set of practices and in each other as they use them.	Appraisal work to communally evaluate the worth of a set of practices.
Sub-construct	<i>Individual specification</i>	<i>Legitimation</i>	<i>Skill set workability</i>	<i>Individual appraisal</i>
Definition	Sense-making work to	Relational work of ensuring that	The allocation work that	Appraisal work by individuals to

	understand specific tasks and responsibilities around a set of practices.	other participants believe it is right for them to be involved, and that they can make a valid contribution to it.	underpins the division of labour that is built up around a set of practices as they are operationalized in the real world.	appraise the effects on them and the contexts in which they are set.
Sub-construct	Internalization	Activation	Contextual Integration	Reconfiguration
Definition	Sense-making work to understand the value, benefits and importance of a set of practices.	Relational work of participants to collectively define the actions and procedures needed to sustain a practice and to stay involved.	The resource work. Managing a set of practices through the allocation of different kinds of resources and the execution of protocols, policies and procedures.	Appraisal work by individuals or groups which may lead to attempts to redefine procedures or modify practices - and even to change the shape of a new technology itself.

NPT can be used as a heuristic tool to identify and explain factors that may inhibit the likelihood of a new innovation becoming normalised. NPT suggests that if an innovation can positively influence these constructs then it will be more likely to become part of routine practice than if it produces a negative effect. For example, with the construct of coherence, if healthcare professionals understand how a new technology is different to current ways of working, collectively agree about the purpose of the innovation, understand what the innovation requires of them and construct potential value of the innovation for their work the innovation is more likely to be embedded into practice than if they do not.

With the cognitive participation construct, in order for an innovation to be embedded healthcare professionals must: agree that the innovation should be part of their work, buy in to the intervention, have a key individual(s) to drive the innovation forward and all continue to support the intervention.

Positive appraisal of the collective action construct requires healthcare professionals to: perform the tasks required by the innovation and maintain their trust in each other's work and expertise through the intervention. The work of the innovation must also be appropriately allocated to participants and adequately supported by its host organisation.

Finally, to achieve positive reflexive monitoring healthcare professionals must access information about the effects of the intervention, individually assess the innovation as worthwhile, collectively assess the innovation as worthwhile and modify their work in response to their appraisal of the intervention (191).

In the selection of specific strategies to effect change, NPT can be used as a sensitising tool to help in the assessment of whether a strategy is appropriate for the target group in the target setting. For example, when selecting a strategy to implement HeLP-Diabetes in routine practice, by considering the constructs of NPT I was able to question whether the target group understood what was being asked of them, whether it fitted with their skills and whether they reflected positively on it.

4.5 Summary

Implementation has been described as an active and systematic process of getting new evidence or innovations incorporated into routine practice (177) which involves identifying barriers to change and targeting strategies to promote change. In attempting to implement a complex intervention like HeLP-Diabetes I have suggested that it is necessary to consider the application of theory to the implementation process. Theories, frameworks and models of implementation can be applied to: implementation planning and organisation, forming hypotheses and assumptions about how implementation activities will facilitate a desired change; and to identifying and addressing the facilitators and barriers for success.

Using selection criteria derived from a systematic review of implementation models (176), I selected a planning model and a theory of implementation to inform the implementation plan for the implementation of HeLP-Diabetes into routine NHS practice. Grol, Wensing and Eccles's model of effective implementation (2) was used when designing the approach to implementation and as a tool to guide thinking during the stages of planning. NPT has been selected as a theory by which to make theoretical assumptions about implementation strategies and was also used as a framework for assessing barriers and facilitators to the implementation that may arise and for evaluating the success of the implementation.

In the next chapter the process for using this model and theory for developing the implementation plan for implementing HeLP-Diabetes into routine NHS practice is described.

5 CHAPTER 5: METHODS 1: DESIGNING THE IMPLEMENTATION PLAN FOR HELP-DIABETES

5.1 Chapter summary

This chapter applies the implementation model and theory selected in the last chapter to the design of an implementation plan to implement the HeLP-Diabetes intervention into routine NHS practice. I present a detailed description of this plan here.

5.2 Introduction

In the last chapter, a model and theory of implementation were selected to inform the plan to implement HeLP-Diabetes into routine NHS practice. The use of theory in implementation can aid implementation planning and organisation and help form hypotheses and assumptions about how implementation activities will facilitate a desired change, as well as providing explanations to the facilitators and barriers that may be encountered (182).

As described in Chapter 4, Grol, Wensing and Eccles's model of effective implementation (2), is a planning model which provides a step-by-step guide to thinking about the implementation and the planning work that should be done before any attempt is made to implement an innovation in practice. The first part of this chapter outlines some of the main considerations raised by this model when thinking about implementing a new change in practice and how the model was applied to design an implementation plan for HeLP-Diabetes. In the second part of this chapter I will describe the specific approach that I took to implement HeLP-Diabetes in practice.

5.3 Planning the implementation

Grol, Wensing and Eccles's model of effective implementation is designed to help plan and manage the change process. It provides a guide, in general terms, of how to set up a programme designed to introduce change in healthcare. The model includes a number of steps or processes to introduce change (Figure 5-1), the sequence of which and applicability depends upon the specific circumstances. The steps of the model to consider before the implementation takes place are described below, along with a description of how they have been addressed for the implementation of the HeLP-Diabetes intervention.

Figure 5-1 Stages for implementing change from Grol, Wensing and Eccles's model of effective implementation



5.3.1 Step 1: development of concrete proposals/ targets for improvement or change.

The model suggests that innovations must be of good quality, fit in with the needs of the target group, be useable and easily available and be designed attractively. A good understanding of the characteristics of an innovation that are likely to affect its ultimate adoption is required.

Characteristics may include:

- The way the development has taken place- the quality and credibility of the process
- Developers- the amount of support for the innovation
- Design- it's accessibility and attractiveness
- Scope for adapting the innovation to suit the local situation

As well as this stage's emphasis on designing a fit for purpose, easy to use and accessible intervention (a discussion of which is outside of the scope of this thesis as it applies to the development stage of HeLP-Diabetes), this stage of the planning model stresses the need to have clear targets for the desired change. In developing an implementation plan the tasks that need to be undertaken by healthcare professional and the goals of implementation must be made clear (2).

5.3.1.1 Step 1 applied to the implementation of HeLP-Diabetes

The desired tasks required of healthcare professionals in order to implement HeLP-Diabetes within routine practice were to agree to adopt HeLP-Diabetes, recommend the use of HeLP-Diabetes to patients, assist patients to register to use HeLP-Diabetes and facilitate patient use. How practices utilized HeLP-Diabetes with patients once they agreed to adopt it was governed

by some prescriptive requirements placed on use (including the need for patients to be registered to use it and complete an online registration form) but also, in order to promote implementation, there was a high degree of flexibility and individuality in the way that HeLP-Diabetes was offered to patients by each practice. In order to make sense of HeLP-Diabetes it was important for healthcare professionals (individual or groups or both) to decide how HeLP-Diabetes best fitted in with their current practices including the way they worked with patients with type 2 diabetes and how they allocated resources. For example, some practices wanted to use HeLP-Diabetes as a tool at annual review, others saw it as a resource health care assistants could use with patients during routine appointments, others dedicated a Nurse to take the lead on offering HeLP-Diabetes to all type 2 patients.

The desired targets for change were therefore for practices to adopt HeLP-Diabetes as an additional service for their patients with type 2 diabetes, which required providing resources (time, healthcare professionals, and space) to offer the website to patients. For healthcare professionals in the practices additional behaviours were required to recommend HeLP-Diabetes to patients and to register the patients on the website. The desired behaviours from patients were to register to HeLP-Diabetes and use it.

5.3.2 Step 2: analysis of performance, target group and setting

The second step outlined by the model is to perform an analysis of the context within which changes in routines are to take place, the characteristics of the target group, the factors that stimulate and hamper change and the aspects of performance that show the greatest deviation from the proposed behaviour. Factors that determine whether the implementation is successful or not may be connected to the setting in which the change is to be implemented, the relationship between individuals within the setting, the goals of the implementation, the actual care provision proposed, the professionals who have to carry out the innovation, the patients who have to co-operate with the implementation, the resources available and the organisational or structural conditions for its effective introduction.

Another analysis suggested within this step is to measure the current practice and compare how it matches to the desired practice. The measurement of current practice identifies where it does not match the patterns of care proposed by a guideline, best practice or new procedure. Based on this data it is possible to identify what changes in current practice are needed and which aspects of care the implementation plan should target. These may include:

- To start a completely new routine, the use of a new technology
- Stop a current routine
- To reduce specific routines
- To adapt specific routines

5.3.2.1 Step 2 applied to the implementation of HeLP-Diabetes

Target group and setting:

Although the HeLP-Diabetes intervention is designed to be used by patients, it is designed to be offered to patients as an NHS service and therefore the focus of this thesis is on the implementation of HeLP-Diabetes into the NHS where it will be offered to patients as a service by healthcare professionals. NHS services that could potentially offer HeLP-Diabetes to patients include GP practices, community clinics and hospital clinics.

It was hoped that patients would be referred to HeLP-Diabetes during routine appointments and therefore the target groups of the implementation were those healthcare professionals involved in the delivery of routine appointments to patients with diabetes including GPs, nurses and health care assistants, consultants and psychologists. Target-group factors commonly found in healthcare settings that can stimulate or hinder the implementation of innovations include healthcare professional knowledge, skills, motivation, and social influence amongst colleagues (192). Healthcare setting factors that might influence the implementation include features of the organisation such as the available facilities and material and the structure such as protocols and routines.

Different healthcare professional groups may be the target of strategies to promote implementation at different stages of the implementation process. It may be important to target interventions designed to engage healthcare professional and persuade them to adopt HeLP-Diabetes at the GP and practice manager levels as these healthcare professional groups have the authority to agree to adopt a new service. Interventions that target changing behaviour to perform new tasks i.e. the work of offering HeLP-Diabetes to patients may be better targeted at nurses who are likely to be the group within practices who will offer HeLP-Diabetes to patients as they are the group who predominantly currently provide patients with referrals to diabetes education.

Current practice:

With the implementation of HeLP-Diabetes I aimed to introduce a new technology which was a completely new and additional routine (to register patients), but could also involve healthcare professionals adapting specific existing routines (such as diabetic appointments and referring patients to diabetes educational programmes) to fit the introduction of HeLP-Diabetes into existing practice. Box 5-1 outlines the NICE guidelines related to offering education to patients with diabetes which was used as an indication of current practice.

Box 5-1 Healthcare professional guidelines for offering education to patients with type 2 diabetes

Healthcare professional guidelines for offering education to patients with type 2 diabetes

The current healthcare professional guidelines for offering education to patients with type 2 diabetes laid out by the National clinical guideline for management of type 2 diabetes in primary and secondary care (193) recommends NHS healthcare professionals:

1. *Offer structured education to every person and/or their carer at and around the time of diagnosis, with annual reinforcement and review. Inform people and their carers that structured education is an integral part of diabetes care.*
2. *Select a patient-education programme that meets the criteria laid down by the Department of Health and Diabetes UK Patient Education Working Group.*

However, prior to the start of the study, data from the National Audit Office suggested that only 11.5% of people with type 2 diabetes were being offered structured education (194). This suggested that the majority of healthcare providers found it difficult to implement and resource quality education programmes that meet these standards and that there appeared to be an urgent need to ensure that all people with type 2 diabetes were offered high-quality structured education (193). This suggested that the work of referring patients to HeLP-Diabetes would be in line with what healthcare professionals were expected to do for patients with type 2 diabetes at that time, but that strategies may be needed to improve the referral rates. The additional work of having to register a patient to use the HeLP-Diabetes website may need additional strategies to bring about this behaviour in healthcare professionals.

5.3.3 Step 3: selection of the implementation strategies

Grol, Wensing and Eccles describe the stages of the implementation process as:

- Orientation
- Insight
- Acceptance
- Change and
- Maintenance

The model suggests that each stage may require a selection of different strategies. Strategies in the 'Orientation' phase must promote awareness of the innovation and stimulate interest and involvement, in the 'Insight' phase they must create understanding and develop insight into the routines of healthcare professionals, strategies in the 'Acceptance' phase should foster a positive attitude to the change and create positive intention or decisions toward change. In the 'Change' phase strategies need to allow healthcare professionals to try the change out in practice and confirm benefit and value. Strategies in the 'Maintenance' phase need to facilitate the integration of the new practice into routines and embed the practice within the organisation. These stages will be used to guide the implementation plan set out in the next section.

5.3.3.1 Step 3 applied to the implementation of HeLP-Diabetes

In this stage the factors I identified in the first two steps, along with other relevant information, were used to develop methods and strategies to implement HeLP-Diabetes. The selection of strategies to implement HeLP-Diabetes was based on: early development work with healthcare professionals (conducted as part of the programme grant); the knowledge gained from reviewing literature on the barriers and facilitators to implementing e-health; the understanding of target groups, setting and current practice; as well as NPT, which can be used as a sensitizing tool to think about how methods and strategies may impact on the work of healthcare professionals as well as a tool for understanding barriers and facilitators and for selecting appropriate strategies to target these.

5.3.4 Step 4: development, testing and execution of an implementation plan

In this stage, the methods and strategies are developed into a plan of action. Attention has to be paid to effective dissemination (to arouse interest and to guarantee sufficient knowledge) both to encourage the intervention's acceptance (to foster a positive attitudes and willingness to bring about real behavioural change) and to promote the actual implementation and integration into normal working routines and care processes.

5.3.4.1 Step 4 applied to the implementation of HeLP-Diabetes

The development of the implementation plan (described in the next section) was an iterative process. Grol, Wensing and Eccles recommend starting on a small-scale and testing strategies on a modest sized motivated group, as what has been developed before implementation usually turns out differently when put into practice (2). Therefore, the intention was for the first iteration of the implementation plan to be tried out on a small group of GP practices. Following the implementation of HeLP-Diabetes in this first batch of practices, a staged roll out was then planned for the remaining services, whereby the implementation plan would be targeted at another few practices at a time, and then another few, as opposed to a widespread implementation targeted at all practices at once. The aim of the staged roll out was to learn from the experience of implementing on a small scale and apply this learning to adapting strategies for implementation at subsequent practices and to avoid implementing unsuccessful strategies across all practices.

5.3.5 Step 5: evaluation and adaptations to the plan

A final step in the model is to evaluate the results of the implementation. An evaluation will answer questions such as, have the goals been achieved? Has the desired change occurred? And where this is not the case, to consider what can be done to ensure better success.

Evaluation should be a continuous process and may result in:

- Adaptation of the plan
- Supplementary analysis of stimulating or hampering factors
- Further strategies and measures to bring about change
- Revise the plan and conduct widespread implementation

5.3.5.1 Step 5 applied to the implementation of HeLP-Diabetes

Chapter 6 outlines the methods selected to evaluate the implementation of the HeLP-Diabetes intervention within routine practice and Chapter 7 details the adaptations to the implementation plan which arose in response to identified challenges, barriers and facilitators.

5.4 The HeLP-Diabetes Implementation Plan

The first iteration of the HeLP-Diabetes implementation plan which was structured around the stages of the implementation process (Orientation, Insight, Acceptance, Change and Maintenance) outlined by Grol, Wensing and Eccles's model is outlined in this section. This is a very linear description of the implementation plan for the purpose of presenting it easily in this thesis. Normalisation Process Theory was applied in the development of this plan to inform the selection of strategies to implement HeLP-Diabetes (as summarised in Table 7-3 on page 140).

5.4.1 Orientation

This part of the plan was designed to employ strategies that would raise awareness of HeLP-Diabetes and stimulate interest. Healthcare professionals had to be made aware that HeLP-Diabetes was available.

Strategy:

To create initial awareness of HeLP-Diabetes, an email was sent to GP practices. This email was designed to concisely inform healthcare professionals that there was a new tool available to support their patients with looking after their diabetes.

The cost of a new technology was a common theme that arose from the systematic review on the barriers and facilitators to implementing e-health. In order to prevent any barriers related to costs of the technology itself, the email made clear that HeLP-Diabetes was a free tool being offered to practices.

In order to build credibility about the source of the website and to waylay any barriers related to commercial websites (identified in early development work with healthcare professionals as a potential barrier to implementation), it was made clear that HeLP-Diabetes had been developed at a University as part of a research project.

It was hoped that the issues of type 2 diabetes and self-management would be interesting to the GPs receiving the email, as these were current NHS areas of priority. The emails were sent to people identified by Elizabeth Murray as having an interest in diabetes within the practice.

5.4.2 Insight

The target group had to understand what HeLP-Diabetes involved and the arguments behind it. Care providers needed to know exactly what was expected of them and why it was important.

Strategy:

NPT suggests, that in order for a new innovation to become routine in practice it must be coherent to those who will be working with it. Communal and individual specification are two components of the coherence construct of NPT that postulate that in order to operationalize a new innovation, shared and individual understanding of the aims, objectives and benefits of a set of practices must be built. Following the initial email contact made with practices, arrangements were made to set up a meeting with practices who had expressed an interest in finding out more about HeLP-Diabetes. The purpose of these meetings was to provide healthcare professionals with information about HeLP-Diabetes and the implications for their working practice to allow them to decide whether or not to adopt it in their practice.

Specific strategies to engage healthcare professionals during these meetings included: presenting the evidence base behind the development and content of HeLP-Diabetes; outlining the potential benefits to the practice and patients of adopting HeLP-Diabetes; demonstrating how HeLP-Diabetes meets identified clinical needs; and through a live demonstration, showing the usability and attractiveness of HeLP-Diabetes.

Following these meetings healthcare professionals were given time to ask questions and have queries answered. All of these questions were recorded and were proactively addressed in subsequent meetings with other practices. The intention was to use the learning gained from the questions and concerns that arose at these early meetings and apply it to future meetings. The intention was that if needed, additional strategies would be incorporated into the plan to address barriers that were identified at these early stages.

Access to practice meetings was difficult to achieve and the length of time for the meetings was limited due to the busy nature of General Practice. In order to engage practices quickly and build credibility within these meetings Elizabeth Murray attended these meetings with me. This increased the NPT construct of coherence as her professional experience being a GP meant she could address concerns that arose at the practice meetings about the use of HeLP-Diabetes in General Practice.

5.4.3 Acceptance:

Grol, Wensing and Eccles's model suggests that at this stage healthcare professionals must gain: insight into exactly what is being recommended; an understanding of what is involved for them; acceptance, weighing up the advantages and disadvantages; and becoming convinced that the innovation is valuable, effective, useful or that it leads to saving time or money (2). Factors that may hinder a positive appraisal include healthcare professionals viewing HeLP-Diabetes as unfeasible in their own work setting, if they doubt the scientific basis of the proposed change or if they doubt the credibility or expertise of those who developed HeLP-Diabetes. The work required of healthcare professionals in order to implement HeLP-Diabetes is detailed in Box 5-2.

The work required of healthcare professionals in order to implement HeLP-Diabetes was to:

- Identify patients who are suitable to use the website
- Recommend the use of the website to the patients
- Conduct a facilitation appointment with patients. This facilitation appointment was initially designed to take 40 minutes and achieve the following objectives:
 - Introduce patients to HeLP-Diabetes providing explanations of what it is, how it's been developed, what it can be used for.
 - Register patients on HeLP-Diabetes so that they have a username and password to access the content.
 - Collect patient registration data on the online form including; contact details (name, email address, contact telephone number), socio-demographic details (date of birth, gender, ethnicity) questions about diabetes (date of diagnosis or duration of diabetes, how diabetes is managed, practice attended, areas of diabetes self-management that they would like help with) computer skills and internet access in order to tailor content and send engagement emails to patients and describe the type of patients who register.
 - Facilitate access: Once a patient has been registered healthcare professionals will demonstrate how to locate the website and how to login.
 - Facilitate use: Healthcare professional will show patients particular parts of HeLP-Diabetes that are of interest to the patient. The particular areas of interest can be gained from discussions with the patient, from responses to the question on the registration form about what help patients want or from knowledge of the patient.
 - Provide the patient with an activity booklet which is designed to be used at home. The booklet recommends specific activities that can be undertaken on the website and details of how to locate the relevant webpages
 - Encourage patient continued use of the website through discussions about it in routine appointments

Strategy:

One strategy to promote positive adoption decisions is to reduce the uncertainty an individual or a group may have about the new innovation. Grol, Wensing and Eccles state that an opportunity to try out the new innovation on a small scale is important to allow the target group to gain experience in using it and to learn the skills involved (2). This strategy also fits with NPT which holds that healthcare professionals must make sense of the new innovation and understand how it will fit in with existing practices. In order for healthcare professionals to try out HeLP-Diabetes they were offered a username, password and the URL to access it so that they could explore the website themselves. The collective action construct of NPT refers to the operational work that people have to do to enact a new innovation, providing healthcare professionals with

access to HeLP-Diabetes allowed them to see how HeLP-Diabetes fitted with the skill sets of the healthcare professionals in the practice (skill set workability), what resources were needed to make it part of routine practice (contextual integration), what knowledge was needed to be confident with HeLP-Diabetes as a new way of working (relational integration), and the impact that HeLP-Diabetes would have on interaction with colleagues and patients (relational integration).

In order to increase acceptance I had planned to work with practices individually to devise ways to ensure that HeLP-Diabetes worked well in their setting, with their healthcare professionals and patients. It was hoped that by allowing healthcare professionals the flexibility to use HeLP-Diabetes in a way that fitted best with their current practices they would have more positive attitudes towards it.

5.4.4 Change:

Once a decision to adopt HeLP-Diabetes had been made by the practice, the overt work of implementing it into routine practice would begin. Grol, Wensing and Eccles suggest that specific training may be required at this stage and that the temporary help of experts can support people through this stage. In this stage healthcare professionals had to be convinced that HeLP-Diabetes delivered the anticipated advantages. Collecting data and providing feedback about the achievements and documenting any positive reactions from patients can support the motivation to continue during this phase.

Strategy:

Once a practice had decided to adopt HeLP-Diabetes, healthcare professionals were provided with a training session. As identified in the systematic review, training healthcare professionals on using a new innovation is a strategy that can facilitate implementation or impede it if not provided, or provided inadequately.

Training was open to any healthcare professional, and the decision as to which healthcare professional(s) attended the training session at each practice was left up to the practices. In this way, the work of collective action was delegated to the practice who had to decide who would do the work of implementing HeLP-Diabetes (initiation) and how it would be organised (enrolment). It was important for the practice to make this decision, as they had knowledge about the availability of resources and what was likely to work best in their current routines. NPT suggests that it is important that new ways of working fit well with the specific skill sets of the people doing the work; the work of implementing HeLP-Diabetes appeared to align well with the skill set of nurses who work closely with patients with diabetes, have a good knowledge about which patients may benefit from HeLP-Diabetes, have frequent appointments designated to patients with diabetes, and have experience in dealing with self-management issues. As such, I planned to recommend to practices that nurses may be particularly suitable to attend the training sessions and use HeLP-Diabetes with patients.

The aims of the training session were to inform healthcare professionals about HeLP-Diabetes and to teach them how to use it. Specific objectives within the training were to:

- Register healthcare professionals on HeLP-Diabetes so that they have a username and password to access the content.
- Highlight core parts of the website and teach them how to access these.
- Demonstrate how to register a patient on the system.
- Provide an opportunity for healthcare professionals to role play the patient registration process.
- Provide paper based resources. These were designed to act as aids to registering patients and demonstrating HeLP-Diabetes to patients.
- Provide an opportunity for healthcare professionals to ask questions and discuss logistical aspects of using HeLP-Diabetes with patients.

Once HeLP-Diabetes was being used by patients it was planned that I would collect feedback from them on their experiences of using the website and feed this back to practices to encourage them to continue offering the website to their patients.

I planned to offer my time to practices during this stage in order to facilitate the change at the practice. It was intended that I would offer each practice help in doing the tasks required to get patients using the website, with a view to demonstrating the ease of the procedures and teaching healthcare professionals to do it themselves. The idea was that once they had observed me doing it they would feel confident to take over and to undertake these tasks themselves.

5.4.5 Maintenance:

Once a way of working with HeLP-Diabetes had been decided upon and was being used within a practice, strategies were needed to encourage its continued use and to facilitate these new working practices becoming part of routine practice. The NPT construct of reflexive monitoring describes the work that healthcare professionals do to assess a new innovation once in practice; systemization is the evaluation work that can be done either formally or informally to determine how effective or useful a new innovation is. Communal and individual appraisals take place which include discussions and interactions about the effectiveness and usefulness of the new innovation and appraisals about how the new innovation is impacting on individuals, work practices, patients and the context. Appraisal work may lead to reconfiguration where processes and innovations are modified to make them more workable in practice.

Strategy:

Implementation strategies including regular communication with practices, making frequent contact with individual healthcare professionals, and providing on-going support to problem solve and register patients were employed to facilitate positive reflexive monitoring, maintenance and continued use of HeLP-Diabetes. At this stage an adaptive approach was taken to addressing barriers that arose and further strategies were employed to tackle them as and when they were identified. It was planned that continued feedback would be provided to

practices about their progress in signing patients up to HeLP-Diabetes. Feedback, defined as returning information about their actions to professionals, practices or institutions to increase insight into these actions (2), is a common strategy in the implementation of innovations in the healthcare setting (195). Individual feedback was planned to be given to practices via email and telephone calls at regular intervals, especially to practices that were slow to sign patients up to HeLP-Diabetes. A newsletter was also sent to all practices which aimed to remind healthcare professionals about using HeLP-Diabetes and also contained figures on how practices were doing at signing patients up to HeLP-Diabetes.

In order to keep patients motivated, engaged and informed about HeLP-Diabetes healthcare professionals were asked to regularly encourage patients' use of HeLP-Diabetes. This could have been done by mentioning HeLP-Diabetes in consultations, asking patients how they were getting on with using it, setting reminders with patients to log on, posting out HeLP-Diabetes related information and giving patients quick follow up phone calls to check on their use of HeLP-Diabetes and provide any additional support required in using it. Newsletters and emails were also regularly sent to registered patients (see Chapter 2) that included links to content, suggestions of activities to complete, ways of connecting with other users, and contact details for support and suggestions.

5.5 Discussion

This chapter presents the first iteration of an implementation plan designed to assimilate HeLP-Diabetes into routine NHS practice. This plan was constructed using a model and theory of implementation. The importance of planning implementation has been stressed by models of implementation which recommend that all steps in the implementation process are given attention before the implementation commences (2). In developing this implementation plan, Grol, Wensing and Eccles's model of effective implementation was used as a guide to identify the important stages of the implementation process and to guide the selection of strategies at each of these stages to promote implementation. NPT was used to guide the selection of strategies by taking into consideration the work that individuals must do to make HeLP-Diabetes part of routine practice and by selecting strategies that promote the constructs of NPT that may increase implementation success.

This plan was designed to be iterative and flexible and was expected to evolve over the course of the implementation period. In Chapter 7 changes that were made to the implementation plan are documented.

6.1 Chapter summary

This chapter describes the methods selected to evaluate the implementation plan and provides details of the study design, methods, data collection and data analysis.

6.2 Introduction

The plan to implement HeLP-Diabetes into routine NHS practice was developed drawing on a model of effective implementation (2) to guide the different stages that an implementation process can take (see Chapter 5). The final stage of this model describes the need to evaluate the implementation plan. Grol, Wensing and Eccles *et al* (2) state that the results of an evaluation are needed to determine whether the energy that has been invested into the implementation planning has led to the desired change and, if not, consider what changes can be made. Evaluations of implementations may result in: adaptations to the proposal for change, for instance by revising the goals if these prove to be unrealistic; supplementary analysis of promoting or inhibiting factors; further strategies and measures to bring about change, or revisions to the plan or the conduct of the implementation. Grol *et al* stress that although evaluation is the final step in their model, it should not be the final step of an implementation project. Ideally, the evaluation should be conducted in parallel with implementation, with constant assessment of whether the desired change is being achieved leading to constant improvement and revisions of the processes and strategies of implementation. This approach lends itself to an iterative research methodology that allows adaptations to the intervention and the implementation plan to be made throughout the implementation phase in response to findings from the evaluation.

As discussed in Chapter 1, there are several types of implementation studies described in the literature (90). The MRC describe implementation studies that establish the real-life effectiveness of interventions in unselected populations as Phase IV studies (196). The aims of these implementation studies include determining intervention effectiveness over the long term and identifying rare or long term adverse effects. In contrast, there are implementation studies that aim to determine how well interventions are taken up and used in unselected populations (197, 198). Researchers from the Veterans Association Quality Enhancement Research Initiative (VA QUERI) have argued for “hybrid” designs, which combine both types of research question (94). They have suggested a taxonomy for such “effectiveness-implementation hybrid designs” where type 1 tests effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; type 2 tests clinical and implementation interventions / strategies equally; and type 3 tests an implementation strategy while observing and gathering information on the clinical intervention’s impact on relevant outcomes

This current study is of the latter type of implementation research (type 3) as its primary objective is to describe the uptake and use of the HeLP-Diabetes intervention in routine NHS practice. The effectiveness of the HeLP-Diabetes intervention is being assessed in a separate,

parallel randomised control trial (199)) described in Chapter 2. Studies like this that describe the adoption and use of interventions in routine practice and the factors that influence their implementation are valuable as in order for interventions to be effective, they must be used (55). Data from these studies provide valuable additional data to data collected in even very pragmatic randomised control trials (discussed in Chapter 2) such as what happens in routine practice when interventions are made available, what actions and resources are needed for successful implementation, what actions and resources are needed in order to realise potential benefits of the intervention (94, 200).

This chapter describes the methods that have been selected to evaluate the implementation of the HeLP-Diabetes intervention within routine NHS practice. A comparison between the methods of this implementation study and that of the RCT it was conducted alongside is presented in Chapter 2.

6.3 Aims/objectives

The aim of this evaluation was to evaluate the implementation of HeLP-Diabetes into routine National Health Service (NHS) practice.

The specific research questions addressed were:

- To what extent was HeLP-Diabetes adopted by NHS services?
- To what extent was HeLP-Diabetes implemented within NHS services?
- What was the uptake of HeLP-Diabetes by patients?
- How was HeLP-Diabetes used by patients?
- Were there any factors that predicted patient use of HeLP-Diabetes?
- Were there any factors that predicted HeLP-Diabetes registration method?
- What barriers and facilitators did staff identify to the adoption and implementation of HeLP-Diabetes by NHS services?
- What barriers and facilitators did patients identify to the uptake and use of HeLP-Diabetes?

Please see the glossary on page 13 for definitions of the following terms related to the research questions: adoption, implementation, uptake and use.

6.4 Study design

The implementation of HeLP-Diabetes was evaluated using a multi-site case study approach using mixed methods. The evaluation was ongoing for a period of 26 months between July 2013 and August 2015 and was iterative in nature. As such the procedures detailed in this section were adapted and modified over the duration of the study period. Changes to the implementation plan are detailed in Chapter 7 (section 7.4) and changes to the research protocol are described below in section 6.5.7.

6.4.1 Case study design

A case study approach allows detailed, multi-faceted explorations of complex issues in their real-life settings and is a particularly useful approach when there is a need to obtain an in-depth appreciation of an issue, event or phenomenon of interest, in its real-life context (201). Case studies can be used to explain, describe or explore events or phenomena in the everyday contexts in which they occur (202). They address issues such as how interventions are being implemented and received on the ground, why one implementation strategy might be chosen over another and offer insights into gaps that exist in intervention delivery. An instrumental case study approach was selected for this study. In instrumental case studies the focus of the research is often known in advance and the study is designed around established theories or methods (203). As this study is driven by the research questions and has a theoretical underpinning (based on Normalisation Process Theory (NPT)), this type of case study was deemed most appropriate. The strengths of this design is that it allows an in-depth understanding and appreciation of a particular issue and offers thick description of a particular site (204). The selected case for study was a whole Clinical Commissioning Group (CCG) which contained 37 General Practices, a community diabetes service and a Hospital Trust.

Selecting an appropriate case is crucial to case study research. In selecting case sites the following issues should be considered. Sites should be open to allowing the research team access, which may include access to a group of individuals, the organisation, or processes. As the researcher needs to come to know the case study sites well and work cooperatively with them, selected case sites need to be hospitable to the inquiry if they are to be informative and answer the research questions (203). Access to sites is of importance and should be a key consideration (201). The CCG selected for this research study was chosen pragmatically: firstly, the CCG was familiar to the study team, it was local and therefore physical access to sites was easy; it was also known as being receptive to research and new innovations; in addition the CCG was in the process of introducing initiatives surrounding self-management and diabetes and were therefore considered to be receptive to an intervention which aimed to support patient self-management for people with diabetes.

One major feature of case study methodology is that different methods are combined with the purpose of illuminating a case from different angles. In order to develop a thorough understanding of the case, data derived from multiple sources of evidence are collected, using a range of techniques. Approaching the same issue from different angles can help develop a holistic picture of the phenomenon (201). In this evaluation a mixed methods approach which employed qualitative and quantitative approaches to explore the implementation of HeLP-Diabetes was taken.

6.4.2 Mixed methods design

The social sciences have traditionally been dominated by two opposing philosophical positions; positivism and constructionism. Positivism asserts the existence of 'social facts' that exist independently of the actions of researchers. Constructionism states that there are no 'social

facts', but rather, multiple forms of social reality, which are constructed by researchers and their participants. These issues are important, as they have implications for the methodological decisions that are made during a research study. For example, researchers who take a stance akin to positivism are concerned with objectivity and believe that the best way to investigate social phenomena is by applying the research methods adopted by the natural sciences, whilst researchers who adopt a constructionist stance query if objectivity is ever possible and instead embrace reflection upon the values, assumptions and objectives researchers bring to the research.

In terms of methodological approach, quantitative methodologies tend to fit more readily with a positivist paradigm, whilst researchers who employ qualitative methods tend to fit more comfortably with a constructionist position. Advocates of the 'incompatibility thesis' state that qualitative and quantitative methods should not be mixed, because their underlying assumptions about the nature of knowledge are incompatible (205), with the suggestion researchers should situate themselves within one philosophical paradigm. In recent years however, particularly with the growth in applied research in areas such as health or social care, where researchers are interested in practical, rather than philosophical questions (206), there has been an increase in the number of studies which have adopted a mixed method approach. Mixed method researchers identify their concerns as primarily resting with selecting the best method for answering a research question, and so rather than aligning themselves with a particular ontological perspective, work across both positivist and constructionist worldviews (207). This is known as a pragmatic approach (208) and allows researchers to draw upon the strengths of both research paradigms. Philosophical issues about the nature of knowledge are still considered by pragmatists, but are used to inform, rather than dictate, their choice of methods.

This PhD adopted a mixed methods approach with both quantitative and qualitative approaches used to describe the implementation, uptake and use of HeLP-Diabetes. The reasons that a mixed methods research design was selected for the current study were twofold. Firstly, within this thesis there were research questions that were addressed most suitably either with quantitative methods (for example: 'What was the uptake of HeLP-Diabetes by patients?') or through qualitative enquiry (for example: 'What barriers and facilitators did patients identify to the uptake and use of HeLP-Diabetes?'). Secondly, there were research questions that benefited from the combination of both approaches in order to bring together a more comprehensive account (for example: 'How was HeLP-Diabetes used by patients?').

In this thesis, quantitative and qualitative data were collected independently during the same time period of this study. The two approaches were given equal priority and were kept separate during data analysis. The two approaches were synthesised at the point of data interpretation in order to provide a more complete understanding of the research questions by obtaining and merging different but complementary data on the same topic. By comparing and synthesising the results in the discussion, conclusions and inferences could be drawn that reflected what was

learnt from illustrating quantitative results with qualitative findings and synthesising results to develop a more complete understanding of the research question (209).

6.5 Methods

6.5.1 Ethics and research governance

Ethics and research governance approval for the study design, materials and procedures were obtained from the NRES Committee East Midlands-Leicester ref: 13/EM/0033, the local Trust (Islington) and the Whittington Hospital. Letters of access were issued by the Trust for the research to be conducted with primary care healthcare professional and patients at practices in their Trust. University College London was the study sponsor.

6.5.2 Steering group

Ongoing conduct of the study was monitored and guided by a multidisciplinary project steering group made up of two academic GPs (Elizabeth Murray and Kingshuk Pal), a GP with experience of implementing e-health (Brian Fisher), a medical sociologist (Fiona Stevenson), a consultant in diabetes (Maria Barnard) a consultant cardiologist with experience of implementation within the NHS (David Patterson), a Professor of Healthcare Innovation (Carl May), two statisticians (Michael Sweeting and Mohammed Huddah), a healthcare librarian (Richard Peacock), two Health Psychologists (Susan Michie and Lucy Yardley), two Health Economists (Steve Parrott and Jinshuo Li) and two user representatives (Bindie Wood and Malcolm Knox). The steering group met quarterly to review progress, advise on issues relating to recruitment and data collection and to discuss results.

6.5.3 Recruitment

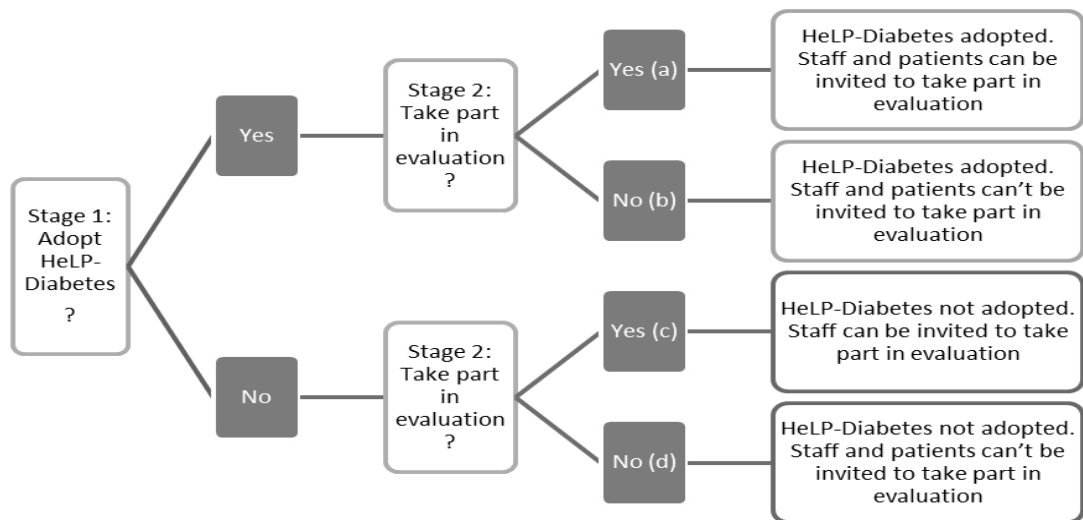
6.5.3.1 Site recruitment

The research was conducted in GP practices, community diabetes clinics and hospital based diabetes clinics within an inner city London Clinical Commissioning Group (CCG): There were 37 GP practices, a community diabetes service and one hospital running diabetes clinics within this CCG at the commencement of this study. Each individual service, practice or clinic shall be referred to as sites throughout this chapter.

As the implementation of HeLP-Diabetes was planned to take place in batches of sites at a time (see implementation plan in Chapter 5), I planned to start with sites within the CCG which were known to be research friendly, and then move on to offer HeLP-Diabetes and participation in the research to further batches of sites at a time. Research friendly sites were identified through the North and Central London Research Consortium (NoCLoR) (a partnership between Camden, Islington, Barnet, Enfield and Haringey Primary Care Trusts, Camden and Islington Mental Health and Social Care Trust, and Barnet Enfield and Haringey Mental Health Trust) which covers a large ethnically and socio-economically diverse area of London. Selection of the sites to approach first was guided by Elizabeth Murray who is a practicing GP in the CCG and a Research Engagement Consultant from NoCLoR who was responsible for promoting research

opportunities in GP practices in the CCG. The use of HeLP-Diabetes was offered to these sites free of charge for the duration of the study (26 months). Once sites decided they wanted to use HeLP-Diabetes they were asked to take part in the evaluation of the implementation study (Figure 6-1 presents the site recruitment procedure). However, as will be described in Chapter 7 (section 7.4.2), the original batch roll out of HeLP-Diabetes changed to a widespread roll out to all sites and thus participation in the research study was also offered to all sites at a similar time.

Figure 6-1 Site recruitment procedure



6.5.3.2 Staff recruitment

Staff at sites who agreed to take part in the research study were invited to take part in the research activities throughout the study period.

6.5.3.3 Patient recruitment

Once a site agreed to adopt HeLP-Diabetes they were able to offer HeLP-Diabetes to their patients. If the site had also agreed to participate in the research study eligible patients could be invited to participate.

Eligible patients were invited to participate in the research study by me or a member of staff at the site. The inclusion and exclusion criteria for patients taking part in the research study were as follows:

Inclusion criteria:

- Aged 18 or above
- Registered at a participating GP surgery, or attending a community diabetes clinic or hospital based diabetes clinic
- Have a diagnosis of type 2 diabetes

Exclusion criteria:

- Are unable to provide informed consent, e.g. due to psychosis, dementia or severe learning disabilities
- Are terminally ill (life expectancy less than 12 months),
- Are unable to use a computer due to physical or mental impairment

6.5.4 Sample

6.5.4.1 Sites

Of the 37 general practices and the community and hospital based diabetes clinics in the CCG, based on what I estimated to be achievable within the study period, I aimed to offer HeLP-Diabetes to up to 30 general practices and both the community and hospital based clinics.

6.5.4.2 Patients

As an implementation study the focus was on measuring uptake of HeLP-Diabetes when it was made available to an unselected population, therefore, a sample size calculation was not deemed appropriate for the patient uptake of HeLP-Diabetes. There were 9447 people (4.9 % of the population) with a recorded diagnosis of diabetes in Islington (210) at the time of the commencement of the study (July 2013). Globally, type 2 diabetes accounts for 90% of all diabetes cases and using these figures it was calculated that there were up to 8502 potential users of HeLP-Diabetes in Islington. However, the number of patients HeLP-Diabetes was actually made available to was dependent on the number of sites who adopted it and how many patients each site offered it to.

Sampling for patient interviews aimed to recruit a purposive sample that reflected a range of participant characteristics that were thought, based on the literature, may influence perceptions and use of an internet intervention for diabetes self-management. Two factors that may influence participant's perceptions of and engagement with the HeLP-Diabetes intervention are the digital divide and participants' experience of illness. The digital divide, as described in the introduction is the gap between those with access to technologies such as the internet and those who do not; disparities are found to be associated with age, education and income (62, 66). In order to address whether perceptions and use of the HeLP-Diabetes intervention are influenced by the digital divide participants were purposively sampled to include, older participants, a range of ethnicities, those with lower educational attainment, those without home internet access and those with basic computer skills. Another factor that may influence perceptions and use of HeLP-Diabetes is participants' experience of illness. Patients' perceptions of wellness, absence of complications and appraisal of current self-management have been found to influence attendance at DSME (37) and therefore may have similar influence on the use of an internet based intervention for self-management. Gender differences have also been observed in the prevalence of diabetes, diabetes control, self-management

(211) and accessing health information online (212). Participants were therefore sampled to include a range of self-management treatment methods, range of diabetes duration and both genders.

6.5.4.3 Staff

Sampling for staff interviews was purposive. As it was likely that different professional groups would have varying experiences with patients with type 2 diabetes and different perceptions of HeLP-Diabetes, it was important to capture the views of staff from different professional groups. As such, a range of staff including GPs, nurses, health care assistants, administrative staff, practice managers, commissioners and diabetes consultants were contacted throughout the duration of the study period and invited to take part in an interview. Healthcare professionals in practices and clinics that had agreed to adopt HeLP-Diabetes were sampled as were healthcare professional from sites that had either not adopted HeLP-Diabetes, or who had agreed to adopt it but had not offered it to any patients. This was in order to gain the perspectives of healthcare professionals from a range of sites with a range of engagement with HeLP-Diabetes. It was hoped that this may elicit a wider breadth of views on the barriers and facilitators to implementing HeLP-Diabetes within routine practice.

6.5.5 Consent

6.5.5.1 Patient consent

All patients who registered on HeLP-Diabetes had to agree to accept the terms and conditions of use which included having anonymous data related to their use recorded including the number of unique registrations, the pages accessed and the temporal use of HeLP-Diabetes.

Patients who were invited to take part in the research study were given a copy of the Patient Information Sheet (Appendix E) to read. There was an opportunity for them to discuss this and have any questions answered. They could take the information home and ask a family member to read it with them if desired.

Those interested in participating were then asked to read the Patient Consent Form (Appendix F), and agree to 10 points (including their right to withdraw without giving any reason) listed on the form and sign to participate. Participants were given a copy of the signed Consent Form to keep for their own records.

Participants who completed the Patient Consent Form were allocated a unique study ID number and asked to provide their email address, postal address and contact number for data collection purposes.

6.5.5.2 Staff consent

Staff who agreed to take part in the research study were given a copy of the Staff Information Sheet (Appendix G) to read. There was an opportunity for them to discuss this with me and for them to have any questions answered.

Those interested in participating were then asked to read a Staff Consent Form (Appendix H), and agree to 8 points (including their right to withdraw without giving any reason) listed on the form and sign to participate. Staff participants were given a copy of the signed Staff Consent Form to keep for their own records.

6.5.6 Participant data and confidentiality

Participants' names, addresses, email addresses and contact telephone numbers were stored securely in a locked filing cabinet at UCL as were completed consent forms. Patient data collected by NHS staff were either collected by me from the sites or faxed to me securely. Patient data collected at the practice were stored securely in line with procedures followed in normal clinical practice.

Participants in the study were informed that the information they gave throughout the study would be treated with the strictest confidence and used for the purpose of this research study only. The only exception where a breach of confidentiality might be required was if during an interview a participant disclosed information that I deemed potentially threatening or damaging to their health. Participants were informed that if this occasion arose I would discuss it with the participant and my duty of care would be explained before breaking confidentiality to the participants' healthcare professional. However, this situation did not arise.

6.5.7 Protocol and ethical amendments

Nine months after the commencement of recruitment, in December 2013, I submitted a substantial amendment to the Research Ethics Committee to make several changes to the protocol to increase patient recruitment to the research study (at this time only 6 patients had been recruited). Two new models of implementing HeLP-Diabetes into routine practice had been proposed: a patient registration method and a peer facilitation model, for more details see Chapter 7 (section 7.5). In light of these new models, and because at some sites it was proving very difficult for healthcare professionals to recruit patients into the research study because of limited time in consultations, I created an alternative online and automated study entry, participant information and consent procedure.

I added a question to the HeLP-Diabetes registration form as follows: *'We are asking patients to help us with some research about HeLP-Diabetes, would you be happy for us to contact you about this?'* The possible responses were 'Yes' or 'No'. The following additional information about this question was provided in a hover over. *'We (the research team who developed HeLP-Diabetes) are asking patients to help us evaluate and improve HeLP-Diabetes and the way it is offered to patients by the NHS. It won't take much time, it would be a great help to us,*

and saying yes at this stage does not commit you to anything. If you say yes you will receive an email or phone call from the HeLP-Diabetes research team'. If a patient ticked 'Yes' they would be sent an email automatically on completion of the online registration form which thanked them for their interest in the research study and gave them a link to the online study entry website which hosted online versions of the Participant Information Sheet and Patient Consent Form and a page to enter contact details. Once a participant had completed these I was sent an automatic notification that study entry had been completed and I could then contact patients about taking part in an interview. In essence this change allowed the participants to enter themselves into the research study without the need for healthcare professionals to conduct the research procedures. It was hoped that this would increase the number of participants being offered the opportunity to join the research study and reduce the burden on healthcare professionals' time.

Fourteen months after the commencement of recruitment in May 2014, I submitted an additional substantial amendment to alter the recruitment process for the patient interview part of the research study. Prior to this, using the existing procedures, I had only been successful in conducting an interview with one patient. These changes allowed me to contact any patient who had registered on HeLP-Diabetes by email and invite them to take part in an interview (apart from those patients who had explicitly opted out of being contacted about the research study by ticking 'No' to the question detailed above). This meant that I could contact all the patients who had registered on HeLP-Diabetes in the 9 months before the first substantial amendment who may not have been invited to participate in the research study because of the problems with staff not having time to recruit them. In addition I could also contact patients who had self-registered (see Chapter 7, section 7.5 for details on this).

Following the approval of this amendment I emailed all prior registered patients (and from that point onwards any newly registered patient who agreed to find out about the research study). This email gave a description of what was involved in taking part in an interview along with my contact details so any interested patients could contact me, via email or phone. When patients made contact they were emailed a copy of the Participant Information Sheet and asked to read it and confirm they were happy to take part, they could also ask any questions they had about the study, by email or phone. If they were happy to take part I arranged a date and time for interview. At the time of the interview I again checked that the patient had read and understood the Participant Information Sheet and allowed further opportunity for discussion and questions. Before the interview began consent was taken. This was taken verbally in the case of telephone interviews and was recorded on an audio recording device. Consent was taken on a paper copy of the Consent Form in the case of face-to-face interviews.

A summary of these amendments along with the patient recruitment rates throughout the duration of the study are presented in Table 6-1.

Table 6-1 Summary of patient recruitment to the research study

Strategy	Description	Dates implemented	Total number of patients registered to HeLP-Diabetes	Total number of patients completed study entry	Number of interviews conducted
Original recruitment strategy	Staff would recruit patients and take consent.	July 2013-December 2013	30	6	0
Amendment 1	Online and automated study entry, participant information and consent procedure	January 2014-May 2014	60	8	1
Amendment 2	Any patient who had registered on HeLP-Diabetes was emailed and invited to take part in an interview	June 2014-study close	115	28	14
Total			205	36	15

6.6 Data collection and analysis

A summary of the research questions, data collected and analysis methods used in this evaluation is presented in Table 6-2 and then described in more detail below.

Table 6-2 Summary of research questions, data collection methods and analysis

Research question	Data needed to describe:	Sources of data	Data analysis
To what extent was HeLP-Diabetes adopted by NHS services?	Number of diabetes services in the CCG	Communication with CCG officers	Descriptive
	Type of services	QOF data Proformas GP practice websites Staff discussions	Descriptive analysis to describe the type of practice who adopted
	Proportion of services who adopted HeLP-Diabetes	Implementation spreadsheet	Descriptive analysis to describe proportion of services that adopted
To what extent was HeLP-Diabetes implemented within NHS services?	Number of patients registered	Patient online registration forms	Descriptive analysis
	Number of patients registered correlated with length of intervention availability	Patient online registration forms and implementation spreadsheet	Correlation analysis
	How HeLP-Diabetes was implemented	Research diary	Descriptive and explanatory using NPT
What was the uptake of HeLP-Diabetes by patients?	Number of registered patients	Intervention software	Descriptive analysis
	Characteristics of	Patient online registration forms	Descriptive analysis

	registered patients		
How was HeLP-Diabetes used by patients?	Overall engagement with HeLP-Diabetes	Intervention software	Descriptive analysis
	Number of patients who used HeLP-Diabetes	Intervention software	Descriptive analysis
	Temporal use of HeLP-Diabetes	Intervention software	Descriptive analysis and graphical presentation
	Content accessed	Intervention software	Descriptive analysis
Were there any factors that predicted patient use of HeLP-Diabetes?	Characteristics of registered patients	Patient online registration forms	Univariate and multivariate multinomial logistic regression analyses
	Overall engagement with HeLP-Diabetes	Intervention software	
Were there any factors that predicted HeLP-Diabetes registration method?	Characteristics of registered patients	Patient online registration forms	Univariate and multivariate binary logistic regression analyses
	Registration method	Intervention software	
What barriers and facilitators did staff identify to the adoption and implementation of HeLP-Diabetes by NHS services?	Barriers and facilitators to NHS services uptake and use.	Interviews with staff	Qualitative thematic analysis Explanatory analysis mapping themes onto NPT
What barriers and facilitators did patients identify to the uptake and use of HeLP-Diabetes?	Barriers and facilitators to patient uptake and use.	Interviews with patients with type 2 diabetes	Qualitative thematic analysis

6.6.1 To what extent was HeLP-Diabetes adopted by NHS services?

In addressing this research question, data were collected and analysed to describe the number and type of services who adopted HeLP-Diabetes as a proportion of all the diabetes services within the CCG.

6.6.1.1 Data collection

Number of services that adopted HeLP-Diabetes

To describe the proportion of NHS services that adopted HeLP-Diabetes it was necessary to collect data to describe the total number of diabetes services within the CCG. Data on the number of services within the CCG serving patients with type 2 diabetes were gained from communication with healthcare professionals working in the CCG. Additional information about the available services was also obtained from the CCG website and from interviews with healthcare professionals who took part in the research.

Type of diabetes services

To describe the type of diabetes services within the CCG data were collected from three sources.

Data describing the GP practices within the CCG were available from the Quality and Outcomes Framework (QOF) publication provided by the Health and Social Care Information Centre (210). The Quality and Outcomes Framework (QOF) is a voluntary annual reward and incentive programme for all GP practices in England, detailing practice achievement results. Practice level data collected between April 2013 and March 2014 detailed the following information which was used to describe practices who adopted HeLP-Diabetes:

- List Size
- Number of registered patients with a diagnosis of diabetes
- Overall QOF Achievement Score (Max 107)
- The percentage of patients newly diagnosed with diabetes, on the register, in the preceding 1 April to 31 March who had a record of being referred to a structured education programme within 9 months after entry on to the diabetes register

To collect data to describe the number of patients attending the hospital and community clinics, lead contacts at each site were asked to complete a proforma (see Table 6-3). In instances where this form could not be completed, data were collected from individual services websites and discussions with commissioning officers at the CCG.

Table 6-3 Hospital and community proforma

Type	Variable	Response options
Patient numbers	Number of patients attending the clinic	Free text
	Number of patients registered with type 2 diabetes	Free text

Implementation progress

From the information collected about the number and type of diabetes services within the CCG, a spreadsheet was created which contained details of the names of GP practices, Hospital and Community clinics within the CCGs and the contact details for each service. This spreadsheet was then used to record all communication with each service regarding the adoption of HeLP-Diabetes. Specifically, it recorded:

- The number of services within the CCG that HeLP-Diabetes was offered to
- Whether and how each site responded to initial contact about HeLP-Diabetes
- If an initial meeting had been agreed, when it was, who was in attendance, what the outcome of the meeting was
- Whether the site had decided to adopt HeLP-Diabetes
- If and when a healthcare professional training session had been arranged and who was in attendance
- When the site had started registering patients on HeLP-Diabetes
- Whether a site was also taking part in the research study

6.6.1.2 Data analysis

Number of services that adopted HeLP-Diabetes

A descriptive analysis based on the implementation progress spreadsheet was conducted to describe the proportion of diabetes services within the CCG who were offered HeLP-Diabetes, agreed to adopt HeLP-Diabetes or declined adoption.

Type of services who adopted HeLP-Diabetes

A descriptive analysis was conducted to describe the type of services that adopted HeLP-Diabetes using data collected from QOF and healthcare professional completed proformas to describe: list size, number of patients with a diagnosis of diabetes, overall QOF achievement score, percentage of patients referred to diabetes structured education, number of patients with type 2 diabetes, length of time the services had access to HeLP-Diabetes.

QOF data only provides details of the number of patients with diabetes at each practice, and does not distinguish between type 1 and type 2 diabetes. Based on the World Health

Organisations' (213) estimation that 90% of all cases of diabetes are type 2 diabetes, an estimate of the prevalence of type 2 diabetes for each practice was calculated, based on the total number of patients with diabetes provided by the QOF data for 2013/4. A search of the hospital register was conducted by the lead consultant to provide the number of patients who attended diabetes clinics with type 2 diabetes. A search was also conducted by the manager of the community services for the number of patients with type 2 diabetes who were referred to the services in 2014/15.

As services adopted HeLP-Diabetes at different points during the study, the length of time each service had access to HeLP-Diabetes was calculated. From the spreadsheets that documented implementation progress, the date that a service received training and/or materials (which from that point on would allow them to offer HeLP-Diabetes to patients) was used as the date HeLP-Diabetes was available at the service. Using a round down method in Excel, with the date the study ended as the later date, it was possible to calculate the number of months each service had access to HeLP-Diabetes.

6.6.2 To what extent was HeLP-Diabetes implemented within NHS services?

In addressing this research question data were collected and analysed to describe the number of patients registered to use HeLP-Diabetes from each service as well as the way that each service implemented HeLP-Diabetes.

6.6.2.1 Data collection

Number of patients registered

To describe the number of patients that each service registered to HeLP-Diabetes, information was extracted from the online patient registration form (see Appendix I) which recorded each patient registration along with the name of the service they were referred from.

How HeLP-Diabetes was implemented

To document how HeLP-Diabetes was being implemented at each site data were recorded in a research diary throughout the duration of the study. Research diaries facilitate the research process through recording observations thoughts and questions as they happen for later use by the researcher and to stimulate reflective thinking about the research (214). They can be used to "reach the parts that other methods cannot" (215). This diary was used to record detailed information gained from informal feedback, the experiences of supporting each practice to implement HeLP-Diabetes, personal reflections, discussions with staff during training sessions, email communication and ongoing feedback to detail how the implementation was taking place including;

- how HeLP-Diabetes was responded to by staff during initial communication and at introductory practice meetings
- who was in attendance at the practice/clinic meetings
- what questions were raised by staff about HeLP-Diabetes
- the level of engagement and enthusiasm about HeLP-Diabetes from individual staff

- what the adoption decision was and how this came about
- who within the practice was responsible for implementing HeLP-Diabetes
- how this decision came about
- who attended training sessions
- how the training sessions were received
- what questions or concerns were raised during the training
- any additional support provided to the site
- email correspondences and other communication
- reflections

The notes that formed the research diary were recorded in a notebook during or directly after interactions with GP practices or diabetes clinics. These notes were then transferred to an Excel spreadsheet, which had a row for each site and columns to document the research notes including dates and locations.

6.6.2.2 Data analysis

Number of patients registered

The number of patients registered to HeLP-Diabetes from each site was used to calculate whether a site made use of HeLP-Diabetes or not. Sites who registered one or more patients to HeLP-Diabetes were classed as having used it, whereas those who didn't register any patients were classed as not using it.

The number of patients from each service that signed up to HeLP-Diabetes was described as a proportion of all eligible patients at that service. The number of patients with type 2 diabetes at each service was used as the number of eligible patients.

To determine whether the number of patients registered by each service was related to the length of time that the service had access to HeLP-Diabetes a test of correlation was conducted. As the number of patients registered was not normally distributed a Spearman's non-parametric correlation was conducted.

How HeLP-Diabetes was implemented

The research diary was firstly analysed to create a description for each site of how the implementation had taken place at each site and specifically detailing:

- which implementation models were employed at each site
- how HeLP-Diabetes was introduced to each site
- what training was given and who received it
- the staff that were involved in implementing HeLP-Diabetes
- how HeLP-Diabetes was incorporated into practices

These detailed notes kept during the implementation were analysed and statements relating to factors influencing the implementation were extracted from the spreadsheet. These statements were then coded thematically to describe the data. As the themes were emerging from the data

it was clear from previous work in this thesis with Normalisation Process Theory (NPT) (7, 97) that there was strong resonance between the statements, emergent themes, and NPT constructs. Therefore, to extend the analytical process these themes were mapped onto the constructs of NPT.

As described in detail in Chapter 4 (section 4.4.2), NPT is a theory which is concerned with the extent to which complex interventions (in particular new technologies) are implemented and embedded in healthcare and is useful in explaining observed variations in implementation processes rather than simply focusing on notions of barriers and facilitators. NPT is designed to be of practical value to researchers by enhancing understanding about the manner in which new innovations become embedded in healthcare systems (216). Table 6-4 (page 121) provides a summary of the constructs of NPT and a set of questions that have been derived from the constructs of NPT and applied to the implementation of HeLP-Diabetes.

As described in more detail on page 117, operationalising NPT requires that its abstract core constructs are translated into a working model with real-world correlates (7). These then form a basis for the conceptual work of describing, explaining, making, and testing claims about observed phenomena. In order to operationalise NPT for the purpose of evaluating the implementation of HeLP-Diabetes, questions relating to each NPT constructs (and the four sub-constructs of the Collective Action construct) were generated. The generation of questions in order to operationalise NPT has been used by several authors (8, 187). These questions were used to assist the mapping of the themes onto constructs of NPT. This method was first used for the analysis of the staff interviews within this thesis, and is therefore described in greater detail in that data analysis section (page 117).

The mapping process was iterative, moving backward and forward between the emergent themes and the NPT definitions and questions. Coding was discussed with Elizabeth Murray and Fiona Stevenson until I was satisfied all the themes had been mapped correctly onto the constructs of NPT. This analysis using NPT moved the analysis from description to a theoretically supported analysis as to whether and how HeLP-Diabetes was implemented within the practices and clinics within the CCG.

6.6.3 What was the uptake of HeLP-Diabetes by patients?

In addressing this research question, data were collected and analysed to describe the number of patients registered to HeLP-Diabetes within the CCG and their characteristics.

6.6.3.1 *Data collection*

Number of patients registered

The number of patient users of HeLP-Diabetes was recorded by HeLP-Diabetes software (Joomla). On registering, a unique ID for each patient was automatically assigned.

Characteristics of registered patients

Data to describe the characteristics of patients who registered to use HeLP-Diabetes were recorded using a form I designed which was embedded into HeLP-Diabetes. Data collected with this form included: age, gender, ethnicity, educational attainment, duration of diabetes, diabetes management style, computer skills and internet access. Full details of the data collected by this form are presented in Appendix I. The registration process required each patient to complete this online form.

6.6.3.2 Data analysis

Number of patients registered

The uptake of HeLP-Diabetes by patients was calculated by the number of unique registrations that were made to the website during the implementation period (01.07.2013-31.08.15) which were recorded on HeLP-Diabetes server and stored with a unique ID number.

Characteristics of registered patients

Descriptive statistics were conducted to describe the characteristics of patients who joined HeLP-Diabetes from data captured in the online registration form which were downloaded from HeLP-Diabetes software into Excel spreadsheets and then transferred into SPSS for analysis.

Educational attainment was a question that was introduced to the patient registration form later than the other variables, and as such there was only education data for 122 patients (59.51%). Educational attainment was introduced in order to address the research question around whether different patient registration methods could reduce the digital divide. Educational attainment was used as the proxy measure for the digital divide (as well as computer skills and ethnicity variables) as it was easier to complete on an online form than occupation and less sensitive than household income. Originally this variable was not included on the online form when patient registration to HeLP-Diabetes was completed in practices and clinics by healthcare professionals and this information could not be easily obtained by staff without patients being present to ask. This variable was therefore introduced as soon as the patient registration method had been introduced. There were also missing data for computer skills (n=21), computer access (n=19), management of diabetes (n=10), duration of diabetes (n=5) and age (n=3) due to errors in registering patients by healthcare professional in participating GP practices.

6.6.4 How was HeLP-Diabetes used by patients?

In addressing this research question, data were collected and analysed to describe the number of patients who used HeLP-Diabetes, the amount patients used HeLP-Diabetes, temporal patterns of use and HeLP-Diabetes content accessed

6.6.4.1 Data collection

Use of HeLP-Diabetes by patients

Details of all logins made (time and date) to HeLP-Diabetes and pages viewed by patients who were stored under each patient's unique ID number were automatically recorded on HeLP-Diabetes server. At the end of the study period, this data was exported from HeLP-Diabetes server into an Excel spreadsheet. Each row represented a page view and columns provided data on participant ID, date, time, and the URL of the page. A technical problem with intervention software meant that patient use of HeLP-Diabetes was only recorded from 01.01.2014, meaning that the first six months of data were not captured.

6.6.4.2 Data analysis

Overall engagement with HeLP-Diabetes

The number of days a patient visited HeLP-Diabetes following their registration date was used as the main measure of engagement with HeLP-Diabetes (alternative measures of engagement that were considered but discounted are described in Box 6-1). As each patient visited HeLP-Diabetes in order to register to use it (either alone or with assistance from a healthcare professional), only logins made on days after the date of registration were counted as actual intervention use to avoid someone who only registered (with no subsequent use) being counted as someone who used HeLP-Diabetes. This measure of engagement was calculated for each participant by counting the number of separate dates they accessed HeLP-Diabetes and discounting their date of registration.

Box 6-1 Alternative measures of engagement considered

The number of unique logins to HeLP-Diabetes was also considered as a measure of overall engagement with HeLP-Diabetes, however this measure was deemed to be less reliable as there were cases observed during testing phases where patients did not log out following the end of a visit and on their return to HeLP-Diabetes were not required to log back in, in these cases the number of visits to HeLP-Diabetes may not have been accurate.

The number of pages each patient viewed was also calculated for the data, but was not selected as the main measure of engagement as it did not reflect the frequency of intervention use. For example a patient may have looked at a hundred pages on their first visit to HeLP-Diabetes but subsequently made no further visits, in this case, using number of page views as a measure of engagement they may be classed as engaging a lot with HeLP-Diabetes, when in fact they only used it once. It is also not possible to determine whether participants looked at a lot of pages because they were engaging in a meaningful way with HeLP-Diabetes, or because they could not find what they were looking for.

Number of patients who used HeLP-Diabetes

The proportion of patients who used HeLP-Diabetes again following registration was calculated using the measure of overall engagement. Patients who did not make use of HeLP-Diabetes again following registration were classed as 'non users' whereas those who did make use of it again were classed as 'users'.

Temporal use of HeLP-Diabetes

The date and time stamps for each page view were used to determine the times of day and the days of the week that HeLP-Diabetes was used. Days of the week were calculated in Excel from the dates of each page view, and this data was imported into SPSS software where it was plotted graphically in order to give a visual representation of the temporal patterns of use.

Content accessed

The URLs of HeLP-Diabetes pages that were accessed were sorted by the frequencies with which they were requested by patients. Views of the registration pages and lost password pages were excluded as they were not classed as intervention content. The remaining URLs were sorted so that the pages viewed most frequently were at the top and those least frequently at the bottom. From this the top 20 most visited pages were described by the page title (rather than URL) and are presented with the frequency of views and the percentage of overall views each page accounted for.

6.6.5 Were there any factors that predicted patient use of HeLP-Diabetes?

In addressing this research question, data were collected and analysed to describe the use of HeLP-Diabetes by patient characteristics.

6.6.5.1 Data collection

Characteristics of registered patients

It was hypothesised that there may be differences in intervention use according to certain patient characteristics such as age, gender, educational qualifications, computer access, and computer skills have been found to be important in determining patterns of internet use, the prevalence of diabetes, diabetes control, self-management (211) and accessing health information online (212). Also of interest was ethnicity and educational status, as discussed in Chapter 1, as these have been found to be important in determining between those who have access to technologies and those who do not. Several clinical factors might also be plausibly associated with use of HeLP-Diabetes. For example, recent diagnosis of diabetes may increase patients' need for and interest in self-management information and support. As described in Chapter 7 (section 7.5), different registration models were developed throughout the study period. It was of interest to explore whether the method by which patients were registered to HeLP-Diabetes had any effect on their use of HeLP-Diabetes.

As described above, data to describe the characteristics of patients who registered to use HeLP-Diabetes were recorded by a form I designed which was embedded into HeLP-Diabetes (Appendix I).

Overall engagement with HeLP-Diabetes

As described above, data were collected by HeLP-Diabetes software which allowed a variable to be created to describe the overall level of engagement each patient had with HeLP-Diabetes.

6.6.5.2 Data analysis

Recoding variables

Four patient characteristic variables (ethnic group, duration of diabetes, education and how diabetes is managed) had to be recoded in order to provide enough cases for statistical analysis to be conducted. Appendix J presents this recoding.

Logistic regression of predictors of intervention use

Number of days using HeLP-Diabetes was selected as the measure of intervention use for the analysis. This variable was highly positively skewed, with a floor effect that meant attempts to transform the data would be unlikely to achieve normally distributed data. The distribution of the data did not improve when those who had never used HeLP-Diabetes following registration were removed (see Appendix K for histograms representing the distribution of intervention use). As a result HeLP-Diabetes use data were not suitable for use as a dependent variable in linear regression analysis. Instead, ordinal categories of intervention use were coded from number of days using HeLP-Diabetes data and a logistic regression analysis was conducted.

Dependent variable: Level of intervention use

Two categories of intervention use were coded from the total number of days visits were made to the intervention: those patients who made 0 visits to HeLP-Diabetes following registration were categorised as having made no use of HeLP-Diabetes; those participants who had visited HeLP-Diabetes on ≥ 1 day following registration were categorised as having made use of HeLP-Diabetes.

Predictor variables:

Based on the rationale provided in the data collection section, the predictors selected for inclusion in analyses predicting intervention use were:

- age (years)
- gender (male/female)
- Ethnicity (white British/other ethnicities)
- Educational qualifications (none or school leaver with no further educational qualifications/A levels or higher)
- Duration of diabetes (less than a year/1-5 years/5-10 years/more than 10 years)
- Diabetes management (lifestyle alone/tablets/insulin or other injectables)
- Computer skills (Basic/Intermediate /Advanced)
- Registration method (staff registration/ patient registration)

Computer access was not included as a predictor variable as there were too few cases of public internet access to include in the analyses.

Analyses conducted

Separate univariate and multivariate logistic regression analyses were conducted predicting intervention use.

Analyses were conducted for all complete cases of data (n=114). Ninety one cases were removed due to missing data on one or more of the following variables; age (n=3), duration of diabetes (n=5), management of diabetes (n=10), computer skills (n=21) and education (n=84, 41%).

6.6.6 Were there any factors that predicted intervention registration method?

In addressing this research question, data were collected and analysed to describe the method by which patients were registered to HeLP-Diabetes and the characteristics of patients registered by each method.

As described in more detail in Chapter 7 (section 7.5), a natural experiment arose during the research study, with practices adopting one (or a combination) of two different registration methods to register patients to HeLP-Diabetes (staff registered/patient registered). This research question explores whether certain types of patients were more or less likely to have assistance from a member of staff in registering to HeLP-Diabetes and whether staff assisting in the registration might be important for overcoming barriers to accessing internet interventions for some groups.

6.6.6.1 Data collection

Characteristics of registered patients

Data to describe the characteristics of patients who registered to use HeLP-Diabetes were recorded by a form I designed which was embedded into HeLP-Diabetes (see Appendix I). Data were collected to describe the age, gender, educational qualifications, computer access and skills of patients as these have been found important in patterns of internet use (211) and accessing health information online (212). Also of interest was ethnicity and educational status, as discussed in Chapter 1, these have been found to be important in the digital divide between those who have access to technologies and those who do not.

Registration methods

Patient registration data was recorded and stored separately for each registration method by the use of separate registration URLs. This allowed the number of unique registrations to HeLP-Diabetes to be analysed by the different registration methods as well as collectively.

6.6.6.2 Data analysis

Recoding variables

As above, four patient characteristic variables (ethnic group, duration of diabetes, education and how diabetes is managed) had to be recoded in order to provide enough cases for statistical analysis to be conducted. Appendix J presents this recoding.

Logistic regression of predictors of registration method

In order to explore whether any patient characteristics could predict which registration method was used to register to HeLP-Diabetes, a logistic regression was conducted.

Dependent variable: Registration method:

The way that patients were registered to use HeLP-Diabetes was recorded by the URL used for registration and was coded as either 'healthcare professional registered' or 'self-registered'. This categorical variable was selected as the dependent variable.

Predictor variables:

The predictors selected for inclusion in analyses predicting registration method were therefore:

- age (years)
- gender (male/female)
- Ethnicity (white British/other ethnicities)
- Educational qualifications (none or school leaver with no further educational qualifications/A levels or higher) Computer skills (Basic/Intermediate/Advanced) As above, computer access was not included as a predictor variable as there were too few cases of public internet access to include in the analyses.

Analyses conducted:

Separate univariate and multivariate logistic regression analyses were conducted predicting registration method. Analyses were conducted for all complete cases of data (n=117). Eighty eight cases were removed due to missing data on one or more of the following variables; age (n=3), computer skills (n=21) and education (n=84, 41%).

6.6.7 What barriers and facilitators did staff identify to the adoption and implementation of HeLP-Diabetes by NHS services?

6.6.7.1 Data collection

Qualitative data was collected to explain the adoption, implementation and use of HeLP-Diabetes by NHS services and healthcare professional.

Interviews were conducted face to face, generally in the health professionals' consulting rooms. Semi-structured interviews were selected as the most appropriate type of interview to conduct (see discussion on page 123 for justification). All interviews were one to one and lasted for between 30 minutes and an hour, with the exception of one focus group that I conducted with

three Nurses and a Health Care Assistant from the same general practice. This focus group arose opportunistically from an offer from one of the nurses to invite her colleagues to join in the interview I had arranged with her. This focus group took place in the Nurse's consultation room over their lunch break.

All healthcare professional participants completed a data collection form to describe demographic characteristics, professional characteristics and internet experience (see Appendix L for full details of the data collected). All interviews, with participants' consent, were audio recorded using a digital voice recorder.

The topic guides for the staff interviews were informed by Normalisation Process Theory (NPT) (7, 97), a theory which identifies factors that promote and inhibit the routine incorporation of complex interventions into everyday practice and offers explanations as to how interventions work (or fail to) in routine practice, looking not only at early implementation, but beyond this to the point where an intervention becomes so embedded into routine practice that it 'disappears' from view (i.e., it is normalised) (see Chapter 4, section 4.4.2 for a detailed description of this theory). The main concepts of NPT: collective action, coherence, collective action and reflexive monitoring (see Table 4-2 page 77, for definitions of these constructs) were used as a guide to develop questions that focused on: the way that HeLP-Diabetes was being conceptualised by staff; the work that was being conducted at sites to incorporate HeLP-Diabetes into practice, how well HeLP-Diabetes was being embedded and how staff appraised and reflected upon the implementation. These questions were also designed to elicit data on the barriers and facilitators to the implementation.

The topic guide evolved and developed over time in response to themes that emerged in individual interviews (see Appendix M for the original staff' topic guide). Topic guides were also tailored to specific staff groups; e.g. the questions asked to GPs, receptionists and commissioners were tailored to reflect the different roles these groups had in implementing HeLP-Diabetes and the differences in the ways they may have worked with it.

6.6.7.2 Data analysis

Data collection and analysis were conducted concurrently, with analysis starting as soon as early interviews were transcribed. Audio recordings were transcribed verbatim by Way With Words transcription service and I checked each one against the original interview recordings for accuracy and to anonymise the transcripts by removing names of people and places. Corrected transcripts were loaded into Atlas.ti software ready for coding.

A two stage process to the analysis was taken whereby data were firstly analysed thematically and then the emergent themes were mapped onto the constructs of Normalisation Process Theory (NPT). This two stage method has been utilised by other authors exploring the uptake of interpreting services by GPs (216), and nurse's experiences and views of home telecare services (217). The strength of the NPT framework to interpret the data is that it enhances

understanding about the implementation interventions, in this case HeLP-Diabetes and provides a conceptual tool that moves the analysis beyond description. However, there are concerns about applying pre-determined conceptual frameworks to data and the risk of forcing data into pre-determined categories (218). Employing this two stage process enabled the emergent themes from the interviews to be data driven (although it is acknowledged that the use of the NPT to develop interview topic guides influenced the emergent themes), and meant that the robustness of NPT in explaining the data could be tested against the themes during this mapping process. This process ensured that any data that could not be mapped on to NPT would still be captured and would form the basis of a critique of the scope of NPT in explaining this data.

Firstly, each transcript was read and summaries of the main themes and impressions from each transcript were written to generate a feeling for each of the interviews and as a quick reference point for each interview. The themes that were identified in this initial analysis were discussed with Elizabeth Murray and Fiona Stevenson who had read all 21 corrected interview transcripts. In order to obtain other interpretations of the data from a range of perspectives these themes were presented to the project's multidisciplinary steering group where the themes were discussed in terms of how they could inform the ongoing project. In addition to the steering group, a data clinic was held in order to explore the rigor and reliability of the themes that were emerging from the initial thematic analysis. Qualitative researchers from a range of disciplines were invited from the department of Primary Care and Population Health to attend this clinic. Eight researchers from sociology, psychology and epidemiology research disciplines attended the data clinic in April 2015. Prior to the clinic an interview transcript was selected for circulation to the attendees. This particular transcript was a HCP interview with a GP which had been chosen because it included data on nearly all of the themes that were emerging from the staff data set as a whole. The transcript was independently read by each researcher and they were asked to identify themes for discussion at the clinic.

An introduction to the research questions was provided to the group at the beginning of the clinic and then each member was asked to give their general impressions of the interview transcript and briefly describe any themes that they had identified. Following this, a more focussed discussion was held with the whole group that centred on the themes that emerged from the individual impressions. These discussions brought to light alternative view points and interpretations of themes that had already been identified, as well as suggestions for new themes to explore and additional questions that could be asked in future interviews.

All discussions in the data clinic were audio recorded with the consent of the participants and this recording was drawn upon several times during the analysis phase to keep the discussions in mind. Notes from the data clinic were made under the following headings: Other questions/issues to explore in further interviews; interpretations of themes already identified; and new themes to explore. Following the data clinic, all interview transcripts were reread and

the themes were refined and additional ones created. Once all the transcripts had been read and initial themes had been developed the second stage of analysis began using NPT.

Firstly, questions relating to each of the constructs of NPT were generated in order to apply NPT to the context of the implementation of HeLP-Diabetes. Although NPT provides general definitions of the constructs, the study-specific meaning of the constructs is not predetermined and can only be determined by the specifics of each study setting including the staff involved, the nature of their work, the innovation being introduced, the immediate clinical context, and the wider organisational context in which implementation is taking place (216). May and Finch describe the need to operationalise NPT by translating its abstract core constructs into a working model with real-world correlates which allows researchers to undertake the conceptual work of describing, explaining, making, and testing claims about observed phenomena (7).

Creating questions of the NPT constructs as applied to the implementation of HeLP-Diabetes increased confidence in the fact that data from the HCP interviews were not being forced into predetermined categories but instead the analysis was benefitting from NPT as a conceptual framework to enhance the understanding of the issues arising from the data.

The questions developed to apply to the NPT constructs for the staff interviews developed naturally from the general descriptions of the constructs provided in the literature and the NPT online manual and toolkit which breaks the constructs down into a series of general questions that can be applied to individual settings and contexts (191). Once developed, these questions were talked through with Elizabeth Murray and Fiona Stevenson and at a meeting with two implementation researchers familiar with NPT (Rosa Lau and Susanna Dowrick). In these meetings the questions were discussed and refined. Table 6-4 presents the definitions of the NPT constructs and the questions developed to apply NPT to the implementation of HeLP-Diabetes.

Originally it was planned that data would be mapped to the sub-constructs of NPT; however it became clear during the coding of the first few transcripts that choosing between sub-constructs was problematic as there was often a lot of overlap and uncertainty. The decision was therefore made to map themes to the main NPT constructs of coherence, cognitive participation, and reflexive monitoring. However, for the construct of collective action mapping remained at the sub-construct level (interactional workability, relational integration, skill set workability, contextual integration) as the collective action sub-constructs are the most well defined and widely used aspect of NPT and the distinction between these for these data appeared more pronounced. The collective action construct was also the basis for the original Normalisation Process Model (NPM) and has been used widely by other researchers to explain their implementation research findings (see (219) for a review of studies that have applied NPT and NPM) and has been applied specifically by authors to explain the implementation of e-health interventions (189, 220). As such, mapping to the sub-constructs of collective action allowed for the possibility of comparing study's findings with other research.

The method of mapping themes on to NPT suggested by Macfarlane and O'Reilly-de Brun (216) was used to guide this process. This involved using my understanding of the themes and the NPT constructs and determining ways in which they related to each other. This was achieved through suspending my understanding of the themes as they were formulated in the thematic analysis and applying the questions related to the constructs of NPT to them. Where the themes appeared to be related to constructs of NPT, illustrative quotes from the raw data were drawn upon to demonstrate this relationship. Of equal importance in this process was the identification of themes that did not map neatly on to the constructs of NPT. These data were used to critique the applicability of NPT for explaining these data.

Table 6-4 Definitions and questions relating to each of the constructs of NPT

Construct/sub construct	Definition*	Questions that NPT poses of the implementation of HeLP-Diabetes?
Coherence	The sense-making work that people do individually and collectively when they are faced with the problem of operationalizing some set of practices	How is HeLP-Diabetes conceptualised by staff? What is the work of implementing HeLP-Diabetes?
Cognitive participation	The relational work that people do to build and sustain a community of practice around a new technology or complex intervention	How do staff come to engage with HeLP-Diabetes? How do they decide on engagement and the purpose that it serves?
Collective action	The operational work that people do to enact a set of practices	How do staff enact HeLP-Diabetes? How are their activities structured and constrained?
<i>Interactional workability</i>	The interactional work that people do with each other, with artefacts, and with other elements of a set of practices, when they seek to operationalize them in everyday settings	How does HeLP-Diabetes affect interactions between people and practices?
<i>Relational Integration</i>	The knowledge work that people do to build accountability and maintain confidence in a set of practices and in each other as they use them	How does a HeLP-Diabetes relate to existing knowledge and relationships?
<i>Skill set workability</i>	The allocation work that underpins the division of labour that is built up around a set of practices as they are operationalized in the real world	How is the current division of labour affected by HeLP-Diabetes?
<i>Contextual Integration</i>	The resource work. Managing a set of practices through the	How does HeLP-Diabetes relate to the organisation in

	allocation of different kinds of resources and the execution of protocols, policies and procedures	which it is set?
Reflexive monitoring	The appraisal work that people do to assess and understand the ways that a new set of practices affect them and others around them	How do staff appraise HeLP-Diabetes? What are the effects of appraisal? How are they mediated?

*Definitions taken from the online NPT toolkit (191)

6.6.8 What barriers and facilitators did patients identify to the uptake and use of HeLP-Diabetes?

6.6.8.1 Data collection

Qualitative data were collected to explain the adoption and use of HeLP-Diabetes by NHS patients and to identify barriers and facilitators to initial and ongoing use.

All eligible patients were contacted to participate in interviews. As described earlier, recruitment to interviews took place purposively in order to capture the views of patients from a range of ethnic backgrounds, ages, educational attainment, length of time with diabetes, treatment types, and associated complications as well as experience with computers and the internet and use of HeLP-Diabetes. Interviews were conducted with all patients who agreed to be contacted about participation.

As the implementation of HeLP-Diabetes was an iterative process and adoption at practices happened at different times throughout the study period, recruitment of patients took place on several occasions during the study period in order to recruit patients from a range of practices/clinics, and not just from those sites who were first to adopt HeLP-Diabetes.

Interviews with patients were conducted both face to face and over the telephone. All interviews were one to one and lasted approximately 30 minutes to an hour. Data were collected to describe the characteristics, diabetes related information and internet use and experience (see Appendix H for details of variables collected by HeLP-Diabetes registration form) of patient interview participants. All interviews, with participants' consent, were audio recorded using a digital voice recorder.

The topic guides for patient interviews explored themes including; experience with having diabetes, self-management, current NHS care, information seeking and use, the use of the internet, the introduction of HeLP-Diabetes, use (or non-use) of HeLP-Diabetes, barriers and facilitators to signing-up and use, and recommendations for improvement of HeLP-Diabetes and the way it was introduced to them. An iterative approach was taken, where the interview data helped develop and refine the topic guide and informed analysis based on emerging ideas (for original topic guide see Appendix N).

The implementation of the HeLP-Diabetes intervention into routine practice took place from July 2013. Interviews were conducted with patient users of HeLP-Diabetes between April 2014 and February 2015, therefore the interview participants varied in length of exposure to the HeLP-Diabetes website and recency of visit.

Given the aim of this study was to explore patients' experience with and perceptions of an internet based self-management intervention for people with type 2 diabetes, a qualitative study

design using semi structured interviews was employed. Semi structured interviews allow the researcher to pose specific questions in order to address pre-defined research questions, at the same time giving the interviewee the opportunity to provide open responses in their own words. They allow for the discovery or elaboration of information that is important to participants but may not have previously been thought of as pertinent by the research team (221). Moreover they facilitate individual experiences of having diabetes, self-management and accessing DSME which may influence the perception of and use of HeLP-Diabetes. Thus semi-structured interviews were selected over in-depth interviews which attempt to avoid any preconceived ideas and are led by the participants agenda to a greater extent (221). Semi-structured interviews were selected over more consensus building approaches such as focus groups. Semi-structured interviews with multiple participants allow a range of perspectives to be captured and differences and similarities between accounts to be explored. As the way in which people engaged with and used HeLP-Diabetes as part of their daily lives was of interest, as were factors related to non-use and non-engagement with HeLP-Diabetes, semi-structured interviews provided the most appropriate way of exploring these issues. An alternative approach, used during the development phase of HeLP-Diabetes, would have been to observe participant use of HeLP-Diabetes and conduct 'think aloud' interviews. However, as I was interested in how participants would actually make use of HeLP-Diabetes by themselves in their own time without the presence of a researcher which may influence how they used the intervention, this approach was deemed unsuitable.

Semi-structured interviews were initially conducted over the telephone. Telephone interviews are increasingly used in health services research as they allow a geographically wider range of participants to participate, can be more time and cost effective compared to face to face interviews, may be more acceptable to participants because they take less time to complete (222) and place less burden on participants compared to face to face interviews where travel and other arrangements may have to be made. As has been shown with accessing face to face DSME, accessibility issues are a barrier to attendance for people with type 2 diabetes who have caring responsibilities, who work or who have other physical health problems. It was hoped that by conducting interviews over the telephone the range of participants able to take part would be optimised. The first eight (of 15) interviews were conducted over the telephone with participants. Although the majority of these interviews produced valuable data, there were some cases where I felt the data were a little sparse and there were topics that had not been elaborated on as much as I had hoped and which I wanted to explore in more depth. In order to test out whether the data were sparse in these cases because of the topic area or because of the data collection method, I conducted the rest of the interviews face to face with participants. It has been suggested that responses to telephone interviews may be shorter with less information divulged than might be during a face to face interview where visual cues are present to aide probing and to encourage the participant to continue with answers. Factors such as perceived confidentiality and the relative impersonality of telephone interaction may also impact on the nature and length of the discussions (222). After conducting all of the interviews I felt that the ones conducted face to face did indeed provided richer data and allowed me to explore issues

in more depth than the telephone interviews had, suggesting that the method of data collection, rather than the topics I was exploring had contributed to the less rich data collected in the telephone interviews.

The face to face interviews were conducted either at UCL or at the participant's General Practice according to the participant's preference. At the start of all interviews, my role as a researcher from UCL was reiterated before the commencement of the interview. Socially desirable responses to interview questions, whereby participants may distort their answers to questions in order to present themselves as having more socially desirable or respectable characteristics or behavioural histories (223), are a concern in qualitative research. As the professional background of the interviewer has been found to influence interviewing (224, 225), I felt it was important to clarify my role, especially in the face to face interviews which were conducted in an environment (GP practices) where participants' may be used to a different kind of interview with healthcare professionals. As I would be asking question about participants' diabetes, self-management, and their perceptions of healthcare, I felt it important to remind participants that; I was not part of their healthcare team, I was not affiliated with the GP practice or NHS, that I did not have a clinical background and that the purpose of the interviews was to elicit views on the HeLP-Diabetes intervention.

My role as a researcher who had worked on the development of the HeLP-Diabetes intervention was also made clear to participants. Although my role as a developer of HeLP-Diabetes had the potential to elicit socially desirable responses to questions about it, this did not appear to be the case. Many participants did not seem to make the connection that HeLP-Diabetes that they had been provided with through the NHS had been developed at UCL (despite being told again at the beginning of the interviews) with many perceiving it to have been developed by the NHS. Before interviews, participants were informed that the findings would be used to develop and improve HeLP-Diabetes and the way that it was offered to patients; thus giving participants' permission to be critical or negative. Indeed, many participants' were very forthcoming about their non-engagement with HeLP-Diabetes and with their perceptions (good and bad) of HeLP-Diabetes, suggesting that participants felt comfortable giving honest accounts.

6.6.8.2 Data analysis

Unlike the staff interview data that lent itself well to a two phase approach to data analysis, with a secondary analysis of the data being conducted through an NPT lens, data from the patient interviews did not. There was limited data on the 'work' involved in implementing HeLP-Diabetes in the patient interviews which made it difficult to develop definitions using the categories outlined in NPT. It was therefore decided not to pursue this line of analysis with the patient interviews, and instead the data were analysed using a detailed thematic analysis (226). This process began by familiarisation with the data by reading the transcripts and listening to the interview recordings several times and noting down areas of interest and potential codes. Initial codes were generated for as much as the data as possible and applied systematically to the corresponding text in the transcripts using Atlas.ti software to assist with the organisation of

the data. Once the entire dataset was coded, data extracts were collated under each of these codes. The codes were then organised into broader themes and sub-themes (see Chapter 10). All transcripts were read by Elizabeth Murray and Fiona Stevenson, and discussions around my coding of the data were held with them. This helped refine the codes and resulted in additional themes. An inductive approach to analysis was taken with themes directly linked to the data (i.e. data-driven). Themes were reviewed by re-examining corresponding data extracts and uncoded, outlying data were examined for disconfirming evidence. An iterative process was taken, where the transcripts were revisited throughout the process of coding, theme allocation and written presentation.

7 CHAPTER 7: METHODS 3: CHANGES TO THE HELP-DIABETES IMPLEMENTATION PLAN

7.1 Chapter summary

This chapter describes how the implementation took place in the case study CCG. Firstly a description of the CCG is presented detailing the CCG as a whole and the diabetes services provided within it. Secondly, the changes that occurred to the original implementation plan (described in Chapter 5) since its introduction into practice are described. Finally, all the strategies that were employed to implement HeLP-Diabetes into practice are brought together and presented graphically as the final implementation plan to implement HeLP-Diabetes into the CCG.

7.2 Introduction

Grol, Wensing and Eccles (2) describe the evaluation of implementation efforts as an ideally continuous process rather than the final stage of an implementation project, as such the changes to the implementation plan described below were made iteratively during the implementation period (July 2013-August 2015), in response to feedback from staff, emerging barriers and facilitators and attempts to problem solve.

Adaptive implementation methodologies hold that the implementation of new innovations can be improved by processes that enable initial plans to be adapted to unfolding events and decisions (227). Adaptive implementation plans allow research sites that are not responding to an initial implementation plan to receive an augmented version (228). Due to the large number of potential barriers to the implementation of HeLP-Diabetes that may be site specific, an adaptive approach to implementation was deemed most appropriate. As this research is concerned with addressing how best to implement an intervention in real world settings, it was also important not to persist with an implementation plan that was proving ineffective, and instead to identify solutions that could facilitate the implementation.

Drawing from principles of action research, which is an iterative process in which researchers and practitioners act together in the context of an identified problem to discover and effect positive change (229), problems that arose with the implementation plan were addressed. Action research involves participatory, pragmatic, democratic processes to explain social situations and implement change. Although not true action research, the concepts of collaborative working between researchers and those intended users of interventions and iterative problem solving were applied to the HeLP-Diabetes implementation plan. Working collaboratively with those tasked with implementing HeLP-Diabetes in practice enabled the implementation plan to be tailored to the specific needs that arose at different sites. This also meant that effective strategies that were developed in collaboration at one site could be applied at other sites with the aim of developing a refined and effective overall implementation plan.

In this Chapter, the implementation context, adjustments that were made to the implementation plan, problems identified with the implementation plan and strategies employed to address them are presented.

7.3 Implementation context

7.3.1 Islington CCG and the wider NHS

The borough of Islington is the most densely populated in the United Kingdom, with just under a quarter of a million people (230) living in an area under six square miles, which as the CCG website reports, brings unique challenges to healthcare (231). The area of London that the CCG serves is multi-ethnic, with more than half of residents being of non White British (230). Islington is the fifth most deprived Borough in London and 14th most deprived in England. Islington has the highest percentage (6.4%) of people reporting they are in bad or very bad health among London boroughs and it is higher than both the London and England averages (5.0% and 5.5% respectively) with 24% of households having a person with a long term health problem or disability (230). It is estimated that 9,747 have a diagnosis of diabetes, with many more living with the condition undiagnosed (232).

Islington CCG established an Integrated Care programme in 2013 to develop new ways of commissioning and delivering healthcare. This programme involved (amongst others) changes to the management of long term conditions, including new pathways of care for people with long term conditions. For diabetes care, the aims of this approach were to enhance the management of diabetes and those at risk of developing diabetes in primary care, and increase the number of people who are able to self-manage their health.

During the period of time that HeLP-Diabetes was being implemented into Islington CCG (July 2013- August 2015), several major changes were taking place in the way that diabetes care was provided. The CCG was beginning the early stages of implementing the Integrated Care diabetes care pathway (described above). In addition, in February 2013 the diabetes locally commissioned service (LCS) was launched. The aim was to provide every person with diabetes with an enhanced care plan, created through an extended collaborative consultation with their clinician, who had been trained in motivational interviewing, coaching and behavioural change. The LCS also offered identification of patients at high risk of developing diabetes with proactive follow up and recall for annual review; regular review of patients with history of gestational diabetes; implementation of enhanced care planning with a “Year of Care” (233) approach (an approach which uses care planning as a central component to drive a proactive process of care designed to improve patient involvement, provide a more personalised approach and support self-management of diabetes and other long terms conditions) to all patients with diagnosed diabetes; and a medicines management audit around metformin prescribing. It aimed to provide every GP and practice nurse in Islington with Year of Care (YOC) training by April 2016.

HeLP-Diabetes was designed as a service to support people with type 2 diabetes to self-manage their condition, and as such, it appeared to have real synergy with the priorities of Islington CCG, a borough that was also demonstrating their capacity to implement new innovations into existing practice. It was therefore hoped that this would be an ideal case study for the implementation of HeLP-Diabetes. However, the implementation of HeLP-Diabetes took place between July 2013 and August 2015, a time of great flux in the NHS due to the Health and Social Care Act 2012. The Guardian described this time as *“the biggest reorganisation of the NHS in England since it was created”* (234). The changes brought about by this act, including the abolition of primary care trusts and the establishment of new statutory bodies came into effect on 1 April 2013 in Islington (235), with HeLP-Diabetes being made available in July 2013. In recent years NHS general practice has become increasingly under strain, and concerns have increased that primary care is overwhelmed (236) with the NHS being in the grip of the biggest crisis in its history (237). Complexity in patient cases, reduced workforces, reduced primary care budgets, an increase in resources being spent on contractual and regulatory requirements such as the Quality and Outcomes Framework (QOF) and enhanced services, GP time being spent on duties other than care giving, and political and public pressure on GPs and practices for increased access to GPs over extended hours and seven day working, have all contributed to a fatigued system (236-239). This is exemplified by the closure of many GP practices. In 2014 there were 7,875 general practices in England, a decrease of 87 (1.1%) on 2013 (240). Since April 2013, it was reported that 22 London GP practices have closed (241). Three of these London practices were based in Islington CCG which closed down during the implementation of HeLP-Diabetes (July 2013-August 2015) (as reported by the Islington CCG Clinical Commissioning Officer) placing additional pressure on remaining local NHS services. These factors all contributed to a very strained NHS context within which to introduce a new intervention.

In addition there was evidence during this time that referrals to diabetes education were not optimally delivered. Although patient self-management of diabetes was a key NHS priority, during the time of the implementation of HeLP-Diabetes, calls were made for GPs to do more to ensure that patients have access to diabetes education. In the first all party parliamentary meeting for diabetes in June 2014, experts called for GPs to do more to refer patients to diabetes education services. The report suggests that reasons for the lack of referrals by GPs include: healthcare professionals not valuing, or being unaware of, the benefits of education programmes; GPs being too busy to refer people to education; and the very few incentives to encourage healthcare professionals to develop services in this way (242).

7.3.2 Diabetes services in Islington

Within the CCG there were three main tiers of diabetes services: primary care, intermediate care and secondary care. Primary care services were delivered by staff in GP practices. Intermediate care is provided to those patients with enhanced clinical need and was delivered through the community based intermediate diabetes services located in a Primary Care Centre. Secondary care for diabetes was a consultant led specialist multi-disciplinary service, delivered

through hospital based clinics and aimed at patients with complex needs requiring specialist input.

7.3.2.1 Primary care

In Islington there were 37 GP practices at the time the implementation began, however, as described earlier, during the course of the implementation, three of these closed down, with their patient registers being absorbed by other GP practices within the CCG. Within general practice, a range of staff contribute towards the care of people with diabetes including GPs, practice nurses, healthcare assistants and practice managers, administrators and reception staff. The majority (n=29) of GP practices in Islington were group practices, run by several GPs. There were fewer (n=8) single-handed practices, with just one GP in charge. All of the practices that closed down during the implementation period were single-handed practices.

Within general practice, certain diabetes care processes, recommended by the National Institute for Health and Care Excellence (NICE) for diabetes are incentivised through the Quality and Outcomes Framework (QOF) (243). The QOF is a voluntary incentive scheme for GP practices in the UK, rewarding them for how well they care for their patients, and helping them target resources for where they are most needed. It consists of groups of indicators against which practices score points according to their level of achievement. The diabetes indicators include ensuring patients receive a number of clinical checks and tests as well as being referred to a structured education programme (there are no points awarded for the number of patients who actually attend structured education).

7.3.2.2 Intermediate care

The diabetes intermediate care service in Islington is comprised of a team of diabetes specialist nurses, diabetes specialist dietitians, diabetes psychologists with support from a diabetes consultant, based primarily in one of the Primary Care Centres in the borough. Group education and self-management are key components of the service. The intermediate service runs DESMOND (diabetes education and self-management for ongoing and newly diagnosed) (32) for people with type 2 diabetes. Also available to patients is Co-creating Health (244), a seven week self-management programme. Co-creating Health aims to help participants build skills, knowledge and the self-belief needed to effectively manage their diabetes.

7.3.2.3 Secondary care

Diabetes secondary care is located primarily in hospitals, with the Whittington being the main hospital to serve the borough of Islington, although Islington patients may attend clinics at other hospitals in neighbouring boroughs. A team comprised largely of diabetes specialist nurses, consultants and junior doctors at the Whittington hospital run diabetic clinics which provide

services including: outpatient clinics, specialist paediatric endocrinology clinics, follow-up phone clinics and self-management programmes for patients with type 2 diabetes.

7.4 Adjustment to the implementation plan

In this section changes that were made to the implementation plan throughout the course of the implementation and the reasons for these changes are described.

7.4.1 Changes to target group and setting

Initially, the plan had focused on General Practice only. However, during an early steering group meeting, it was decided that in order to fully integrate HeLP-Diabetes into routine NHS care it should be made available to patients through a range of settings. The target settings were therefore extended to include hospital and community diabetes clinics (as well as GP practices). In making HeLP-Diabetes available across settings it was hoped that this would: act as a strategy to raise awareness of HeLP-Diabetes, with patients being exposed to HeLP-Diabetes in the GP practice and hospital and community clinics; raise the credibility of HeLP-Diabetes as an NHS service being promoted throughout the range of services that provide diabetes care; increase the communication around HeLP-Diabetes between services and promote a buzz which would encourage more practices and clinics to adopt HeLP-Diabetes.

7.4.2 Changes to staged roll out

Through networking, a slot was made available for HeLP-Diabetes to be presented at one of the CCG's diabetes steering group board meetings in December 2012 before the implementation had begun in the borough. This was a very important meeting to raise awareness of HeLP-Diabetes as it was attended by Commissioning Officers, Consultants from the local hospitals, local GP's with a specialist interest in diabetes, specialist Nurses, Practice Managers and patient representatives. The outcome of this meeting was extremely positive with the CCG offering to support and promote the roll out of HeLP-Diabetes across the borough. The involvement from the CCG changed the planned batch roll out of HeLP-Diabetes as the CCG wanted HeLP-Diabetes to be made available to as many practices as possible as quickly as possible. The justification of this from the CCG point of view was that if they were to endorse HeLP-Diabetes as a service to its patients, it had to be available to all patients and not just those from a few practices. The implications of this were that rather than targeting a few practices at once, the commissioning officer from the CCG sent a blanket email to all practices in the borough introducing HeLP-Diabetes and urging all GPs and Practice Managers to set up practice meetings to find out more.

As discussed in the systematic review in Chapter 3 (section **Error! Reference source not found.**), the identification and engagement of a key figure or opinion leader is a well-recognised strategy for facilitating implementation. Having the support and influence of the Commissioning Officer from the beginning of the implementation process was highly beneficial in terms of providing access to the target setting, raising awareness of HeLP-Diabetes throughout the

borough and enhancing credibility. Hence, overall, I welcomed this involvement, although it did mean that I lost control of the process.

7.4.3 Changes to facilitating integration within practices

Initially, when a batch roll out of HeLP-Diabetes to practices and clinics was planned it was intended that I would provide support to individual practices at the start of implementation. It was envisaged that I would work closely with each practice, training staff and demonstrating how to register patients. It was planned that I would spend a few weeks within each practice helping to register patients while staff observed and learnt the process. It was then hoped that the staff would feel confident and able to take over this role and register all future patients. This strategy was employed in two practices, however, when all practices were offered HeLP-Diabetes at once, it became impossible to offer this service to all practices. Therefore, this strategy continued in the practices that had already been offered it, but it was not subsequently offered to any further practices.

7.5 Addressing barriers to implementing HeLP-Diabetes

Throughout the implementation phase, barriers to the implementation were identified by staff within practices and clinics through informal discussions and qualitative interviews. As an iterative study, in cases where it was possible, these barriers were tackled by making adjustments to the implementation plan. Below is a description of the barriers reported by staff towards the implementation and the adjustments made to the implementation plan and/or strategies employed to address these. These are summarised in Table 7-1.

Table 7-1 Summary of the problems encountered during the implementation and the adjustments made to the implementation plan to address them

Barrier	Adjustment/Strategy
Constraints on time within consultations	Reduced the time needed to offer HeLP-Diabetes to patients
Workload	Alternative patient registration methods created <ul style="list-style-type: none"> • Patient registration method • PDF leaflets • Paper registration forms • Peer supported registration
Staff forgetting to recommend HeLP-Diabetes	Integrating with practice templates to prompt recommendations
Access to patient medical records perceived as controversial	Removal of feature
Lack of patient awareness of HeLP-Diabetes	Additional patient focussed advertising: <ul style="list-style-type: none"> • TV screen adverts • Patient self-management groups • Diabetes UK events • Practice newsletters • Mail out
Lack of staff awareness of HeLP-Diabetes	Additional staff focussed advertising: <ul style="list-style-type: none"> • Locally Enhanced Services • Map of medicine • Staff education events • GP bulletin.

7.5.1 Barrier: Appointment time

Several consistent barriers to implementation were observed across practices during the implementation process. Two interrelated barriers were time and workload. Practice staff stated they did not have enough staff time or staff availability to conduct the patient registration appointments. To tackle this barrier, several alternative implementation strategies were devised. These were offered and introduced to sites pragmatically based on discussions with practice staff and took into account what staff believed would work best in their services.

Strategy: Reducing time needed to offer patients the intervention

As described in Chapter 2 (page 34), HeLP-Diabetes was designed to be offered to patients by a member of staff who would provide facilitation to use it. It was initially estimated that it would take staff about 10 minutes to sign patients up to HeLP-Diabetes and an additional 30 minutes to take them through the website and help them to complete an activity on the site. However, it was identified by staff during initial practice meetings, that 40 minutes per patient would be unworkable in current GP practice. Subsequently, the registration process was streamlined so that it could be completed in 5 minutes and the facilitation aspect of the appointment (showing patients the website and taking them through an activity) was made into an optional (but encouraged) extra.

7.5.2 Barrier: Workload

As HeLP-Diabetes was being offered as a NHS service, patients needed to complete an online registration form and create a username and password to access it (see page 34). The need for patients to be registered by staff remained a barrier to offering HeLP-Diabetes to patients in many practices even after the reduced time of the registration and facilitation appointments. Staff cited competing demands on their workloads as reasons for not being able to register patients. In response to this several alternative methods of patient registration were devised and offered to practices.

Strategy: Alternative patient registration methods

Patient registration method:

A separate registration URL was created so that patients could register themselves on HeLP-Diabetes. Staff in practices using this model would identify suitable patients to give information leaflets to. These leaflets included details of how to access the HeLP-Diabetes online registration page and contained an individual access code (see Appendix O). These codes allowed patients access to the website and ensured that only the intended patient could access the site. Each code was linked back to the practice/clinic that gave the patients the leaflets so that the effectiveness of this strategy could be monitored.

PDF leaflets:

The patient registration leaflets had originally contained individual access codes (one code per patient) due to limitations of the software. However, by April 2015, with help from HeLP-

Diabetes software company, I had been able to develop a system that allowed multi-use access codes to be generated. This meant that each practice could be provided with just one code for all of their patients and would still allow me to monitor where each patient had registered from. This also meant that rather than batches of individual paper leaflets having to be created and sent to each practice, each practice could just have one leaflet. This could be emailed to the practice in a PDF format, shared with all staff in the practice, printed whenever needed and readily stored on desktop computers which, it was hoped, would make offering HeLP-Diabetes to patients much easier.

Paper registration forms:

A strategy that was tried initially in one practice was to provide paper copies of the online registration form which could be used in the following ways: staff could promote HeLP-Diabetes to patients during consultations and interested patients could be given a copy of the paper registration form to complete in reception after their appointment and before leaving the practice. Or practices could mail out a copy of this registration form to all patients with type 2 diabetes. Patients could then return the completed forms to a member of the practice team who could add all the completed forms to the online system at a convenient time. This method was used in one practice.

Peer supported registration:

In order to support practices to register patients a peer tutor was trained to help with the registration process within practices. This peer tutor was a member of the study steering group who had type 2 diabetes. She was trained by me on the registration process and to facilitate patients' access to HeLP-Diabetes. It was envisaged that she would work within practices, where patients identified by staff would meet with her to be registered to HeLP-Diabetes and taken through the content. It was hoped that a peer approach to this would engage patients, and also provide them with more time to explore HeLP-Diabetes than would be possible with a staff given the time constraints of appointments. This idea was discussed with the CCG who were positive about the approach. Following the training of the peer tutor, all practices were contacted and offered this service. Despite continued offers, email and newsletter correspondence about the availability of a peer tutor, no practices took up the offer. Informal feedback from one GP within a practice suggested that the reason for this lack of uptake was due to the fact that it would still involve additional work for practices to set the peer tutor up within the practice and to refer patients to her.

Therefore the two main ways in which patients were registered to HeLP-Diabetes during the study were by staff registering patients and patients registering themselves with an access code. These registration methods are summarised in Table 7-2.

Table 7-2 Ways in which patients registered to HeLP-Diabetes

	Staff registration	Patient registration
Online registration form completed by?	Member of staff with patient usually present	Patient once they had left the practice/clinic
Assistance provided to make first login?	Yes	No
HeLP-Diabetes demonstrated to patients by staff?	Yes (usually but optional)	No

7.5.3 Barrier: Staff forgetting to recommend intervention

Informal feedback from staff suggested that a barrier to offering HeLP-Diabetes to patients was staff forgetting about it during appointments with patients.

Strategy: Integrating with practice templates

During a meeting with a practice nurse in February 2015, the nurse mentioned that she had been able to create a tick box on the diabetes EMIS (Electronic patient record systems and software used in GP practices in the CCG) template which prompted her to offer patients access to HeLP-Diabetes during routine appointments with patients with diabetes. She had also uploaded the patient leaflet PDF to the template for ease of access. I suggested this strategy to other practices as a way of increasing patient registrations to HeLP-Diabetes and it was implemented in three practices. A lack of technical support in other practices prevented this from being more widely implemented.

7.5.4 Barrier: Access to patient medical records

Another barrier to adoption raised at an initial practice meeting by a GP was in relation to a specific feature of HeLP-Diabetes. HeLP-Diabetes was designed to allow patients to access summary data from their electronic health records. This access would have to be agreed by the practice and the individual patient. However, this feature had been subject to delays and was not functional at the time of initial practice meetings, but staff were made aware that it might be available in the future. One GP was uncomfortable with this possibility and would not consider adopting HeLP-Diabetes until HeLP-Diabetes had been approved by the Local Medical Committee.

Strategy: Removal of feature

In order to address this, advice from the commissioning officer for the CCG was sought. The officer offered to raise this issue at the IT working group for the borough. It was also recommended that in the meantime, until approval was granted, this feature of the website was not promoted at future practice meetings. Based on this recommendation, the fact that the CCG IT working group never gave approval and the continued delays with the functionality of this

feature; this feature was turned off and no longer formed part of the HeLP-Diabetes intervention offered in the CCG.

7.5.5 Barrier: Patient awareness of HeLP-Diabetes

Originally, the strategy to raise awareness of HeLP-Diabetes amongst patients relied on staff to promote HeLP-Diabetes during routine appointments and the use of posters and leaflets in practices and clinics. As these strategies alone were not attracting much interest from patients, the following additional strategies were developed and implemented.

Strategies:

- TV screen adverts
I created an advert to be displayed on the TV screens within GP practice waiting rooms which advertised HeLP-Diabetes to patients and provided information on how they could find out more about it.

- Patient self-management groups
I was invited by several practices during the implementation to attend events that they had arranged at the practices. These included patient self-management evenings where all the services within the practice to support patient self-management were discussed, and patient evenings for patients with diabetes. At these sessions I presented HeLP-Diabetes, gave a live demonstration, answered patient questions and then registered interested patients then and there.

- Diabetes UK events
I was invited to attend an event hosted by Diabetes UK which aimed to raise awareness of diabetes services for patients within the borough. This was attended by over 100 patients with diabetes. I held an exhibition stall and provided live demonstrations of HeLP-Diabetes as well as providing patients with literature and information on how to register to use HeLP-Diabetes.

- Practice newsletters
Several GP practices produced their own regular newsletters for patients and HeLP-Diabetes was often included in these to raise awareness with patients.

- Mail out
The hospital within the CCG conducted a mail shot of patient registration leaflets to the 1000 patients with type 2 diabetes that it serves. This was conducted in February 2015.

7.5.6 Barrier: Staff awareness of HeLP-Diabetes

To further promote HeLP-Diabetes among staff the following strategies were devised and implemented.

Strategies:

- Locally Enhanced Services

HeLP-Diabetes was included by the CCG as one of their Locally Enhanced Services (LES) for type 2 diabetes in November 2014. This raised the profile of HeLP-Diabetes, consolidated the CCG backing of HeLP-Diabetes and raised awareness of it through the LES documentation. The intervention was seen by the CCG to support the following aspects of the diabetes LES and these features of HeLP-Diabetes were promoted to staff:

- Supporting care planning by allowing patients and staff to share a common record and by the provision of a care planning component within HeLP-Diabetes which uses the Islington care planning document.
- enabling patients (of practices that use EMIS) to access their investigation results (e.g. in advance of the 2nd care planning appointment);
- encouraging patients to obtain and record the “9 essential processes” recommended by NICE;
- Providing education and support to enable patients to self-manage.

- Map of medicine

Following the integration of HeLP-Diabetes into the diabetes LES, HeLP-Diabetes was added to the Map of Medicine system used by GP practices in the CCG. This map displays care pathways and referral guidance within the CCG so that staff can readily access relevant information at the point of care and save forms within patient records.

- Staff education events

I was invited by the CCG to attend GP educational events on several occasions during the implementation. At these events I held an exhibition stall with a laptop to demonstrate HeLP-Diabetes, and produced promotional materials including posters, flyers, mugs and pens to attract interest. At these events I talked to GPs and promote HeLP-Diabetes, took details of interested GPs and followed up interest with an offer of me attending a practice meeting to give them more information.

- GP bulletin

The intervention was frequently advertised in the CCG's bulletin to GPs informing them of its availability and giving my contact details for further information.

7.6 Barriers that could not be addressed

There were several barriers to the implementation identified by staff which were beyond the scope of this research to address. These were:

7.6.1 Barrier: Change in staffing

In several cases staff who had been trained to offer HeLP-Diabetes subsequently left the practice or clinic and no other members of staff continued to advocate HeLP-Diabetes to patients. Despite me offering to attend practice meetings and provide training to alternative staff to try and engage new staff, these were not responded to.

7.6.2 Barrier: Closed practice

During the implementation, as described in the context section above, three practices in the CCG closed down and had their patient lists absorbed by other neighbouring practices. This meant that HeLP-Diabetes could not be implemented within these practice, but also that the additional strain on the neighbouring practices hindered the implementation of HeLP-Diabetes there.

7.6.3 Barrier: Non responsive practices

There were eight practices who, despite continued efforts by the CCG's Commissioning Officer and I to establish contact, did not respond to any correspondence about HeLP-Diabetes. Through discussions with the Commissioning Officer during our regular meetings potential reasons for the non-engagement by these practices were ascertained. The most common reason was that the practice was a single handed practice (with only one GP working there) which meant that there was no additional capacity to take on new interventions and implement them. Other reasons provided by the Commissioning Officer included GP's disinterest in diabetes and long term conditions, GP's being off work due to long term sickness, practices facing difficult times financially and the closure of practices.

7.7 Other uses for HeLP-Diabetes

Teaching aid for health care assistants

HeLP-Diabetes was also used in an unanticipated way by the lead Diabetes Specialist Nurse within the CCG as an educational tool to teach health care assistants about care planning, goal setting and behaviour change for patients with type 2 diabetes. The videos within HeLP-Diabetes were played during these training days to increase the health care assistants' knowledge about diabetes and the goal setting and action planning tools were demonstrated. The health care assistants were also provided with login details for HeLP-Diabetes so that they could use it with patients in routine practice.

7.8 The final implementation plan

Table 7-3 presents a summary of the implementation strategy and its components in generalizable terms.

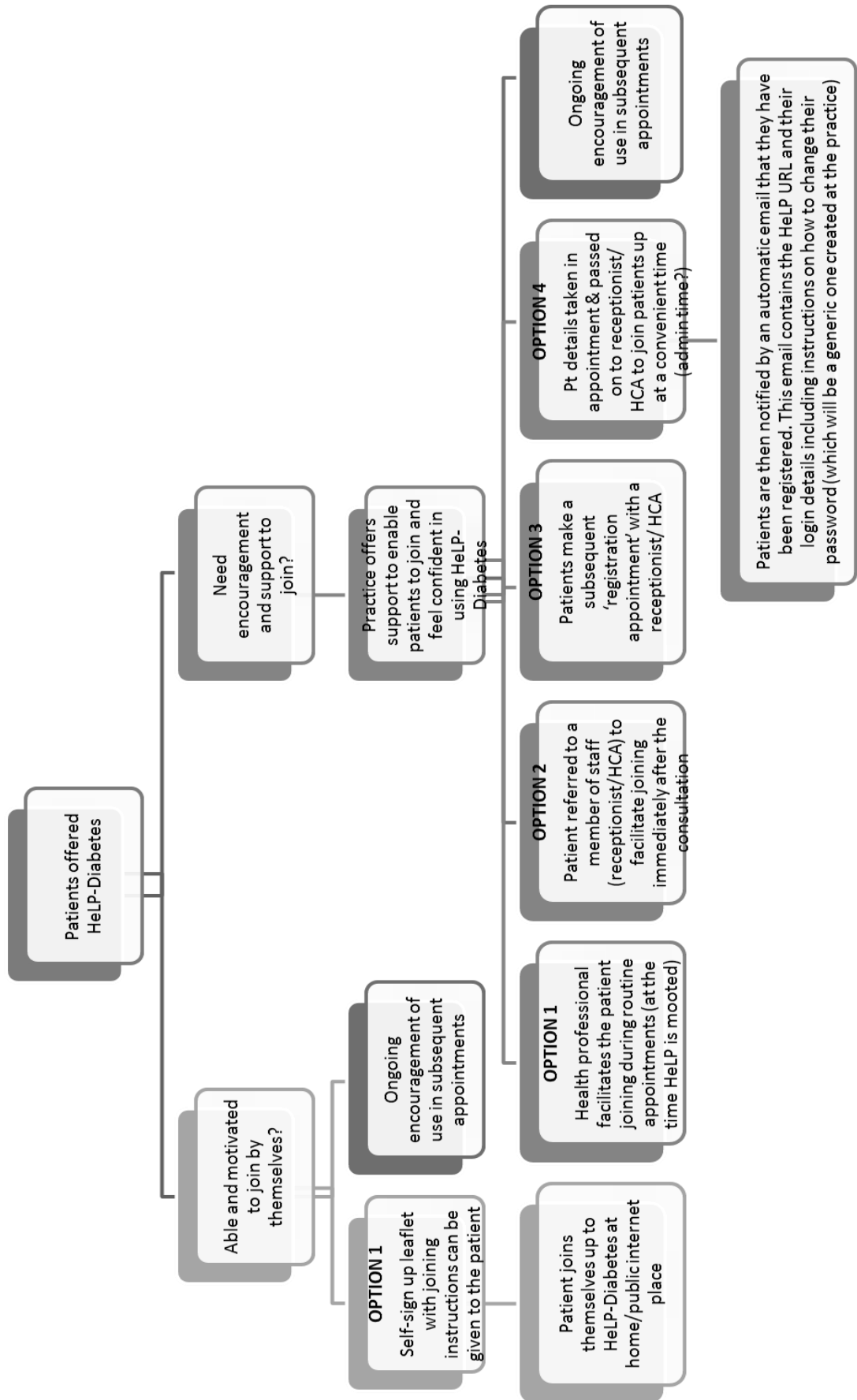
Figure 7-1 summarises the result of this iterative implementation plan and displays the different ways which were devised during the study for practices and clinics to offer HeLP-Diabetes to patients within routine practice.

Table 7-3 Summary of the HeLP-Diabetes implementation plan

Stages of implementation process and goals of strategies at this stage.	NPT constructs to target	HeLP-Diabetes implementation plan
<p>Orientation: Raise awareness of HeLP-Diabetes and stimulate interest</p>	<p>At this stage the plan needed to start to build a sense of <i>coherence</i> towards HeLP-Diabetes.</p>	<p>An email was sent to all practice/clinic managers and lead GPs/consultants for diabetes to inform them that there was a free new tool available to support their patients with looking after their diabetes. In order to increase coherence the email emphasised that HeLP-Diabetes was an online programme thus different from other self-management programme, that it was free to use and had been developed by a university.</p>
<p>Insight: Create understanding of what HeLP-Diabetes is and what was expected of staff.</p>	<p>At this stage, staff <i>coherence</i> was further targeted.</p>	<p>Meetings were arranged with services who had responded to initial emails. The purpose of these meetings was to provide healthcare professionals with information about HeLP-Diabetes and the implications for their working practice to allow them to decide whether or not to adopt it in their practice.</p> <p>Specific strategies to engage healthcare professionals during these meetings included: presenting the evidence base behind the development and content of HeLP-Diabetes; outlining the potential benefits to the practice and patients of adopting HeLP-Diabetes; demonstrating how HeLP-Diabetes meets identified clinical needs; and through a live demonstration, showing the usability and attractiveness of HeLP-Diabetes.</p>
<p>Acceptance: foster a positive attitude towards HeLP-Diabetes and create positive intention or</p>	<p>The <i>collective action</i> construct was targeted at this stage to demonstrate that the operational work needed to implement HeLP-</p>	<p>Services were provided with login details in order to try out HeLP-Diabetes before they made a decision to adopt.</p> <p>Trying out HeLP-Diabetes allowed staff to see how HeLP-Diabetes fitted with the skill sets of the healthcare professionals in the practice (skill set workability), what resources were needed to make it part of routine</p>

decisions to adopt.	Diabetes was achievable.	practice (contextual integration), what knowledge was needed to be confident with HeLP-Diabetes as a new way of working (relational integration), and the impact that HeLP-Diabetes would have on interaction with colleagues and patients (relational integration).
<i>Change:</i> confirm benefit and value of HeLP-Diabetes once a service had agreed to adopt it.	The <i>cognitive participation</i> construct was targeted at this stage to promote a sense of willingness to take part amongst staff in services.	Once a service had decided to adopt HeLP-Diabetes, healthcare professionals were provided with a training session. This training session provided the opportunity for staff to understand the actions and procedures needed to sustain HeLP-Diabetes in practice and to be convinced that HeLP-Diabetes could deliver the anticipated advantages. The majority of training was with groups of staff which allowed the opportunity for them to discuss and decide how the work of implementing would be shared.
<i>Maintenance:</i> Encourage HeLP-Diabetes continued use and facilitate new working practices becoming part of routine practice.	At this stage <i>reflexive monitoring</i> construct was targeted to create positive appraisals of the worth of undertaking the work of implementing HeLP-Diabetes.	Ongoing support and communication was provided to each service who adopted HeLP-Diabetes in order to problem solve and maintain awareness. Feedback was provided to service to promote positive reflexive monitoring. Feedback included details of how many patients were using HeLP-Diabetes, how each service was performing and feedback from patients using HeLP-Diabetes.

Figure 7-1 The Final Implementation Plan



8 CHAPTER 8: RESULTS 1: ADOPTION, UPTAKE AND USE OF THE HeLP-DIABETES INTERVENTION BY NHS SERVICES AND PATIENTS.

8.1 Chapter summary

This is the first of three chapters presenting the results of the study. The results presented in this chapter address the adoption, uptake and the use of HeLP-Diabetes by NHS services and patients. Findings related to interviews conducted with staff and patients that explore factors important for the adoption, uptake and use of HeLP-Diabetes are presented in Chapters 9 and 10.

8.2 Introduction

In this chapter, the main findings which relate to the following research questions are presented.

- To what extent was HeLP-Diabetes adopted by NHS services?
- To what extent was HeLP-Diabetes implemented within NHS services?
- What was the uptake of the HeLP-Diabetes by patients?
- How was HeLP-Diabetes used by patients?
- Were there any factors that predicted patient use of HeLP-Diabetes?
- Were there any factors that predicted HeLP-Diabetes registration method?

To aid interpretation, definitions of terms from the glossary (page13) used throughout this chapter are provided again in Table 8-1. A description of how these terms specifically apply to the implementation of HeLP-Diabetes is also provided.

Table 8-1 Definition of terms

	Definition	Operationalisation of definition
Adoption	A decision to make full use of an innovation as the best course of action available.	The decision made by NHS services to take on HeLP-Diabetes as a tool to offer to their patients.
Implementation	The active process of putting to use or integrating evidence-based interventions within a setting.	Staff making use of HeLP-Diabetes within practices and clinics
Uptake	The action of taking up something that is available	The decision by patients to register to HeLP-Diabetes and the act of registering

Use	The action of or making use of something that is available	Patients making use of HeLP-Diabetes again after registering.
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8.3 To what extent was HeLP-Diabetes adopted by NHS services?

8.3.1 Number of services that adopted HeLP-Diabetes

There were 37 GP practices, a hospital and a community service running diabetes clinics in the CCG. Of the 37 GP practices, twenty two (59.5%) practices agreed to adopt HeLP-Diabetes as did the hospital and community clinics.

Six (16.2%) GP practices expressed initial interest in HeLP-Diabetes but then did not respond to further correspondence regarding the process of implementing it within their practice. It was not possible to establish any contact with eight (21.6%) GP practices despite efforts from both me and the CCG, and one (2.7%) GP practice explicitly declined to adopt HeLP-Diabetes. As described in detail in Chapter 7 (page 136), this practice declined to adopt HeLP-Diabetes based on concerns the GP had about the potential link HeLP-Diabetes was offering to patients electronic health records. In an effort to resolve this, this specific function feature of HeLP-Diabetes was removed from HeLP-Diabetes. However, despite communicating this back to the GP, this practice still decided not to adopt HeLP-Diabetes. This practice was one of the ones which closed down during the implementation period (July 2013- August 2015). The other two practices which closed were ones with whom it had not been possible to establish any contact with regarding HeLP-Diabetes.

8.3.2 Type of diabetes services

A description of the twenty two GP practices (ordered by the number of patients registered to use HeLP-Diabetes) and the hospital and community clinics is provided in Appendix P.

The list sizes of these twenty two practices ranged from 2,101 to 12,941 and the practices collectively served 5,117 patients with type 2 diabetes. The services had access to HeLP-Diabetes for varying amounts of time (ranged between 3 and 25 months) depending on when they adopted it during the implementation period. QOF scores for the diabetes indicator for these practices ranged from 76% (of total achievable points for the indicator) to 100% with higher scores reflecting better achievement and thus greater financial reward for practices.

8.4 To what extent was HeLP-Diabetes implemented within NHS services?

8.4.1 Number of patients registered

Of the twenty two GP practices that decided to adopt HeLP-Diabetes, eighteen (81.8%) implemented it, as did the hospital and community clinics. Implementation was defined as a practice or clinic registering one or more patient to use HeLP-Diabetes.

The number of patients registered to use HeLP-Diabetes ranged greatly between GP practices, between 1 and 40 patients per practice, with a median value of 3. The number of patients registered to HeLP-Diabetes by these practices comprised approximately 3.4% of their potentially eligible patients (see Chapter 6 page 98 for eligibility criteria and Appendix P for details of the percentage of eligible patients registered by each service). The hospital registered 30 patients and the community clinic registered one patient (As shown in Appendix P the community clinic adopted HeLP-Diabetes much later than the other services).

Four practices did not implement HeLP-Diabetes (did not register any patients from their practices to use it). It was not possible to tell in these cases if HeLP-Diabetes had been offered to patients but not taken up by them, or whether the practices simply had not offered HeLP-Diabetes at all. Therefore, of the 37 GP practices, 48.6% (n=18) adopted HeLP-Diabetes and made use of it. The hospital clinic and the community clinics were both classed as having used HeLP-Diabetes as patients from both services were registered to use HeLP-Diabetes.

In order to explore whether differences in the number of patients signed up to HeLP-Diabetes was related to the length of time a practice had provided patients access to HeLP-Diabetes, a one-tailed Spearman's test for correlation between these factors was conducted but revealed a non-significant relationship between these variables ($r=0.32$, $n=18$, $p=0.98$), suggesting that other factors than length of time were important for actually putting HeLP-Diabetes to use.

8.4.2 How HeLP-Diabetes was implemented

As described in detail in Chapter 6 (section 6.6.2.1), a research diary (Appendix Q) was kept during the research to document the implementation progress at each site. The data in this diary (collected from informal feedback from staff, personal experience of supporting the implementation at each site, discussions with staff during training sessions, email communications and ongoing feedback from staff) were coded into descriptive themes and then mapped onto constructs of NPT in order to explain how HeLP-Diabetes was implemented into practice.

As a reminder, and to aid the reader's interpretation, definitions of NPT and questions relating to each of the constructs which were used to facilitate the mapping process (described in Chapter 6, section 6.6.2.2) are provided again in Table 8-2. Table 8-3 presents descriptive themes, illustrative examples and the NPT constructs that themes were mapped to.

Table 8-2 Definitions and questions relating to each of the constructs of NPT

Construct/sub construct	Definition*	Questions that NPT poses of the implementation of HeLP-Diabetes?
Coherence	The sense-making work that people do individually and collectively when they are faced with the problem of operationalizing some set of practices	How is HeLP-Diabetes conceptualised by staff? What is the work of implementing HeLP-Diabetes?
Cognitive participation	The relational work that people do to build and sustain a community of practice around a new technology or complex intervention	How do staff come to engage with HeLP-Diabetes? How do they decide on engagement and the purpose that it serves?
Collective action	The operational work that people do to enact a set of practices	How do staff enact HeLP-Diabetes? How are their activities structured and constrained?
<i>Interactional workability</i>	The interactional work that people do with each other, with artefacts, and with other elements of a set of practices, when they seek to operationalize them in everyday settings	How does HeLP-Diabetes affect interactions between people and practices?
<i>Relational Integration</i>	The knowledge work that people do to build accountability and maintain confidence in a set of practices and in each other as they use them	How does a HeLP-Diabetes relate to existing knowledge and relationships?
<i>Skill set workability</i>	The allocation work that underpins the division of labour that is built up around a set of practices as they are operationalized in the real world	How is the current division of labour affected by HeLP-Diabetes?
<i>Contextual Integration</i>	The resource work. Managing a set of practices through the	How does HeLP-Diabetes relate to the organisation in

	allocation of different kinds of resources and the execution of protocols, policies and procedures	which it is set?
Reflexive monitoring	The appraisal work that people do to assess and understand the ways that a new set of practices affect them and others around them	How do staff appraise HeLP-Diabetes? What are the effects of appraisal? How are they mediated?

*Definitions from (191)

Table 8-3 Descriptive themes, illustrative examples and mapping to constructs of NPT

Theme	Illustrative Examples	NPT Construct
Available Resources/Training	Time constraints to offer intervention	Contextual Integration
	Lack of space to register patients privately	Contextual Integration
	Lack of computers to conduct registration	Contextual Integration
	Very old computers and very slow internet connection	Contextual Integration
	Healthcare professional training	Skill Set Workability
Compatibility	Intervention fitted well into existing extended appointments designated for people with diabetes	Interactional Workability
	Competing pressures with many other services to implement	Cognitive Participation
Complexity of intervention	Perceptions of the ease and difficulty of the patient registration process	Interactional Workability
	Tasks associated with the research study perceived as overwhelming	Cognitive Participation/ Interactional Workability
	Healthcare professional unconfident with computers/internet	Skill Set Workability
Feedback	Positive feedback received from patients using it.	Reflexive Monitoring
	Feedback from me on numbers of patients being registered.	Reflexive Monitoring
Fit for purpose	Practice nurse did not think many patients would have computer/English language skills to use it	Cognitive Participation
	Practice nurse thought intervention was better aimed as an educational tool for healthcare professional	Cognitive Participation
	Receptionist thought intervention wasn't appropriate	Cognitive Participation

	for the age of the patients she saw	
Fit with external policies/priorities	Strong push from the CCG to implement HeLP-Diabetes	Contextual Integration
	Intervention incorporated into LES for the CCG	Contextual Integration
	Perceived fit with CCG policies and intervention	Contextual Integration
Implementation process	GP involvement in driving intervention forward	Cognitive Participation
	Assisting patient registration	Interactional Workability/ Skill Set Workability
	Ongoing communication and support	Relational Integration
	Provision of materials	Relational Integration
Intervention source	Credibility given to HeLP-Diabetes because it was developed at a University	Coherence & Cognitive Participation
	The lack of commercial affiliation was viewed as a positive	Coherence & Cognitive Participation
	Strong academic evidence base for HeLP-Diabetes	Coherence & Cognitive Participation
Perceptions of the value of HeLP-Diabetes	GP had a strong interest in diabetes and self-management and saw value in HeLP-Diabetes	Cognitive Participation
	Healthcare professional could see value in intervention over group based education for some patients	Coherence & Cognitive Participation
	Comparisons with other existing websites	Coherence & Cognitive Participation
Healthcare professional roles and responsibilities	Only the GP took ownership of HeLP-Diabetes and did not communicate about it with other staff	Contextual Integration/ Relational Integration
	HCA's enjoying feeling upskilled by undertaking new role	Skill Set Workability
	Healthcare professional who were responsible for implementing were not always	Relational Integration

	those who had agreed to adopt	
Staff and stability	Large healthcare professional turnover	Contextual Integration
	Reliance on agency healthcare professional	Contextual Integration
	Problems with estate forcing practice to close down temporarily	Contextual Integration
Support for HeLP-Diabetes	Teams of healthcare professional all interested in intervention	Cognitive Participation
	Competing organisational pressures	Cognitive Participation
	Lack of support from senior healthcare professional	Cognitive Participation
	Strong support and push for intervention by lead GP	Cognitive Participation
	Support for intervention among healthcare professional	Cognitive Participation
	Lack of replacement healthcare professional to carry intervention forward	Contextual Integration
Tailoring	Positive feedback received from patients using it.	Reflexive Monitoring
	Feedback from me on numbers of patients being registered.	Reflexive Monitoring
	Addition of local services information	Reflexive Monitoring
Teamwork and communication	Big nurse/NCA team who worked closely together	Relational Integration
	Intervention had not been well communicated by GPs to the nurses/HCAs	Relational Integration
	Intervention was not well communicated to other healthcare professional in practice	Relational Integration/ Interactional Workability
	Tensions between healthcare professional within the practice	Relational Integration

8.4.3 Explaining the implementation using Normalization Process Theory

The data are now presented using an NPT lens to describe the work involved in implementing HeLP-Diabetes and to identify barriers and facilitators to implementation.

Coherence: The sense making work that healthcare professional perform around HeLP-Diabetes

In most cases during practice meetings it was clear that the value, benefits and importance of HeLP-Diabetes was understood by staff. The fact that HeLP-Diabetes had been developed by academics with input from healthcare professionals and patients with type 2 diabetes at a university, and was evidence-based served to distinguish it from other available websites and increase staff perceptions of its value. HeLP-Diabetes was clearly distinguishable from current resources available to patients, such as group based education, which was mentioned by several staff as unsuitable for certain patients. Self-management was a clear priority throughout the CCG and as such many staff commented on how useful a tool to help patients self-manage was perceived to be, as it would help them to achieve the goals of supporting self-management. The demonstration of HeLP-Diabetes during clinical meetings and the opportunities for practice staff to ask questions around what would be involved in implementing it served to increase both individual and shared understandings of what the work involved in implementing HeLP-Diabetes would be.

Cognitive participation: The relationship work that staff perform around HeLP-Diabetes

Despite a strong sense of coherence around understanding the value and potential benefits of HeLP-Diabetes, in many practices and clinics there appeared to be little cognitive participation to embed HeLP-Diabetes in routine practice. Although these practices had signed up to adopt HeLP-Diabetes it did not emerge as a priority and failed in the majority of practices and clinics to normalize within routine practice. Staff within practices were working to a set of tasks which were dictated by practice priorities such as ensuring that financially incentivised targets set out by the QOF were reached. HeLP-Diabetes, as a non-incentivised task, was not prioritised over other work and therefore was often not carried out in favour of other incentivised tasks.

Another barrier to cognitive participation arose around staff not feeling that HeLP-Diabetes was a legitimate part of their work due to the limitations they perceived of HeLP-Diabetes. In their coherence work some staff had concluded that HeLP-Diabetes would not be suitable for certain patients and therefore decided against putting the required effort in to implementing it. In a few cases during practice meetings concerns were expressed that as an internet intervention written in English there would be certain patients who would not be able to use HeLP-Diabetes, and therefore questioned its effectiveness and suitability. It was frequently asked whether HeLP-Diabetes was available in other languages. At some practices staff perceived the content of HeLP-Diabetes as too complex for many of their patients and viewed HeLP-Diabetes as a tool

that would be better suited for healthcare professionals. Indeed in three cases, HeLP-Diabetes was used in a different way than intended. It was used by two health care assistants to teach themselves more about diabetes, and used by a diabetes specialist nurse who had responsibility for training all the health care assistants in the CCG about providing self-management support to patients with long term conditions (especially around using goal setting and action planning). In other cases staff expressed concerns that the age of the population with type 2 diabetes would preclude them from using technologies to access self-management support.

The responsibility of supporting self-management of diabetes in general, as well as for the delivery of HeLP-Diabetes, seemed to be passed down the chain. Pressures from wider NHS policies for self-management of long term conditions were passed on to the CCG, who then placed this responsibility for patients better managing their conditions onto GPs practices. GPs within practices delegated the responsibility of self-management to nurses, who in turn placed it onto the patients. As described in Chapter 7, HeLP-Diabetes was originally designed to be used collaboratively with staff and patients during appointments however, in many practices this interaction around HeLP-Diabetes was reduced to the handing out of a leaflet and as such, patients had to undertake the work of registering themselves to use HeLP-Diabetes.

However, there were a smaller number of practices and clinics where the work of implementing HeLP-Diabetes did become part of routine practice. In cases where there were key individuals to drive it forward and to engage other staff, HeLP-Diabetes was taken up by more patients than in practices and clinics where there were no such individuals. However, this was not common, and in the majority of practices and clinics the work of implementing HeLP-Diabetes was the responsibility of one or two staff who received little support from the wider practice or clinic team. Some staff expressed the opinion that HeLP-Diabetes should not be delivered through primary care and that patients should just be able to search for it online like services like Diabetes UK; thus suggesting that they did not think the delivery of HeLP-Diabetes was a legitimate part of their work.

Collective action: The operational work that people do to enact a set of practices.

Interactional workability

In their attempts to enact HeLP-Diabetes within practices many staff viewed the logistics of giving patients' access to HeLP-Diabetes by registering them and introducing them to it as problematic. A number of options were developed (as discussed in Chapter 7) in order to ease the work of operationalising HeLP-Diabetes within practices including printable forms, patient registration leaflets, peer supported registration as well as the original staff registration method. However the majority of practices lacked the impetus to consider change, or immediately dismissed the possibility of engaging in the work needed to adjust routines in order to register patients. This was largely as a result of their concerns about workload and time pressures.

Handing out leaflets which allowed patients to sign themselves up to HeLP-Diabetes rather than the staff registration method was viewed as more desirable a method to implement. Handing out leaflets presumably fitted more readily into existing ways of working as staff are used to doing this. In this way leaflets proved minimally disruptive and were more acceptable than the staff registration method.

Some practices did however enact the work of offering HeLP-Diabetes to patients, and were able to integrate the staff registration method within the practice. This was a result of a small team or an individual nurse/HCA changing their work practices and having the support of the practice to make these autonomous decisions over changing their way of working. However, in a couple of cases where this had occurred, when the healthcare professional who had taken the lead on the implementation left the practice, the use of HeLP-Diabetes within the practice ceased as it was not incorporated into the wider practice and there was no one else available or willing to take over this role.

Relational Integration

In many cases there was a lack of communication between staff around the implementation of HeLP-Diabetes. Adoption decisions were often made by GPs and practice managers during initial clinical meetings that I attended to demonstrate HeLP-Diabetes. However, in most cases it was practices nurses, healthcare assistants and receptionists who were identified as having the specific skills, time and opportunity to deliver HeLP-Diabetes. There was a discord between who was accountable for the implementation of HeLP-Diabetes and who was responsible for carrying out the work of implementing it within practice. The staff who were identified (usually by GPs) to deliver HeLP-Diabetes were often not involved in the decision to adopt it, and in some cases when I arrived to deliver training to these healthcare professionals they had no knowledge of HeLP-Diabetes or the work expected of them.

Skill set workability

Training sessions proved valuable in engaging staff tasked with doing the work of implementing HeLP-Diabetes. In an environment where practices and clinics are overwhelmed by competing priorities, having the opportunity to view HeLP-Diabetes and interact with it increased staff confidence in their ability to use it and in HeLP-Diabetes itself as a worthwhile tool to promote to patients (Cognitive Participation). In addition, the ongoing support available I provided to staff, and the hands-on assistance I provided in some practices at the beginning of implementation were viewed as helpful to allow staff to gain confidence in the processes.

In some practices where receptionists and health care assistants were enacting the work of implementing HeLP-Diabetes they informally reported to me a positive impact of this work on their role identity. Undertaking training, being provided with HeLP-Diabetes which provided them with an information resource and using it with patients provided a sense of taking on additional responsibilities which they valued and perceived as fitting well with their career aspirations as several were in the process of taking on additional clinical responsibilities.

Contextual integration

HeLP-Diabetes had strong support from the CCG and fitted well with its priorities. The CCG offered support in implementing HeLP-Diabetes through contacting practices, raising it as an agenda item at diabetes steering group meetings with clinicians and by incorporating it into the LES for the CCG. However, no resources were provided to practices and clinics to implement HeLP-Diabetes. This lack of resource arose as the main challenge for practices to implement HeLP-Diabetes, with a lack of staff, staff turnover, time pressures, limited physical space and old and slow computers described as barriers by staff during clinical meetings and ongoing communication. In contrast, in practices where I undertook the work of implementing the intervention by registering patients and facilitating their access, this additional resource seemed to make the work of registering patients possible.

Reflexive monitoring: The appraisal work that is performed around HeLP-Diabetes

In cases where staff were given feedback from patients using HeLP-Diabetes, this helped to confirm that it was a worthwhile intervention to promote, however due to the low number of patients signed up by practices and clinics this was uncommon and this lack of feedback served to undermine the perceived value of HeLP-Diabetes. I provided practices and clinics with regular updates on the number of patients that were being registered to HeLP-Diabetes from their practices in order to help them appraise the worth of continuing with implementing it. There were several examples of staff making changes to HeLP-Diabetes to make it more workable in practice. One nurse asked for more content to be added around sexual dysfunction as she found this a challenging area in her discussion with men with diabetes and believed HeLP-Diabetes could help her address this. A GP asked for a page to be created for pre-diabetes as a lot of his work was with this patient group and he believed HeLP-Diabetes would be useful in this area too.

8.5 What was the uptake of HeLP-Diabetes by patients?

8.5.1 Number of patients registered

In total 205 patients registered to use HeLP-Diabetes from the 18 GP practices, hospital and community clinics during the implementation period (July 2013 to August 2015).

The majority (n=143, 69.3%) were registered to HeLP-Diabetes via the staff registration method with a further 62 (30.7%) patients using the patient registration method. It was not possible to determine how many patients were actually offered use of HeLP-Diabetes but decided against using it, as it was not feasible due to time constraints and workload for the staff at participating sites to record the number of patients they offered HeLP-Diabetes to.

8.5.2 Characteristics of registered patients

The intervention attracted a wide range of patient users including a range of ages, ethnicities, educational attainment and computer skills. Over half (n=107, 52.2%) of registered users were male and 47.3% (n=97) were from non-white British backgrounds, with African, Caribbean, Bangladeshi, Indian and other ethnicities represented (see Figure 8-1). The sample contained a wide spread of ages, from nineteen to eighty-one years, and represented a range of educational levels, with 15.1% (n=31) with no formal education and a further 16.1% (n = 33) being school leavers (see Figure 8-2). Participants ranged with regards to the duration of their diabetes, including patients who had been diagnosed for less than a year to those who had had diabetes for more than twenty years, with the majority (n=119, 58%) having diabetes for less than five years (see Figure 8-3) . The majority of patients managed diabetes through lifestyle modification and medication, with a smaller proportion (n=26, 12.7%) taking insulin (see Figure 8-4). Although the majority of patients who registered to use HeLP-Diabetes had home internet access (n=177, 86.3%), over a third (n=79, 38.5%) described their computer skills as basic, and 31% (n=65) as intermediate skills (see Figure 8-5). Table 8-4 presents a full description of the characteristics of the patient users of HeLP-Diabetes.

Table 8-4 Characteristics of patients registered to HeLP-Diabetes

Variable	Response options	Number of patients (n=205)	% of all patients
Age	Range	19-81	
	Mean (standard deviation)	56.8 (11.8)	
Gender	Male	107	52.2
	Female	98	47.8
Ethnic Group	White - English/Welsh/Scottish/Northern Irish/British	98	47.8
	White - Irish	7	3.4
	White - Other	16	7.8
	Black or Black British - African	20	9.8
	Black or Black British - Caribbean	11	5.4
	Black or Black British - Other	3	1.5
	Asian or Asian British - Bangladeshi	8	3.9
	Asian or Asian British - Chinese	1	0.5
	Asian or Asian British - Indian	8	3.9
	Asian or Asian British - Other	5	2.4
	Asian or Asian British - Pakistani	1	0.5
	Mixed - White and Asian	1	0.5
	Mixed - White and Black African	1	0.5
	Mixed - Other	1	0.5
	Other ethnic group - Arab	3	1.5
	Other ethnic group - Other	11	5.4
	Prefer not to say	10	4.9
Highest educational attainment	None	31	15.1
	School leaver (e.g., CSE, GCSE, O-Level, NVQ1-2)	33	16.1
	A-level or vocational equivalent (e.g. NVQ 3)	16	7.8
	Degree or NVQ 4, HND or similar	20	9.8
	Post-graduate degree or NVQ 5	22	10.7
	Not stated	14	6.8
	Not asked at registration*	69	33.7
Duration of diabetes	<1 year	53	25.9
	1-5 years	66	32.2

	5-10 years	37	18.0
	10-20 years	35	17.1
	>20 years	9	4.4
	Not answered	5	2.4
How diabetes is managed	Lifestyle alone (i.e. diet and physical activity)	40	19.5
	Lifestyle and tablets	128	62.4
	Lifestyle tablets and insulin	26	12.7
	Other injectables	1	0.5
	Not answered	10	4.9
Internet access	Home	177	86.3
	Public	9	4.4
	Not answered	19	9.3
Computer skills	Basic	79	38.5
	Intermediate	65	31.7
	Advanced	40	19.5
	Not answered	21	10.2
Implementation model	Patients registered by healthcare professional	142	69.3
	Patients self-registered	63	30.7
NHS service type	GP practice	175	85.4
	Hospital	30	14.6
	Community clinics	1	0.5

*As discussed in Chapter 6, the question about educational attainment was not added to the online patient registration form until March 2014 and therefore was not asked of patients who registered before this time

Figure 8-1 Ethnicity of patients registered to HeLP-Diabetes

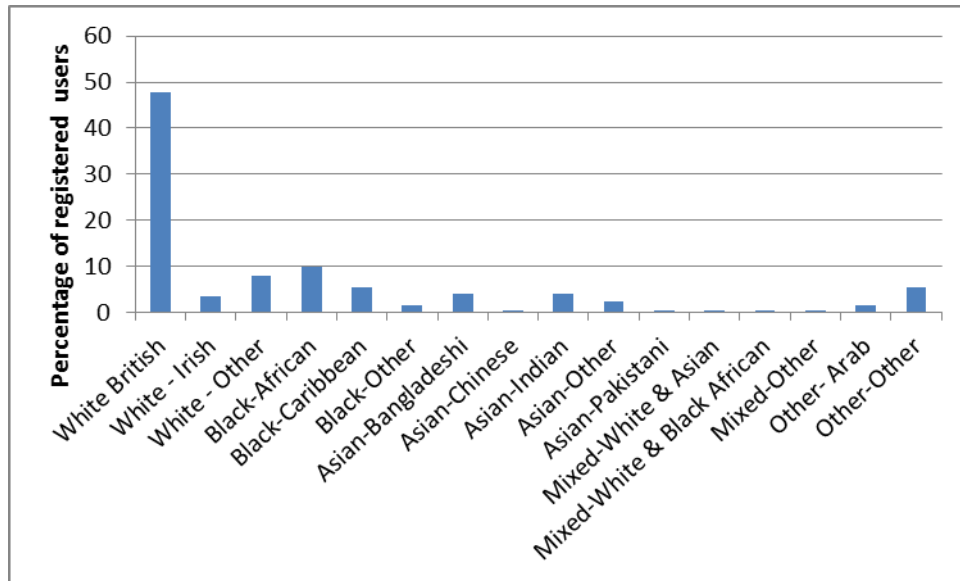


Figure 8-2 Educational attainment of patients registered to HeLP-Diabetes

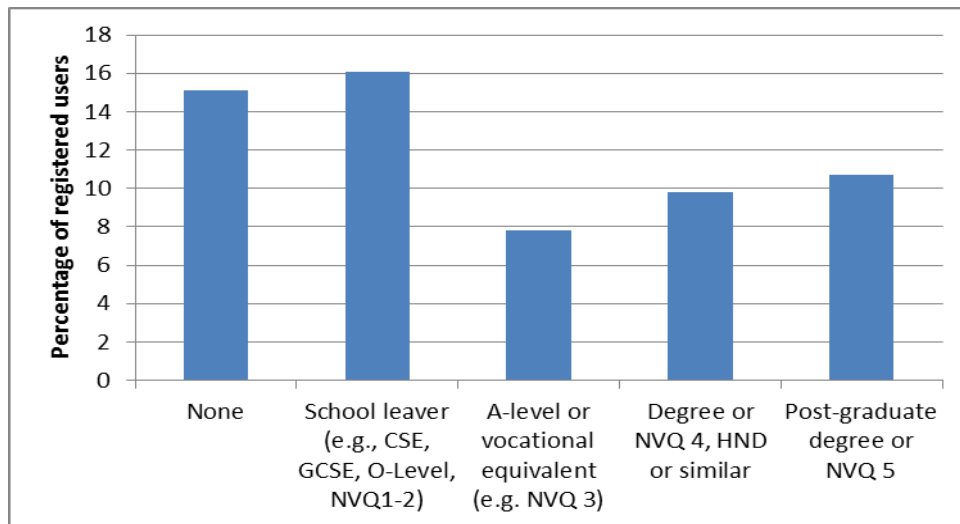


Figure 8-3 Duration of diabetes of patients registered to HeLP-Diabetes

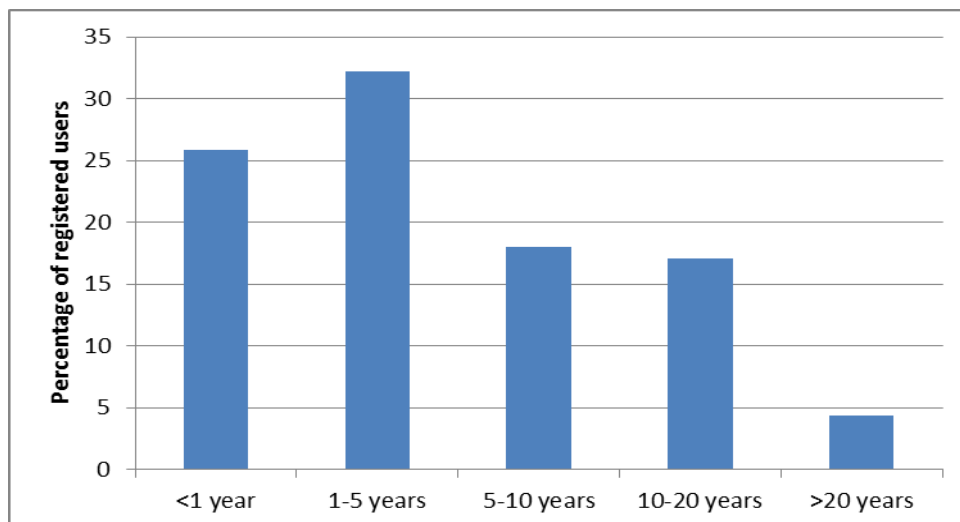


Figure 8-4 Diabetes management of patients registered to HeLP-Diabetes

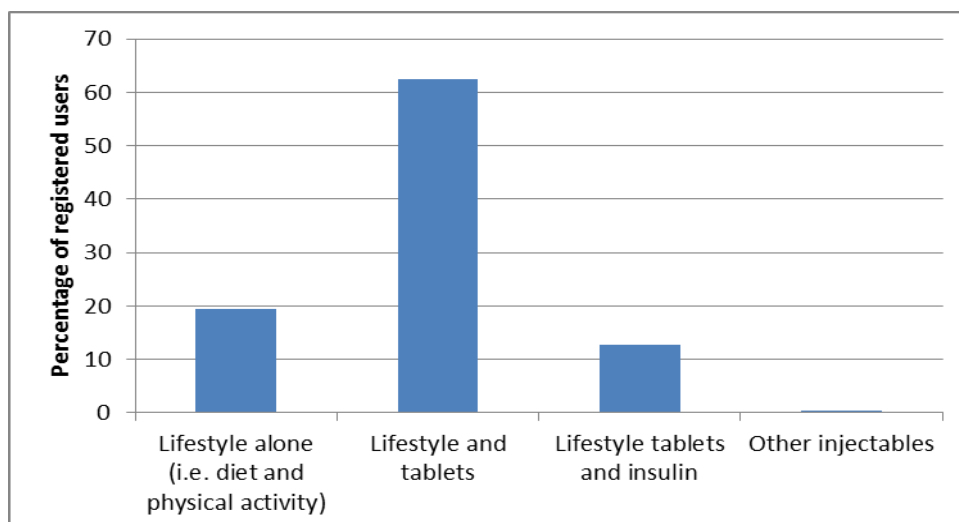
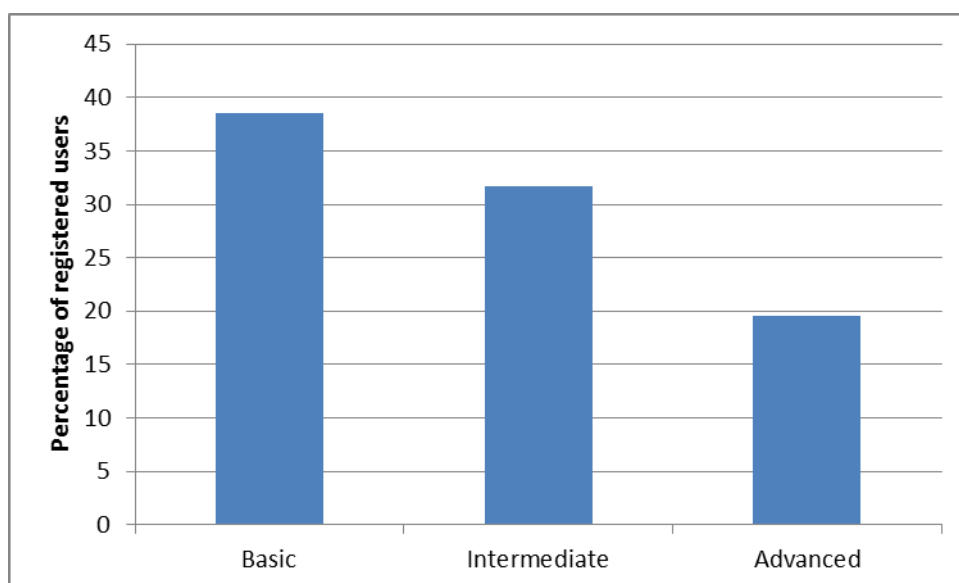


Figure 8-5 Computer skills of patients registered to HeLP-Diabetes



8.6 How was HeLP-Diabetes used by patients?

8.6.1 Number of patients who used HeLP-Diabetes

Overall, 104 (50.7%) patients were classed as having used HeLP-Diabetes.

As described in Chapter 6 (section 6.6.4.2), a recorded login on a date other than the date of registration was the measure of patient use of HeLP-Diabetes.

8.6.2 Days of use and page views

Excluding patients who did not make use of HeLP-Diabetes again following registration (n=101, 49.3%), the number of days patients visited HeLP-Diabetes ranged between one 1 and 77, with a median of 2 days of use per patient.

The total number of pages visited by individual patients ranged from 1 page to 271 pages with a median value of 15.5 page views per patient.

Using the number of days following registration that a patient visited HeLP-Diabetes, it was calculated there were 439 visits in total to HeLP-Diabetes by patients and during these visits a total of 3,221 page views were recorded for all patients.

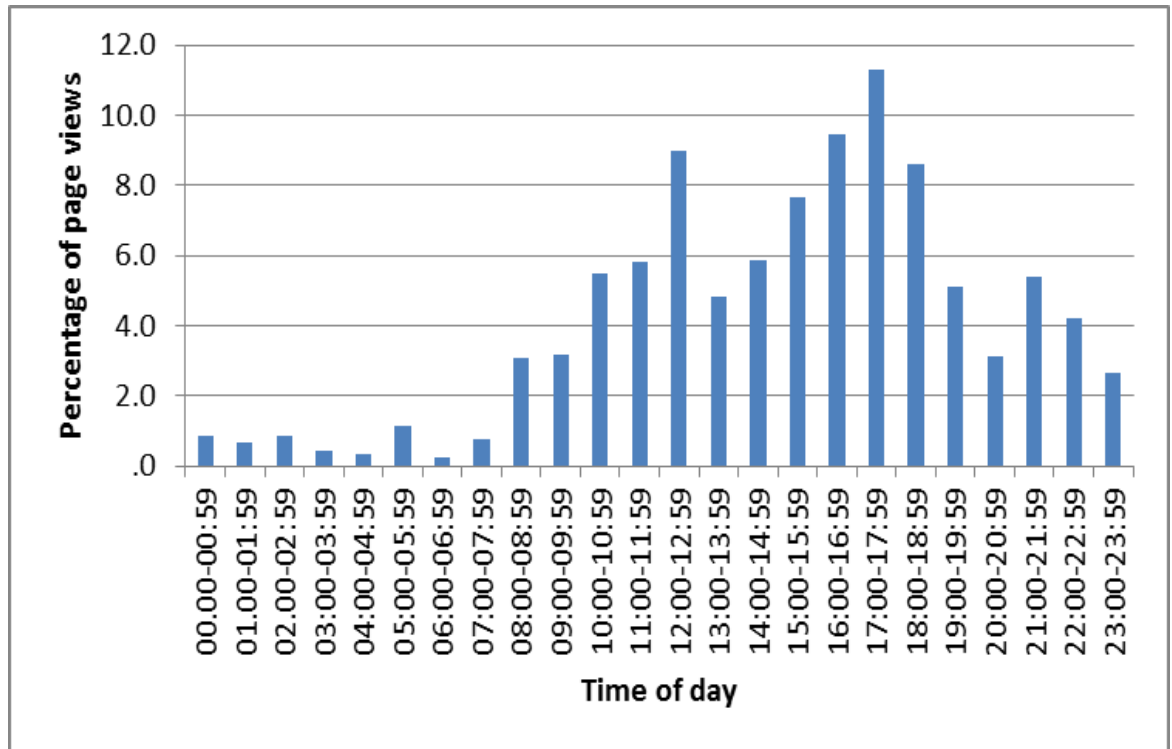
8.6.3 Temporal use of HeLP-Diabetes

8.6.3.1 *Time of day*

51.2% (n=1,651) of all page views occurred outside of working hours (9am-5pm) suggesting HeLP-Diabetes may be more accessible for some than face-to-face education which is held during working hours (see Figure 8-6).

Page views were recorded for every hour of the day, suggesting that patients took advantage of the fact that as an internet intervention, it was available 24 hours a day. Peaks of pages viewed were recorded between 12pm and 1pm (290 page views, 9.0%) and between 5pm and 6pm (364 page views, 11.3%), which could reflect patients viewing HeLP-Diabetes during lunch breaks and at the end of the working day.

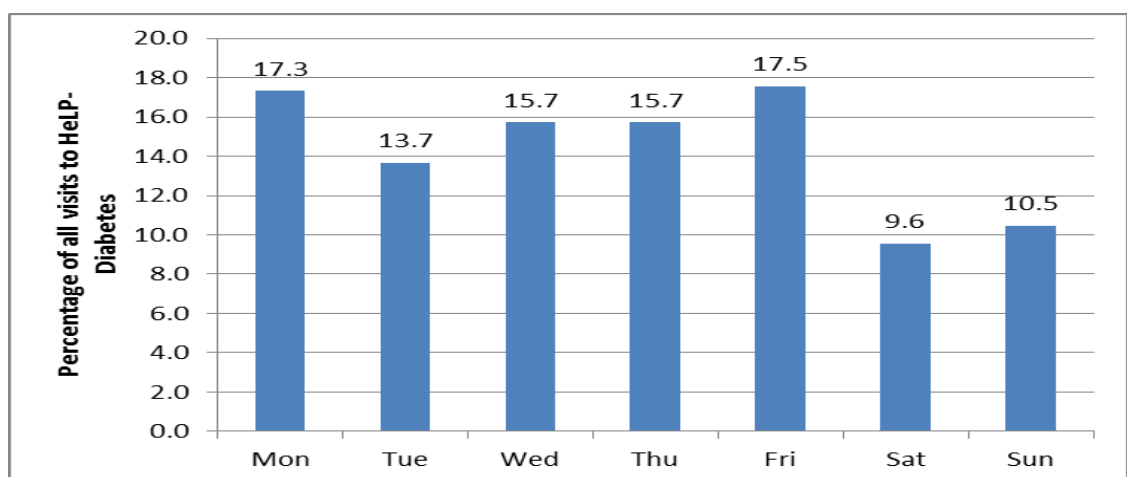
Figure 8-6 Percentage of page views by time of the day



8.6.3.2 Days of the week

Mondays and Fridays were the days that HeLP-Diabetes was accessed the most with 76 (17.3%) and 77 (17.5%) of the 439 visits to HeLP-Diabetes recorded on these days respectively. There were less visits to HeLP-Diabetes at the weekend with 42 (9.6%) visits on Saturday and 46 (10.5%) visits on Sunday (see Figure 8-7).

Figure 8-7 Percentage of visits to HeLP-Diabetes by day of the week



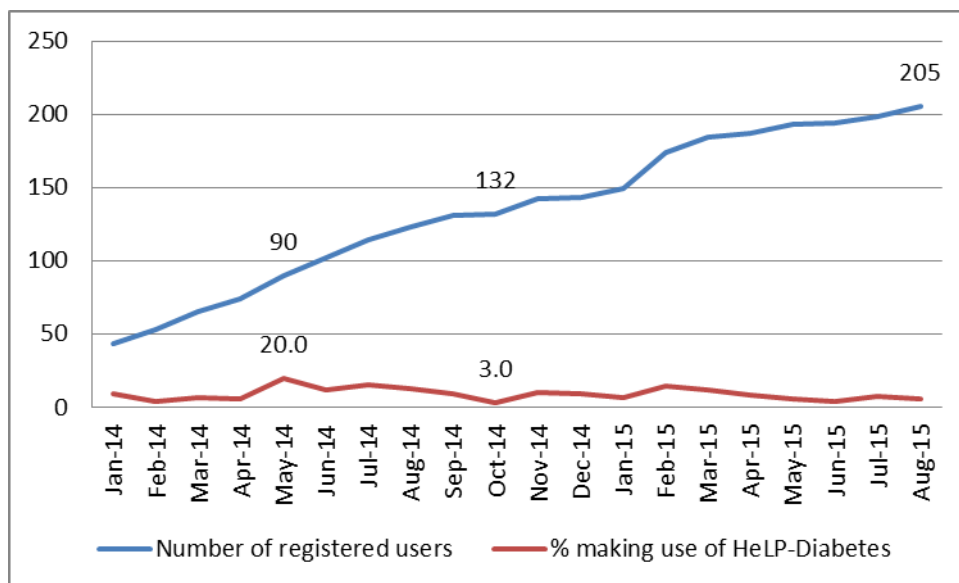
8.6.3.3 Monthly use

In any given month, the number of patients accessing HeLP-Diabetes did not go above 20% of the number of registered users. Figure 8-8 presents the number of registered users and the number of registered users making use of HeLP-Diabetes for each month of the study.

Despite the number of patients registered to HeLP-Diabetes increasing cumulatively each month, the percentage of registered patients actually using HeLP-Diabetes did not change markedly from month to month. October 2014 had the lowest percentage of registered users making a visit to HeLP-Diabetes with 3.0% (n=4) of registered users visiting HeLP-Diabetes (on one or more occasions). May 2014 saw the highest percentage of registered users using HeLP-Diabetes (20% n=18).

This relatively consistent pattern of use suggests that patients may have stopped using HeLP-Diabetes over time, otherwise a more upwards trend of percentage of registered users making use of HeLP-Diabetes might be expected.

Figure 8-8 Number of registered users and the percentage making use of HeLP-Diabetes each month



8.6.4 Content accessed

Patients viewed a total of 396 (68.9%) of the 574 HeLP-Diabetes pages, suggesting a wide range of content was of interest to patients. The most frequently viewed pages are displayed in Table 8-5. Apart from the homepage, pages on food (62 views), common diabetes questions (54 views), care planning (43 views) and the forum (42 views) were accessed the most frequently.

Table 8-5 Most frequently viewed HeLP-Diabetes pages

Title of page accessed	Frequency of page views	Percentage of all page views
Homepage	520	16.1
Food	62	1.9
Common diabetes questions	54	1.7
My diabetes care plan	43	1.3
Help Diabetes Forum	42	1.3
How my body can be affected	39	1.2
My health profile	39	1.2
Eating & drinking	35	1.1
Exercise videos	32	1.0
My test results	32	1.0
Understanding diabetes	32	1.0
Staying healthy	28	.9
My appointments	22	.7
Understanding my moods	22	.7
How is type 2 diabetes treated?	21	.7
Living & working with diabetes	20	.6
Physical activity	20	.6
Looking after yourself	19	.6
My health record	19	.6
Snacks and desserts	19	.6
My health tracker	17	.5
Practical diet advice	17	.5
Quick guides	17	.5
Sexual problems	17	.5

8.7 Were there any factors that predicted patient use of HeLP-Diabetes?

Univariable and multivariable regression analyses predicting overall HeLP-Diabetes use (no use compared to use) were carried out. Multivariable analyses were conducted on all complete cases of data (n=114).

Registration method was shown to be a significant predictor of HeLP-Diabetes use (see Table 8-6).

8.7.1 Univariable results

Univariable logistic regression analyses found that relative to no HeLP-Diabetes use those who made use of HeLP-Diabetes were more likely to have advanced computer skills (OR=2.46, 95% CI=1.12, 5.40) (OR=2.07, 95% CI=1.14-3.74) and be registered via the patient registration method (OR=5.54, 95% CI=2.80-10.96).

8.7.2 Multivariate results

Multivariate logistic regression analysis found that relative to no HeLP-Diabetes use those who made use of HeLP-Diabetes were more likely to be registered by the patient registration method (i.e. registered themselves to use HeLP-Diabetes) (OR=5.91, 95% CI=2.84-12.31).

Despite being a significant predictor in the univariable analysis, advanced computer skills did not significantly predict HeLP-Diabetes use in the multivariable analysis (OR=3.15, 95% CI=0.81, 12.21).

Table 8-6 Univariable and multivariable logistic regression for predictors of some usage of HeLP-Diabetes

Characteristics associated with some use of HeLP-Diabetes	Univariable			Multivariable N=114	
	N	Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
Age (years)	202	1.01 (0.99, 1.04)	0.23	0.99 (0.95, 1.04)	0.74
Sex:	205		0.30		0.54
Male		1.00		1.00	
Female		0.75 (0.43, 1.29)		1.34 (0.53, 3.42)	
Ethnicity:	205		0.08		0.28
White British		1.00		1.00	
Non-white British		0.61 (0.35, 1.06)		0.61 (0.25, 1.50)	
Education:	122		0.08		0.62
None/School leaver		1.00		1.00	
A-level or higher		1.96 (0.93, 4.12)		1.30 (0.47, 3.65)	
Duration of diabetes:	200		0.17		0.73
<1 year		1.00		1.00	
1-5 years		0.62 (0.30, 1.28)		0.65 (0.15, 2.87)	
5-10 years		1.17 (0.50, 2.73)		1.38 (0.25, 7.73)	
>10 years		1.42 (0.63, 3.19)		1.00 (0.15, 6.65)	
Management of diabetes:	195		0.31		0.59
Lifestyle alone		1.00		1.00	
Lifestyle and tablets		1.03 (0.73, 5.50)		1.11 (0.23, 5.45)	
Lifestyle, tablets and insulin		2.00 (0.73, 5.50)		0.53 (0.05, 5.04)	
Computer Skills:	184		0.046		0.19

	Basic	1.00		1.00
	Intermediate	1.86 (0.96, 3.61)		2.08 (0.70, 6.17)
	Advanced	2.45 (1.12, 5.40)		3.15 (0.81, 12.21)
Registration model:		205	<0.0001	0.0020
	Staff registered		1.00	1.00
	Self-signup	5.54 (2.80, 10.96)		5.21 (1.83, 14.82)

8.8 Were there any factors that predicted HeLP-Diabetes registration method?

Univariable and multivariable binary regression analyses predicting registration method (staff registered or patient registered) were carried out. Multivariable analyses were conducted on all complete cases of data (n=117).

Education was found to be a significant predictor of registration method (see Table 8-7).

8.8.1 Univariable results

Patients who registered themselves to HeLP-Diabetes were more likely to have A-level qualifications or higher (OR=4.52, 95% CI=2.10, 9.75), and have advanced computer skills (OR=2.76, 95% CI=1.25, 6.12).

8.8.2 Multivariable results

Patients who registered themselves to HeLP-Diabetes were more likely to have A-level qualifications or higher (OR=3.90, 95% CI=1.59, 9.57).

Despite being a significant predictor in the univariable analysis, advanced computer skills did not significantly predict self-sign up in the multivariable analysis (OR=3.50, 95% CI=(1.06, 11.31)).

Table 8-7 Univariable and multivariable logistic regression investigating the association between patient characteristics and the likelihood of patient self-registration

Characteristics associated with self-registration	Univariable			Multivariable N=117	
	N	Odds Ratio (95% CI)	p-value	Odds Ratio (95% CI)	p-value
Age (years)	202	1.01 (0.98, 1.03)	0.56	1.00 (0.97, 1.03)	0.95
Sex:	205		0.12		0.42
Male		1.00		1.00	
Female		0.62 (0.34, 1.14)		1.43 (0.59, 3.46)	
Ethnicity:	205		0.57		0.27
White British		1.00		1.00	
Non-white British		0.84 (0.46, 1.52)		0.62 (0.27, 1.44)	
Education:	122		0.0001		0.0030
None/School leaver		1.00		1.00	
A-level or higher		4.52 (2.10, 9.75)		3.90 (1.59, 9.57)	
Computer Skills:	184		0.037		0.12
Basic		1.00		1.00	
Intermediate		1.23 (0.59, 2.54)		1.60 (0.61, 4.16)	
Advanced		2.76 (1.25, 6.12)		3.50 (1.06, 11.31)	

8.9 Discussion

HeLP-Diabetes was adopted by two thirds of the GP practices within the CCG, and by both the hospital and community clinic. Taking into account that it was not possible to establish any contact with eight GP practices about HeLP-Diabetes, HeLP-Diabetes was adopted by three quarters (75.9%) of practices who had received information about it. Only one practice explicitly declined adoption.

As there are relatively few other studies describing adoption of an internet intervention within routine care by health services, it is hard to draw comparisons between the rates of adoption seen here with rates in other studies. Many other implementation studies focus on patient rates of uptake of interventions from services that have opted to take part in research. For example, a recent study by Aarts *et al.* (220) explored the implementation of an internet based fertility website in a clinic that had agreed to act as a research site, and thus not representative of everyday routine care. Generalizing from these studies is difficult because organisations that participate in research may differ in systematic ways to those that do not (245). They may exhibit greater readiness to change and usually receive advice and support to implement interventions. Participation in research may also give interventions greater salience than they might otherwise receive. For practices implementing interventions into everyday routine care, the interventions must compete with other priorities without the help of compensating factors provided through participation in research (245). The current study, where adoption of HeLP-Diabetes was not contingent on participation in research, adds valuable information on rates of adoption of an internet intervention by NHS services, which has not been explored previously. More studies of this nature are needed as patient access to interventions delivered by the NHS and other health services is dependent on gate keepers such as these adopting them.

Half of the GP practices in the CCG (48.6%) implemented HeLP-Diabetes to some degree. Implementation was defined as a practice registering (or a patient self-registering) one or more patients to use HeLP-Diabetes. Both the hospital and community clinic also implemented HeLP-Diabetes. The number of patients registered to HeLP-Diabetes from each practice or clinic ranged from 1 to 40. There was no correlation between the time that a service had access to HeLP-Diabetes and the number of patients they registered suggesting that the extent to which HeLP-Diabetes was used by services was not related to how long it had been available. Four practices who had decided to adopt HeLP-Diabetes did not implement it (did not register any patients).

A research diary was kept during the study. Analysis of this using Normalization Process Theory (NPT) (7, 97) suggested that the high rates of adoption of HeLP-Diabetes was related to good coherence and cognitive participation, however, the low use of HeLP-Diabetes by practices and clinics was related to collective action. In other words, those practices and clinics were generally willing to participate but the reality of putting the work in to implement HeLP-Diabetes was too much for many of them. This had a negative impact on reflexive monitoring as few patients were

registered, which in turn led to reduced cognitive participation (i.e. reduced desire to participate).

Previous studies have reported that implementing diabetes management strategies can be challenging for primary care practices (187, 245-247) and the NHS context in which HeLP-Diabetes was being implemented (discussed in Chapter 7) likely played a considerable role in the ability of practices and clinics to implement it. During the time HeLP-Diabetes was being implemented, the NHS was in the grip of the biggest crisis in its history (237, 248). Complexity in patient cases, reduced workforces, reduced primary care budgets, an increase in resources being spent on contractual and regulatory requirements such as the Quality and Outcomes Framework (QOF) and enhanced services, GP time being spent on duties other than care giving, and political and public pressure on GPs and practices for increased access to GPs over extended hours and seven day working, have all contributed to a fatigued system (236-239). The fact that three practices within the CCG closed down during the study period suggests that practices were under a high degree of stress.

Many previous studies of the implementation of innovations within healthcare settings have pointed to the influence of context (249). The systematic review conducted as part of this thesis found that the implementation of e-health initiatives can be affected by financial, legislative and policy factors and by the availability of resources to enable implementation. A systematic review of the causes of the evidence to practice gap in primary care (the delay of translating new innovations into everyday clinical practice) stresses the importance of external contextual factors such as policies and legislation, economic climate, incentives, and the specific context into which interventions are being embedded (250). A systematic review of challenges in primary care relating to the delivery of diabetes care describes clinicians facing multiple challenges in the management of diabetes including struggling to meet evolving treatment targets within limited time and resources (246). Similarly a systematic review of barriers to diabetes management found that over-stretched primary care services and a myriad of competing tasks act as barriers to diabetes care (247). Work from the NPT literature often points to issues of contextual integration as inhibiting the implementation of initiatives. A study by Kennedy *et al.* (187) evaluating the implementation of self-management support for type 2 diabetes within primary care found that competing priorities such as incentivised targets stopped a new intervention from becoming prioritised. A study of the implementation of a care co-ordination model by nurses in general practices was hindered by the lack of time available to allocate to the task and the fact that time to implement the intervention was not considered feasible in busy general practices (251).

205 patients were registered to use HeLP-Diabetes from the eighteen GP practices and the hospital and community clinics which implemented HeLP-Diabetes. This comprised approximately 3.4% of the eligible patients attending these services.

There is limited evidence from previous research about the rates of patient uptake of internet interventions within routine primary care. One other study identified explored the patient uptake of a web-based alcohol misuse service that was implemented within routine practice in one primary care trust. Low rates of uptake were also reported with only thirty-one patients referred to the service in a twelve month period (252). The authors suggest that low rates of referral were due to reluctance on the part of health professionals to discuss alcohol with their patients and difficulty in remembering the existence of the new service. Uptake of non-internet based diabetes interventions delivered through NHS services report similarly low rates of patient uptake. As discussed in Chapter 1, group based, face-to-face diabetes education to which patients are referred as part of routine care is attended by only 5.3% of patients in England (35). In order to understand the potential of internet interventions like HeLP-Diabetes that are intended to be delivered to patients through healthcare services, there is a real need for more studies that address uptake into everyday routine practice in order to help identify interventions most likely to have a meaningful impact on population health and to fit local settings and priorities. Diabetes interventions measured as part of trials consistently report higher rates of patient uptake than found in the current study. For example, two computer based diabetes health behaviour change programmes, the Diabetes Priority and Diabetes Health Connection were reported to reach (defined as the patient participation rate) 50% and 38% respectively of all patients in participating practices with type 2 diabetes (253). Results like this are unlikely to reflect rates of adoption by patients outside of research trials in which services have opted to participate and deliver the interventions and where patients who participate are often self-selecting and self-motivated (254).

A wide range of patients registered to use HeLP-Diabetes. A third (31.2%) of patients who registered either had no education or basic education, just under half (47.5%) were from non-white British ethnic backgrounds, and 38.5% had basic computer skills. The users of HeLP-Diabetes appeared to be representative of the Islington population as a whole in terms of ethnicity and education. Office for National Statistics census data from 2011 (230) reported that 48% of Islington residents were white British and 51% were from other ethnic backgrounds including white other (20%), Black/African/Caribbean/Black British (13%), Asian/Asian British (9%) and other and mixed ethnicities (9%). Grouping users of HeLP-Diabetes into these categories shows a very similar distribution: White British (47.8%), white other (11.2%), Black/African/Caribbean/Black British (16.7%), Asian/Asian British (11.2%) and other and mixed ethnicities (8.4%). Census data shows that 17% of Islington residents had no education, 16% had basic education, 9.8% had A-level qualifications and 48.1% had a university level qualification. Categorising HeLP-Diabetes users in this way reveals a similar picture with the exception of higher education, for which there was not as high a proportion of HeLP-Diabetes users with university level qualifications as in Islington as a whole (15.1% had no education, 16.1% had basic education, 7.8% had A-level qualifications and 20.5% had a university level qualification). Patients registered to HeLP-Diabetes had exactly the same proportion of home internet access as the UK average (86%) (45).

Arguments have been made in the literature that participants in studies of internet interventions are not generally representative of wider populations (255). It has been reported that participants in internet intervention research tend to be more highly educated, with a high percentage having a university degree (256), and in the UK tend to be White British (257, 258). This research is the only (to my knowledge) to explore uptake of an internet intervention within routine practice, where use of the intervention was not dependent on enrolment into a research study or limited by any eligibility criteria other than diagnosis. Overall the patients who have registered to use HeLP-Diabetes seem representative of the wider CCG population in terms of education and ethnicity and the UK population in terms of home internet access.

Overall use of HeLP-Diabetes varied considerably between participants. Just under half (49.3%) of registered users made no further use of HeLP-Diabetes following the day they were registered. Of those who did go on to make further use of it (50.7%) there was great variability in the amount of use. Although the median number of days using HeLP-Diabetes was two, actual use ranged from patients who used it on one further day to those who used it on 77 further days.

Comparisons of HeLP-Diabetes use with other internet interventions for type 2 diabetes is complicated by the fact that many studies of internet based diabetes interventions do not provide details of the use of the intervention (259-263), and for those that do, the differences in analyses of usage data and study design make direct comparisons difficult. In comparison to studies that report different measures of usage, relatively low use was made of HeLP-Diabetes by patients (38, 264-266). However, many of the interventions in these comparison studies also crucially differed to HeLP-Diabetes, as in HeLP-Diabetes patient use was not prescriptive or regularly encouraged by staff. The interventions in other studies either provided specific components for patients to complete over a certain time period, introduced tailored content at a certain time point after registration to increase patient engagement or provided consistent staff encouragement of patient use. Commonalities between use of HeLP-Diabetes and use of interventions in these studies were however observed in terms of patient attrition to the interventions. The proportion of registered users using HeLP-Diabetes on a monthly basis did not increase incrementally as the number of registered patients increased throughout the study. This suggests that registered users did not continue to make ongoing regular use of the intervention over long periods of time, or that use was sporadic. A declining pattern of use is commonly reported with internet interventions (68, 266).

A potential advantage of internet interventions for supporting self-management is their availability for use at any time of day or night, and it was notable that use of HeLP-Diabetes was recorded for every hour of the day. One of the most commonly reported barriers to attendance at group based diabetes education is accessibility (37, 39, 41) and the fact that these courses are usually held during working hours and are therefore not convenient for people who work. Over half of all page views were conducted outside of working hours suggesting that HeLP-Diabetes may fit well into peoples' lives, being used at the most convenient times for them.

The most commonly accessed HeLP-Diabetes pages included those containing information about food, common diabetes questions and complications of diabetes ('How the body is affected'); pages that allowed patients to input their own data ('My diabetes care plan', 'My health profile') and understand test results; the forum and exercise videos. These pages reflect the wide range of tasks that someone living with diabetes has to engage with in order to manage their condition. Previous studies have found that the most important information for people with diabetes is information on diet, complications of diabetes and exercise (267) which seems to be reflected in the use of HeLP-Diabetes. The diversity of content viewed is in keeping with the range of areas of diabetes management identified in the HeLP-Diabetes development work with people with type 2 diabetes (268). Patients taking part in those focus groups reported wanting a wide range of content that included details of the biomedical aspects of the disease and covered practical aspects of living with type 2 diabetes such as dietary advice, physical activity and information about health services.

An area of concern for delivering healthcare through the internet is the issue of the digital divide. The digital divide refers to the gap between those who have access to information technologies such as the internet and those who do not (66). For people with diabetes, it is often those who experience the higher burden of diabetes who are also most likely to lack access to the internet, as older age, lower educational status and income are negative predictors of diabetes outcomes and internet use (62). However, the characteristics which have previously been reported to influence the digital divide (age, ethnicity, computer skills and education) did not appear to affect the level of use patients made of HeLP-Diabetes. The lack of association of age, ethnicity, computer skills and education with use of HeLP-Diabetes supports other studies of engagement with internet based interventions. A study of diabetes self-management education delivered via the internet indicated that patients with a variety of education, age, income levels, ethnic backgrounds, socio-demographic, psychosocial, and clinical characteristics were able to use the intervention. Moreover, older patients, ethnic minority patients as well as those with a higher risk of diabetes complications, lower health literacy, and little experience of computers were as engaged with the intervention as other participants (38). There was no association with gender and HeLP-Diabetes use which is in contrast to previous studies which have found that females are more likely to engage in self-management education than males (42) and have observed gender differences in self-management (211) and accessing health information online (212).

There were also no differences in use of HeLP-Diabetes by the duration that patients had had diabetes for and diabetes management style. Some models of chronic illness have argued against the notion that patient information and support needs are determined by the length of time that a person has had a condition. For example, the Shifting Perspectives Model of Chronic illness (269) suggests that needs are determined by patients' perceptions of wellness and illness which continually change throughout a lifetime and which may be influenced by social context and life events rather than just the duration of their condition. This has implications for diabetes education (as will be discussed in Chapter 11) which is traditionally targeted at newly diagnosed patients.

However, patients who made most use of HeLP-Diabetes registered using the patient registration method and patients who registered themselves to HeLP-Diabetes (rather than being registered by a member of staff) were more educated. Those less education were more likely to be registered by a member of staff. Being registered by a member of staff was likely to have facilitated access for uneducated patients and thus helped to bridge the digital divide in accessing this internet based intervention, especially as education was not a predictor of level of use. A study of patient factors associated with non-uptake of group based structured education also did not find an association with patient education and uptake (42). The findings from the current study suggest that if patients with basic education are given support to access internet interventions this may bridge the digital divide so that their ongoing use of the intervention is comparable to patients with higher educational attainment.

Facilitating access to internet interventions has been found to promote engagement with internet based health interventions (270). A review of factors that influence user engagement in internet-based behavioural interventions for chronic illness found that interventions with the lowest attrition rates included features such as professional feedback, social networking and the ability to make contact with a health care professional. A previous study of a diabetes self-management internet intervention investigated the effects of adding tailored self-management training or peer support components to a basic information-focused comparison intervention. Intervention usage was reported as greater at all points during the study for participants who received the additional tailored self-management training or peer support components compared to those not receiving these interventions (68).

The implications that these findings have for practice, policy and research are discussed in the overall discussion chapter (Chapter 11), as are the methodological strengths and weaknesses of the studies in this thesis.

9 STAFF PERCEPTIONS OF AND EXPERIENCES WITH THE IMPLEMENTATION OF HELP-DIABETES

9.1 Chapter summary

This chapter presents the findings from the analysis of semi-structured interviews conducted with staff. The interviews explored the adoption and implementation of the HeLP-Diabetes intervention within routine NHS practice in order to address the following research question:

- What barriers and facilitators to the adoption and implementation of HeLP-Diabetes by NHS services did staff identify?

9.2 Introduction

As described in detail in Chapter 1, the referral of patients with type 2 diabetes to self-management education is now an incentivised part of routine NHS diabetes care. However, patient attendance at group based education is not incentivised and uptake is extremely low. HeLP-Diabetes, an internet based self-management programme, offers an alternative to group based structured education and has been developed to be delivered through the NHS by staff (see Chapter 2).

Studies suggest that health professionals may influence patient uptake of group based diabetes education (37). However, little is known about what healthcare staff think about self-management support for diabetes, including group based diabetes education. In addition, to my knowledge, no studies have explored the views of staff towards an online structured education intervention for type 2 diabetes, designed to be delivered to patients through NHS services.

A detailed implementation plan to integrate HeLP-Diabetes into routine practice was developed (see Chapter 5) and put into practice in one CCG in London between July 2013 and August 2015. In order to understand why or why not something is implemented it is important to understand the views of those doing the work of implementation (187). The implementation of innovations like HeLP-Diabetes requires a change in professional behaviour which in turn requires an understanding of the context in which they work and the values which they espouse. In order to identify insights and experiences that can usefully shape the future direction of HeLP-Diabetes implementation and other web-based services within routine NHS care, this qualitative study explores the perceptions of staff towards delivering diabetes care and their views as to how an intervention like HeLP-Diabetes, designed to support patient self-management, can be best implemented within routine care.

9.3 Aim

To investigate, from the perspective of those implementing it and using it in practice, aspects of the HeLP-Diabetes implementation plan that succeeded, the aspects that were less successful,

the barriers and facilitators to adoption and widespread implementation and future directions to improve adoption of HeLP-Diabetes.

9.4 Results

9.4.1 Interview subsample

Twenty one members of practice and clinic staff took part in seventeen interviews and one focus group (with four staff from the same GP practice). The interview sample represented a diverse range of professional roles including GP partners (3/21), a salaried GP (1/21), a practice manager (1/21), diabetes specialist nurses (2/21), practice nurses (6/21), an advanced nurse practitioner (1/21), healthcare assistants (3/21), receptionists/administrators (3/21) and a commissioning officer (1/21). There were fewer male participants (6/21) than female (15/21) and the sample was predominantly white British (16/21) with other staff representing Irish (1/21), White/Black Caribbean (1/21), Sri Lankan (1/21), Indian (1/21) and New Zealand/USA (1/21) ethnicities. The majority of staff described their skills with the internet as 'Experienced' (e.g. used or currently use the Internet regularly) (19/21), with the remainder (2/21) describing themselves as 'Expert' (e.g. work is to do with the Internet). Staff tenure in their current role ranged from less than a year to 20 years' experience.

The majority of staff worked in GP practices (18/21), with a further two based in the hospital clinics and one at the CCG headquarters. Unfortunately, no member of staff from community clinics participated. Most of the staff worked in services where HeLP-Diabetes had been adopted and implemented to some extent (19/21). The number of patients registered to HeLP-Diabetes from these services ranged from 1 to 40. One participant worked in a GP practice where adoption of HeLP-Diabetes had been declined and another worked in a GP practice where HeLP-Diabetes had been adopted (adoption agreed), but hadn't actually been implemented (no patients registered). Table 9.1 presents details of the characteristics of the interview sample.

Table 9-1 Characteristics of the staff participants

ID	Age range	Gender	Professional Role	Service setting	Years in current role	Ethnic background	Internet experience	Practice/clinic implementation status	Number of patients registered
ST1:	35-44	Male	GP Partner	GP practice	11	White British	Experienced	Adopted and implemented	40
ST2:	55-64	Female	Diabetes Specialist Nurse	Hospital	12	White British	Experienced	Adopted and implemented	30
ST3:	45-54	Male	Commissioning Officer	N/A	2	White British	Expert	Adopted	N/A
ST4:	25-34	Female	Practice Nurse	GP practice	2	White British	Experienced	Adopted and implemented	28
ST5:	45-54	Female	Health Care Assistant	GP practice	10	White British	Experienced	Adopted and implemented	40
ST6:	35-44	Male	GP Partner	GP practice	3	Indian	Experienced	Adopted and implemented	8
ST7:	35-44	Female	Receptionist/Admin	GP practice	9	White British	Experienced	Adopted and implemented	40
ST8:	18-24	Male	Receptionist/Admin	GP practice	1	White and Black Caribbean	Experienced	Adopted and implemented	11
ST9:	55-64	Female	Advanced Nurse Practitioner	GP practice	4	White British	Experienced	Adopted and implemented	3
ST10:	35-44	Male	Practice Manager	GP practice	7	White British	Experienced	Not adopted	0
ST11:	35-44	Female	GP Partner	GP practice	17	White British	Experienced	Adopted and implemented	15

								implemented	
ST12:*	45-54	Female	Practice Nurse	GP practice	4	White British	Experienced	Adopted and implemented	11
ST13:*	45-54	Female	Practice Nurse	GP practice	9	White British	Experienced	Adopted and implemented	11
ST14:*	35-44	Female	Health Care Assistant	GP practice	<1	Sri Lankan	Experienced	Adopted and implemented	11
ST15:*	25-34	Female	Practice Nurse	GP practice	8	White New Zealand/USA	Experienced	Adopted and implemented	11
ST16:	55-64	Female	Diabetes Specialist Nurse	Hospital	1	White British	Experienced	Adopted and implemented	30
ST17:	45-54	Female	Health Care Assistant	GP practice	7	White British	Expert	Adopted and implemented	40
ST18:	25-34	Female	Receptionist/Admin	GP practice	5	White British	Experienced	Adopted and implemented	1
ST19:	45-54	Male	Salaried GP	GP practice	1	White Irish	Experienced	Adopted and implemented	11
ST20:	65-74	Female	Practice Nurse	GP practice	17	White British	Experienced	Adopted but not implemented	1
ST21:	55-64	Female	Practice Nurse	GP practice	20	White British	Experienced	Adopted and implemented	3

***staff who took part in the focus group**

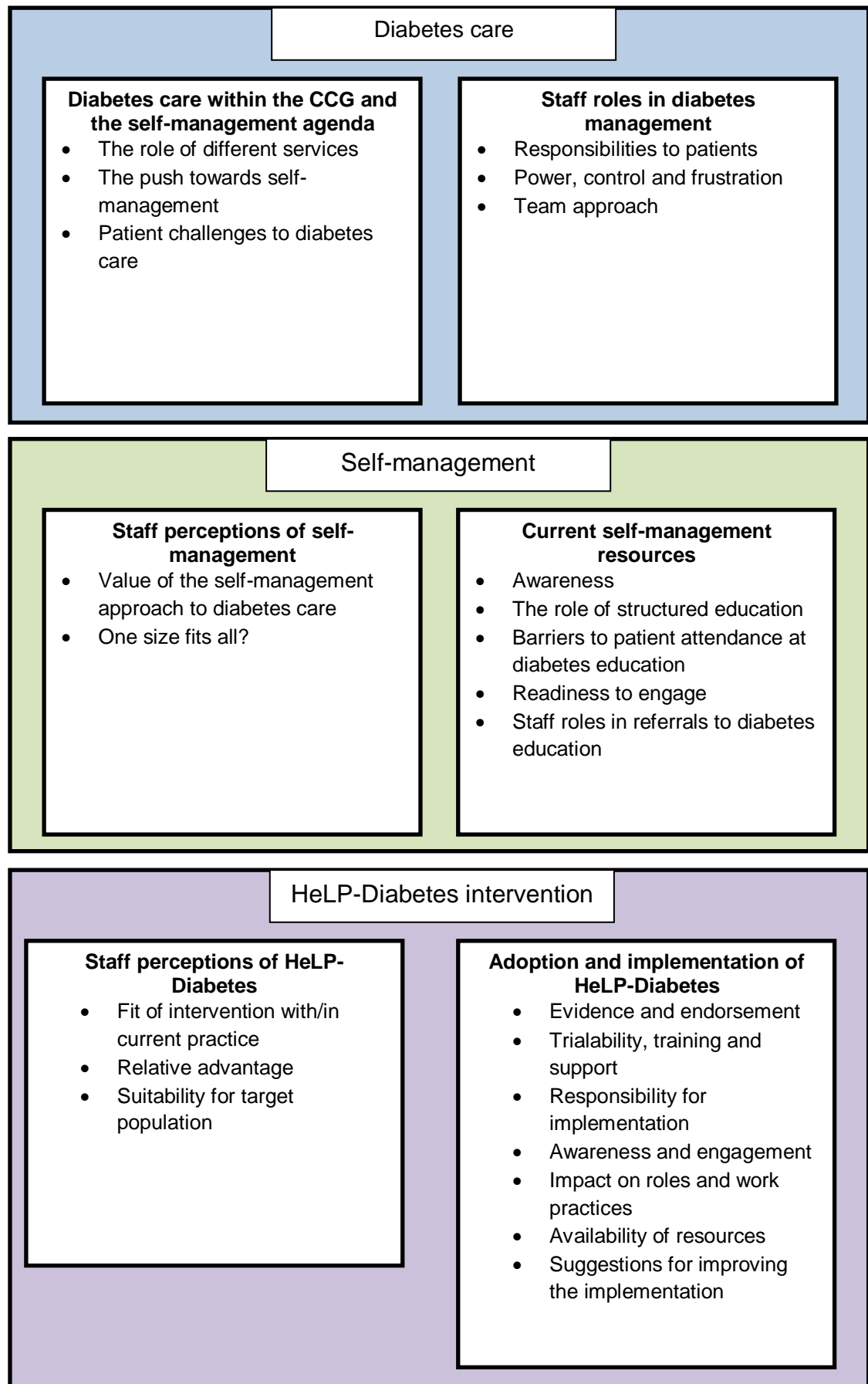
9.4.2 Results of thematic analysis

Presented below are the findings from the thematic analysis of the interviews with staff. The main themes that emerged from the data related to:

- Diabetes care within the CCG and the self-management agenda
- Staff roles in diabetes management
- Staff perceptions of self-management
- Current self-management resources
- Staff perceptions of HeLP-Diabetes
- Adoption and implementation of HeLP-Diabetes

To help interpretation, these themes and the subthemes within them are presented in Figure 9-1. Also for ease of interpretation, participant ID numbers and the participant's professional role are provided with each illustrative quote. In instances where questions I have asked are presented I am referred to as R (researcher).

Figure 9-1 Themes and sub themes identified from the analysis



9.4.3 Diabetes care within the CCG and the self-management agenda

The role of different services

There was a clear distinction made by staff as to the role of primary and secondary care services in the treatment of patients with type 2 diabetes within the CCG. GP practices provide the majority of care to people with diabetes and those with more complex problems are escalated through intermediate and secondary care services.

ST3: we have primary care service, of course, which is basic GMS contract services looking at just basic diabetes care with no major complications. Anything slightly complicated gets escalated into the intermediate service and then into a secondary care if they become particularly complex, or have multiple co-morbidities.

(Commissioning Officer)

The care of patients with diabetes within General Practice, was recognised by staff as still relatively new, but had become very central to the role of being a healthcare professional within General Practice.

ST1: When I started in general practice diabetes was still, you know, it was a Secondary Care thing, but we did a little bit in general practice. Now it's very much, you know, type 2 diabetes is, I would say, very much the bread and butter of what we do as GPs

(GP partner)

The aim within the CCG was for patients to be discharged back to primary care services as soon as possible.

ST3: even if they have multiple co-morbidities the idea is that ultimately a patient with diabetes should be treated in primary care and that's our aim in [Name of Borough] certainly.

(Commissioning Officer)

However, it was recognised that this was not always the case, and that patients may remain being treated in secondary care services for longer than desired.

ST16: we see more complex type two patients so people with perhaps heart problems, difficult to control hypertension, foot problems, renal problems, people who are needing multiple therapies to control their diabetes so they are not the straightforward patients. That having been said there are a number of people who perhaps could be discharged if that was the ethos of the clinic which it doesn't seem to be.

(Diabetes Specialist Nurse)

The importance of these different services within the CCG working together in order to provide the best possible care for people with diabetes was mentioned often. It was a particular aim of the CCG to make the care pathway for patients with diabetes as seamless as possible.

ST3: it's about integrating services so that the patient is unaware, should be, theoretically, unaware of however many people involved in his care, they just follow it pathway. And that's all that they need to think about, you know, and that's the aim for what we've all been working for.

(Commissioning Officer)

The push towards self-management

Staff described how there had been a recent shift in emphasis towards an increased focus on self-management within the CCG, driven by the introduction of care planning for all patients with long term conditions.

ST3: One of the things that [Name of Borough] was committed to when we became CCG was implementation of care planning into all patients, all management of patients with long term conditions

(Commissioning Officer)

The drive from the CCG to promote the Year of Care (an approach which uses care planning as a central component to drive a proactive process of care designed to improve patient involvement, provide a more personalised approach and support self-management of diabetes and other long terms conditions) and make patient self-management of diabetes a priority was felt by the majority of staff within the CCG. They all reported receiving training on care planning recently and were aware of the increased focus on long term condition management. This new focus had created a change in practice.

ST10: before people would just come in and then you would respond to what they were presenting with, you know? They'd say, oh, you know, you'd do your blood test and then you'd say, okay, oh, looks like your control's gone a bit high, you know, Mrs. Biggins, whatever, so, you know, what's changed, you know? And then just dealing with it like that. But now, it's, like, a bit more, kind of, proactive I suppose is the word which people might use.

(Practice Manager)

Although generally received positively by staff, there were some staff who presented resistance to the changes necessary in order to meet the new demands of the Year or Care. One nurse discussed the difficulty that she has experienced changing the focus of consultations to fit in with the Year of Care approach.

ST9: It's been a huge change for me because, I mean, I've been a nurse for 40-odd years, and it was always that we advise patients or we empower patients... We're now trying to get the patients to change their way of thinking, and for them to actually identify ways of addressing their problems, setting goals, how they're going to do it... And it's quite hard for me to take on.

Staff discussed the conflicts within time limited appointments to achieve the new approach to diabetes care advocated by the Year of Care whilst also providing a personalised service to patients.

ST21: We're trying to follow the Year of Care format, but time pressure is huge...you're supposed to be asking open questions and helping the person to find their own solutions... when they've also got the, sort of, whilst I'm here, I'd like you to look in my ears, I'd like you to look at this wound on my leg, I'd like you to tell me how I can get the housing people to sort out my heat or whatever.

(Practice Nurse)

In particular, the ever increasing demand for staff to work through a designated list of Quality and Outcomes Framework (QOF) targets within the appointment time led to frustration by some that individualised care was being missed, or pushed to the end of appointments. Staff expressed a tension around being able to deliver different measures of quality of care. Contrasts were drawn between achieving measurable outcomes defined by the QOF and being able to provide a level of service to patients that they perceived to be quality care.

ST20: it's not just about earning GPs money, it's about quality of care, and advice, that you're giving to people. And I very often say to them, sorry, you're sitting there, and I've got to keep turning away from you to the screen, to tick all these boxes.

(Practice Nurse)

Time pressures within consultations proved a constant source of frustration for many staff, who reported feeling constrained by time and workload pressures which impacted on their ability to provide the level of care to patients with type 2 diabetes that they desired. Many recognised that the care they were able to provide was not optimal because of these constraints.

ST13: within that time there are practical things to do: foot checks, filling out various forms and referrals for things that they... if they haven't had their eye screening and things like this. So, you're packing it full of things to do: blood pressures, heights and weight and stuff, so there isn't a huge amount of time within that for a lot of conversation

(Practice Nurse)

Patient challenges to diabetes care

Patient related factors also influenced the level of care that could be optimally delivered. Staff often described co-morbidities associated with diabetes as having an impact on the care that could be delivered. These challenges were often described as outside of the control of staff.

ST2: I think a major barrier to caring for people with type 2, by the time they get into the secondary care system, so these are people far down the line, maybe

they've got complications, they've ended up on very complex treatment regimens.

(Diabetes Specialist Nurse)

In many of the interviews patients' socio-economic and occupational circumstances were discussed as barriers to staff being able to engage patients with diabetes care. Language barriers and educational limitations were most frequently mentioned, and the demographic characteristics of the CCG was often contrasted with other areas of the country, with this CCG often described as 'challenging'

ST20: ... it's the poor starting point that you have with a lot of the patients clinically, if I'm honest. As I say, we know that with deprivation goes an awful lot of this...they're victims of their own lifestyle. Poor lifestyle, one way and another.

(Practice Nurse)

Discussion around the challenges of providing care to patients who didn't speak English arose frequently. Often staff expressed frustration that they were unable to provide adequate care in these situations.

ST6: Understanding, whether that is by the patient, for the patient. Language barrier. A lot of... our population's quite diverse so the language barrier's quite difficult.

(GP Partner)

Unsurprisingly, in such a diverse, multi-faith and multi-ethnic CCG, issues of culture in providing care to patients were often mentioned. Some staff talked about the way culture gave rise to patients having a fatalistic approach to diabetes care which impacted on their motivation to engage with looking after their condition.

ST2: that fatalistic, cultural approach, God will take me when it's my time anyway so it doesn't matter what I do. So all those things make it difficult to get through to people with type 2

(Diabetes Specialist Nurse)

One clinician described frustration with patients who returned to their countries of origin for long periods of time, during which they took breaks from looking after their diabetes, only to return having very poor glycaemic control. In this example, this GP expresses frustration with the ability to provide ongoing care when patients are away and 'opt out' of treatment for part of the year. This represents a mismatch between a western model of care which focusses on the idea of continuity of care on the part of the HCP and patient and patients' lifestyle and cultural constraints.

ST6: a lot of our Bengali patients seem to disappear and go to Bangladesh for six months. They only take three months' worth of medication with them. They don't bother getting their medication while they're over there and then they

come back, they do their... say, I've been away, can I have a blood test? Do the blood test, you're like, oh my God. So, you have to start from scratch again. And then they do that every year. So, it's really difficult.

(GP Partner)

9.4.4 Staff roles in diabetes management

Responsibility to patients

Staff presented their role in the care of patients' diabetes differently. Many viewed themselves as a partner in the management of diabetes, with a responsibility to collaborate successfully with patients in order for them to manage their condition.

ST1: working with patients, and being responsive to patients' needs, so more of a partnership working with patients

(GP partner)

Others however, recognised limitations in what they could achieve with patients and suggested that it is ultimately up to patients to take on the responsibility of managing their condition. This view point was often associated with the acknowledgement that staff simply did not have adequate time to provide the amount of care they might ideally like to be able to give to patients.

ST20: you see a healthcare professional for about three hours a year, and the remaining, I don't know, I forget how many hours it is, you're out there, I'm not saying we've thrown you to the wolves, but you're out there looking after yourself.

(Practice Nurse)

Some staff talked about a desire to be able to do more for patients, whereas others were resigned to the fact that there was only so much they could do.

ST16: when they come to us they don't want to make changes and if people don't want to make changes there is little that we can do. We can't force people; we're only here to support guidance if they want to make those changes

(Diabetes Specialist Nurse)

Many staff described a large part of their role as trying to engage patients with their diabetes, and reported having to spend a considerable time convincing patients of the benefits of looking after their diabetes and encouraging them to undertake actions of self-care.

ST1: I think there is a medical side to it, and it is important to address the medical factors, but that needs to be tailored with the patient, and actually is part of the engaging of the patient to realise that is an important aspect of it.

(GP Partner)

Power, control and frustration

Staff members' own sense of responsibility for patient's diabetes was reflected in concerns that without guidance and follow up patients might lose enthusiasm for managing their condition, use medications incorrectly, avoid seeking help when needed and not continue to follow advice.

ST9: And they may go through this honeymoon period where they're willing to do everything. They'll try. But you can tell when you bring them back, you know, you may say to them, okay, let's go through what your diet's like. You know, what have you had for breakfast, lunch and dinner yesterday. And then you can tell by what they're telling you that they've perhaps not looked at food labels and they've not really taken on-board

(Advanced Nurse Practitioner)

Others discussed a perceived lack of control with regards to knowing what their patients were doing to self-manage. One nurse described having to take on the role of 'detective' to uncover the 'truth' of what her patients were actually doing to self-manage.

ST2: they don't necessarily share with you the truth of what they're doing. So you don't really know whether people are actually taking all their medications, you might suspect... often they will tell you what they think you want them to say rather than what is actually true. And so a lot of the time it's like being a detective

(Diabetes Specialist Nurse)

Clinicians reported experiencing a range of often negative emotions in dealing with diabetes, especially around patient adherence to management plans.

ST20: I do feel a bit defeated sometimes, I must admit. Because, the usual suspects, and you think oh, blimey. Put on another couple of kilos.

(Practice Nurse)

A tension was described between staff feeling frustrated at patients' non-adherence and concern that they are pestering patients with their continued efforts to get patients to engage.

ST11: So there's quite a few of our 20 to 30 year olds who aren't seen at hospital, because they never turn up, so we have to see them and we have to chase them, and make them come in for prescriptions, and one feels a bit of a nag, really.

(GP Partner)

The responsibility to self-manage diabetes can result in patients being more 'expert' about their condition than their healthcare professionals. The majority of staff viewed patients becoming more knowledgeable about their condition positively and recognised that given the restrictions on the care staff are able to provide to patients, the more expert the patient in looking after their condition the better.

ST16: in a year so much of the time they are their own experts, we're not here for them, they have a very limited amount of time with a healthcare professional so self-management is pivotal to caring I guess for all long term conditions

(Diabetes Specialist Nurse)

One GP reported an experience of an informed patient challenging his knowledge. In this extract an irritation with the patient is evident under the surface, suggesting that there may be a tension between self-management and the possibility that patients may begin to challenge accepted medical thinking and question what they have been told. This could be viewed as the opposite side of self-management to those patients described earlier who did not want to take control of their diabetes at all, and leaves staff in a situation where they may have to manage potentially challenging interactions.

ST1: the sort of informed person, who likes to think he's... thinks he's very informed. He'll come in and he likes to challenge a bit, he likes to sort of throw a few things out there, and sometimes it's like... And I don't see it as authority, but if you like, challenging the authority of, you know, the doctor, and therefore this sort of perceived wisdom. And that's cool, that's fine

(GP Partner)

Team approach

Having a well organised and engaged team within the GP practice was also considered important in promoting providing adequate support to patients with diabetes.

ST19: having the practice, the GPs as a team organising themselves so that they've got appointments that are suitable, that they can go into the depth that you can't go into in a ten minute appointment.

(Salaried GP)

Other staff perceived that having the right mix of staff and good communication between team members was crucial to staff being able to support patients with diabetes.

R: it's quite a big practice, isn't it? Do you think that makes a difference when it comes to caring for people with diabetes?

ST5: No. I don't think that the size of the practice matters, I just think if you've got the right staff to do it. Yes. And I think education about it. Obviously as a receptionist, or even as a healthcare assistant, you only need to know so much, but we always have regular updates in meetings.

(Health Care Assistant)

9.4.5 Staff perceptions of self-management

Value of the self-management approach to diabetes care

Self-management of diabetes by patients was recognised by staff as necessary given the pressure on finances in the NHS and the increasing prevalence of people living with long term conditions, making more traditional models of care unfeasible.

ST2: Well, because of the context of the times that we're in, you know, and limited resources that we've got to deal with the increasing number of people who have long term conditions. So it's economic, isn't it? It makes sense.

(Diabetes Specialist Nurse)

As well as the economic necessity reported, self-management of diabetes was generally viewed as a positive approach to the management of diabetes by the majority of GPs and nurses, who valued patients being involved in the management of their health.

ST16: The emphasis should be on self-management. People need to be able to make informed decisions themselves and they need to have the confidence and skills to do that.

(Diabetes Specialist Nurse)

Using self-management as an approach was discussed as a way of enabling patients to take responsibility for their condition, preventing complications of diabetes, empowering patients and achieving better clinical outcomes.

ST4: Hopefully people eventually will be more inclined to take responsibility, because they feel like they're achieving something for themselves, and hopefully they've decided that they want to make those changes and so more likely to stick to them, rather than being told this is what you need to do, and then probably less likely to follow it.

(Practice Nurse)

One size fits all?

It was recognised that patients' desire and capacity to managing their own condition ranged greatly between individual patients, and that the emphasis on self-management might not be appropriate for all. Staff spoke of patients who wanted to be told what to do, rather than having to take responsibility and self-manage their diabetes.

ST9: The main challenges are... some patients prefer to be told what to do.

(Advanced Nurse Practitioner)

Some GPs related patients' resistance to the notion of self-managing their condition to cultural differences. It was noted that patients from cultures where a doctor led approach to disease management prevailed found it more difficult to understand and engage with the responsibility to self-manage diabetes, and the lack of input from staff was perceived as 'neglect'.

ST16: I suppose for some people... some people their health beliefs, they believe, particularly from our ethnic minority groups believe the doctors should be telling them what to do. And they feel that if we encourage them to look after themselves and self-manage more that we're neglecting them so that can be an issue.

(Diabetes Specialist Nurse)

Some reported that as a relatively new concept in healthcare, patients, especially of an older generation, may need time to adjust to the new role that self-management places on them in the management of their diabetes.

ST12: ...it's a really new concept for them, and it takes... it probably will take a while for many of them to buy into that idea

(Practice Nurse)

Some staff also recognised that patients might experience emotional barriers to being able to take on the role of managing their own condition.

ST17: ...a lot of them, once they're told they're diabetic, they get a bit scared. And some of them don't sort of really want to take it on board and manage it.

(Health Care Assistant)

Staff spoke about the need to recognise that placing the responsibility for diabetes management on the patients was not possible in all cases. It was suggested that staff had to retain majority responsibility for patients' diabetes care in some cases, for example where people had mental health problems or learning difficulties.

ST11: you still have to, if you like, retain responsibility as a professional a bit more for some of these hard to reach people, all the learning difficulties people, and the people with schizophrenia. And I think it's important not to throw the baby out with the bathwater, and say, oh, diabetes is all about the patients' responsibility...but one has a professional responsibility to try and enable the best care to be available to people.

(GP Partner)

Others suggested that there were patients for whom self-management was made very difficult because of a lack of education and a lack of cognitive ability to grasp the tasks required of them.

ST2: And it's understanding, it's cognition and it's, you know, sort of level of health literacy, you know, knowing who to go to, when, for help, and so, and intelligence. Many of our patients have had no formal education.

(Diabetes Specialist Nurse)

There was recognition that people have priorities other than diabetes. Many staff acknowledged that self-management of diabetes was often low down on the list of priorities for patients facing a range of social, financial and other health problems. Some expressed concern that adding the responsibility for managing diabetes alongside other challenges was too much for many patients.

ST16: Yeah lots of people who are struggling really who are typically perhaps elderly who don't have English as a first language, who are on a very low income, perhaps their housing isn't very good and they've got diabetes on top of it. It's tough and it's a huge challenge.

9.4.6 Current self-management resources

One of the QOF targets to be achieved for diabetes is that people diagnosed with type 2 diabetes should be referred to structured education within six months of diagnosis. Within the CCG several self-management programmes were available for patients, the two main ones being DESMOND and Co-creating health. This theme discussed HCP's views on this self-management education.

Awareness

Most staff were aware of the self-management programmes available to their patients in the CCG. The perceived difference between these two resources were that DESMOND focused on information provision and Co-creating health on learning to put information into practice.

ST2: DESMOND, it's more about information giving at the beginning of your condition and what do you need to do to look after yourself...co-creating health is much more about, okay, well, we've got the basic information, now how do you put that into practice? How does diabetes impact on you, on your social life, your emotional life, your work life, how does it all balance?

(Diabetes Specialist Nurse)

In general staff perceived these resources as very valuable for their patients. GPs in particular highlighted the benefit of gaining knowledge and sharing experiences with other patients.

ST1: it's a way of just being able to put down some, not ground rules, but sort of, a good foundation for someone's understanding of their diabetes...You've got a group that meets up regularly, for a period of time, and there's a very powerful thing about being in a group and the support you get from that

(GP Partner)

Some staff however reported not being sure what the structured education entailed, and that the information they had about the content was gleaned from patients feeding back to them.

ST4: I haven't been to one, but from what patients have told me it, sort of... I think they do have access to a dietitian, looking at type 2 diabetes, I guess what causes it, and then lifestyle changes, so I guess exercise, diet and then, I guess, where they might go from there.

(Practice Nurse)

The role of structured education

Many staff viewed this education as an important addition to the care that patients received in consultations. Recognising the limitations of providing care in time pressured consultations, staff believed this education allowed patients more time to address important issues and gain further knowledge.

ST2: I think that you don't have enough time, one-to-one, to do the information giving, which you do need to do and the self-management support. And so you can see that when people go on programmes, they come back so much better informed and, you know, they know what they're doing much better.

(Diabetes Specialist Nurse)

One GP suggested that the peer nature of the support gained from group based education gave patients permission to admit to engaging in behaviours not conducive to diabetes management in a supportive, non-judgmental way, as well as support to then move forward to change this.

ST1: And the fact that someone sitting next to you admits to eating too many cakes, and then that gives you the permission to actually admit to yourself, yes, actually, I eat too many cakes as well. But it's okay to have that, because that's nature, we all like eating cakes. It's just that the difficulty is now this is something that I need to address, and the group can help with that.

(GP Partner)

The group based nature of currently available diabetes education was also perceived as beneficial to patient learning through the sharing of experiences and working together. Several staff highlighted the value of the experiential knowledge that was shared in groups.

ST2: it gives you just so much more benefit than one-to-one work, partly because people are working together, problem solving together, seeing all the sorts of problems that others have, picking up tips from each other and so forth. And lots of time to reflect and practice.

(Diabetes Specialist Nurse)

Barriers to patient attendance at diabetes education

There was a widespread concern, that despite the perceived benefits of structured education courses, the courses were not suitable for all patients. Problems identified included patients' busy lives which made attending a programme that lasts several days and is held during working hours difficult for those in full time work or with caring responsibilities.

ST1: younger people's lives can be more complicated, with childcare, and work commitments, and what have you, and often people are travelling a lot through their work. You know, they can't commit to a DESMOND type programme, or even, the self-management programme is actually seven weeks, which is quite daunting

(GP Partner)

Other issues related to the group based nature of the courses such as patients feeling embarrassed to ask or answer questions and feeling anxious within a group setting.

ST9: I had one lady who had anxiety, she just couldn't be there with all those people, even though it's... I think the group's only six or eight, isn't it? She felt... She was overwhelmed by it, so...

(Advanced Nurse Practitioner)

Staff also referred to the fact that patients who could not speak English could not attend these groups.

ST11: I know that we have quite a lot of Turkish and Bengalis who we are not allowed to refer which is a great shame

(GP Partner)

Readiness to engage

There was discussion about when structured education should be provided to patients. Several staff believed that there was an optimal time period in which to engage patients with their diabetes, and after which time patients lose the initial impetus to engage.

ST3: if you get diagnosed and somebody refers you onto a programme and you start within two weeks then you're most likely going to do it. If it's six, eight, 12 weeks, even beyond as it was at one point, almost four months, people have lost the immediate anxiety of learning that they've got a long term condition.

(Commissioning Officer)

One Advanced Nurse Practitioner referred to this as the 'honeymoon period', which occurred shortly after diagnosis, when patients would be willing to try things to help them manage their diabetes

ST9: they may go through this honeymoon period where they're willing to do everything

(Advanced Nurse Practitioner)

It was reported that problems with long waiting lists to attend these courses resulted in patients losing interest or feeling that they no longer needed to take up the education when it became available.

ST9: They've got a long waiting list. Then by the time the patient was actually approached, they didn't feel that they needed it.

(Advanced Nurse Practitioner)

There was also a large cohort of patients within the CCG who had missed out on attending any education for their diabetes because they were diagnosed before the education was available.

ST13: DESMOND is relatively new. So, some people have been sent to it later along the line because they never did go at the beginning. And some people, I think, probably never did go on it.

(Practice Nurse)

Staff roles in referrals to diabetes education

Many staff had no idea how many of their patients actually attended these programmes after they had provided them with a referral to attend. Follow up with patients regarding attendance was very rarely reported.

ST4: We offer them to all newly diagnosed patients, they're all meant to be offered the programme, and I would say a lot of them probably don't go

(Practice Nurse)

Staff felt that their role in getting patients to attend the education courses ended with the handing out of referrals.

ST6: We can only give them the form, I mean, there's no... I can't walk them up there.

(GP Partner)

Some staff reported giving patients an initial referral but not following this up with patients.

ST20: So, I do... I'm really terribly bad at reinforcing it. I tend to offer it de novo, and then not again, which is a fault of mine, really.

(Practice Nurse)

A few staff suggested that patient engagement with self-management was dependent on the level of interest of staff and their skills in encouraging patients with self-management.

ST19: one of the biggest barriers to self-management is GPs, and one of the biggest potential solutions as well... so how GPs can help, so one is actually being interested in self-management, having the skills to be able to get the patient on board with or at least establish where a patient is at with that

(Salaried GP)

One diabetes specialist nurse alluded to the fact that referring patients to structured education had not yet become fully part of routine practice in the CCG and suggested that staff need to improve the way it is marketed to patients to get them engaged.

ST2: I think we don't have an expectation that people will need to do that as, you know, as a normal next step; get diagnosed and then everybody does it. You know like how everybody, every woman, expects to have a smear test?...So I think that that is something that needs to be created and it's how it's marketed, how it's sold, because a lot of people will be ambivalent, I imagine, about going to it. So it's about pushing people.

(Diabetes Specialist Nurse)

9.4.7 Staff perceptions of HeLP-Diabetes

Staff generally perceived HeLP-Diabetes very favourably and described how it would fit well within current practice helping to fill gaps in knowledge and information provision resulting from

time pressured consultations. HeLP-Diabetes was perceived to have several advantages over group based education and other formats of information provision, although mention was made of people with certain characteristics for whom staff did not think it would be suitable for.

Fit of HeLP-Diabetes with current practice

Overall, HeLP-Diabetes was viewed positively by staff in the CCG.

ST16: I had look at it before ... and I think it's great, it's fabulous.

(Diabetes Specialist Nurse)

HeLP-Diabetes was viewed as having synergy with the policies and priorities of the CCG and therefore fitted well with what staff were trying to achieve with patients with diabetes.

ST15: ... it fits in with the practice of, sort of, Year of Care and encouraging people to self-manage, which is quite positive.

(Practice Nurse)

The majority of staff perceived HeLP-Diabetes to be a complimentary resource to offer to their patients. Having a menu of options available to patients seemed particularly important as many staff spoke about one type of diabetes education not fitting all.

ST3: I think if you're going to do self-management courses you have to have a menu of options, because there's nothing, you know, one size doesn't fit all so there's no way that everybody's going to want to do DESMOND.

(Commissioning Officer)

Staff perceived that HeLP-Diabetes would fit well into the current care that they provided to patients, addressing some of the barriers that currently exist to patient information seeking. It was recognised that patients might sometimes feel embarrassed asking multiple questions of staff and was suggested that HeLP-Diabetes allowed patients to bypass the traditional routes to information, allowing patients to access information by themselves.

ST5: ... I mean, you can't keep going back to... you feel embarrassed when you keep going back to talk to your doctor or the hospital. Maybe not for the serious, you know, but for general... I wonder if I could eat that really. I wonder if I... okay, so I'm putting on weight. How can I lose weight? And you can put it all in on there [HeLP-Diabetes] and find that out.

(Health Care Assistant)

Some staff talked about patients potentially feeling bombarded by information when they are first diagnosed, and that HeLP-Diabetes could be used as and when needed by patients to access information.

ST4: it just gives them a basis in their own time, rather than being bombarded with information, especially when they're maybe newly diagnosed and they don't want to hear about everything at once understandably.

(Practice Nurse)

Many staff talked about the fact that currently the majority of information is provided to people with diabetes all at once at the time of diagnosis. Staff perceived that at diagnosis people might not know all the questions that they will eventually have about their diabetes, and having a resource that patients can keep going back to was perceived as very useful.

ST14: I think because when they come to us they only have a certain time, sometimes they might not have all the questions on the top of their head...so when we give them website information, they are free to use anything of the available information...I think it's really helpful.

(Health Care Assistant)

With the focus within the CCG on providing education to those patients who are newly diagnosed with diabetes, staff recognised that patients who have had diabetes for a longer time and who may not have had any form of diabetes education might be particularly suited to using HeLP-Diabetes.

ST4: we'll see patients that have been diagnosed maybe for ten years, so you don't know what information they got at the beginning or what they may have forgotten, so it's quite nice that they can go back and look over maybe why we are doing some of the things we're doing.

(Practice Nurse)

It was also suggested that there might be some diabetes related issues that patients might find more comfortable finding out about via the anonymity of the internet rather than from a healthcare professional.

ST14: Sometimes they would hesitate to discuss certain things. For example, when we ask, do you suffer from an erectile dysfunction...if they have resources available, like, when they go home it would be better, yes.

(Health Care Assistant)

HeLP-Diabetes was perceived positively in terms of having the potential to relieve time pressures within consultations with patients. Many staff reported that being able to offer such a comprehensive resource for patients to use following appointments took the pressure off them having to cover all necessary areas in details within time limited appointments and that patients could use HeLP-Diabetes to continue their learning and information seeking after appointments.

ST4: I think giving them time to look at the areas that they want to look at, rather than us, sort of, trying to cover everything in a 20 minute or 15 minute appointment, maybe trying to pick out a few bits and let them have a bit of time to read about it.

(Practice Nurse)

ST8: ...the website's very good, clear, concise, everything's in one place, it's, I, I could only see it reducing the GP's workload in the long run.

(Receptionist/Admin)

HeLP-Diabetes was perceived by most staff to be a useful tool that patients could use to supplement the information they received from staff, and could be used in between appointments.

ST4: It's quite nice to just remember that they can just focus on one area and then we can see them in between.

(Practice Nurse)

ST5: I think they'd still need their regular checks, but I just think that for in between questions and things, and to keep a chart, as well, of their weight and their HbA1C, I think that's really good.

(Health Care Assistant)

The use of technology to deliver care to patients was viewed by many staff as the future of the healthcare, and many spoke about the positives of technology for the management of long term conditions. Staff viewed the use of technology within practice as a way to make services more accessible to patients.

ST8: Well, I think it's amazing, I mean, I mean, we're living in a technological age, things are only going to get more that way in the future, so, it's good that people can just manage themselves if they, if they want to.

(Receptionist/Admin)

Many staff were already familiar with recommending websites in their consultations, and the use of the internet in general with patients was viewed positively.

ST21: I think it's good and I think it's the way forward. The number of people who come in and they've already looked something up on the website, on a website, and it's something, well, I'm getting more used to doing it.

(Practice Nurse)

However, there were some patients that staff didn't perceive would ever feel the need to use an online intervention like HeLP-Diabetes as they were satisfied with the way their current care was handled.

ST18: They come in and see the doctor and obviously if they've got any questions then they come in and make another appointment so I think a lot of patients are quite happy in that routine already and some, yes, some people don't like change.

(Receptionist/Admin)

Relative advantage

The problems that were identified with current face-to-face group based education available in the CCG provided a strong sense of need among staff for alternative forms of education that could be offered to patients. Views of HeLP-Diabetes were generally presented in contrast with group based education.

The main advantages of HeLP-Diabetes compared to existing services were reported to be related to accessibility. Accessibility was described in terms of the simplicity and clarity of the information provided as well as the fact that HeLP-Diabetes was accessible at any time, as often as patients liked.

ST1: I think, as I said, because it's a resource that patients can... You know, it's a resource with a lot of very relevant, patient accessible information that, yes, that people can access, sort of, online.

(GP Partner)

HeLP-Diabetes was viewed as much more accessible for certain groups of patients than current face-to-face education. Staff perceived that their younger patients, those who worked, those with caring responsibilities and those who travelled a lot would particularly benefit from an online resource compared to a face-to-face resource.

ST4: I think again people can tailor it or get the information that they want out of it. In terms of timing they can access it whenever they want, rather than having to miss work, which is obviously quite a big issue for these patients.

(Practice Nurse)

However, there were certain features of face-to-face education that staff thought could not be replicated or delivered via an online resource.

ST8: Well, I suppose with things like Desmond, it's good because it's obviously a community activity, you are actually physically there with other people, which can be hugely important for some people, so, it's just, essentially for the elderly. It's good because there's a little bit of, you get to have a chat and see some people and stuff like that.

(Receptionist/Admin)

As well as staff perceiving HeLP-Diabetes as being distinct to current face-to-face diabetes education, it was also perceived as different to other online resources that are available to patients. Staff drew comparisons with Diabetes UK online resources, and perceived HeLP-Diabetes to have advantages over this because of its interactivity.

ST1: I think that, particularly, the accessibility of this, yes, and I suppose also pointing out to people that it is very different to Diabetes UK. Although there are a lot of resources in Diabetes UK, this is more interactive

(GP Partner)

ST7: Well, I think the website is more on a personal level, whereas I think the Diabetes UK is more clinical whereas the Help Diabetes it's more personal.

R: And you think that's better in a way?

ST7: Yes. A hell of a lot better because I think people can relate to it more.

(Receptionist/Admin)

Staff perceived patients using HeLP-Diabetes as preferable to general searching on the internet for diabetes related information. The fact that HeLP-Diabetes is a dedicated website, specific to one condition was seen advantageous as was the potential of HeLP-Diabetes to be tailored to the needs of patients.

ST4: I think again people can tailor it or get the information that they want out of it.

(Practice Nurse)

Some staff talked about information and guidelines constantly changing which often rendered more traditional forms of information resources such as leaflets and booklets obsolete after a short time. The online format of HeLP-Diabetes allows regular updates to help overcome this problem.

ST21: ...it's constantly updated whereas you give them a booklet and then a year later, the Department of Health has said as a diabetic, you mustn't have five fruit, you've got to have one fruit and four vegetables or something.

(Practice Nurse)

Suitability for target population

There were certain groups of patients identified by staff as not being able to benefit from HeLP-Diabetes. Language barriers to use arose frequently, as well as people who were unable to use a computer.

ST16: A lot of the patients we see are elderly frail, as I've said, perhaps don't have English, and mostly importantly don't have a computer at home or are computer literature.

(Diabetes Specialist Nurse)

Although some suggested that HeLP-Diabetes could be used by patients with support from English speaking relatives.

ST13: I mean, we can ask them, have they got people in the family that would show them it? You know, link them in with it at home. Perhaps a grandson can come and click the right buttons and get them going.

(Practice Nurse)

ST1: I suggested HeLP-Diabetes to, not so much for her but more for the family, and they can maybe sit with her, and they can actually... And the great thing with the Internet is, you can play this video on diabetes, and all the keys

going in [animation used to explain diabetes], and actually press pause and explain it in Bengali, and then it's there.

(GP Partner)

Due to the perceived level of literacy needed to use the internet to access HeLP-Diabetes, there was the perception by some that HeLP-Diabetes, like the other existing services in the CCG, was only suitable for patients who were literate with some degree of motivation to self-manage.

ST19: So yes, the basic is that a patient has to be motivated to do it. Then they have to be able to use the internet as well. They have to have the intellect, the... a connection of the internet.

(Salaried GP)

There was a concern that within the CCG, there were still no adequate solutions to engage patients deemed as 'hard to reach' with diabetes education.

ST1: I think, one of the things we've been discussing in the steering group is how do we reach the hard to reach groups. Because, actually, the way I look at the challenge, and particularly with diabetes, we haven't quite.

(GP Partner)

Other staff however, recognised that these 'hard to reach' patients were the ones for whom face-to-face input was the most valuable. Whereas perhaps for some patients, interventions such as HeLP-Diabetes could do some of the work that staff would traditionally do, for others there was no substitute for healthcare professional input.

ST11: ...I don't think DESMOND or HeLP makes a difference to the hard to reach people. I think that you have to chip chip away, build a relationship, you know, and try to gradually keep them on board. And they are the people, if you like, who often take up the most time, and we spend the most time to do, because you're still trying to find what will help get them on board.

(GP Partner)

The age of diabetes patients was raised as a concern for the use of an online intervention like HeLP-Diabetes with staff perceiving that the older age of the diabetes population might prevent them from engaging with online resource.

ST18: because it's computer based more than anything. I mean, it's kind of like trying to teach an old dog... old dog new tricks kind of thing. You do have patients who are set in their ways. I mean like electronic prescribing, a lot of our elder patients hate it.

(Receptionist/Admin)

It was suggested by some that the use of HeLP-Diabetes may increase over time as the diabetes population gets younger and computer skills become more ubiquitous in older populations.

ST6: as time goes on, you're going to find more and more people using the internet, aren't you? So, they'll prefer it.

(GP Partner)

9.4.8 Adoption and implementation HeLP-Diabetes

Even though HeLP-Diabetes was generally viewed favourably by the staff, there was not widespread use of it. Here I describe how HeLP-Diabetes was actually used within routine practice and the factors that were identified as facilitating or inhibiting its use.

Evidence and endorsement

HeLP-Diabetes had very strong support from the CCG from the outset. The Commissioning Officers at the CCG held the expectation that HeLP-Diabetes would become a service that would gradually become embedded in practice. The CCG recognised that this could take years because of the many competing priorities placed on staff.

ST3: ...we're anticipating that it would be...second nature within practices. And that's going to take a long time because these things take two to three years to bed in, realistically, no matter how much buy-in you have because there are so many other things to think of you know. But I think once it gets to that stage, you know, I think it would just be offered alongside all the other things straightaway, you know, on diagnosis.

(Commissioning Officer)

The CCG actively helped to promote HeLP-Diabetes by incorporating it into diabetes nurses' job descriptions and making it part of the diabetes Locally Enhanced Services (LES).

ST3: ... We're trying to put it into the service spec for the diabetes nurses and into the long term conditions LES. It's mentioned in there as one of the options in self-management which we're promoting.

(Commissioning Officer)

This support from the CCG was important for many staff in their decision to adopt HeLP-Diabetes. The support gave HeLP-Diabetes a sense of credibility and encouraged staff to feel that this was a service that they should be offering to their patients.

ST1: ...being validated by an organisation that you respect. So it's ...the CCG, or the steering groups saying this is a good thing

(GP Partner)

Staff also thought the fact that HeLP-Diabetes aligned with current CCG policies facilitated their use of it.

ST12: And the fact that most of it had the same action plan as Year of Care facilitated because it's, sort of, in line with what you're learning.

(Practice Nurse)

Apart from the endorsement that HeLP-Diabetes received from the CCG, staff talked about different types of evidence being important in their decisions to adopt HeLP-Diabetes.

For many, the fact HeLP-Diabetes had a strong evidence base and came from a university was extremely important in the decision to take it on.

ST3: We wouldn't have taken it on if it wasn't evidence-based. We really wouldn't. And we're pioneers now so we are creating the evidence, but for something like this, you know, the fact that it was validated and evidence-based. That really just underscored everything.

(Commissioning Officer)

Others talked about generating the evidence they needed to continue implementing HeLP-Diabetes by taking it on, trying it out and obtaining feedback from patients to evaluate its worth.

ST6: I suppose it's just trying it out and seeing if people go on it and if people like it and then any sort of... informal, sort of, feedback is good. I haven't had any complaints and people said... a couple of people said some nice things about it so, I, you know... if people find it helpful, then obviously we need to look at it ourselves and see, you know, what's the information like? Is it reputable and so on and so on?

(GP Partner)

Other staff gained evidence of the ease of implementing HeLP-Diabetes from the experience of other practices that had adopted it. One GP discussed how the need for staff to register patients to HeLP-Diabetes was an initial barrier to their adoption, but hearing from other practices that this had been done successfully had changed their mind to adopt.

ST11: Well, initially, I think I remember we weren't one of the first adopters. Which is unusual for us for diabetes... and then...there was one of those education sessions, and a GP and [Name of Commissioning Officer] talked about how their patients had found it useful, and they'd managed to do it as a practice, I thought, oh, well, we'd better get on, and not be laggards, so you know, we then did it

(GP Partner)

Before agreeing to adopt HeLP-Diabetes, one practice nurse had conducted her own research to provide evidence that there would be suitable patients to use HeLP-Diabetes at her practice. She had a preconceived notion that none of her patients with type 2 diabetes would use a computer and therefore didn't think HeLP-Diabetes would be suitable.

ST20: I did a fantastically huge piece of research, a hundred patients. I got the girls, the receptionists, to ring round 100 of our type 2 patients. I should actually have fiddled it, and said only the ones that are over 70, or something like that.

And, I was quite surprised, because of the 100, 54 or 56 did use a computer, which surprised me.

(Practice Nurse)

Trialability, Training and Support

The demonstration of HeLP-Diabetes to staff during practice meetings and the training sessions held with staff on how to offer HeLP-Diabetes to patients were perceived very favourably by staff.

ST12: And I think perhaps the fact the partners invited you [researcher] in to come and present about HeLP-Diabetes gave great weight to it as a programme, and because we obviously respect their judgement and they felt this was a good service and something important to promote in the practice.

(Practice Nurse)

In some cases there was a sense of trepidation about taking on another new initiative in practice. However, when staff saw HeLP-Diabetes and were trained to use it they reported feeling pleasantly surprised by it, and it was at these times that staff reported becoming engaged with HeLP-Diabetes.

ST7: ... it was mentioned before by the practice manager and I think one of the doctors, and we were like, well, what's all this about? And to be honest with you it was a case of, oh, here we go, another one of these things that's... not going to take off. It's going to be a five minute wonder and that's why when you came in and you trained us up, it was just such a shock to what we've... to what other ones we've been on. It was more useful than what...

(Receptionist/Admin)

Having the opportunity to try out HeLP-Diabetes and become familiar with it before deciding to adopt it also proved useful for staff.

ST5: I think because we signed up ourselves and we sort of like got to know the website ourselves, so then we could... because it's no use selling somebody something if you don't know what the product's going to do.

(Health Care Assistant)

In two practices, I helped staff to register patients during the initial stages of implementation. The support that I was able to offer to these practice to implement HeLP-Diabetes was viewed as very helpful for staff within the practices, and it was these two practices that went on to register the most patients.

ST4: I would say it was really nice having you here... we were quite slow, you know, just getting used to it. So I think having you here... I think it would be really helpful to have you there for a few sessions and one beforehand to go through it like you did with us, to show us to show us how to login and

everything. Then maybe have you there for a few sessions seeing the patients. And then I think it's been nice when we've had... been able to email you so with questions and if we did need you to come in

(Practice Nurse)

Responsibility for implementation

In the original implementation plan it was perceived that the role of facilitating patient access to HeLP-Diabetes would be a role best suited to nurses who traditionally take on the majority of self-management work with people with long terms conditions like diabetes and who have the opportunity to introduce HeLP-Diabetes to patients during routine consultations. However, there were mixed perceptions amongst staff as to whether this role was actually a good use of nurse time.

Some staff agreed that nurses had the necessary access to patients and that during consultations would be the easiest way to register patients to HeLP-Diabetes.

ST15: ... you almost have to seize the moment, really. So, in that sense, it would probably be easier done in the appointment with the nurse

(Practice Nurse)

However, it was called into question by some GPs and nurses whether the task should be undertaken by nurses, as it was not perceived to be a good use of clinical time. Instead it was suggested that other staff such as health care assistants and receptionists within the practices might be better suited to this role.

ST1: Actually, I would argue it shouldn't be done by the nurse because, you know, it's quite a low-key IT thing...I would rather our practice nurses spend their time, you know, doing the clinical work that they are most skilled at doing, and you can have someone else.

(GP Partner)

In the majority of practices the role of offering HeLP-Diabetes to patients actually ended up being taken on by health care assistants and receptionists, with nurses and GPs only undertaking the role in a few practices. The role was perceived as particularly suited to health care assistants and reception staff as they were described as IT literate, willing to help out with other tasks, and keen to learn new skills, and importantly, perceived to have more time to undertake the role.

ST12: Or, in our case, having [Name of receptionist]...he was very willing to drop whatever he was doing and come and chat to people. He was IT literate and very personable. So, I think you had... he was a very good, sort of, face of HeLP-Diabetes. And nothing was a problem and, oh just sign up here, fantastic. And he would just appear and swoop people off and sort it out, and it was magic. So, actually having that combination of someone who's quite

keen, ...who feels confident about doing it and... can stop whatever they're doing and just come and take over.

(Practice Nurse)

Awareness and Engagement

Between practices there was much variation in awareness of HeLP-Diabetes and the level of involvement of practice staff. In the practices that signed up the most patients to HeLP-Diabetes, HeLP-Diabetes was known by the majority of staff who all worked together to offer HeLP-Diabetes to patients.

ST7: GPs and nurses, they're sort of...100% behind it and I think that does make a difference...you go to a GP and they say to you, well, there's this programme you can do... and then send them to either me or (HCA'S name) and we can explain it to them more then.

(Receptionist/Admin)

In this case, the buy in to HeLP-Diabetes by the GPs in the practice gave the receptionist confidence in using HeLP-Diabetes with patients and gave HeLP-Diabetes an approval that was perceived as necessary in order to offer it to patients.

ST7: if they weren't behind us and they went into one of the GPs and said, oh, your HCA or your admin assistant has just given me this leaflet for this, what do you think, if they're not behind you they're just going to say, oh, don't worry about it, just throw it away, do you see what I mean? But when they're behind you, it does... yes.

(Receptionist/Admin)

However, in practices where HeLP-Diabetes wasn't being offered to many patients, there was a perceived lack of buy in from GPs and other staff within the practices.

ST20: I kind of have to hoe my own row. He's [GP partner] not obstructive, but he's got a very clear idea of what he thinks is important, and what isn't. It's not always easy.

(Practice Nurse)

Some staff reported difficulties in trying to engage other staff with HeLP-Diabetes. The lack of involvement was frequently attributed to other staff being too busy to engage.

ST21: In an ideal world, I would have liked to get reception more involved...I half mentioned it and it was very clear at the time that there weren't the resources

(Practice Nurse)

The pressure of all the existing services that nurses had to deliver acted as a barrier to them becoming engaged with HeLP-Diabetes which was perceived as yet another new initiative to take on and implement.

ST1: ...neither of our nurses were really in to it...they said they can't cope with the new LES, and all of the new templates, and everything else. And I said, now there's a great new IT tool, and they said, go away, we've got enough to be getting on with

(GP Partner)

Impact on roles and work practices

There was a strong perception from many staff that the work involved in offering HeLP-Diabetes to patients would be too time consuming and too difficult to take on. This was described as the main barrier to HeLP-Diabetes being implemented successfully within practices after the decision to adopt had been made.

ST11: And the barrier was this notion that we'd got to get the receptionist trained to fill in a form, and to go online. That all sounded like a bit of a nightmare

(GP Partner)

However, in stark contrast to this were the views of staff within practices where HeLP-Diabetes had been implemented who were actually doing the work of registering patients. There was a clear sense from those doing the work successfully that the task of registering patients was not a difficult or time consuming one. This suggests a mismatch between the fear of HeLP-Diabetes being time consuming before it is adopted (as in the quote above) and the reality of the time implications.

ST8: I would register patients as they, as they came, and then maybe at the end of the week, send a list of the people we've registered. So, yes, it would be ten, ten minutes out of my day here and there... It wouldn't be a massive, massive burden, no.

(Receptionist/Admin)

Some staff described the work of registering patients to HeLP-Diabetes as fitting in well within their current practices, and in some cases using HeLP-Diabetes with patients during consultation was reported to be time saving.

ST4: ...if the patient has identified something or if we identify something, you know, if the HbA1c's gone up or the patient's identified that they want to, I don't know, lose weight, then we can use that as a resource. So it's quite good, because it probably does save us time

(Practice Nurse)

In addition, in some cases, the staff doing the work of registering patients felt that this new task was adding something to their job satisfaction and adding a new skill to their set.

ST7: Yes, and then a patient could phone up and just sort of like you don't... I don't have to then wait to speak to a doctor. I can either offer them that facility

to look up on the Help Diabetes or I can look it up for them and explain it to them and then...

(Receptionist/Admin)

One receptionist who was allocated the task of registering patients perceived it as a position of responsibility and felt pleased that it had been designated to her.

ST18: It felt nice that the doctors thought they could trust me with that responsibility so that was quite nice.

(Receptionist/Admin)

Two health care assistants, from practices where HeLP-Diabetes was being offered successfully to patients, distinguished the new way of working with HeLP-Diabetes to previous ways of working. From using HeLP-Diabetes the health care assistants now had more knowledge about type 2 diabetes and felt more able to help patients with their queries. Before the use of HeLP-Diabetes these health care assistants did not feel confident enough to answer questions about diabetes and had referred the patients straight on to a GP. In this way the use of HeLP-Diabetes helped these staff to transcend their traditional roles and also gave patients access to information more quickly than if they had had to wait to have their queries answered by a GP.

ST5: Yes, yes, yes. Yes. I mean, obviously I'm not diabetic. I'm not an expert on the subject. I only know bits and pieces. But I'll say to them, well, look, if I don't know the answer, we'll ask the doctor, but let's have a look first and we'll see if the answers are on the site, you know.

(Health Care Assistant)

For practices that did not implement HeLP-Diabetes due to the perceived workload implications of staff having to register patients, alternative strategies were introduced to help them overcome this problem, including the introduction of patient registration leaflets (see Chapter 7 for more details of alternative implementation strategies).

The patient registration strategy was perceived favourably by many staff as it took much of the workload implications of offering HeLP-Diabetes away from them.

ST12: Because now we have new leaflets there's a number that they type in where they can join. So, I think that's really taken out the middleman and forms getting lost, and things not... access not working and that. So, I think that's really been a big step forward

(Practice Nurse)

Some staff viewed their role in the offering of HeLP-Diabetes as unnecessary, as in the quote above, this nurse referred to the role as that of a 'middleman', suggesting that she viewed this as a redundant step.

However, other staff recognised the value of staff supporting patients to register, showing patients what HeLP-Diabetes is and its ease of use.

ST13: Well, I think it's really important to actually put it on screen in front of everyone, and click through it and just show how easy it is to use.

(Practice Nurse)

Availability of resources

Although perceived favourably, HeLP-Diabetes was often reported to be forgotten in consultations when staff felt under pressure to complete lots of other tasks within the time. In this way, HeLP-Diabetes had not become a priority in comparison to the other tasks that are required within time limited consultations.

ST6: you do forget, I forget. I see diabetic patients and I go... after they've left, I go doh, I should have given them the leaflet. But, you know, you just forget because there's a million things and a million questions.

(GP Partner)

In other practices and clinics there were more practical barriers to implementing HeLP-Diabetes. In one small practice it was reported that they lacked the physical space to register patients to HeLP-Diabetes.

ST6: Well, for us, it [HeLP-Diabetes] was great but it was going to be really difficult to implement in our surgery because of staffing- no space for receptionists to go off and talk to the patients and log them in and stuff.

(GP Partner)

And in the hospital clinics, offering HeLP-Diabetes to patients was described as almost impossible because of the very old computer systems that staff had to work with.

ST16: Well we're working with Windows 2003 I think, we don't have Google Chrome, I have kind of slightly overcome it, I've inherited a very ancient laptop which is like a museum piece but it has been loaded with some newer software on there. But it's locked in the drawer and realistically I'm not going to get it out and fire it up between patients in the clinic.

(Diabetes Specialist Nurse)

Suggestions for improving the implementation

Several suggestions to improve the implementation plan in order for HeLP-Diabetes to become more widely used within routine practice were described by staff. Feedback on how individual practices were performing with regards to registering patients was suggested as a way to motivate staff to register more patients.

ST11: You know, GPs, like everybody, feel slightly competitive and if they see only five of theirs have enrolled, and somebody else has got 100, it makes you think.

(GP Partner)

Feedback from patients on their views of using HeLP-Diabetes was also suggested as a way to encourage staff to continue to offer HeLP-Diabetes as they could use patient feedback as a tool to promote HeLP-Diabetes to other patients.

ST5: I have asked some of them to get back in touch and let me know how they find it...because it would be interesting to know, and then I could say to other patients, well, actually patients have found this really helpful, you know.

(Health Care Assistant)

Many staff thought that if HeLP-Diabetes was simply searchable on the internet then it would be much easier to implement within practice and would have many more patients using it.

ST1: ...it would be nice if it could be as easy as possible...if you could just be told, there is this great tool out there, have a look at it, and you could just type in www.helpdiabetes, whatever.

(GP Partner)

There were other places that staff suggested that HeLP-Diabetes should be introduced to patients including at group based structured education, at pharmacies, in centres for older people, in supermarkets and local libraries.

Identifying a champion at each practice was advocated by some staff who thought this would be the only way of pushing HeLP-Diabetes through in each practice.

ST1: HeLP-Diabetes is part now of the nursing dialogue. It's what we want to try and do, but again, as I said, there's so many other initiatives going on it gets a bit lost. But I think the key is having the champions in the practice, and just, sort of getting the word out there.

(GP Partner)

Some staff talked about the need for HeLP-Diabetes to be incentivised by becoming part of the QOF. Some staff suggested that this would make it much more of a priority for staff.

ST6: You need to be part of ... the QOF. It needs to be part of that. If it's part of that, it will be done.

(GP Partner)

Similarly, staff suggested that if practices received money for referring patients to HeLP-Diabetes then this would boost the rates of patient signups.

ST8: a cash incentive for signing people up, yes, yes, something like that, I mean, it's a, you know, a bit heartless to say that, but unfortunately, that would make the GPs refer people, and it would make the nurses refer people.

(Receptionist/Admin)

9.4.9 Applying concepts of Normalization Process Theory to the data

Analysing the data thematically provided an overview of staff views on the implementation of HeLP-Diabetes. Normalisation Process Theory (NPT) is now used as a lens through which to reanalyse the data focusing on the 'work' participants report engaging in in relation to the implementation and normalisation of HeLP-Diabetes in practice.

As described in detail in Chapter 6, the constructs of NPT that the themes (see Figure 9-1) were mapped to were:

- 'Coherence' which refers to the extent to which HeLP-Diabetes makes sense to staff.
- 'Cognitive participation' which concerns the commitment and collective engagement of staff towards HeLP-Diabetes.
- 'Collective action' which refers to the relationships and the work required for HeLP-Diabetes to be taken up in practice and to identify the factors that serve as barriers to implementation and embedding. As this was of particular interest the four sub-constructs of 'Collective action' were considered:
 - *interactional workability*, ways in which HeLP-Diabetes helps or hinders care for patients with diabetes.
 - *relational integration*, confidence in worth and safety of offering HeLP-Diabetes;
 - *skills set workability*, the allocation of the work and fit with routine;
 - *contextual integration*, how well HeLP-Diabetes is supported by infrastructure and culture in the practices and clinics;
- 'Reflexive monitoring' which holds that successful embedding of HeLP-Diabetes in everyday practice relies upon a continuous process of evaluation that can feedback into refining the process of implementing HeLP-Diabetes

The mapping of each theme onto constructs of NPT is presented in Table 9-2 followed by the analysis of the data through the lens of NPT.

Table 9-2 Mapping on themes onto constructs of NPT

Theme	NPT construct
Sub-theme	
Staff perceptions of HeLP-Diabetes	
<i>Fit of intervention with/in current practice</i>	Contextual integration Interactional workability
<i>Relative advantage</i>	Coherence
<i>Suitability for target population</i>	Cognitive participation Interactional workability
Adoption and implementation of HeLP-Diabetes	
<i>Evidence and endorsement</i>	Cognitive participation Reflexive monitoring Contextual integration
<i>Trialability and training and support</i>	Coherence Skill set workability Interactional workability
<i>Responsibility for implementation</i>	Relational integration Skill set workability
<i>Awareness and engagement</i>	Relational integration Cognitive participation Contextual integration
<i>Impact on roles and work practices</i>	Interactional workability Skill set workability Contextual integration Cognitive participation
<i>Availability of resources</i>	Contextual integration Cognitive participation
<i>Suggestions for improving the implementation</i>	Reflexive monitoring Contextual integration Cognitive participation

Coherence (the extent to which HeLP-Diabetes makes sense to staff)

The way that staff described HeLP-Diabetes demonstrated a strong sense of coherence towards the value and benefits that it could offer. It was described as accessible and updatable with excellent content.

All staff demonstrated that they understood what HeLP-Diabetes was and could distinguish HeLP-Diabetes from their current ways of working; it was commonly discussed in contrast to the group based education and to other websites that they currently recommended to patients.

ST1: what HeLP-Diabetes does is it gives people that information that they can access at any time, because it's on the computer.

(GP partner)

The demonstration of HeLP-Diabetes during the practice meetings where it was introduced to staff was described as particularly useful to enable the sense making work around the potential benefits to take place.

ST12: you took the time to come in to talk to us about it that you took the time to come. And, yes, I think it really promoted it well

(Practice Nurse)

However, there were some staff who although could see the potential benefit for some patients, didn't think that the patients they encountered would benefit from it.

ST6: Those with background retinopathy or if they can't really see or they've got language issues, can't read, write, illiterate people, then yes they would struggle.

(GP Partner)

Cognitive participation (the commitment and collective engagement of staff towards HeLP-Diabetes)

Despite strong coherence towards HeLP-Diabetes, staff in the majority of practices and clinics struggled to build and sustain a set of practices around HeLP-Diabetes in order to implement it. This was contributed to in part by the view that although HeLP-Diabetes was seen to be of potential benefit for some patients, there were many groups for whom staff did not think would benefit which impacted on their willingness to invest the required time and effort into implementing it.

ST20: I must admit, I did think it... it did seem to me more, that it was for, it was for staff. I know it's supposed to be for people with diabetes, some of the people on my list, I don't think we... and I'm not being defeatist now, we wouldn't get past the gate.

(Practice Nurse)

Whereas there were other staff, who although recognising that it might not be suitable for everyone were determined to make sure everyone had the opportunity to use it.

ST5 A lot of them are basic, yes. They know they can go to www dot. Some of them are not too sure of it, and I say to them, just look, you won't break it. Just play with it, you know. Yes, but even the... as I say, even the elderly ones, the non-English speaking.

(Health Care Assistant)

The fact that HeLP-Diabetes was created at a university and promoted by the CCG was influential in staff decisions as to whether they wanted to take part in implementing it, providing a sense of credibility and reassurance that that HeLP-Diabetes was worthwhile.

ST3: We wouldn't have taken it on if it wasn't evidence-based. We really wouldn't.

(Commissioning Officer)

Some staff reported undertaking the work of generating their own evidence. They sought out evidence of how likely HeLP-Diabetes was to be of benefit to their patients which factored into their decision about whether HeLP-Diabetes was something worthwhile to invest in.

ST20: I did a fantastically huge piece of research... I want to kind of get round the mythology, that nobody over 60 uses a computer,

(Practice Nurse)

The importance of cognitive participation from other members of staff was also discussed. Buy-in to HeLP-Diabetes from senior staff was viewed as important for nurses and healthcare assistants in order to feel that it was a worthwhile task to take part in.

ST12: And I think perhaps the fact the partners invited you in to come and present about HeLP-Diabetes gave great weight to it as a programme, and because we obviously respect their judgement and they felt this was a good service and something important to promote in the practice

(Practice Nurse)

Some staff talked about the difficulty in engaging other staff in the work of implementing HeLP-Diabetes which made it difficult to enact the work of implementing within the practice.

ST20: I don't think [Name of GP] took it on board at all, unfortunately. And that's... and I really haven't myself, I'm ashamed to say

(Practice Nurse)

The task of registering patients to HeLP-Diabetes was often not perceived to be a suitable use of time and resources, and staff questioned why this had to be part of the work of implementing HeLP-Diabetes.

ST15: Or for patients to do it themselves with the leaflet; that would be perhaps the best option.

(Practice Nurse)

However, other staff could see the value in registering patients and allocated resources to carrying out the registrations.

ST13: Well, I think it's really important to actually put it on screen in front of everyone, and click through it and just show how easy it is to use.

(Practice Nurse)

Suggestions by staff to improve the implementation of HeLP-Diabetes often centred on strategies to increase cognitive participation. The incentivisation of the work and the identification of a champion were described as having the potential to increase the prioritisation that was attributed to HeLP-Diabetes and to increase buy-in.

ST1: ...priorities get lost, and so to successfully implement, be it HeLP-Diabetes, be it Year of Care, you need a champion at each step of the way.

(GP partner)

Collective action (the relationships and the work required for HeLP-Diabetes to be taken up in practice and to identify the factors that serve as barriers to implementation and embedding)

Interactional workability

HeLP-Diabetes was perceived by staff in practices where it was being implemented as having a positive impact on consultations with patients.

There was the perception by some that offering HeLP-Diabetes was beneficial to consultations as it provided additional information to patients that staff might otherwise struggle to deliver due to time constraints in consultations.

ST13: it's a brilliant website that patients can access really good quality information at home, and take their time over it. Because when they come in to the doctors, sometimes we give information really rapidly and we're always under time pressure. So, they can actually take their time. They can look things up. They can advance their knowledge about their condition, which a lot of patients would be very interested in, because it is their condition.

(Practice Nurse)

One GP reported that his use of HeLP-Diabetes had changed the way in which he explained certain diabetes related concepts to patients in consultations.

ST1: In fact, I've found I've got a whole different language of explaining what diabetes is to patients, having seen the video that's on there, explaining what is diabetes. I think the whole thing of the keys is really good, and that sort of visual...

(GP partner)

The use of HeLP-Diabetes also helped some staff to answer question that they might not otherwise have been able to. For example, the information provided on HeLP-Diabetes allowed healthcare assistants to feel confident in providing clinical advise to patients.

ST5: I'll say to them, well, look, if I don't know the answer, we'll ask the doctor, or let's have a look and we'll see if the answers are on the site, you know.

(Health Care Assistant)

Some staff reported that because their patients had been using HeLP-Diabetes, this had changed the patients' understanding of their condition and this had changed the nature of subsequent consultations as patients were now more informed.

ST5: It just gives them a little bit more, sort of, insight into what their illness is because it also explains if it's within the normal range. They then have a subsequent appointment with the doctor, which then, it means if any questions come out of that, you know, transpose specifically, they'll have had time to consider them as well.

(Health Care Assistant)

Some staff perceived that referring patients to HeLP-Diabetes through the patient registration method was very much in line with current work practices

ST7: Yes. No, I think... for me and (HCA'S name) it is more of a routine because it's sort of... because (HCA'S name) does it every day and I've sort of like... if I ain't sending letters, I've got people phoning up to change appointments and whatever. I think it's just something else that we do on a daily basis.

(Receptionist/Admin)

It was not perceived to impact on consultations negatively as it could be incorporated easily into the parts of the consultations that were already dedicated to providing patients with diabetes resources.

ST6: If I'm going to talk to them about Desmond, it doesn't really take much more to talk to them about HeLP.

(GP Partner)

Similarly staff reported already being used to the work of recommending internet resources to patients during consultations and had now replaced the recommendations that they had previously made with recommendations of HeLP-Diabetes because of the perceived additional benefits that HeLP-Diabetes could offer to patients.

ST7: If they mention Diabetes UK we say to them, no, you should look at this. I'll give you the leaflet for the Help Diabetes. There is a lot more information on there.

(Receptionist/Admin)

Some staff reported having changed the way they offered HeLP-Diabetes to patients in order to make it operationalise better in practice. There were examples of staff who offered HeLP-Diabetes to a patient's relative because the patient didn't speak good English. Several staff also recommended that patients should use HeLP-Diabetes with family members if they didn't have good computer skills or had trouble understanding English.

ST5: Well, I've had one woman who didn't speak a word of English. Her granddaughter came with her. And as I was doing it... it took a long time because as I'm showing, the granddaughter's then explaining it to the Nan. But we got there and she seemed quite enthusiastic. And the young girl said, my Nan hasn't got an email, but we'll use mine.

(Health Care Assistant)

However, there were a few cases where HeLP-Diabetes was perceived to have negatively impacted on consultations and current practice. This largely centred on time, with the referral to HeLP-Diabetes perceived as taking away from valuable time within consultations.

There were several staff who reported wanting to be able to make HeLP-Diabetes easier to offer to patients.

ST9: the most difficult thing when we were trying to incorporate it... was really the time factor of registering the patients on it, that process, selling it and then registering it. And I... so that didn't really work particularly well for us.

(Advanced Nurse Practitioner)

Relational integration

HeLP-Diabetes was introduced to practices and clinics during clinical meetings, and following these meetings the decision whether to adopt it was made. In some cases all staff within a practice or clinic were in attendance, however, most often these meetings were held only with GPs. This resulted in the decision to adopt HeLP-Diabetes being made by those who then did not take responsibility for implementing it, as the work of implementing was passed on to either nurses, healthcare assistants or receptionists.

In some practices it was reported that there had been minimal, if any, communication around HeLP-Diabetes before these staff were expected to take up the role.

ST5: I was just called in to the meeting, and I didn't know nothing about it. And I just got told this is what we're going to do and we thought you'd be good. Okay, fine. Because I suppose I do both things. I have the contact with the people on the desk, but I also have a clinic as well

(Health Care Assistant)

The work of engaging of staff to undertake the work of implementing HeLP-Diabetes was in some cases very opportunistic. One GP had tried to delegate the work to the nurses within the

practice who were proving resistant to taking on this responsibility, and so instead the GP approached the receptionist who was put on the spot to take on the responsibility.

ST1: we sat them [practice nurses] down, and we said, look, this is it, and they said, oh, yes, that would be a good idea but she didn't have time to do it. At which point I ran out and got hold of [NAME OF RECEPTIONIST]

(GP partner)

Once the task of enacting the work of implementing HeLP-Diabetes had been delegated, there was little evidence of GPs checking on how the staff charged with this responsibility were getting on with delivering it to patients.

ST19: I don't know what quantities there are. I'm not sure the last time she [receptionist] registered anybody. You might want to have a quick word with her on the way out.

(Salaried GP)

However, there were other practices where staff reported that there was good communication and commitment from the whole team around implementing HeLP-Diabetes. Healthcare assistants in one practice described how they would work collaboratively towards ensuring that all patients were offered the chance to use HeLP-Diabetes.

ST17: Most of the doctors are aware of it. So if they feel that they [patients] need sort of help with the website, they'll email myself or [Name of receptionist], and then we'll go through it with them.

(Health Care Assistant)

And nurses in another practice discussed how the decision to adopt had been made collaboratively.

ST4: I think [Name of nurse] and I were keen for it, keen to use it and because we see all the diabetic patients and the doctors were quite happy and they liked the sound of it as well, so it was, sort of, a... we all agreed

(Practice Nurse)

The relational work between senior staff and health care assistants helped to provide legitimation to health care assistants that this work was worthwhile to be undertaken.

ST5: Yes. I think it has to come from practice managers, partners, and then down. And are they willing to, you know, allocate a person or two people to do this, you know, whether it's just to register, like me, or whether it's the nurses or... yes, I just think it needs... I couldn't take it upon myself to say do this, do that. It has to come from [GPs]...

(Health Care Assistant)

Skill Set Workability

Although nurses were originally assumed (see implementation plan in chapter 5) to be the most appropriate group of staff to deliver HeLP-Diabetes as they do the majority of self-management

work with patients, it was often health care assistants and receptionists who undertook the work within practices. As the facilitation of patient use of HeLP-Diabetes became optional (see chapter 7), the work of implementing HeLP-Diabetes changed in nature and became much more of a clerical task rather than a clinical one and thus was not perceived as suitable for nurses who were perceived as over qualified for the role.

There was the perception that the work of registering patients to HeLP-Diabetes and (optionally) demonstrating some content was particularly suited to healthcare assistants.

ST2: Practice nurses might be a lot more interested in it. The HCAs were.

R: Yes, why do you think that is?

ST2 Because, do you know... Jamie, they're more keen. They're more sort of... they're more impressionable, if you like, and they want to extend their roles, a lot of them. They're not stuck in their ways and, to them, it's all new and exciting, you see.

(Diabetes Specialist Nurse)

Receptionists were another group of staff who were identified as being able to deliver HeLP-Diabetes due to their computer skills.

In practices, the role of implementing HeLP-Diabetes was reported to add to healthcare assistants and receptionists' job satisfaction. One receptionist reported feeling honoured to have been given the responsibility of offering HeLP-diabetes to patients.

ST18: It felt nice that the doctors thought they could trust me with that responsibility so that was quite nice.

(Receptionist/Admin)

As described earlier, the work of implementing HeLP-Diabetes was reported as work that was developing the skills and knowledge of health care assistants. Using HeLP-Diabetes with patients allowed some staff to transcend their traditional roles and provide more clinical advice to patients.

Training on using HeLP-Diabetes was viewed as very important in increasing the confidence of those doing the work of implementing HeLP-Diabetes in their ability to deliver it correctly.

ST13: You did a little bit on motivational training when you came. It was quite helpful because that was fairly new to all of us at that time. So, I think that kind of value added...it seemed doable.

(Practice Nurse)

Contextual integration

HeLP-Diabetes was supported by the CCG through endorsement, promotion and encouragement of staff within practices and clinics to offer it. However, there was no resources made available by the CCG to help integrate HeLP-Diabetes within practices and clinics.

It became evident during the implementation that it was crucial to have a dedicated person to support the implementation. When I undertook this work at two practices it was perceived to be extremely valuable, and it is likely that this initial support was one of the key reasons that these two practices went on to be the ones to register the most patients to HeLP-Diabetes.

ST4 I would say it was really nice having you here... we were quite slow, you know, just getting used to it. So I think having you here... I think it would be really helpful to have you there for a few sessions and one beforehand to go through it like you did with us, to show us to show us how to login and everything.

(Practice Nurse)

ST16: I think it would be helpful even if somebody could just come occasionally
(Diabetes Specialist Nurse)

The lack of cognitive participation by some practices and clinics with the intervention was likely due to a lack of available resources in terms of time but also in terms of physical space and adequate computers which made it difficult for practices to implement HeLP-Diabetes.

ST6: Well, for us, it was great but it was going to be really difficult to implement in our surgery because of staffing - no space for receptionists to go off and talk to the patients and log them in and stuff.

(GP Partner)

With such limited time within consultations and a large number of competing priorities staff had to decide upon the priority of delivering HeLP-Diabetes.

Reflexive monitoring (process of evaluation that can feedback into refining the process of implementing HeLP-Diabetes)

In order to be able to appraise whether HeLP-Diabetes was worth the effort and was bringing about the perceived value, staff talked about engaging in work to try and gain feedback from the patients that they had offered HeLP-Diabetes to.

ST5: I have asked some of them to get back in touch and let me know how they find it...because it would be interesting to know, and then I could say to other patients, well, actually patients have found this really helpful, you know.

(Health Care Assistant)

Assessing whether HeLP-Diabetes was benefiting patients was the main source of feedback that staff reported seeking in order to make decisions as to whether the investments they had made in implementing HeLP-Diabetes were worth it.

ST10: there's two decision you need to make... no, two factors if you like that will lead to a decision and one is that, is it worth it financially? Right. And then the second thing, really more important, is it worth it for the patients?

(Practice Manager)

9.4.9.1 Degree of normalization

The degree to which HeLP-Diabetes had become integrated within practices varied greatly. There were practices who had integrated it, using the staff registration method where it had become part of routine practice.

ST7: The thing is it's so... because it's not hard work, it just slots in. It's easy to sign someone up, it's not... it doesn't drag it out, it's not a lot of rigmarole in answering this question and that question. It's simple, it's sort of idiot proof really. And then even working your way round the website, it's... I think it's easy.

(Receptionist/Admin)

There were practices that having failed to integrate the staff registration method had begun, more successfully, to integrate HeLP-Diabetes using the patient registration method.

ST12: ...now we have new leaflets...that's really taken out the middleman and forms getting lost, and things not... access not working and that. So, I think that's really been a big step forward.

(Practice Nurse)

And there were practices where HeLP-Diabetes had failed to become part of practice and provided a good example of the difference between adoption and normalization.

R: So in terms of how it's worked in this practice?

ST18: It hasn't if I'm being honest.

(Receptionist/Admin)

9.5 Discussion

Interviews with staff suggest that the high rate of adoption of HeLP-Diabetes from services within the CCG was driven by a strong sense of the value and benefit that it could bring. Staff perceived HeLP-Diabetes as being able to plug gaps in the provision of information due to time constraints within appointments. HeLP-Diabetes was also perceived to be able to address barriers to the use of group based education including it not being suitable for people who work and people who might dislike being in groups. The findings from the systematic review (Chapter 3) also suggest that staff being able to see the relative advantage of a new innovation over current ways of working is important for the decision to adopt and implement new technologies.

The endorsement of HeLP-Diabetes by the CCG and buy in to HeLP-Diabetes by senior staff within practices was important for adoption and the work of implementing HeLP-Diabetes. Staff

described the importance of feeling supported to undertake the work and the importance of a collaborative team approach to implementing HeLP-Diabetes. The endorsement from the CCG and engagement of the whole team increased the sense that HeLP-Diabetes was important and legitimate to engage with. Previous studies of the implementation of e-health have also reported that in order for e-health implementations to be successful there must be participation and collaboration amongst all staff within an organisation (135, 150, 163) as collaboration may help to: combat health care professionals' resistance to the implementation of e-health systems caused by the perception that the new technologies will disrupt delivery of care (162); create a more positive image of e-health as an integral component of routine health care; and bring together the latest IT expertise and practical clinical expertise in the organisation (146). A lack of collaboration around the use of HeLP-Diabetes within practices resulted in some staff feeling overwhelmed by the responsibility to implement HeLP-Diabetes. Often the role of offering HeLP-Diabetes was delegated to members of staff by GPs without discussions or prior agreement. Ongoing encouragement and support for this role by GPs following the delegation of the task was rarely reported, which contributed to staff feeling that this may not be a task worth prioritising over others.

When HeLP-Diabetes was implemented and used within services it was reported to have beneficial effects on consultations with patients. Staff perceived it as a useful resource to offer to patients which could supplement the information they were able to provide within consultations. Two health care assistants reported that being able to use HeLP-Diabetes as an information resource had allowed them to help patients through the provision of information that they otherwise would not have had access to. Other staff reported that HeLP-Diabetes had provided them with a simpler way of explaining some of the complex diabetes information to patients in consultations. As such HeLP-Diabetes was generally perceived to fit well with the current work of the health professionals using it. A systematic review of the implementation of innovations into primary care stresses the importance of the fit between interventions and different levels of context in order for them to become successfully implemented. How well interventions fit with existing work practices, daily work as well as professional beliefs and attitudes has an impact on the degree of implementation (250).

The role of implementing HeLP-Diabetes and registering patients fitted particularly well with the skills of health care assistants and receptionists. HeLP-Diabetes allowed them to support patients with self-management, provide clinical advice which increased the remit of their usual roles and the use of technology to do this was seen as beneficial rather than undermining. Several staff reported feeling that the role was not suitable for GPs or nurses. A possible explanation for this may be that for more highly skilled staff the use of HeLP-Diabetes to support self-management and address patients' questions within consultations could be perceived as undermining knowledge and skills. Technology use in routine care has been suggested to have the potential to hamper individuals' creativity and undermine their pride in their knowledge and skills and ability to solve problems creatively, removing their freedom to act in ways they consider most appropriate. This, in turn, diminishes individuals' sense of control over their work

(271). For staff such as GPs and nurses who are used to drawing on their own knowledge to address patient problems, the use of HeLP-Diabetes as a tool to do this may not have been perceived as necessary or desirable. However, for less knowledgeable staff, HeLP-Diabetes provided them with the opportunity to help patients in a way they previously couldn't. This has important implications for who might best be targeted to deliver future internet interventions to patients in practice.

HeLP-Diabetes was not however, implemented successfully in the majority of services that adopted it. Difficulties arose with staff mobilising time and effort to do the work required to make HeLP-Diabetes integrated into practice. Some staff reported feeling that HeLP-Diabetes wouldn't be suitable for many of their patients including non-English speaking and older patients which impacted on their willingness to invest resources to implement it. This was not however supported by the quantitative data (reported in Chapter 8) as no differences were observed in use of HeLP-Diabetes by patients' ethnicity or age. Being able to feed these results back to staff could have been a useful strategy in promoting their views of the suitability of HeLP-Diabetes; however, the timing of the data analysis did not permit this.

The registration process was one of the most widely reported barriers to more widespread use of HeLP-Diabetes. There was a lack of agreement by staff as to whether this was a legitimate part of their role with some reporting that it wasn't a suitable use of time or resources. Some staff described a negative impact of registering patients to use HeLP-Diabetes as taking time away from other important tasks to be achieved within consultations. In such a resource tight context, staff were reluctant to take on any more work on top of all the other incentivised tasks they had to perform. Other studies have reported that time and resource limitations impact upon health care professionals' ability to provide diabetes care (246), and the need to perform incentivised tasks as part of the QOF has been reported to impact on the willingness of staff to take on any additional diabetes self-management support work (187). This raises important considerations for the future of non-incentivised interventions within routine practice with regard to the prioritisation that they are given by health professionals. Some staff suggested that if HeLP-Diabetes could become part of the QOF then the registration of patients would get done. Although there was support from the CCG through promotion and endorsement work, there were no resources in terms of finance or extra personnel provided to services to implement HeLP-Diabetes.

The implications that these findings have for practice, policy and research are discussed in the overall discussion chapter (Chapter 11), as are the methodological strengths and weaknesses of the studies in this thesis.

10 CHAPTER 10: RESULTS 3: PATIENT PERCEPTIONS OF THE IMPLEMENTATION OF AN INTERNET INTERVENTION TO SUPPORT SELF-MANAGEMENT OF TYPE 2 DIABETES

10.1 Chapter summary

This chapter presents the findings from the analysis of semi-structured interviews conducted with patients which explored the uptake and use of HeLP-Diabetes in order to address the following research question:

- What barriers and facilitators did patients identify to the uptake and use of HeLP-Diabetes?

10.2 Introduction

As described in detail in Chapter 1, effective self-management of type 2 diabetes by patients can improve glycaemic control and reduce diabetes related complications (30); but optimal self-management is often difficult to achieve. Diabetes self-management education (DSME) has emerged as a resource to assist individuals to actively participate in their diabetes care, however, data from the UK National Diabetes Audit suggests attendance rates at DSME are low only 5.3% of patients attending (35). Non-uptake of DSME by patients is associated with poorer health outcomes (36) and as these programmes are of considerable cost to the NHS (37), non-uptake by patients reduces the cost-effectiveness for health services.

As argued in Chapter 1, delivering DSME over the internet may also reach a broader population and prove to be cost-effective (55). Recent evidence demonstrates that internet based DSME interventions have the potential to improve clinical, behavioural, psychological, emotional, and psychosocial outcomes in patients with type 2 diabetes. However, what is lacking from the literature is an insight into patients' experiences of using internet interventions that gauges whether these interventions meet user needs. Patient perceptions of internet interventions have been found to influence use (272), and intervention use is crucial for actualising potential benefits. Although the relationship between level of engagement and outcomes of internet programs is unclear, a threshold level of involvement is necessary to obtain benefit (38). It is therefore important to understand how patients with type 2 diabetes perceive, make use of and evaluate internet DSME interventions when they are made available in routine practice and to understand factors that may influence engagement.

10.3 Study aim

This study explored patients' experiences and perceptions of an internet based DSME programme for type 2 diabetes (HeLP-Diabetes) which was made available to an unselected patient population as part of routine NHS care. The aim is to understand the role of internet-based interventions such as HeLP-Diabetes in helping people self-manage and to determine the specific barriers and facilitators of use and continued engagement with HeLP-Diabetes.

Specific objectives were to:

- Explore how HeLP-Diabetes is perceived by patient users
- Explore how HeLP-Diabetes is used by patients
- Identify barriers and facilitators to use

10.4 Results

10.4.1 Interview subsample

As described in chapter 6 (section) sampling for the patient interview was designed to be purposive and interviews were conducted with all patients who consented. The participants' who took part in the interviews (n=15) represented a reasonably diverse sample. There were fewer female participants (4/15) than male (11/15), however, there was a good range of age (43-76 years), and ethnicity represented. Sixty percent of participants' were white British (9/15), but Black or Black British- African, Black or Black British- Caribbean and Other (Turkish, Italian and mixed) ethnicities were represented. The length of time since participants were diagnosed with diabetes ranged from less than a year to between 10 and 20 years. Treatment modalities included participants who managed their diabetes through diet only and participants who managed through diet and medication. Unfortunately, no participants managing their diabetes with insulin or other injectable medication participated. A range of educational attainment was represented in the sample including those with no educational qualifications, school leavers, degree and post-graduate degree level qualifications. Participants with a range of computer skills were sampled with basic (4/15), intermediate (6/15) and advanced (5/15) computer skills represented. Home internet access was all but universal, with only one participant reporting public internet access as their main way of connecting to the internet. A full description of the characteristics of each interview participant is presented in Table 10-1.

Table 10-1 Characteristics of patient interview participants

ID	Gender	Age	Ethnicity	Duration of diabetes	Diabetes management style	Computer skills	Internet access	Highest educational attainment
PT1	Male	58	White British	5-10 years	Lifestyle and tablets	Advanced	Home	A-level or vocational equivalent (e.g. NVQ 3)
PT2	Male	63	White British	10-20 years	Lifestyle and tablets	Advanced	Home	Degree or NVQ 4, HND or similar
PT3	Male	59	White-Other (Turkish)	1-5 years	Lifestyle and tablets	Advanced	Home	Degree or NVQ 4, HND or similar
PT4	Female	43	Black or Black British-African	1-5 years	Lifestyle and tablets	Basic	Home	School leaver (e.g., CSE, GCSE, O-Level, NVQ1-2)
PT5	Male	76	White British	1-5 years	Lifestyle	Intermediate	Home	Post-graduate degree or NVQ 5
PT6	Male	58	White British	1-5 years	Lifestyle and tablets	Intermediate	Home	None
PT7	Female	68	White British	5-10 years	Lifestyle and tablets	Intermediate	Home	School leaver (e.g., CSE, GCSE, O-Level, NVQ1-2)
PT8	Male	68	White British	10-20 years	Lifestyle and tablets	Intermediate	Home	Post-graduate degree or NVQ 5
PT9	Male	66	White British	<1 year	Lifestyle	Basic	Home	None
PT10	Male	67	Mixed-Other	5-10 years	Lifestyle and tablets	Intermediate	Home	Degree or NVQ 4, HND or similar
PT11	Male	46	White British	10-20 years	Lifestyle and tablets	Advanced	Home	Degree or NVQ 4, HND or similar

PT12	Female	52	White British	<1 year	Lifestyle	Basic	Public	Degree or NVQ 4, HND or similar
PT13	Male	52	White-Other (Italian)	<1 year	Lifestyle and tablets	Intermediate	Home	A-level or vocational equivalent (e.g. NVQ 3)
PT14	Male	56	Black or Black British-Caribbean	1-5 Years	lifestyle	Advanced	Home	A-level or vocational equivalent (e.g. NVQ 3)
PT15	Female	58	Other-(Turkish Cypriot)	1-5 years	lifestyle	Basic	Home	None

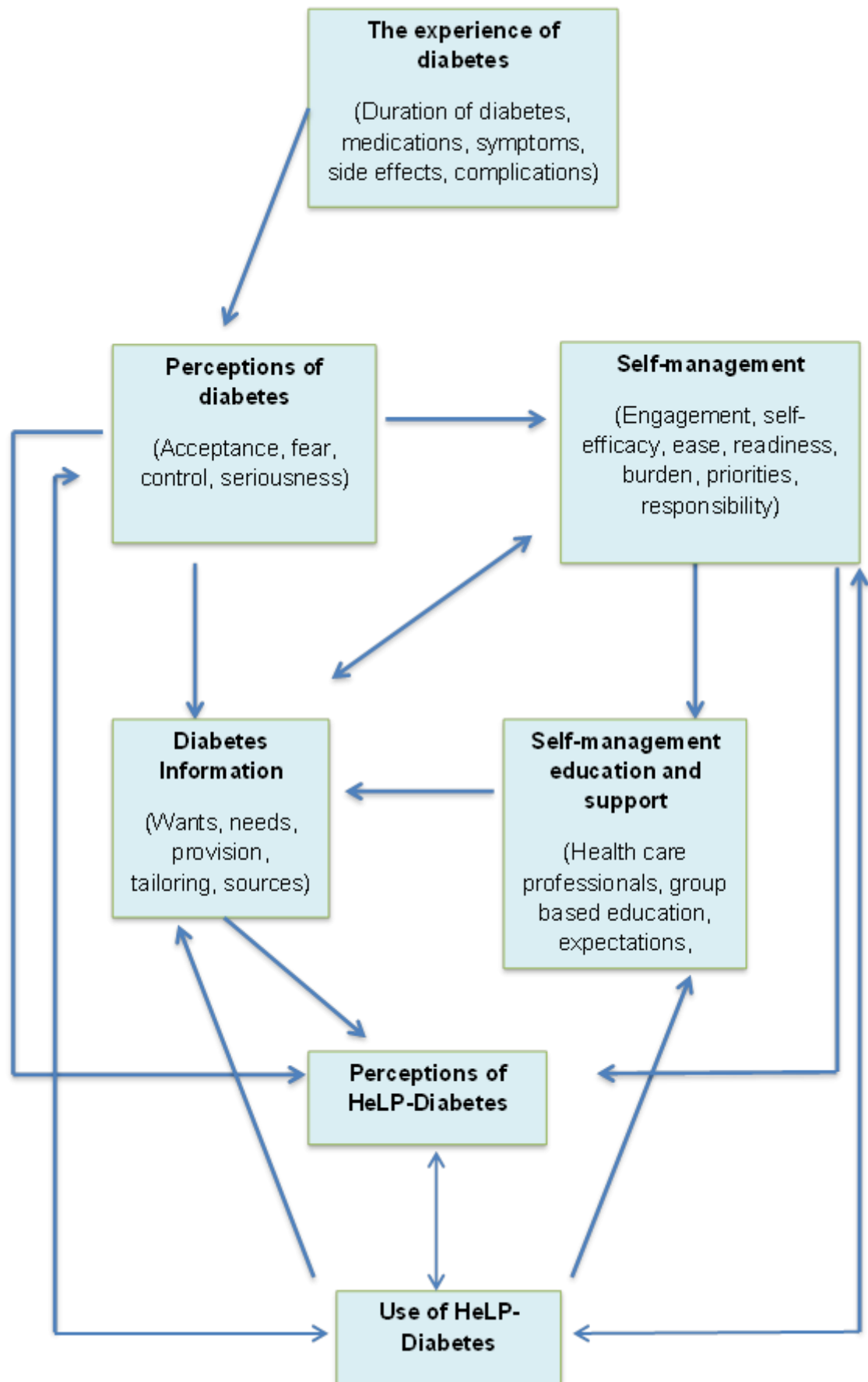
10.4.2 Findings from the thematic analysis

Presented below are the findings from the thematic analysis of the interviews with patient users of HeLP-Diabetes. The main themes that emerged from the data related to:

- The experience of diabetes
- Perceptions of diabetes
- Self-management
- Self-management education and support
- Diabetes information
- Perceptions of HeLP-Diabetes
- Use of HeLP-Diabetes

To help interpretation, the connections between these themes which will be discussed next have been presented graphically in Figure 10-1. Also for ease of interpretation, participant ID numbers, age, gender and experience with computers is provided after each illustrative quote. In instances where questions I have asked are presented I am referred to as R (researcher).

Figure 10-1 Themes identified from the analysis and connections between them



10.4.2.1 *Participants' experiences and perceptions of diabetes*

The experience of having diabetes influenced all the other themes present in the interview data. Through influencing perceptions of diabetes and self-management, the experience of having diabetes indirectly affected participants' perceptions and use of HeLP-Diabetes.

Factors in this theme include the duration of time participants' had had diabetes for, whether participants took medications to manage their condition, and the presence or absence of symptoms, side effects and diabetes related complications. These factors were presented as linked to participants' perceptions of diabetes in terms of their acceptance of diabetes and the extent to which they perceived diabetes to be a serious condition that demanded attention and prioritisation which influenced participants' self-management of diabetes. In turn, perceptions of diabetes and self-management factors influenced whether participants viewed HeLP-Diabetes (as a tool to support self-management) as valuable, and determined in part, the extent to which they engaged with it. In this section the experience of diabetes and the way it influenced participants' perceptions of diabetes and self-management is presented.

Diabetes often does not initially present with symptoms and side effects and several participants reported not having experienced any symptoms which heavily influenced the way in which they perceived diabetes. An absence of symptoms led to feelings of surprise and shock at being diagnosed with diabetes and influenced how well participants had come to terms with having diabetes; with some participants with no symptoms reporting being unable to accept the fact that they have diabetes.

PT13: Well, at the beginning obviously it was quite difficult to accept it, especially because I had no symptoms

(52 year old male, intermediate computer skills)

At diagnosis, it is usual for healthcare professionals to recommend patients try to manage diabetes through lifestyle changes first before the introduction of medications. For some participants, the fact that they had been advised to control their diabetes through dietary and lifestyle changes alone; without prescribed medications, made it difficult to accept that they had diabetes. This highlighted an association that was held by several participants between being unwell with the taking of medications, or being well and the absence of medications.

PT9: I do not feel that I've got diabetes. I don't feel, you know... I mean, I don't take no medication. I don't take nothing at all. I don't test myself, because I'm not on medication.

(66 year old male, basic computer skills)

As well as influencing acceptance of diabetes, the presence and absence of symptoms and medication influenced perceptions of seriousness. Participants made judgments about the seriousness of diabetes by forming comparisons with other conditions and treatment methods.

PT7: I went in to see my doctor...and she said by the way, you've got diabetes, and I just went, oh, right. Okay, whatever. And in a way I didn't, I mean she said type two, so not having to take insulin or anything

(68 year old female, intermediate computer skills)

In this quote, the participant presents the moment she was given the diagnosis by her healthcare professional as something that occurred almost flippantly '*by the way, you've got diabetes*' which she constructs as influencing how seriously she perceived the diagnosis to be '*Okay, whatever*'. Also she describes the fact that she did not have to use injectable medications like insulin to manage her condition as a factor in her judgement that her condition is less serious than type 1 diabetes.

Other participants reported having experienced a range of symptoms and complications associated with diabetes including tiredness, erectile dysfunction, wounds not healing and frequent urination. These participants were more likely to perceive diabetes as a serious condition because of their experiences with the complications. One participant who had experienced several complications of diabetes wanted to urge others to take it more seriously from the beginning because of the potential for future complications, highlighting the progressive nature of diabetes.

PT2: they don't realise until something like osteomyelitis or heart failure or retinopathy or whatever else comes along that it's not a joking matter. It's an all over shroud of illness that you live under

(63 year old male, advanced computer skills)

Acceptance of diabetes and perceptions of its seriousness influenced the way that participants reported engaging with self-management activities. A fear of disease progression and a desire to prevent future complications and worsening of health was a main priority for participants engaging with self-management. Participants who had witnessed the seriousness of the disease or who were concerned about it were more likely to see the value in self-management. This participant who was motivated to make lifestyle changes in order to manage his condition reported being motivated by having witnessed the serious complications that can arise if self-management isn't taken seriously.

PT14: I think my biggest motivation is that my dad and all of his brothers bar one have all died from diabetic related diseases, like strokes, stuff like that, and they talk the talk, but they never did any exercise, and they were still drinking their rum like every two or three days

(56 year old male, advanced computer skills)

Medication was viewed by many participants as a marker for seriousness. As the progressive nature of diabetes means the taking of medications is inevitable for most people, having to take medication symbolised a worsening of diabetes for some participants.

PT5: Well, I really don't want to be a diabetic and I certainly don't want to reach a level where I... where I have to take medication.

(76 year old male, intermediate computer skills)

Some participants reported that being able to avoid or delay the taking of medication was a reason that motivated them to engage in self-management of their diabetes.

R: You don't take any tablets at the moment?

PT9: Not at the moment. If I've got to I will take them, right? But I think, at the moment...if I can lose a lot a lot of weight it might stop me going on tablets.

(66 year old male, basic computer skills)

A few participants were motivated to engage with having diabetes because they felt as though doing so enabled them to have a sense of control over their condition and the disease trajectory.

PT10: ...I think the thing about self-management, it also implies being proactive, it means not sitting there and waiting for something to happen, but being preventative about it, so that's, that to me, is the key bit.

(67 year old male, intermediate computer skills)

10.4.2.2 *Self-management*

Participants' perceptions and experience of self-management were important in their engagement with HeLP-Diabetes. This relationship was complex and multifaceted. In general participants who reported engaging with self-management of their diabetes were more likely to see benefit and value in HeLP-Diabetes than those participants who were not. There was much variation reported by participants with regard to how well they perceived themselves to be managing their diabetes. For some, self-management activities to control diabetes were perceived to be easy to undertake and therefore interventions such as HeLP-Diabetes to support self-management were not perceived necessary. For others who perceived themselves to be managing their diabetes well, HeLP-Diabetes was perceived positively as an additional and useful resource to support this. Similarly, these differences in the perceptions of the value of HeLP-Diabetes were present among those participants who reported not self-managing well. For some, it was perceived to be useful in providing support and information that they had not gained elsewhere; however, others craved a type of support that they did not feel they could gain from HeLP-Diabetes, being an online intervention. Factors related to participants' self-management are described here.

As described in depth in Chapter 1 self-management tasks for people with diabetes may involve taking medications, attending appointments, modifying behaviours such as eating and physical activity, managing the impact of diabetes on relationships with others and learning to manage the emotions associated with having a long term condition. In order to undertake the self-care

tasks required of managing diabetes, a level of engagement with the idea of self-management and the activities required of it must be present.

Engagement with self-management of diabetes by participants varied greatly in terms of whether or not they had initiated self-management activities and if so, the extent to which they had made lifestyle modifications. Factors that influenced participants' engagement with self-management were related to four main factors; self-efficacy, readiness, the relative prioritisation of self-management *vis-à-vis* the rest of their lives, and perceived responsibility for self-management.

As described in the literature, people with diabetes often find it difficult to achieve the lifestyle modifications required to self-manage diabetes. Participants in this study varied markedly in terms of how well they perceived they were engaging with these self-management activities. Engagement with making lifestyle modifications was often related to the participants' self-efficacy in their ability to perform the tasks. Some participants who reported having not engaged with self-management activities described feeling overwhelmed by the tasks required of them and expressed a lack of confidence in their ability to achieve the changes necessary to manage their diabetes.

PT15: I know, like, when you say, like, lifestyle changes, I know, like, diet, exercise. I mean, I know it all but it is can I really do it all? That is the hard thing for me.

(58 year old female, basic computer skills)

Conversely, there were participants who had engaged with self-management activities who reported feeling confident in their ability to undertake these tasks.

PT10: ...swimming, and walking...I just sort of embraced that. So, I was very, completely religious about the medication, of course I took it, and... I sort of also took seriously, the diet issue, and the exercise, so yes, I didn't have any difficulty with that, at all

(67 year old male, intermediate computer skills)

Although the majority of participants reported that they had embarked on some self-management activities, there were participants who reported having not started to address their diabetes and self-managing their condition due to not yet being ready to do so.

PT12: It's basically something that I have to address, that's on my mind a lot, but I'm finding excuses not to deal with it

(52 year old female, basic computer skills)

For some, engaging in self-management activities would make diabetes, and moreover the possible future complications of diabetes, feel real. Some participants reported that they were not yet ready to engage with the fact that they had diabetes as this would place a burden on

them in terms of the work that they would feel obliged to undertake in order to control their condition, which they were not ready to undertake yet.

PT11: ...I don't deal with that sort of thing otherwise I'll be... I mean, I'm a worrier anyway and that would just be another thing just to... I've, kind of, put my head in the sand about the long term.

(46 year old male, advanced computer skills)

In some cases, not being ready to engage in self-management was related to not being ready to make lifestyle changes that may disrupt the participants' sense of leading a normal life. Although, the medical literature suggests that undertaking tasks to achieve optimal self-management of diabetes is of utmost importance for diabetes outcomes, in many cases participants described the strain that undertaking these self-management activities placed on them. Undertaking these activities, which are intended to improve diabetes outcomes, actually disrupted participants' everyday lives and placed great burden on them.

PT4: Tired. I get so tired very easily... as I say, I have to watch all of the time, you know, what I eat, for example, I have to watch what I eat and I have to watch my toes, my feet, I have to look after them. Whereas before I never did that, I just got on with everything, I think, but now, you know, especially you have to know about your sugar levels, if they're up, if it's down, so all that, it affected me, naturally.

(43 year old female, basic computer skills)

PT2: ...it's a pain having to go to all these appointments and clinics and such like

(63 year old male, advanced computer skills)

A dissonance between the goals of self-management for the medical profession and the goals of self-management for patients was apparent. Whereas, adherence to medication, attending appointments, achieving glucose control are reported in the literature as clinical goals of self-management; participants' described their priorities as being able to lead a normal life and to not feel as if they are unwell. People reported feeling a tension between making changes in order to self-manage and being able to maintain a normal life, with decisions about which of these had priority being regularly weighed up. One participant reported that taking her medications as prescribed in order to control her diabetes was having a detrimental effect on her daily life as she was experiencing awful side-effects from the drugs. In this instance she had tried to solve this dissonance by taking the prescribed amount of medication at different times than were recommended.

PT7: I'm on Metformin now, medication and I hate it. I'm supposed to take four pills a day and I can't do that unless I'm near a toilet....I just get complete diarrhoea...I find that a bit disturbing, to be honest with you.

(68 year old female, intermediate computer skills)

Social situations seemed to be a particular trigger for this tension between adhering to self-management activities and maintaining a normal life, particularly in relation to dietary changes. For some, the tasks of self-managing were put on hold when they had the potential to impact on others. Maintaining the appearance of being 'normal' was also important to participants in social situations and therefore tasks involved in managing diabetes such as dietary changes were sometimes placed on hold in the presence of others in order to maintain a sense of being like everybody else.

PT6: if I was at somebody's and they put old potatoes on I wouldn't make a comment about it, I would just get on and eat it...I mean, I make the changes in as much as I can in my own life, but that doesn't affect people.

(58 year old male, intermediate computer skills)

PT12: ...I went for a long walk with a friend ...she said will you share a cake with me, and I thought, well, I really shouldn't do this... well, I said yes to it ... basically it's down to me again, it's not her fault. If I don't talk about it and make an issue of it and, you know, make it part of our relationship, you know, to discuss it then, you know, these things happen.

(52 year old female, basic computer skills)

Despite the burden that undertaking self-management activities often placed on participants, in general, there was a sense among respondents that self-management was the best way for their diabetes to be managed. The majority of participants shared the view that caring for their diabetes was largely their responsibility. There was a sense of guilt expressed by some about having diabetes; which led to them feeling that they were to blame for having it and therefore responsible for managing it.

R: whose responsibility do you think it [managing diabetes] is?

PT11: Oh, it's absolutely 100% mine. If my... it's my fault I got into it, it's nobody else's because I wasn't born with it...this is purely my fault because I'm fat.

(46 year old male, advanced computer skills)

Others indicated a feeling of responsibility for looking after their diabetes because they felt that if they did not look after their diabetes then no one else would do it.

PT9: ... if I didn't do it, I can assure you nobody else is going to do it, you know.

(66 year old male, basic computer skills)

Several participants however, reported wanting more involvement from healthcare professionals in controlling their condition, suggesting that perhaps they did not agree with the large responsibility for their diabetes that the notion of self-management places on them.

PT15: I think I want a more practical... I wish there was somewhere where I could go where I could get help and support

(58 year old female, basic computer skills)

10.4.2.3 *Self-management education and support*

Participants' perceptions of self-management education and support were influenced in part by how good they judged their control of their diabetes to be, their perceptions of the responsibility for diabetes management and the extent to which they had unmet needs with regard to information provision and support. Participants' perception of the education and support that was currently on offer was important in their perceptions and use of HeLP-Diabetes. Those who believed they were receiving adequate education and support from elsewhere had less of a need for an additional source of education and support than those who felt they hadn't received the amount or the type of education and support they needed. For some the internet offered a different format of education and support which was better suited to their needs and wants than more traditional formats such as group based education. Factors related to participants' perceptions of the support and education they receive for their diabetes are described here. For most participants, the main source of healthcare professional input for their diabetes came through primary care services, specifically appointments with GPs and nurses in their GP surgeries. The GP practice also provided access to hospital services for specific diabetes related tests and checks, appointments with dieticians and group based DMSE. There were strong opposing feelings about the care and support participants were getting from their GP surgeries for their diabetes. Some reported feeling very satisfied, whereas others thought that their care was minimal and that more should be on offer to support their self-management.

R: How would you describe the care that you receive from the NHS?

PT6: From my doctor it is absolutely top notch excellent.

(58 year old male, intermediate computer skills)

PT14: I see someone every six months, for the six month blood sugar test, and that's the only time they see me. I think I should go more often.

(56 year old male, advanced computer skills)

Often these views were influenced by how well participants' perceived themselves to be self-managing their diabetes, with those who held more positive appraisals of their own diabetes management expressing more satisfaction with the care from the NHS compared to those who felt that they were struggling with self-management.

PT5: ...as for the national health, I'm quite impressed, actually...it sort of went up a click when I reached my 75th birthday... and I'm chased up fairly regularly, and in quite a fierce way, which is very useful.

(76 year old male, intermediate computer skills)

Specific shortcomings of current care provided by the NHS were reported in relation to time and continuity of care. Several participants reported that they felt they did not have enough time with healthcare professionals during consultations to cover all the issues that they wanted to discuss. And others reported a frustration that it was difficult to see the same healthcare professional each time they had an appointment which made it difficult to build relationships.

This also increased the burden on participants, as they had to repeat answers to questions with each new healthcare professional they encountered.

PT13: ...I had to wait a long time to get an appointment, and then not with the doctor I wanted...I should wait months before I get appointment with him

(52 year old male, intermediate computer skills)

PT2: Well, I carry, because you have to answer from healthcare professionals these same questions time after time after time, I carry in my wallet a detailed list of all my meds.

(63 year old male, advanced computer skills)

Participants' judgments of who should be responsible for the care of their diabetes also influenced perceptions of the adequacy of care provided by the NHS. Those participants who believed that responsibility for managing diabetes was largely theirs had more positive appraisals of the level of care they were receiving than those participants who wanted the responsibility to be more shared.

PT12: I think it's as much as they should be giving really. I mean, I think it should be down to me – there's only so much they can do

(52 year old female, basic computer skills)

PT1: ...there is no social support, is there?...There is no social support. We can't go to an AA meeting for sugar addiction; it doesn't exist. There's nothing for diabetics

(58 year old male, advanced computer skills)

There were certain expectations that participants held with regard to the role of their healthcare professionals in managing their diabetes. Participants' perceived a distinction between tasks that were the responsibility of healthcare professionals to undertake and tasks that they perceived as their responsibility. In general, the role of healthcare professionals in the management of diabetes were perceived to be the provision of information, the prescription and adjustments of medications, and performing medical tests and checks whereas the participants' roles included being informed, following advice, attending appointments and making changes to diet and exercise.

PT15 Well, the GP, obviously, they, like, do all your bloods and stuff like that and then once a year I go around there, they check your feet...the clinical side of it, yes, like, obviously the GP but everything else is down to me, you know. I try and look after myself the best way I can like knowing what to eat, how to eat, when to eat.

(58 year old female, basic computer skills)

Not all participants reported having been offered access to group based structured diabetes

education when they were diagnosed or subsequently. This was particularly true of those participants who had been diagnosed with diabetes a long time ago when education may not have been available or recommended. Of those offered access, there were several barriers reported to attending the groups including the fact that they were held during working hours making it difficult for those in paid employment to attend. Others reported feeling that they were too busy to attend a course that lasted several hours.

PT13: I couldn't attend because I had to go to work at the time there, so I couldn't do it.

(52 year old male, intermediate computer skills)

PT10: I think things... my life is so busy, I'm not sure I have the time to go and have a chat to other people, who've got diabetes, do you know what I mean?

(67 year old male, intermediate computer skills)

For those participants who did attend a group education session, their evaluations of the sessions varied greatly. Group based education was particularly suited to participants who reported feeling alone with their diabetes as it provided an opportunity for them to connect with other people with diabetes and helped to alleviate feelings of isolation. Others found the support-group like nature important in encouraging and motivating them in their self-management efforts.

PT4: ... first of all, when you go to a meeting you realise you're not alone. And, second of all, you think again that you are the only one who goes through it, but when you go there you meet other people, share the experience and you realise that other people go through the same thing again and it helps you to cope.

(43 year old female, basic computer skills)

PT1: The class was set up to encourage you... you had to make a sort of promise every week that you wouldn't do anything and you would do a certain thing and then come in the next week and see how you'd got on with that, which was excellent.

(58 year old male, advanced computer skills)

However, there were several negative appraisals of the group based education from participants. One of the biggest criticisms noted was that the courses hadn't lived up to participants' expectations which centred on gaining information and gaining motivation to manage diabetes. Participants who reported feeling like they had a good level of diabetes related knowledge to begin with expressed disappointment that the courses were aimed at a more basic level of knowledge, and did not cater for those who might want more complex issues addressed.

PT7: I go to these I sort of know all the stuff that they're telling me, but at least it's three hours without chocolate.

(68 year old female, intermediate computer skills)

A lack of tailored information provision due to the group based nature of the courses was a criticism by many who felt their specific issues were not addressed or that they did not have time to raise their own concerns.

PT4: I think because the group, you know, you have limited time and a lot of people are there and everybody wants to... they all have to be answered, you know, so you don't get time, as much time as you'd like, to answer everything, what you want

(43 year old female, basic computer skills)

Others felt that despite being provided with the information they needed, the course hadn't been successful in motivating them to act upon it and make changes.

PT12: ...it was mainly about diet, and I felt that I knew most of the stuff. My problem is to do with motivation, it's not that I don't know

(52 year old female, basic computer skills)

Other participants' experienced difficulties with the group based education due to interactions with other attendees. In one case a participant reported that the group was disruptive which obstructed her learning. Another participant who had hearing difficulties found the group interactions challenging to follow.

PT3: I don't like the groups things personally.

PT12: There were problems with that. There were people in the group who were basically a bit cynical about the group and they kind of dominated, so it was a little bit difficult.

(52 year old female, basic computer skills)

PT3: The thing for me is I can't catch the conversation because I have a hearing problem. If I don't see someone else speaking them I am losing it. Sometimes the language also affects my understanding of things.

(59 year old male, advanced computer skills)

10.4.2.4 *Diabetes information*

Central to whether and for what purposes participants accessed HeLP-Diabetes were perceptions of the need for information about diabetes and self-management. Information wants and needs were influenced by participants' appraisal of current sources of information provision and diabetes related factors. Perceptions of the value and usefulness of HeLP-Diabetes were influenced by whether participants desired information about diabetes, and whether they perceived the internet to be an acceptable way of providing this information.

As already mentioned, information provision was viewed as a core responsibility of healthcare professionals in providing diabetes care to participants. Many participants regarded having access to accurate and clear information about diabetes and how to manage it as crucial to being able to self-manage effectively, particularly for those participants who were newly diagnosed. Participants who were given information that they did not understand reported this as a barrier to their being able to control their diabetes.

PT4: ... I think it's very important for someone with diabetes to look after themselves and to take in any... what can I say? To get more, as much information as you can from the GP, from the books, anything which can help you get the information for the diabetes.

(43 year old female, basic computer skills)

PT1: ...I'm not managing it very well and I just feel that the information we get is a bit hit and miss. I hear different things off of different people, supposedly diabetic experts.

(58 year old male, advanced computer skills)

Many participants reported experiencing a lack of consistent and trustworthy information provision from their healthcare professionals and the NHS in general. Concerns were expressed by participants around being provided with information that was conflicting, did not make sense to them, and some even questioned the knowledge of their healthcare professionals.

PT8: I find that the medical advice sometimes, you know, it changes quite drastically sometimes.

(68 year old male, intermediate computer skills)

PT1: Well, I don't feel that the GPs and I'm not blaming... my doctor is a very good doctor, but he's just not up on diabetes. ... And I just feel that they're not really in touch.

(58 year old male, advanced computer skills)

Appraisals of current information provision and need for additional information were influenced by how long participants had had diabetes for. Information needs changed over time with those who were newly diagnosed reporting a greater need for information than those who had had diabetes for longer. Length of time with diabetes was linked to feeling more confident in being able to deal with diabetes and being able to seek out the relevant information and help if it was needed.

PT13 Well, to be honest, you know, at the beginning you look, look, look, but now I don't look very much.

(52 year old male, intermediate computer skills)

PT10: ...I do get enough information. I mean, I'm getting it, I'm getting the information. And I know where to go, if I need to, if something happens. And nothing has happened yet, touch wood. I know where to go for that.

(67 year old male, intermediate computer skills)

In addition to length of diabetes, information seeking behaviour seemed to be influenced by how well participants had come to terms with their diabetes and their engagement with self-management. A few participants reported actively avoiding diabetes related information because of a fear of confronting the condition. Whereas other participants' sought out information because they associated being well informed with being able to better self-manage and prevent the worsening of diabetes.

R: You say you haven't really engaged with any information on diabetes because of the way you're feeling about it?

PT12: ...I would say the bottom line is that ... there is a kind of fear of confronting it which is sort of holding me back a bit.

(52 year old female, basic computer skills)

PT4: ...I used to look on, you know, the exercise, what to eat, how I should take care of myself in general, to prevent my diabetes getting worse, yes.

(43 year old female, basic computer skills)

All participants reported supplementing the information they received from healthcare professionals about diabetes and self-management by seeking information on the internet. One of the main reasons the internet was chosen by participants over other sources of diabetes related information was accessibility. Participants reported being able to access the internet whenever they needed and enjoyed being able to take their time over information seeking, which was viewed in contrast to information provided by their healthcare professionals which was often reported as difficult to access and time limited.

PT4: ...you don't get time, as much time as you'd like, to answer everything, what you want, whereas if you go on a website you can read about it... You can get more information and in your own time, you know; there is no rush

(43 year old female, basic computer skills)

Despite the acceptability of the internet for diabetes related information and the unanimity among participants in accessing information this way, there were several concerns raised by participants about using the internet for health information. Most commonly expressed was a worry about the reliability and trustworthiness of information on the internet. Participants were concerned that some of the information they encountered online could not be trusted and thus tended to seek out information from sources that they deemed to be authoritative and well recognised, websites with an absence of advertising, and websites from England which were deemed as markers of credibility.

PT5: Well, put it this way, I wouldn't... I wouldn't even look at Wikipedia, in that I'd pay, you know, attention to a NHS-backed website, or something, you know, the Royal College does, or something of that sort.

(76 year old male, intermediate computer skills)

Another issue for participants seeking information online, which was similar to one of the reported limitations of group based education, was that the internet could not provide personalised information. Participants expressed concerns that online information could only cater to a general audience and that it might not apply to them specifically, given their individualities.

PT10: ...the trouble with it, is diabetes is always in the context of other things, you see. Witness my inability to exercise, because I had arthritis. So... it may not necessarily be the right thing for you.

(67 year old male, intermediate computer skills)

10.4.2.5 *Perceptions of HeLP-Diabetes*

As discussed briefly above, participants perceptions of HeLP-Diabetes were influenced by several factors; acceptance of diabetes, appraisal of self-management, burden of illness, satisfaction with current diabetes care and education and information wants and needs. Participants' perceptions of HeLP-Diabetes and how these factors influenced these perceptions are discussed in more detail in this theme.

Acceptance of diabetes was influential in whether or not participants had engaged in actively controlling their diabetes through self-management activities and also whether they engaged with HeLP-Diabetes. Participants who reported having not yet fully engaged with having diabetes perceived that using HeLP-Diabetes may force them to become more aware of the condition and possible future complications which they were not yet ready to do.

PT12: ... my life has been blessed with good health and it's only recently that due to hospitalisation I've put on weight and then became diabetic, but generally I've not had to think about my health in my life and it's just basically I want that to continue

(52 year old female, basic computer skills)

PT11: ...I did log on, I have signed up to it but I think that would mean everything becomes a bit more real. At the moment stabbing myself every so often and doing my long term count. I don't want to look at something knowing that it's going to be bad

(46 year old male, advanced computer skills)

Some participants (as exemplified in the quote above from participant PT12), when talking about their health, used language which suggested that they had never taken agency over their health but that using HeLP-Diabetes may force them to take account of it, which they did not want to do. This participant uses the phrase *'blessed with good health'* which suggests a lack of personal influence over her health and she describes *'never having had to think about my health'*. Using HeLP-Diabetes would involve thinking about her health which she describes as not wanting to do.

There were also participants who were confident in their current self-management who did not perceive a need for HeLP-Diabetes. These participants reported being satisfied with their current self-management behaviours and had achieved a level of diabetes control that they were happy with. As such, they reported little need or use for HeLP-Diabetes at present.

PT2: Well, the reason I don't use it, as I explained, I feel I'm sort of self-managing it, so I'm not looking at it because I don't need advice

(63 year old male, advanced computer skills)

For participants who reported experiencing burden from living with diabetes and undertaking self-management activities, the reminders and prompts to use HeLP-Diabetes were perceived as increasing this burden. Participants' reported a feeling of just wanting to be able to get on with their lives instead of having to think about the fact that they have diabetes all the time. Email reminders and newsletters designed to prompt use of HeLP-Diabetes were perceived negatively by these participants because they provided a reminder of their diabetes and along with other forms of reminders, resulted in participants feeling bombarded with information about their diabetes.

PT7 Yes, I get very pissed off actually...you know, it's in the back of my mind. I'm completely conscious of it. I don't need reminding, and there are times when I go, I know!...sometimes I think you don't get time to even think about what you're doing.

(68 year old female, intermediate computer skills)

Participants' appraisals of their current information and support needs influenced judgements of the benefits of HeLP-Diabetes. Participants varied with regard to how much information they had about diabetes and how much they wanted which influenced their reasons for using or not using HeLP-Diabetes. The majority of participants reported a desire for information about diabetes and described information seeking from a range of sources on a regular basis. The internet was viewed by many as a resource which enabled them to keep up-to-date with current diabetes information, and HeLP-Diabetes was viewed as an additional resource which was used for information seeking.

PT6: ...when I first had it I read everything I possibly could, absolutely everything; and I looked up everything on the web about it...But anything that says something about diabetes I do read it, to be honest.

(58 year old male, intermediate computer skills)

There were participants however, who felt that they had a good level of knowledge about their diabetes who did not perceive HeLP-Diabetes to be useful for them as they felt it did not offer anything that they did not already know or have access to.

PT5: the information on it I'm already up to speed on...there's nothing on it, as far as I can see, that's new or different.

(76 year old male, intermediate computer skills)

As described, HeLP-Diabetes was perceived to be a good source of information about diabetes. As well as information, HeLP-Diabetes offers behaviour change tools, emotional management tools, self-monitoring tools and social and peer support features, however, the majority of participants' described it purely for its information content, rather than any of these other features. This may have been due to expectations of what websites usually provide and how participants' typically use the internet for diabetes related support; the presence of these tools are less common on standard information websites.

The reported strengths and benefits of HeLP- Diabetes often reflected shortcomings in other sources of diabetes self-management support. Participants who reported experiencing difficulties with attending or benefitting from group based education perceived HeLP-Diabetes to be incredibly useful in addressing some of these issues. Many made reference to HeLP-Diabetes' accessibility and convenience as well as the privacy that it afforded people to look up information on their own and at their own pace.

PT12: Well, the DESMOND group for me, because my memory is not brilliant it means that... and if they give you a lot of information in one go it's hard to sort of assimilate it all, whereas if there's a site you can take in as much as you want, you know, at certain times.

(52 year old female, basic computer skills)

PT7: ... this is a very private thing and...because you can go on to the website in the privacy of your own space and look things up. Some people don't like to put their hand up at a group thing, they're a bit shy about that, they hope someone else is going to ask the question

(68 year old female, intermediate computer skills)

However, there were other participants, particularly those who valued the social interaction that they gained from group based education who did not perceive HeLP-Diabetes to be able to meet their needs for social support as they craved interaction and support from other people.

PT15 It's okay but... I just thought to myself, like, what's the point? What's the point of it really? You're there just looking at a computer screen, like, answering questions, doing stuff like that and, to me, that is not enough, you know. I'd feel better, you know, like, having somebody to actually talk to. I think that would be better for me, you know.

(58 year old female, basic computer skills)

Perceptions of and satisfaction with current diabetes care was an important factor in perceptions of HeLP-Diabetes. Those participants who were satisfied with their current care from their healthcare professionals and who were confident that their needs were being met elsewhere often did not perceive the need to use HeLP-Diabetes.

R: Is there anything missing from HeLP Diabetes?

PT7:...I don't think so, because actually I've never really had a huge question to ask...I have a really good GP and a very good health centre and they, you know, run a service that if I wanted to speak to a doctor and I couldn't get an appointment then the doctor would phone me.

(68 year old female, intermediate computer skills)

However, other participants who reported dissatisfaction with their healthcare perceived HeLP-Diabetes to be beneficial in being able to supplement and even corroborate or check information that they had been provided with by healthcare professionals which they did not trust or understand. In this way HeLP-Diabetes was seen by some as a resource that allowed them to transcend traditional knowledge boundaries, and allow them access to information that they may otherwise not have been privy to.

PT14: biggest problem I find with the GP, is when I was first diagnosed...didn't like his attitude: you're a diabetic, you will be on your medication, you will have one tablet a day... no talk of exercise whatsoever... so I had to go online, and say, what's the best thing, diet and exercise?

(56 year old male, advanced computer skills)

HeLP-Diabetes was perceived by some as a more trustworthy source of information than information from their healthcare professionals. Often distrust of the information from healthcare professionals was linked to previous negative experiences that participants had encountered with the information provided to them by healthcare professionals. HeLP-Diabetes was used as a second opinion to check information provided by healthcare professionals.

PT2:...twice I've been let down by healthcare professionals in prescribing medication, which has led to other things...so from now on every time I get a drug, I check it and I look at the side effects and I ask what are these going to do?

(63 year old male, White British, advanced computer skills)

Despite participants concern over the credibility of online information in general, HeLP-Diabetes was perceived as a trustworthy and authoritative source of information. This was largely due to the affiliations HeLP-Diabetes has with the NHS and University College London whom participants reported trusting and respecting thus giving it credibility and authority.

PT5: It was a project started by Whittington and the University College, which are my two favourite hospitals, and, I think, the Royal Free as well, I'm not sure... the, sort of, local connections, you might say, so it must be all right.

(76 year old male, intermediate computer skills)

Another important factor in participants' judgements of the credibility of HeLP-Diabetes was the fact that it was offered via their GP practice or hospital clinic. Having HeLP-Diabetes introduced to them through these services with a recommendation from a healthcare professional seemed of central importance in participants' decisions to register and use HeLP-Diabetes. Many spoke of the importance of the endorsement from healthcare professionals which set HeLP-Diabetes apart from other online resources.

R: Was it important to you that it was a website recommended through your GP practice?

PT7: Yes, absolutely.

R: Why is that?

PT7: Well, because you feel it has been researched. You feel that some of the information on it has come from experience and I'm more likely to go onto that website because it was recommended by a place I've been going to for ten or more years.

(68 year old female, intermediate computer skills)

The majority of participants were registered to HeLP-Diabetes through the staff registration method where a healthcare professional at their GP practice or diabetes clinic assisted participants to access and register on HeLP-Diabetes (for more details on the different registration methods please see Chapter 7). In addition, some practices offered a degree of facilitation to participants which included staff introducing HeLP-Diabetes and showing participants parts of it. Participants described this registration and facilitation process positively and suggested that this was a key factor in influencing them to engage with HeLP-Diabetes.

PT14: That was the only reason I signed up, because it was recommended, plus they had a person there to show me what it was like

(56 year old male, advanced computer skills)

The facilitation from staff to access and register on HeLP-Diabetes seemed to be particularly important in order to overcome issues of the digital divide. Participants with basic computer skills and those for whom English was not their first language (PT3) seemed to particularly benefit from the assistance of staff in initially accessing HeLP-Diabetes. Being able to register on HeLP-Diabetes with support and being shown how to access and use it was helpful in

building participants' interest in HeLP-Diabetes and their confidence in being able to access and use it alone.

PT9: The secretary, a lady called (name of receptionist), very helpful. And she set it up for me and, you know, logged me in and you know, you've got a password and everything.

(66 year old male, basic computer skills)

Not all participants received this additional facilitation to access HeLP-Diabetes. One participant with basic computer skills, who hadn't received any support in accessing HeLP-Diabetes suggested that facilitation by a healthcare professional would have helped her discover the content that she was interested in.

PT4: ...if you go on a website I think they should show you...For example... how to fast, how to take care of your feet, how to... exercising. I think there should be like something like that

(43 year old female, basic computer skills)

The other way in which participants accessed HeLP-Diabetes was through the patient registration method. In these cases, staff would recommend HeLP-Diabetes, but would not facilitate registration or access. Instead, participants were given a patient registration leaflet with details of how to register themselves. Most participants who accessed HeLP-Diabetes in this way reported this process as straightforward. However, all the participants in this interview subsample who joined via the patient registration method described themselves as intermediate or advanced computer users and were therefore probably adept at accessing websites and online registration forms. This suggests that the patient registration method may not have been utilised by participants with lower levels of computer skills and stresses the importance of staff facilitation in overcoming issues of the digital divide between those who can access healthcare online and those who can't.

PT10: Oh, the doctor told me. The doctor, so he gave me a leaflet, and a number, and I signed up for it, yes.

R: And how did you find the signing up process?

PT10: Yes, yes, absolutely, no I didn't have any problem with that, at all. No, no.

(67 year old male, intermediate computer skills)

10.4.2.6 *How HeLP-Diabetes was used*

Participants with a range of computer skills reported that accessing and using HeLP-Diabetes was straightforward and unproblematic. The navigation and design of the website appeared to be conducive for participant use, with participants reporting the website to be clear, easy to navigate and well laid out.

PT5: ... it looks... I mean, it looks very attractive and interesting and well laid out

(76 year old male, intermediate computer skills)

Surprisingly, the only participants who expressed having difficulty with accessing content on the website were those who were advanced computer users who expressed difficulty in finding specific content.

PT1: I know the information's there on the website that you've created, but ...I find the website not confusing, but hard to access.

(58 year old male, advanced computer skills)

Some issues with accessing HeLP-Diabetes were encountered when participants attempted to access it from mobile phones, for which it was not optimised. These participants were those who reported not having home internet access and this will be an important issue to consider in the future with regards to issues of the digital divide, especially as use of the internet on devices such as smartphones is rapidly increasing.

PT12: Well, I like the idea of the website – I did like the idea of it. In reality, it's not been practical for me because I've only got a smartphone, I don't have a computer. So, I did like the idea of that because that meant that I could revisit it again and again until I sort of learn things. And so, yes, unfortunately it hasn't worked out because it's been very difficult with my phone, you see.

(52 year old female, basic computer skills)

For those participants who could access HeLP-Diabetes, patterns of use were extremely varied. Some participants reported not using HeLP-Diabetes again after their initial registration, whereas others reported using it weekly and in some cases daily. Frequency of use appeared to be determined by the reasons that participants used HeLP-Diabetes and the tasks that they performed on it.

Those participants who perceived HeLP-Diabetes as an information resource were more likely to be sporadic rather than regular users. These participants' used HeLP-Diabetes in response to particular scenarios, such as being prescribed new medications or to look up a news story that had recently been reported in order to gain further information. Often these participants were those who reported managing their diabetes well and had a low perceived need for additional help and support. In some cases, these participants reported attrition to HeLP-Diabetes because they had used it to answer a specific question and hadn't returned as that need had been met.

PT6: ...If I hear something about diabetes on the news I will invariably go and check it up online and see exactly what it is they're saying

(58 year old male, intermediate computer skills)

In contrast, there were participants who accessed information on HeLP-Diabetes regularly in order to try and control their diabetes better. These participants returned more often and accessed more of the content of the website including the tools. Participants who used HeLP-Diabetes to input their own data in order to self-monitor and track their progress were more likely to return to the website regularly and viewed usage as part of their self-management regime.

PT3: I try checking regularly like a job, duties, not every day, sometimes a week or sometimes a month especially if I get new things like results of a blood test or eye scan or something like that

(59 year old male, advanced computer skills)

For some participants their use of HeLP-Diabetes was prompted by the regular emails and newsletters that were sent from the website (see Chapter 2). These prompts served to remind participants about HeLP-Diabetes and certain topics grabbed their attention and encouraged them to log on.

PT14: ...I kept getting these regular emails and ...I've actually looked on the website and it's okay

(56 year old male, advanced computer skills)

However, a few participants reported ceasing to use HeLP-Diabetes because of these email and newsletter prompts which were perceived as annoying.

PT6: I dreaded it because I seem to get emails every second second from them, and in the end I just stopped, you know, it was just a nuisance.

(58 year old male, intermediate computer skills)

Overwhelmingly the content on HeLP-Diabetes to do with food, weight loss and medication were reported as the most accessed by participants. These were also the areas to do with self-management that participants reported having found particularly difficult to understand with regards to their self-management, with many reporting having received conflicting information about these topics from other sources. HeLP-Diabetes served to provide clearer information on these and fill existing gaps in participants' knowledge.

R: And has it [HeLP-Diabetes] helped you with any specific aspects of looking after diabetes?

PT4 I think the main one was what I should and shouldn't eat, yes. And sometimes they show in little videos, click on it, it's exercises and you see, you know, how it can help, yes.

(43 year old female, basic computer skills)

PT10: ...advice about going further with losing weight, I mean, I'm not vastly fat, but I've now, I have got a tummy. And, it would be a good idea to try and lose some of that...And maybe losing weight, a bit more

(67 year old male, intermediate computer skills)

Certain features of the website were reported as being particularly useful for participants' learning, including the videos and animation content which were viewed as easy to follow and understand. For some this content managed to explain diabetes information in such a clear way that they reported understanding concepts for the first time.

PT13: the two videos I watched about diabetes, anyway, they were very informative and very simple to understand. They weren't very complicated at all...I mean, it presents, I think for me it's a complicated thing, in a very simple way. You know, everybody can understand, anyway, in any case.

(52 year old male, Italian, intermediate computer skills)

Other benefits from using HeLP-Diabetes included raising awareness. Participants reported having found information on HeLP-Diabetes that was useful for them that they had not known before. This was true for serious issues such as the complications of high blood glucose and more practical issues like the need to inform insurance companies about diabetes.

PT4: ... learned about if you have diabetes when your blood sugar levels are very high or those kinds of things I didn't really know anything about it and how important to eat, like, in reasonable quantities because I used to think that if it's fruit you can eat as much as you want, you know, but now I know that you can eat fruit, I have to eat a certain amount

(43 year old female, basic computer skills)

PT5: I didn't know, and really ought to have known, was that if one was diagnosed with Type 2 Diabetes, you tell your motor insurance. And that I've done....that was a very important bit of useful information, you know, I thought.

(76 year old male, intermediate computer skills)

As well as improving diabetes related knowledge and awareness in the participants themselves, one participant reported that she had used HeLP-Diabetes as a tool to explain her condition to her family. She reported that HeLP-Diabetes had worked where other resources had failed in increasing understanding of diabetes in her family members, which in turn increased the support they offered her. Use of HeLP-Diabetes for this participant was beneficial in aiding her social support and her family's understanding.

PT4: they never actually understand why, but now they are more aware of everything...It helps them to understand and it helps me... they are very helpful, now, because if I say really, I'm so tired, you know, before... they were helpful before but now they are more, if there is something which needs to be done you can see they're more caring; we can do it Mum.

(43 year old female, basic computer skills)

Use of HeLP-Diabetes influenced how well participants perceived themselves to be self-managing their condition. For some participants joining HeLP-Diabetes and using it felt like they had taken positive action with regards to looking after their diabetes. And others reported that using HeLP-Diabetes had encouraged them with their self-management.

PT7: I feel as if I'm doing something that is good for me.

R: By going on to the website?

PT7: Yes.

(68 year old female, intermediate computer skills)

PT4: ...I think, when you go there and you read the stories about other people saying what they think about it, you know, it encourages you.

(43 year old female, basic computer skills)

For others, using HeLP-Diabetes had altered their perception of diabetes. For some, using the website had made them feel as though diabetes was more manageable and decreased their feelings of disease burden. This participant, after hearing about the impact that making positive lifestyle changes had had on others using the website, had changed the way he perceived his diabetes. Rather than perceiving it as a burden he now viewed it as an opportunity to make some positive health improvements.

PT14: I find it useful hearing other people's stories to realise that I'm no longer going to look at the diabetes as a... what's the word... it's not even a hindrance... so what's the difference between them and me at the moment, it's exercise, exercise and I've to put more veg on my plate

(56 year old male, advanced computer skills)

For others however, reading information about diabetes and the possible future complications had increased the perceived seriousness of diabetes.

PT4: I never knew it was that serious until when they said... I think I read it, actually, in one of the emails about that, you know, you can lose... if you don't take care of yourself you can end up losing, you know, like your legs, your arms.

(43 year old female, basic computer skills)

Using HeLP-Diabetes influenced participants' interactions with their healthcare professionals. In some cases using HeLP-Diabetes meant that participants did not have to make appointments with healthcare professionals because they had found the answers to their questions on the website. In this way HeLP-Diabetes was time saving for both participant and healthcare professionals as well as being accessible and convenient.

PT2: ...it's all there for you if you want it, and you don't have to wait to go and see a doctor. You don't have to wait for your annual appointment

(63 year old male, White British, advanced computer skills)

Use of HeLP-Diabetes also resulted in participants feeling more informed which improved their consultations with healthcare professionals. Some participants had reported not fully understanding information that they were given by healthcare professionals during consultation, and using HeLP-Diabetes had helped participants to make sense of information and increased their feelings of being empowered during consultations.

PT4: the GP was discussing with me about... asking me if I knew, you know, how to... how to diet how to blood sugar, and I told her that I got a lot of information from Help Diabetes, so I was aware of what she was asking me.

(43 year old female, Black African, basic computer skills)

Participants made several suggestions to improve HeLP-Diabetes and its implementation.

In terms of implementation, more widespread advertising of HeLP-Diabetes was suggested by the majority of the participants as a way to raise awareness and increase access to other people with diabetes. Suggestions for advertising ranged from TV adverts to paraphernalia that could be displayed in pharmacies and libraries.

PT3: I don't know. Media is one of the big things involved but it is expensive. You can't make the programme on the TV

(59 year old male, advanced computer skills)

PT7: ...through chemists, maybe, you know, if the leaflet is there. Hospital waiting rooms. Somewhere where people, you know, are medically minded when they go somewhere, so that it actually grabs the attention. I guess you could put it in libraries

(68 year old female, intermediate computer skills)

Participants overwhelmingly perceived the role of staff in making HeLP-Diabetes available of critical importance and had firmly made the association between HeLP-Diabetes and the health service because of this recommendation. Many participants thought that HeLP-Diabetes should become even more integrated into the health service and suggested that it could be made available to use in waiting rooms, that the registering of patients on HeLP-Diabetes should become a key feature of diabetes related appointments and that medical records should detail whether patients had been offered access to HeLP-Diabetes by their healthcare professionals.

PT4: I think they should put it to any surgery so that people can use it

(43 year old female, basic computer skills)

PT2: ... think that it should be part of the initial diagnosis interview. That web address should be given out and the people should be invited to look at it and to ask the relevant questions. And try and encourage them to use it, and then subsequent visits to the diabetic nurse or whatever, perhaps the nurses could be trained to say what have you looked at recently on the website? Are you using it?

(63 year old male, advanced computer skills)

PT14: ...anyone who is a diabetic should automatically be ... asked if they want to join it and then you should have a record somewhere in your doctor's records that you are on it, so that way they know who's on it, who's not on it, so they can remind people to use it

(56 year old male, advanced computer skills)

Participants also saw the potential for HeLP-Diabetes to be used in alternative ways. Some, particularly those who had expressed a desire for social support in their management of their diabetes, suggested that HeLP-Diabetes could be introduced and used in group settings. This idea seemed to particularly appeal to participants who had previously mentioned preferences for face-to-face diabetes information and support.

PT4: create a group of maybe ten or 15 people for the first time and they bring them that website and they teach them, you know.

(43 year old female, basic computer skills)

In terms of HeLP-Diabetes, the majority of the suggestions for improvement centred on strategies to keep people engaged with HeLP-Diabetes as opposed to suggestions to improve the content. This reflected some participants' usage patterns which displayed attrition to HeLP-Diabetes over time. One participant thought that an information video with a healthcare professional describing what HeLP-Diabetes was and the benefits of using it would facilitate interest and routine use. Alternative forms of prompts to increase engagement were also suggested such as text message reminders and notifications when posts had been made in the forum.

PT3: ...you have to make habits for them then use it regularly....maybe giving a small video, a couple of minutes for example, a short video for information, and maybe a conversation with two people explaining it...a professional person.

(59 year old male, advanced computer skills)

PT2: I don't mind texts....If it's to flag up something to say this month there's going to be information about how to look after your feet, or this month is going to be about how diabetes can affect vision, that would be quite interesting and that would draw my attention to it.

(63 year old male, advanced computer skills)

PT1: Maybe notify customers...You know, every time, not just from say if I put a question just notify me when there's an answer. You know, notify everybody what's going on on the forum. So in other words, reach your hand out and grab hold of the diabetics and drag them in.

(58 year old male, advanced computer skills)

10.5 Discussion

Interviews with patients with type 2 diabetes who had registered to use HeLP-Diabetes aimed to explore perceptions of the implementation of an e-health intervention to support self-management. Generally the interviews confirmed that patients saw potential benefits of an online tool to support self-management of type 2 diabetes, particularly as a resource for gaining and corroborating information.

HeLP-Diabetes was reported to be used most frequently for information provision purposes despite the availability of other features such as behaviour change tools and forums. The use of HeLP-Diabetes for information reflected the fact that patients perceived there to be a lack of clear information about diabetes and self-management from other sources and participants reported valuing HeLP-Diabetes as resource that allowed them to check and corroborate information from health care professionals. This reflected a perception of inadequacy of care from NHS in terms of quality and quantity of information. Previous studies suggest that people with diabetes prefer to gain most of their diabetes information from health professionals (267, 273), however patients in this study reported variability in perceptions of the adequacy and trustworthiness of information from their health professionals, difficulty in accessing information from them when needed, and that there was often not enough time with health professionals in order to meet their information needs. Patients reported regularly making use of the internet in order to search for information about their diabetes. This suggests that the implementation of an e-health intervention was acceptable and valued as a resource to address unmet needs of current information provision. Interviews with staff (presented in Chapter 9) also revealed that there is often not time in consultations to provide patients with all the information that they should have about their diabetes, and therefore HeLP-Diabetes was perceived as useful by both groups as an information provision source. There were patients however, who perceived that all their diabetes related information needs were currently being met by their health professionals and therefore did not need to use HeLP-Diabetes. This is in keeping with findings that people who have a regular primary care physician are more likely to have higher attrition to diabetes education programmes than those who do not (39) and suggests that e-health interventions may not be used by patients who are happy with the support they receive from other sources.

An important finding that highlights the value of an e-health intervention to support self-management was that the ability of HeLP-Diabetes to present information in various formats including, text, animation and video which was perceived as beneficial in helping to explain difficult concepts clearly with patients reporting that HeLP-Diabetes had helped them understand concepts that they previously had not been able to from other mediums of information provision. It may be that for some patients, even if they receive an adequate amount of information from health professionals it is important to have this information presented in different formats in order for it to be clear and understandable, which an online intervention such as HeLP-Diabetes is particularly suited to do.

There were fewer patients who reported in engaging with other aspects of HeLP-Diabetes. A lot of time and money was invested into creating functions such as behaviour change tools and self-monitoring functionality which patients in this study rarely mentioned using (although the usage data presented in Chapter 8 suggests a wide range of content was accessed). A few talked about using the self-monitoring tools for tracking their glucose but this was rare. Given the cost of these features compared to providing information provision only websites, it raises important questions for the design of future interventions. One reason that these tools may have been so scarcely used (or reportedly used) could be due to the lack of facilitation to use HeLP-Diabetes that was provided. Many of these tools, especially the behaviour change ones were designed to be used during consultations with health professionals to set collaborative goals and the self-monitoring tools were designed to help patients stick to these goals and provide patients with a way of sharing their progress with their health professionals. However, this interaction around HeLP-Diabetes during consultations was rarely reported by patients who took part in these interviews.

Certain features of HeLP-Diabetes that were designed to encourage patients to interact with it and stay engaged were perceived as annoying and intrusive by some participants. Although some patients discussed how useful the email and text reminders were in prompting use, others suggested that these reminders were a source of annoyance and actually served to disengage patients from HeLP-Diabetes. This has important implications for the design of future engagement strategies for websites like HeLP-Diabetes which attempt to encourage user engagement with strategies such as text and emails. A possible reason for these negative reactions in the cases reported here is that patients were already experiencing a great burden of managing their diabetes, and these reminders served to increase this sense of burden that having diabetes placed on them. Including an opt in (or out) option at registration rather than relying on patients to unsubscribe might be a way of addressing this problem for future e-health interventions.

However, there were reported benefits of using HeLP-Diabetes including patients feeling more knowledgeable and having increased self-efficacy to manage their condition. Use of HeLP-Diabetes changed the way that patients perceived themselves to be managing their diabetes, making some feel like they had taken a positive step, providing encouragement to others and altering perceptions of the manageability of diabetes for others. Interestingly, patients who reported improved ability to managing diabetes or now having enough information following use of HeLP-Diabetes also described a low continued need to use HeLP-Diabetes. Other studies have found that confidence in knowledge and ability to manage diabetes act as barriers to patients engaging in diabetes education (39) as do perceptions of wellness (37). This represents a tension between the goals of internet interventions for diabetes self-management (to be used) and the goals of self-management education to increase patient knowledge and confidence which may then result in patients not feeling the need to use them. This has

important implications for understanding what might be effective use of an intervention like HeLP-Diabetes and what the expected use should be.

Features of HeLP-Diabetes which were particularly well received by patients were the privacy and accessibility that using a website afforded patients. In terms of lessening the burden of managing a long term condition like HeLP-Diabetes, being able to access information whenever needed and at a frequency and pace that was completely user led was perceived as beneficial and unique to an e-health intervention like HeLP-Diabetes. These perceptions were often presented in contrast to group based education which was consistently reported as difficult for people to attend and unfulfilling in terms of knowledge acquisition because of limitations of group based education. The contrast that patients drew between the value and limitations of group based education and HeLP-Diabetes have important implications for the commissioning and implementation of diabetes education resources, with the two different formats likely to provide a complimentary menu of options for patients to select from. Several patients perceived that the information from group based education was too basic, others reported that the groups were not able to address a patient's specific needs because of time limitations and the group based nature, others reported that the group based nature was not conducive to learning as there were other participants who had been disruptive and one participant reported not being able to participate fully as he had hearing difficulties. These barriers were all seen to be overcome by HeLP-Diabetes which was perceived as useful because of the tailored information, accessibility and the ability for patients to spend as much time using it as they liked. However, there were positive features of group based education which were not perceived as replicable with an internet based intervention. These largely centred on the peer support that patients received from attending groups with others. Some patients felt alone and isolated with their diabetes and the groups helped to alleviate these feelings. Peer interaction was also reported to be encouraging and motivating. The high use of the forum feature on HeLP-Diabetes (as reported in Chapter 8) also suggests the importance of peer support in the management of diabetes, which can be a facilitator for people with type 2 diabetes achieving their self-management goals (274). Previous research with people with long term conditions around use of internet interventions found that interventions that allow the sharing of experiences are perceived most favourably (275). Diabetes interventions with added peer support have also been reported to foster more user engagement than those without added peer support (262). This suggests that e-health interventions should aim to include functions that enable users to gain social support for managing their condition.

HeLP-Diabetes was reported by some to increase social support from family members through access to information and support. Previous studies have found that self-management of long terms conditions can be facilitated by the support of family members (274). As described in the staff interview chapter (Chapter 9), although it hadn't been part of the initial implementation strategy, several health professionals adapted the way they offered HeLP-Diabetes to patients by involving a family member in the registration process and encouraging families to use it

together to support the patient. Going forward, this could be an additional implementation strategy for e-health interventions. This is unique as other sources of diabetes education such as group based education which excludes family and friends. Allowing access to family and carers might be an important consideration of the design and implementation of e-health interventions in the future and may help address the digital divide in accessing online information resources for people with low IT literacy or English language skills.

Also, important for the design of future health interventions like HeLP-Diabetes is the credibility and assurance that patients reported that the affiliation with the NHS and UCL gave to HeLP-Diabetes. Often patients do not trust the internet for health information (276-279) and the source of online information has been reported as particularly important for people's judgments of health information credibility (280). Seals of credibility are important for promoting trust and include the information being provided from a well-known organisation and endorsements or credibility seal such as a logo (279). Similarly, the recommendations patients received from health professionals to use HeLP-Diabetes were perceived as particularly crucial for their registering. In a context where patients are bombarded with information this recommendation helped HeLP-Diabetes to stand out and increased its credibility. Patients reported that being offered HeLP-Diabetes through their GP practice or diabetes clinic made it feel like a legitimate part of care rather than an optional add on. For some patients HeLP-Diabetes being recommended by a health professional was the only reason they decided to register. The importance of health care providers in engaging patients in their diabetes self-management and diabetes education has been stressed and the benefits of communication around self-management in improving patients' self-management behaviours reported (242, 274, 281). Although websites may be traditionally viewed as a medium of information which is generally self-directed, the participants in this study valued the assistance that staff provided in registering to use HeLP-Diabetes. Other studies have found that diabetes internet interventions that include an element of interaction with healthcare providers are seen as attractive to patients (65). There were other patients however, generally who reported having intermediate or advanced computer skills, who reported joining HeLP-Diabetes via the self-sign up method with no problems. These findings have important implications for the way that internet interventions are made available to patients in order to facilitate uptake and use. For example it might be important for health professionals and for the allocation of resources to recognise patients that might benefit from the extra assistance, but also realise there will be many patients who are capable of joining e-health interventions by themselves.

Ongoing use of HeLP-Diabetes was not frequently reported by many patients which suggests that although health care professional recommendations may be beneficial for encouraging patients to register, more might be needed to keep patients engaged. This may be the same for group based education where patients are given a referral to attend by their health professional but then do not attend (as reflected in the high rates of referral and low rates of patient attendance). Patients perceived being able to use HeLP-Diabetes collaboratively with their

health professionals as potentially useful and motivating, although this was only reported to have happened in one case. Patients were particularly keen on making HeLP-Diabetes even more integrated into routine health care. They felt that services should put more effort into registering patients and introducing them to the programme, and that patients should be encouraged to use the programme in routine diabetes appointments. They felt nurses should be trained to routinely ask about use of the programme, and provide encouragement where needed. Although it was hoped that there would be ongoing encouragement of use of HeLP-Diabetes by health professionals in routine consultations, this was not reported to have happened with any consistency, and may be particularly important for encouraging ongoing use of HeLP-Diabetes and other e-health interventions.

Reported use of HeLP-Diabetes varied considerably between participants. The degree to which patients had already engaged in self-management of their diabetes impacted on their use of HeLP-Diabetes, and those at each end of the spectrum of engaged/ not engaged were less likely to report needing HeLP-Diabetes. Those who had not yet engaged often reported not being ready or being afraid of engaging and perceived that using HeLP-Diabetes may force them to address their diabetes, which they were not ready to do. Others who reported being engaged with managing their diabetes and felt that they were managing very well didn't perceive any need to use HeLP-Diabetes as they had no use for it. In both instances patients described having registered to use HeLP-Diabetes as a resource that they could access in the future if needed. This has important implications for the way that interventions to support self-management are offered with a benefit of an e-health intervention such as HeLP-Diabetes being that they are available to patients whenever they are ready to engage with their diabetes and self-management. This also strengthens the argument for ongoing reminders and encouragement by health professionals about the availability of resources like HeLP-Diabetes to ensure that patients have access to them when they are ready. It also raises questions as to whether the incentivisation of referrals to diabetes education through schemes such as the QOF are adequate. Alternatively, incentives could be provided upon evidence that patients have actually attended or engaged with self-management education. Providing feedback on intervention use as well as number of patients who register might be important for commissioning decisions for future e-health interventions and should be considered by those developing e-health interventions.

The implications that these findings have for practice, policy and research are further discussed in the overall discussion chapter (Chapter 11), as are the methodological strengths and weaknesses of the studies in this thesis.

11 CHAPTER 11: OVERALL DISCUSSION

11.1 Chapter summary

This thesis explored the adoption, uptake and use of an internet based self-management intervention for people with type 2 diabetes and determined the barriers and facilitators to implementation within routine NHS care and to patient use. It addressed these objectives through a series of empirical studies, using a range of research methods suited to each research question. Each study mirrored the aims and objectives of the thesis and addressed questions of importance to the development of this emerging field. An in-depth discussion of each empirical study contributing to this thesis was provided in the previous chapters (8, 9 and 10), which included consideration of the existing literature. This chapter begins by drawing together the findings from each study by presenting the main findings of the thesis as a whole. The methodological strengths and weaknesses are then discussed and finally the implications of this work for practice, policy and research are considered.

11.2 Main findings

Overall, the findings from the studies within this thesis suggest that HeLP-Diabetes was attractive to commissioners of diabetes services and to health professionals within practices and clinics. There was a high level of adoption, with three quarters of services making the decision to adopt HeLP-Diabetes. The qualitative data from interviews with staff suggested that HeLP-Diabetes was perceived to fill an unmet need in current diabetes education provision, and the potential for it to alleviate some of the pressures felt within general practice to deliver diabetes care was reported. In particular, HeLP-Diabetes was perceived to offer patients a credible, accessible, and easy to use information source.

The context in which HeLP-Diabetes was being implemented was one of the biggest factors to influence the degree of implementation achieved. The favourable fit that it had with CCG priority areas (diabetes, self-management, and health technologies) meant that there was great support of HeLP-Diabetes at the CCG level. This provided a sense that it was a worthwhile and important intervention for staff to consider and positively influenced adoption decisions. However, the implementation context proved very challenging for health professionals to use HeLP-Diabetes and offer it to patients. Data on patient uptake revealed that less than half of services in the CCG registered a patient to use HeLP-Diabetes, and collectively, the services who adopted HeLP-Diabetes only registered 205 patients, which represented approximately 3.4% of their eligible patients. Staff interview findings suggested that the biggest barriers to the implementation related to the availability of resources. The current NHS context, which sees GP practices stretched to capacity with workloads increasing in both volume and complexity (248) meant that time to implement HeLP-Diabetes was generally not available and that HeLP-Diabetes was not prioritised over other tasks that were incentivised as part of the QOF. Furthermore, despite the support of the CCG towards the idea of HeLP-Diabetes, this was not supported by the allocation of any resources to enable services to implement it, and instead services had to rely on fitting HeLP-Diabetes into existing roles and workloads.

Despite this, the findings on the uptake of HeLP-Diabetes by patients suggest that it appealed to a wide range of patients as patients representing a range of backgrounds in terms of age, ethnicity, educational level, duration of diabetes, and computer skills registered to use HeLP-Diabetes. Fears were reported in the staff interviews that HeLP-Diabetes would not be suitable for certain groups of patients including older patients and those from non-white British backgrounds. These fears appeared unsubstantiated as there was no difference in the use made of HeLP-Diabetes by either of these characteristics. Similarly, there are concerns reported in the literature about the digital divide (the gap that is reported to exist between those who have access to health technologies and those who do not) (66). Data on patient registration methods showed that those with lower education were more likely to be registered to use HeLP-Diabetes by a member of staff, suggesting that staff may be able to increase access for patients traditionally deemed less likely to have access. This study therefore provides some evidence that the digital divide can be overcome, particularly with the involvement of health professionals in supporting patients to access internet interventions.

The role of staff in supporting patients to register to HeLP-Diabetes was regarded very differently by staff and patients. Findings from the staff interviews suggest that there was a degree of resistance by some staff to undertake this work due to a perception that it was not a legitimate part of their role. However, there was a strong perception from patients that staff recommendations to use HeLP-Diabetes, and staff support to access it was extremely valuable in promoting uptake and use.

The majority of patients reported finding HeLP-Diabetes an acceptable form of diabetes education, and particularly valued the accessibility that an internet based intervention can provide. Quantitative data showed that patients made use of HeLP-Diabetes at all hours of the day suggesting that it may be more convenient to access than group-based education which is held during working hours.

11.3 Methodological strengths and weaknesses

The work described in this thesis had many strengths. These included: the use of theory to guide development of the implementation plan, data collection and analysis; the case study design; the mixed methods approach combining both quantitative and qualitative data; and the flexible, iterative approach towards implementation which allowed for rapid responses to identified problems. These are now discussed.

The use of theory within this thesis was viewed positively. A call for a greater explicit use of theory within implementation projects has been made by many authors in order to shorten the time needed to develop improvement interventions, optimise their design, identify conditions of context necessary for their success, and enhance learning from those efforts (2, 175, 181, 182, 282, 283). The application of theory in this thesis helped to strengthen the development of the implementation plan and facilitate the evaluation of the implementation.

Grol, Wensing and Eccles' model of effective implementation (2) helped to sensitise me to the stages of implementation planning that should be considered in order to implement an intervention within healthcare, and provided valuable guidance on this process. Normalization Process Theory (NPT) was used throughout this thesis in order to inform the HeLP-Diabetes implementation plan, develop the topic guide for staff interviews and as a framework with which to analyse the implementation research diary and staff interviews.

It became clear that NPT was a very appropriate theory for use in this thesis. Firstly, given its origins (much of the early work was related to implementation of e-health applications), NPT fitted very well to the nature of the HeLP-Diabetes intervention as an internet based intervention, as well as to the implementation setting. This meant that generating the study-specific meanings of the constructs (a task recommended to operationalise NPT) was not too complicated. Secondly, there are lots of previous examples in the literature of NPT being applied to the implementation of innovations within healthcare settings which provided a point of reference for this work and confidence that I was applying NPT to this work in a way that had previously been undertaken successfully. Thirdly, there were no data from analysis of the research diary or the staff interviews which did not map adequately to one of the constructs of NPT.

The use of NPT in this thesis was deemed to be very beneficial. Firstly, in the development of the implementation plan NPT was used as a sensitising tool in the planning phases of the implementation. By considering the constructs of NPT it helped me to think about how the implementation of HeLP-Diabetes would likely impact upon the work of staff and helped me to develop strategies to increase the likelihood that HeLP-Diabetes would become normalised within practice. For example, when selecting a strategy to implement HeLP-Diabetes in routine practice, by considering the constructs of NPT I was able to question whether the target group understood what was being asked of them, whether it fitted with their skills and whether they reflected positively on it. Secondly, NPT was used as an evaluative tool which was applied to the analysis of the research diary and staff interviews. NPT provided an explanatory theoretical framework which helped me to identify factors that promoted and inhibited the implementation of HeLP-Diabetes. In this context NPT was useful for allowing me to focus on the everyday work of staff in order to find explanations as to why HeLP-Diabetes did not implement well within many practices and clinics. It was particularly useful in explaining observed variations in implementation processes rather than simply focusing on notions of barriers and facilitators.

However, there were limitations to the applicability of NPT to certain areas of this thesis. Firstly, I chose to code data within the systematic review to the constructs of the Consolidated Framework for Implementation Research (CFIR) (122) due to perceived limitations of NPT for this task. The nature of the data within the included reviews often focussed on factors that were not directly related to the processes involved in embedding or integrating interventions. For example, antecedents to adoption decisions, national and international policies, and financial

factors arose in many of the reviews, but were not described within any context of 'work'. Secondly, NPT did not appear to lend itself well to the analysis of the patient interviews. As there was limited data on the 'work' involved in implementing HeLP-Diabetes in the patient interviews it made it difficult to attempt to apply the constructs of NPT to this data which mainly centred on perceptions of diabetes and self-management in general (given that many patients had not made use of HeLP-Diabetes).

The case study design employed here was also considered a strength. Case studies are particularly well suited for studying implementation processes which tend to be fluid, non-linear and context sensitive (202). By employing a case study design I was able to conduct an in-depth analysis of the implementation of HeLP-Diabetes and could compare implementation across different practices and clinics, this in-depth method allowed me to collect rich data from a range of participants and offer rich descriptions of the implementation of HeLP-Diabetes. This method allowed me to gain insight into the complexities of implementation in the everyday context of routine NHS care. However, limitations of case study designs must also be noted, primarily their potential for not generalising to other populations.

The CCG selected as the case for this research study was chosen pragmatically: firstly, the CCG was familiar to the study team, it was local and therefore physical access to sites was possible; it was also known as being receptive to research and new innovations; in addition the CCG was in the process of introducing initiatives surrounding self-management and diabetes and was therefore considered to be receptive to an intervention which aimed to support patient self-management. For more widespread implementation of HeLP-Diabetes, there might be limitations as to how well the findings from this case study would generalise to less familiar, accessible and innovative CCGs.

A mixed methods approach has also been described as particularly beneficial for understanding the implementation of innovations within healthcare settings (284) as quantitative and qualitative approaches in combination can provide a better understanding of research issues than either approach alone. In this thesis, quantitative methods were used to measure the rates of adoption and uptake of HeLP-Diabetes by NHS services and patients and the use of HeLP-Diabetes by patients. Qualitative methods were used to explore and obtain depth of understanding as to the reasons for the adoption, uptake, implementation and use of HeLP-Diabetes allowing a deeper understanding of the implementation of HeLP-Diabetes than if just one approach had been taken. Specifically, combining the two approaches was invaluable to explain why there had been relatively high levels of adoption of HeLP-Diabetes but low use made of it by health services, with the qualitative data shedding light on the important role of the context of the NHS and the resource work needed to implement HeLP-Diabetes.

The iterative nature of the HeLP-Diabetes implementation also proved extremely beneficial in order to allow me to rapidly respond to problems arising with the implementation at various sites and to avoid continuing with strategies that were not working. Having the freedom of an iterative

approach meant that I could develop methodological innovations to overcome challenges of doing research in routine care such as developing online and automated patient recruitment procedures and developing alternative HeLP-Diabetes registration methods.

There were several limitations of this study which proved beyond my control, but that had important implications for the research. Firstly, despite the plan to implement HeLP-Diabetes in a staged way, in batches of practices at a time; as soon as the CCG endorsed HeLP-Diabetes they requested that it be rolled out to all services at once. There were insufficient resources available from the research programme grant to support the widespread roll out, with only me available to support practices. This meant that I was unable to provide the level of support I had planned to practices. This is important, as in the practices where I did manage to give staff the level of support originally planned, they went on to implement HeLP-Diabetes relatively successfully (compared to other practices/clinics). This suggests that if I had been able to continue with the batch roll out, much higher levels of implementation would have been observed. Secondly, although I was interested in the digital divide, and which patients would take up and use HeLP-Diabetes, the nature of the study did not allow for any formal hypothesis about these issues to be tested. The study design was exploratory, with the primary focus on determining the uptake and use by unselected populations. The introduction of alternative patient registration methods arose in response to challenges identified during the study as opposed to being developed at the outset as different methods to be evaluated and compared. The results from the study have generated a hypothesis; that health professional input can help overcome the digital divide; but this needs further investigation.

There are also several limitations of specific aspects of the research that need highlighting. Firstly, the representativeness of the patient interview sample must be discussed in light of the findings. Recruitment of patients to take part in interviews proved difficult, and it is possible that those patients who put themselves forward to take part in the interviews differed to other users of HeLP-Diabetes. Many of the participants expressed extremes of views in relation to HeLP-Diabetes, either extremely positive or extremely negative. It may have been that they volunteered to be interviewed because of these extremes of views, and that other patients who held more moderate views were not as inclined to share these in an interview.

A limitation of the recruitment, that on reflection I would want to address if I was to undertake this research again, is that patients who declined to register on HeLP-Diabetes could not be contacted to take part in the research. I had first hoped that staff within practices would be able to ask any patients who declined use of HeLP-Diabetes to participate; however, it quickly became apparent that asking staff to conduct any of the research components of the study was unworkable in practice. Therefore, the research procedures were moved online, and whilst this was beneficial for the overall research as a whole, it meant that it was not possible to capture the views of patients who declined use of HeLP-Diabetes. This would have been extremely valuable in order to better understand the reasons for patient non-uptake. Due to the low

enrolment in the research study by patients the interview sample was relatively small and it is likely that data saturation was not reached.

For example, I did not manage to sample any patients who were managing their diabetes with insulin. Given that themes arose from the interviews about non-engagement with HeLP-Diabetes being related to perceptions that diabetes was not too serious and the absence of medications and complications, it would have been desirable to gain the views of people for whom diabetes was likely to be more present in their everyday lives.

Similarly, for the staff interviews I would have also liked to be able to recruit staff to take part in interviews from practices that did not respond at all to offers of HeLP-Diabetes in order to gain the views of staff from these services on reasons for non-responses and non-adoption.

Two technical issues with the HeLP-Diabetes intervention are worth noting here. Firstly, as described in Chapter 2, HeLP-Diabetes was intended to have a link to patients' electronic health records. However, due to technical problems with establishing this link, which were outside of the control of the programme grant team, this feature of HeLP-Diabetes was never functional. Anecdotal data gained throughout the study period from both healthcare professionals and patients indicated that the inclusion of this feature may have been successful in promoting engagement with HeLP-Diabetes as access to electronic records would have potentially reduced workload for both health care professionals and engaged patients.

The second issue related to the collection of data concerning patients' use of HeLP-Diabetes. A technical problem with HeLP-Diabetes software meant that patient use of HeLP-Diabetes was only recorded from 01.01.2014, meaning that the first six months of data were not captured. This means that the usage data reported here is actually an under representation of the use of HeLP-Diabetes by patients during the implementation study.

There was also missing data on the patient education variable, which was introduced to the online registration form at a later date than other patient characteristic variables. As described in Chapter 6, originally this variable was not included on the online form when patient registration to HeLP-Diabetes was completed in practices and clinics by health care professionals and this information could not be easily obtained. This variable was introduced as soon as the patient registration model had been introduced in order to explore whether registration method was influenced by any patient characteristics given the potential of staff facilitation to help bridge the digital divide for some patients. Therefore, the quantitative findings related to patient education should be considered with caution.

Finally, as this thesis represents one of very few studies that have explored the implementation of an internet intervention into routine practice and the adoption and use by health services and patients; it is difficult to draw solid conclusions as to whether the implementation succeeded or failed. There were very few yard sticks to guide this exploratory study and therefore definitions

of success or failure could not be generated or judged against. Similarly, for the use of HeLP-Diabetes by patients there were no predefined markers of the amount or type of use that was expected by patients. As described in Chapter 10, a tension between the goals of internet interventions for diabetes self-management (to be used) and the goals of self-management education to increase patient knowledge and confidence which may then result in patients not feeling the need to use them, has important implications for understanding what might be effective use of an intervention like HeLP-Diabetes and what the expected use should be. Further studies of this nature are needed in order to increase understanding of these issues.

11.4 Implications of the findings

The findings of this research have implications for practice, policy, research and the development of internet based interventions for diabetes.

11.4.1 Implications for practice

The findings from this thesis suggest that HeLP-Diabetes can be implemented into healthcare services and does provide an alternative form of diabetes education to patients that is acceptable to both staff and patients. However, in order for an internet intervention like HeLP-Diabetes to become part of routine practice, it needs to be much better resourced within the services in which it is to be used. Resources are needed in terms of staff availability to undertake the tasks of implementing it including promoting it to other staff, recommending it to patients and facilitating patient access. Time pressures within consultations prevented HeLP-Diabetes from being more widely implemented, and given the current NHS climate, this is unlikely to change for GPs and nurses. Mobilising other staff such as health care assistants, receptionists or having a dedicated change manager to undertake the role that I had in the implementation process is likely to increase the chances of implementation.

The findings from staff interviews, and the implementation data from practices where I provided assistance to register patients suggests that it may be crucial to have a dedicated person to take responsibility for the implementation of interventions like HeLP-Diabetes within practices. However, these individuals require the support of other staff within the practice to keep the work as a legitimate part of their role. This research provided useful data to help inform decisions as to which staff may be best suited to deliver interventions like this in practice. Although all health professionals are important in supporting patients to self-manage diabetes, nurses, because of their increased role in long-term condition management within the NHS were originally perceived to be most suitable to undertake the work of implementing HeLP-diabetes. However, as discussed, health care assistants and receptionists were both identified by staff as a more suitable group to undertake the role. Furthermore, interviews with these groups of staff revealed that the work of implementing HeLP-Diabetes was valued and enjoyed by them. In a context where GPs and practice nurses are under a considerable amount of strain to deliver services, the utilisation of the skill sets of other staff members to deliver interventions like HeLP-Diabetes to patients might be beneficial.

The findings from both the quantitative and qualitative data strongly point to the beneficial role of staff introducing patients to HeLP-Diabetes in order to engage them with the intervention. This finding is important as questions were raised by some staff as to why HeLP-Diabetes should be recommended through the NHS rather than just freely searchable on the internet. Patient interviews strongly suggest that the recommendation from staff was the main driving factor in them registering to use it and that this recommendation provided HeLP-Diabetes with a sense of credibility which set it apart from other online resources. Furthermore, the finding that staff facilitation in helping patients to register to use HeLP-Diabetes may help to make interventions like this more accessible to patients with lower education provides further support for the role of health professionals in the delivery of such interventions.

11.4.2 Implications for policy

Currently it is policy for patients with type 2 diabetes to be provided access to structured diabetes education within nine months of diagnosis. The findings from this work suggest that the assumption that diagnosis is the best time to engage people in their diabetes may not be accurate. Many patients may not feel ready to engage at diagnosis as they struggle to accept, come to terms with and cope with the diagnosis. The provision of information at this time was described by some as overwhelming to take in at diagnosis. Uptake of HeLP-Diabetes was not associated with the duration patients had had diabetes, suggesting the view expressed in findings from staff interviews that those who are newly diagnosed are more likely to be engaged with self-management is not necessarily the case. Other theories of living with a chronic condition suggest that people may cycle through periods of wellness and illness which impacts on their willingness to engage with information (269). This raises questions as to whether interventions providing information and support should primarily be focused at the point of diagnosis. People may be more ready to engage later on when the opportunity to take up education may not be so available.

Currently group based education is the only education that is incentivised by the QOF for people with diabetes, however, the use of interventions like HeLP-Diabetes could be considered as a viable alternative. The findings from this work suggest that both patients and health professionals find HeLP-Diabetes to be acceptable as a form of diabetes self-management education, it has similar uptake to group based education, addresses several identified shortcomings of group based education and with facilitation, can reach a wide range of patients. Given the limited financial resources of the NHS, an internet intervention that can be accessed by a nearly unlimited number of patients could also provide a cost-effective alternative to group based education. Given the current drive of the NHS towards utilising health technologies, it seems likely that more health care will be delivered via mediums such as the internet. In order to make these successful, incentivisation through frameworks like the QOF should be considered in order for them to be given equal prioritisation by the health care professionals delivering them.

11.4.3 Implications for research

This study has provided new insights to add to the current implementation of e-health research. Firstly, this study has highlighted the importance of the role of facilitation. Although one of the benefits of e-health interventions like HeLP-Diabetes is that they can be used autonomously by patients whenever and wherever they choose, it may be necessary for patients to be initially supported to join e-health interventions by members of NHS staff in order to encourage uptake and to assist those who have lower levels of education. Similarly, ongoing encouragement of use may be needed to engage patients in using these interventions beyond the initial sign up and to sustain use. In order for this to happen behaviour change needs to occur at the level of the health professionals as well as the patient which may prove challenging. For future researchers developing and implementing e-health interventions like HeLP-Diabetes it would be extremely important to consider the role of facilitation and to plan strategies that will increase the likelihood of facilitation being delivered in order to maximise uptake and use of e-health interventions designed to be used by patients.

Secondly, this study has shown that the digital divide may not be problematic for interventions like HeLP-Diabetes if they are offered to patients in a way that supports patients' access. The population within the study CCG who signed up to use HeLP-Diabetes represented a diverse sample of patients with type 2 diabetes in terms of education and computer skills. The role of facilitating access is again stressed as important for helping those with lower education to access these types of resources, as is the careful design of interventions that are easy to use and accessible to a wide range of people.

Finally, the importance of studying implementation has been argued throughout this thesis and the perceived benefits described. This study was conducted alongside the randomised control trial of HeLP-Diabetes. As described in Chapter 2, it was believed by the programme grant research team that it would be beneficial to have a study based completely in a real world setting to mirror what would happen if HeLP-Diabetes was commissioned by CCGs in the NHS. Conducting these two studies in parallel broke from the traditional linear trajectory of developing, evaluating and implementing complex interventions. Reflecting upon the findings of both the trial (Murray et al, submitted) and this implementation study has led to the conclusion that conducting these two studies in parallel has indeed been of great benefit. For example, the fact that the facilitation model developed in the trial could not be replicated in the implementation study proved the decision to study HeLP-Diabetes in a real world setting was worthwhile and has demonstrated the differences between the study settings. In addition, this implementation study has been able to produce modified strategies to implement HeLP-Diabetes into routine practice that will be valuable to those commissioning it going forward, which would not have been available if the trial had been conducted alone. It is also true that the population in this implementation study varied greatly from the population that took part in the trial in terms of ethnicity, age, education and computer skills, thus supporting the value of conducting implementation studies such as this alongside trials of interventions, as even in trials

designed to be pragmatic and conducted in real world settings face constraints that may limit their generalizability to routine practice and populations.

By conducting the two studies in parallel, there is now (at the end of both studies) data on both the efficacy of HeLP-Diabetes and the adoption and use of it within routine practice. This has substantially closed the gap between the development of HeLP-Diabetes and its implementation into routine practice, which would have been wider had one study followed the other. There is now data to provide to commissioners of services about the expected benefits of HeLP-Diabetes and the expected adoption and reach. This thesis has also provided valuable suggestions and recommendation on ways that HeLP-Diabetes can be delivered within routine care optimally.

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LIST OF ABBREVIATIONS

CBT	Cognitive Behavioural Therapy
CCG	Clinical Commissioning Group
CDSS	Clinical Decision Support Systems
CFIR	Consolidated Framework for Integrating Research
CISs	Clinical Information Systems
DESMOND	Diabetes Education and Self Management for Ongoing and Diagnosed
DSME	Diabetes Self Management Education
EHIS	Electronic Health Information Systems
EHR	Electronic Health Records
EMR	Electronic Medical Records
GP	General Practitioner
HbA1c	Glycated Hemoglobin
HeLP-Diabetes	Healthy Living for People with Type 2 Diabetes
HIE	Health Information Exchange
HISs	Healthcare Information Systems
HITs	Health Information Technologies
ICT	Information and Communication Technologies
LCS	Locally Commissioned Services
LES	Locally Enhanced Services
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NPM	Normalization Process Model
NPT	Normalization Process Theory
PDAs	Personal Digital Assistants
PHRs	Electronic Personal Health Record Systems
PPI	Patient and Public Involvement
QOF	Quality and Outcomes Framework
WHO	World Health Organisation
YOC	Year Of Care

APPENDICES

Appendix A Literature Review Search Strategy

- 1) exp Medical Informatics Applications/
- 2) exp Management Information Systems/
- 3) exp Decision Making, Computer-Assisted/
- 4) exp Diagnosis, Computer-Assisted/
- 5) exp Therapy, Computer-Assisted/
- 6) exp Medical Records Systems, Computerized/
- 7) exp Medical Order Entry Systems/
- 8) exp Electronic Mail/
- 9) exp Videoconferencing/
- 10) exp Telemedicine/
- 11) exp Computer Communication Networks/
- 12) exp Internet/
- 13) 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
- 14) "Routin*" [title, original title, abstract, name of substance word, subject heading word]
- 15) "Normali?*" [title, original title, abstract, name of substance word, subject heading word]
- 16) "Integrat*" [title, original title, abstract, name of substance word, subject heading word]
- 17) "Facilitate*" [title, original title, abstract, name of substance word, subject heading word]
- 18) "Barrier*" [title, original title, abstract, name of substance word, subject heading word]
- 19) "Implement*" [title, original title, abstract, name of substance word, subject heading word]
- 20) "Adopt*" [title, original title, abstract, name of substance word, subject heading word]
- 21) 14 or 15 or 16 or 17 or 18 or 19 or 20
- 22) 13 and 21
- 23) limit 22 to (meta analysis or systematic reviews)
- 24) limit 23 to yr="2009 -Current"

Appendix B Summary details of the forty-four included studies

Author/ Date (date published online if different)/ Country of origin of 1st author	Aim/purpose	Setting	Type of e-Health	Number of papers included	Summary of main factors that influence e-health implementation
Adaji <i>et al.</i> 2008 Australia	To demonstrate the benefits of information technology in supporting a systematic approach to diabetes management in general practice and to increase understanding of perceived barriers to and facilitators to the use of information technology in this context.	Primary care	Information and Communication Technologies (ICT)	29	Barriers: confidentiality concerns, inadequate funding, workforce shortages, lack of time and anxiety about change. Facilitators: Adequate training and integration into the usual process of care.
Archer <i>et al.</i> 2011 Canada	To review the literature on personal health record systems and to describe the design, functionality, implementations, applications, outcomes, and perceived and real benefits of personal	Not defined	Electronic Personal Health Record Systems	130	PHR adoption is dependent on growth in electronic medical record adoption. Patient-oriented functionalities need to be provided to support self-management and disease prevention.

	health record systems, with an emphasis on experience in the USA and Canada.				
Benavides-Vaello et al. 2013 USA	To explore the advances and uses of telecommunications technology, and related issues, in the delivery of mental health and substance abuse treatment services within rural areas.	Mental health and substance abuse treatment services within rural areas	Telehealth	38	Costs; financial sustainability was one of the primary barriers to expansion of telehealth services in rural areas.
Boonstra and Broekhuis 2010 Netherlands	To identify, categorise, and analyse barriers perceived by physicians to the adoption of electronic medical records in order to provide implementers with beneficial intervention options.	Not defined	Electronic Medical Records (EMR)	22	Financial, technical, time, psychological, social, legal, organisational and change process.
Botsis et al. 2008 Norway	To review the literature on home telecare for elderly patients suffering from chronic diseases	Homecare	Home Telecare Systems	54	Organisational, ethical, legal, design and usability issues need to be addressed before widespread implementation
Broens et al.	To identify determinants	Not defined	Telemedicine	45	Factors categorised as:

2007 Netherlands	that influence the implementation of telemedicine initiatives.					technology, acceptance, financing, organisation and policy and legislation
Castillo et al. 2010 Mexico	To identify the critical adoption factors for electronic health records by physicians and to use them as a guide to support their adoption process automatically.	Mixed	Healthcare Information Systems (HIS)	68		User attitude towards information systems, workflow impact, interoperability, technical support, communication among users, and expert support
Demaerschalk et al. 2009 USA	To describe the technology that makes stroke telemedicine possible, the members that should be included in a telestroke team, the hub-and-spoke characteristics of a telestroke network, and the format of a typical consultation.	Hospitals	Telemedicine	not stated		The long term sustainability and growth of telestroke practice remain threatened by unresolved legal, economic, and market factors
Fitzpatrick et al. 2008 USA	To gain a better understanding of communication problems in healthcare settings and identify gaps in the research.	Mixed	Information And Communication Technologies (ICT)	98		Social and organisational culture

Fontaine et al. 2010 USA	To gain a fuller understanding of the factors associated with health information exchange adoption by primary care practices.	Primary Care	Health Information Exchange (HIE)	64	Cost, security and privacy issues, liability, leadership, strategic planning, competition, and technical barriers
Gagnon et al. 2012 (2010) Canada	To systematically review factors that are positively or negatively associated with information and communication technology adoption by healthcare professionals in clinical settings.	Mixed (mostly hospitals)	Information and Communication Technologies (ICT)	101	Facilitators: Perception of the benefits of the innovation and ease of use. Limiting factors: design, technical concerns, familiarity with ICT, and time.
Gagnon et al. 2009 Canada	To carry out a systematic review of the effectiveness of interventions to promote the adoption of information and communication technologies by healthcare professionals.	Mixed	Information and Communication Technologies (ICT)	10	Training and audit and feedback.
Gagnon et al. 2014 (2013) Canada	To review users' perceptions of barriers and facilitators to e-prescribing and	Primary care	E-Prescribing	34 papers accounting for 28 studies	Technical and organisational support.

	implementation in primary care.				
Goldstein et al. 2014 (2013) Canada	To examine physician barriers to adopting electronic medical records as well as anaesthesiologists' experiences.	Not defined	Electronic Medical Records (EMR)	14 papers accounting for 12 studies	Identified barriers to adoption of were financial, technological, and time constraints.
Gruber et al. 2009 Canada	To determine the current evidence about the process and outcomes of the implementation of clinical information systems in healthcare facilities.	Acute care facilities	Clinical Information Systems (CIS)	18	Clinical context and end user support
Hsieh and Lin 2011 USA	To identify benefits and challenges of the development and implementation of electronic medical records, tele-health, and electronic appointment reminders.	Mixed (primary care and behavioural healthcare/mental health settings)	Healthcare Information Systems (HIS)	42	Personnel resistance and fear; availability of training, support and other resources for personnel; security and confidentiality; and infrastructure development to enhance clinical workflow, billing and collection activities, and quality assurance measures.
Jarvis-Selinger et al. 2008	To provide policymakers, administrators, and	Mixed	Telemedicine	225	Necessary technical conditions need to be in

Canada	healthcare professionals with an evidence-based foundation for informed decision-making regarding videoconferencing				place and key strategies for organisational readiness and technology adoption
Jennett and Brandstadt 2005 Canada	To detail and critique the published international peer-reviewed studies that have focused on assessing telehealth readiness for rural and remote health.	Rural	Telehealth	not stated	An appreciation of practice context, strong leadership, and a perceived need to improve practice.
Jennett et al. 2004 Canada	To inform future telehealth policy directions regarding the socioeconomic impact of telehealth	Mixed	Telehealth	57	Barriers and facilitators included confidentiality, reimbursement, and legal and ethical considerations. To become fully integrated into the healthcare system, telehealth must be viewed as more than an add-on service.
Kilsdonk et al. 2011 Netherlands	To systematically review the status quo on what is known on factors contributing to clinical decision support systems	Not defined	Clinical Decision Support Systems (CDSS)	29	Human (system use and user satisfaction), organisation (structure and environment and technology (system quality, information

	acceptance.				quality and service quality
Kukafka et al. 2003 USA	A systematic literature analysis was conducted to confirm the assertion that the literature on information technology use behaviour does not include a multi-level approach	Mixed (academic non-medical, government agency, academic medical centres/hospitals, businesses and other organisation)	Information And Communication Technologies (ICT)	24	Preparing the environment for change and providing economic resources, incentives, and social support to facilitate the change. A comfortable and flexible environment. User knowledge of, and belief in, the new system. Functional system which are compatible with the target population.
Lau et al. 2012 Canada	To examine the impact of electronic medical records in the physician office, factors that influenced their success and the lessons learned.	Ambulatory	Electronic Medical Records (EMR)	43	Micro-level: technical design, performance and support affected usage and user satisfaction. Meso-level: the implementation process and resulting workflow. Macro-level: incentives such as pay-for-performance were seen as an important driver for adoption.
Lluch 2011 UK	To identify the barriers to health information technology adoption from an organisational management perspective	Mixed	Health Information Technologies (HIT)	79	Structure of healthcare organisations, Tasks, People policies, Incentives; and Information and decision processes

Lu et al. 2005 USA	To examine the potential benefits of personal digital assistants as factors that will promote their adoption and identify barriers to their acceptance in healthcare.	Any	Handheld Computers And Personal Digital Assistants (PDA)	95	Major barriers to adoption were identified as usability, security concerns, and lack of technical and organisational support
Ludwick and Doucette 2009 Canada	To identify the current state of knowledge about health information systems adoption in primary care and understand factors affecting implementation outcomes.	Primary care	Healthcare Information Systems (HIS)	86	System design, project management, procurement and users' previous experience effected implementation
Mack et al. 2009 USA	To review the use of clinical decision support systems available in the paediatric intensive care unit.	Paediatric intensive care unit	Clinical Decision Support Systems (CDSS)	not stated	Workflow, technological issues and change management
McGinn et al. 2011 Canada	To categorize, synthesize, and compare the perspectives of targeted groups of users (public, patients, healthcare professionals and managers) and to	Mixed	Electronic Health Records (EHR)	60	Design and technical concerns, ease of use, interoperability, privacy and security, costs, productivity, familiarity and ability with EHR, motivation to use EHR, patient and healthcare

	underline factors influencing electronic health record implementation specific to each user group.				professional interaction, and lack of time and workload.
Mollon et al. 2009 Canada	To evaluate whether certain features of prescribing decision support systems predict successful implementation, change in provider behaviour, and change in patient outcomes.	Mixed (hospital and ambulatory)	Clinical Decision Support Systems (CDSS)	41	A lack of attention to evidence-based optimization of CDSS interventions hampers the development and implementation
Moxey et al. 2010 Australia	To explore the barriers to, and facilitators of, clinical decision support systems uptake by physicians to guide prescribing decisions.	Mixed (ambulatory and inpatient)	Clinical Decision Support Systems (CDSS)	60 papers accounting for 58 studies	Availability of hardware, technical support and training; integration of the system into workflows; and the relevance and timeliness of the clinical messages
Ohinmaa 2006 Canada	To assess telemedicine projects outside the USA and provide examples of promising results that could be disseminated to other countries.	Mixed (non USA)	Telemedicine	not stated	Success factors: key persons' involvement in planning and implementation, extensive planning, the attitudes of participants, remote location, planning readiness,

					leadership readiness, workplace readiness and technical readiness Factors contributing to failure: inadequate needs assessment, lack of 'buy-in', lack of healthcare professional preparation and resistance to change.
Oluoch <i>et al.</i> 2012 Kenya	To identify studies on electronic medical record based clinical decision support systems describing process and outcome measures and reported barriers to implementation.	Mixed (inpatient and outpatient settings)	Clinical Decision Support Systems (CDSS)	12	Technical infrastructure problems
Oroviogicoechea <i>et al.</i> 2008 UK	To review existing nursing research on inpatient hospitals' information technology systems in order to explore new approaches for evaluation research on nursing informatics to guide further design and implementation of	Inpatient hospital setting	Information Technology Systems	39	Social and organisational contexts

	effective information technology systems.				
Orwat et al. 2008 Germany	A systematic overview and analysis of system developments and implementations of pervasive computing in healthcare and highlighting experiences in deployment.	Mixed (ambulatory, home and mobile, clinical, care and rehabilitation)	Pervasive Healthcare	69 (describing 67 studies)	Organisation, personnel, privacy concerns and financial issues.
Peleg 2006 Israel	To understand the challenges facing developers of clinical decision support systems.	Not defined	Clinical Decision Support Systems (CDSS)	not stated	The goals of CDSS are important in developing successful, usable clinical decision support systems as it is the vision that drives the way they are developed, implemented, integrated with the environment, and evaluated.
Police et al. 2010 USA	To better understand current utilisation rates along with benefits and barriers to health information technology adoption in physician practice organisations.	Mixed (physician practice organisations)	Health Information Technologies (HIT)	119	The largest barrier to HIT adoption in physician groups is the high initial and ongoing costs of electronic systems. Lack of sufficient training, a disorganised or non-receptive practice culture and technological problems

					such as inadequate connectivity appear to impede effective HIT use.
Rahimi et al. 2009 Sweden	To organize the knowledge gained in qualitative studies performed in association with healthcare information systems implementations and to use this knowledge to outline an updated structure for implementation planning	Mixed (primary care and hospitals)	Healthcare Information Systems (HIS)	17	Education and training support, information needs assessment, implementation process, management support, work routines and workflow, motivation and rationales, integration of the system, trust, technical system performance, participation and user involvement, system effectiveness.
Saliba et al. 2012 UK	To systematically identify factors that hinder or support implementation of cross-border telemedicine services.	Cross-border telemedicine services	Telemedicine	94	Legal factors; sustainability factors; cultural factors; and contextual factors.
Shekelle et al. 2006 USA	To assess the evidence base regarding benefits and costs of health information technology systems.	Mixed (ambulatory, inpatient and outpatient)	Information And Communication Technologies (ICT)	256 of which 20 focussed on barriers and facilitators to implementation	Barriers were classified as; situational barriers (including time and financial concerns), cognitive and or physical barriers (include physical disabilities and insufficient computer skills), liability

					barriers (including confidentiality concerns), and knowledge and attitudinal barriers.
Stolee et al. 2010 Canada	To identify barriers, facilitators, and recommendations for using electronic health information systems in home care settings.	Homecare	Electronic Health Information Systems (EHIS)	45	Costs, especially during implementation, training, and lack of user acceptance/healthcare professional resistance. The most common facilitators included portable technology, strategies to decrease data entry errors, and managerial support and user incentives
Studer 2005 USA	To systematically review studies assessing the effect of organisational factors on the effectiveness of electronic medical records system implementation.	Mixed (physician practices, group medical practices, hospitals and academic health centres)	Electronic Medical Records (EMR)	23	Factors influencing the effectiveness of EMR system implementation included management support, financial resource availability, implementation climate and implementation policies and practices.
Vreeman et al. 2006 USA	To identify, review, and summarize the benefits, barriers, and key factors for success in	Mixed (physical therapy settings)	Electronic Health Records (EHR)	13	Essential conditions for successful implementation: workflow analysis, involvement of end users,

	implementing electronic health records in physical therapist practice settings.					significant resources for training, adequate software and hardware performance, commit to data standards.
Waneka and Spetz 2010 USA	To determine the impact of health information technologies on nurses and nursing care.	Mixed (hospital and ambulatory)	Health Information Technologies (HIT)	74		Effective leadership and involvement from HIT users at all stages of the development and implementation processes can help improve the effective implementation
Yarbrough and Smith 2007 USA	To increase understanding of physician technology acceptance and barriers to such acceptance,	Any	Information Technology	18		Time/practice-related issues, organisational issues, personal issues, and system-specific characteristics influence a physician's acceptance of a new technology.
Yusof et al. 2007 Malaysia	To present the main findings of a systematic review of selected case studies on healthcare information systems adoption in clinical practices.	Not defined	Healthcare Information Systems (HIS)	55		Critical adoption factors: technology (ease of use, system usefulness, system flexibility, time efficiency, information accessibility and relevancy); human (user training, user perception, user roles, user skills, clarity of system purpose, user

involvement); organisation
(leadership and support,
clinical process, user
involvement, internal
communication) as well as
the fit between them.

CFIR Codebook

Note: This template provides inclusion and exclusion criteria for most constructs. Please post additional inclusion and exclusion criteria, guidance, or questions to the [CFIR Wiki](#) discussion tab in order to help improve the CFIR.

This template only includes CFIR definitions and coding criteria; codebooks may include other information, such as examples of coded text, rating guidelines, and related interview questions.

I. Innovation Characteristics

A. Innovation Source

Definition: Perception of key stakeholders about whether the innovation is externally or internally developed.

Inclusion Criteria: Include statements about the source of the innovation and the extent to which interviewees view the change as internal to the organisation, e.g., an internally developed program, or external to the organisation, e.g., a program coming from the outside. Note: May code and rate as "I" for internal or "E" for external.

Exclusion Criteria: Exclude or double code statements related to who participated in the decision process to implement the innovation to Engaging, as an indication of early (or late) engagement. Participation in decision-making is an effective engagement strategy to help people feel ownership of the innovation.

B. Evidence Strength & Quality

Definition: Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the innovation will have desired outcomes.

Inclusion Criteria: Include statements regarding awareness of evidence and the strength and quality of evidence, as well as the absence of evidence or a desire for different types of evidence, such as pilot results instead of evidence from the literature.

Exclusion Criteria: Exclude or double code statements regarding the receipt of evidence as an engagement strategy to Engaging: Key Stakeholders. Exclude or double code descriptions of use of results from local or regional pilots to Trialability.

C. Relative Advantage	<p><u>Definition:</u> Stakeholders' perception of the advantage of implementing the innovation versus an alternative solution.</p> <p><u>Inclusion Criteria:</u> Include statements that demonstrate the innovation is better (or worse) than existing programs.</p> <p><u>Exclusion Criteria:</u> Exclude statements that demonstrate a strong need for the innovation and/or that the current situation is untenable and code to <u>Tension for Change</u>.</p>
D. Adaptability	<p><u>Definition:</u> The degree to which an innovation can be adapted, tailored, refined, or reinvented to meet local needs.</p> <p><u>Inclusion Criteria:</u> Include statements regarding the (in)ability to adapt the innovation to their context, e.g., complaints about the rigidity of the protocol. Suggestions for improvement can be captured in this code but should not be included in the rating process, unless it is clear that the participant feels the change is needed but that the program cannot be adapted. However, it may be possible to infer that a large number of suggestions for improvement demonstrates lack of compatibility, see exclusion criteria below.</p> <p><u>Exclusion Criteria:</u> Exclude or double code statements that the innovation did or did not need to be adapted to <u>Compatibility</u>.</p>
E. Trialability	<p><u>Definition:</u> The ability to test the innovation on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.</p> <p><u>Inclusion Criteria:</u> Include statements related to whether the site piloted the innovation in the past or has plans to in the future, and comments about whether they believe it is (im)possible to conduct a pilot.</p> <p><u>Exclusion Criteria:</u> Exclude or double code descriptions of use of results from local or regional pilots to <u>Evidence Strength & Quality</u>.</p>
F. Complexity	<p><u>Definition:</u> Perceived difficulty of the innovation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.</p> <p><u>Inclusion Criteria:</u> Code statements regarding the complexity of the innovation itself.</p>

	<p><u>Exclusion Criteria:</u> Exclude statements regarding the complexity of implementation and code to the appropriate CFIR code, e.g., difficulties related to space are coded to Available Resources and difficulties related to engaging participants in a new program are coded to <u>Engaging: Innovation Participants</u>.</p>
G. Design Quality & Packaging	<p><u>Definition:</u> Perceived excellence in how the innovation is bundled, presented, and assembled.</p> <p><u>Inclusion Criteria:</u> Include statements regarding the quality of the materials and packaging.</p> <p><u>Exclusion Criteria:</u> Exclude statements regarding the presence or absence of materials and code to <u>Available Resources</u>. Exclude statements regarding the receipt of materials as an engagement strategy and code to <u>Engaging</u>.</p>
H. Cost	<p><u>Definition:</u> Costs of the innovation and costs associated with implementing the innovation including investment, supply, and opportunity costs.</p> <p><u>Inclusion Criteria:</u> Include statements related to the cost of the innovation and its implementation.</p> <p><u>Exclusion Criteria:</u> Exclude statements related to physical space and time, and code to <u>Available Resources</u>. In a research study, exclude statements related to costs of conducting the research components (e.g., funding for research healthcare professional, participant incentives).</p>
II. Outer Setting	
A. Needs & Resources of Those Served by the Organization	<p><u>Definition:</u> The extent to which the needs of those served by the organization (e.g., patients), as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.</p> <p><u>Inclusion Criteria:</u> Include statements demonstrating (lack of) awareness of the needs and resources of those served by the organization. Analysts may be able to infer the level of awareness based on statements about: 1. Perceived need for the innovation based on the needs of those served by the organization and if the innovation will meet those needs; 2. Barriers and facilitators of those served by the organization to participating in the innovation; 3. Participant feedback on the innovation, i.e., satisfaction and success in a program. In</p>

addition, include statements that capture whether or not awareness of the needs and resources of those served by the organization influenced the implementation or adaptation of the innovation.

Exclusion Criteria: Exclude statements that demonstrate a strong need for the innovation and/or that the current situation is untenable and code to Tension for Change.

Exclude statements related to engagement strategies and outcomes, e.g., how innovation participants became engaged with the innovation, and code to Engaging: Innovation Participants.

B. Cosmopolitanism

Definition: The degree to which an organization is networked with other external organizations.

Inclusion Criteria: Include descriptions of outside group memberships and networking done outside the organization.

Exclusion Criteria: Exclude statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning, and code to Networks & Communications.

C. Peer Pressure

Definition: Mimetic or competitive pressure to implement an innovation, typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.

Inclusion Criteria: Include statements about perceived pressure or motivation from other entities or organizations in the local geographic area or system to implement the innovation.

Exclusion Criteria:

D. External Policy &
Incentives

Definition: A broad construct that includes external strategies to spread innovations including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.

	<p><u>Inclusion Criteria</u>: Include descriptions of external performance measures from the system.</p> <p><u>Exclusion Criteria</u>:</p>
III. Inner Setting	
A. Structural Characteristics	<p><u>Definition</u>: The social architecture, age, maturity, and size of an organization.</p> <p><u>Inclusion Criteria</u>:</p> <p><u>Exclusion Criteria</u>:</p>
B. Networks & Communications	<p><u>Definition</u>: The nature and quality of webs of social networks, and the nature and quality of formal and informal communications within an organization.</p> <p><u>Inclusion Criteria</u>: Include statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning.</p> <p><u>Exclusion Criteria</u>: Exclude statements related to implementation leaders' and users' access to knowledge and information regarding using the program, i.e., training on the mechanics of the program and code to <u>Access to Knowledge & Information</u>.</p> <p>Exclude statements related to engagement strategies and outcomes, e.g., how key stakeholders became engaged with the innovation and what their role is in implementation, and code to <u>Engaging: Key Stakeholders</u>.</p> <p>Exclude descriptions of outside group memberships and networking done outside the organization and code to <u>Cosmopolitanism</u>.</p>
C. Culture	<p><u>Definition</u>: Norms, values, and basic assumptions of a given organization.</p> <p><u>Inclusion Criteria</u>: Inclusion criteria, and potential sub-codes, will depend on the framework or definition used for "culture." For example, if using the <u>Competing Values Framework</u> (CVF), you may include four sub-codes related to the four dimensions of the CVF and code statements regarding one or more of the four dimension in an organization.</p>

	<u>Exclusion Criteria:</u>
D. Implementation Climate	<p><u>Definition:</u> The absorptive capacity for change, shared receptivity of involved individuals to an innovation, and the extent to which use of that innovation will be rewarded, supported, and expected within their organization.</p> <p><u>Inclusion Criteria:</u> Include statements regarding the general level of receptivity to implementing the innovation.</p> <p><u>Exclusion Criteria:</u> Exclude statements regarding the general level of receptivity that are captured in the sub-codes.</p>
1. Tension for Change	<p><u>Definition:</u> The degree to which stakeholders perceive the current situation as intolerable or needing change.</p> <p><u>Inclusion Criteria:</u> Include statements that (do not) demonstrate a strong need for the innovation and/or that the current situation is untenable, e.g., statements that the innovation is absolutely necessary or that the innovation is redundant with other programs. Note: If a participant states that the innovation is redundant with a preferred existing program, (double) code lack of <u>Relative Advantage</u>, see exclusion criteria below.</p> <p><u>Exclusion Criteria:</u> Exclude statements regarding specific needs of individuals that demonstrate a need for the innovation, but do not necessarily represent a strong need or an untenable status quo, and code to <u>Needs and Resources of Those Served by the Organization</u>. Exclude statements that demonstrate the innovation is better (or worse) than existing programs and code to <u>Relative Advantage</u>.</p>
2. Compatibility	<p><u>Definition:</u> The degree of tangible fit between meaning and values attached to the innovation by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the innovation fits with existing workflows and systems.</p> <p><u>Inclusion Criteria:</u> Include statements that demonstrate the level of compatibility the innovation has with organizational values and work processes. Include statements that the innovation did or did not need to be adapted as evidence of compatibility or lack of compatibility.</p> <p><u>Exclusion Criteria:</u> Exclude or double code statements</p>

		regarding the priority of the innovation based on compatibility with organizational values to <u>Relative Priority</u> , e.g., if an innovation is not prioritized because it is not compatible with organizational values.
3.	Relative Priority	<p><u>Definition</u>: Individuals' shared perception of the importance of the implementation within the organization.</p> <p><u>Inclusion Criteria</u>: Include statements that reflect the relative priority of the innovation, e.g., statements related to change fatigue in the organization due to implementation of many other programs.</p> <p><u>Exclusion Criteria</u>: Exclude or double code statements regarding the priority of the innovation based on compatibility with organizational values to <u>Compatibility</u>, e.g., if an innovation is not prioritized because it is not compatible with organizational values.</p>
4.	Organizational Incentives & Rewards	<p><u>Definition</u>: Extrinsic incentives such as goal-sharing, awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.</p> <p><u>Inclusion Criteria</u>: Include statements related to whether organizational incentive systems are in place to foster (or hinder) implementation, e.g., rewards or disincentives for healthcare professional engaging in the innovation.</p> <p><u>Exclusion Criteria</u>:</p>
5.	Goals & Feedback	<p><u>Definition</u>: The degree to which goals are clearly communicated, acted upon, and fed back to healthcare professional, and alignment of that feedback with goals.</p> <p><u>Inclusion Criteria</u>: Include statements related to the (lack of) alignment of implementation and innovation goals with larger organizational goals, as well as feedback to healthcare professional regarding those goals, e.g., regular audit and feedback showing any gaps between the current organizational status and the goal. Goals and Feedback include organizational processes and supporting structures independent of the implementation process. Evidence of the integration of evaluation components used as part of "Reflecting and Evaluating" into on-going or sustained organizational structures and processes may be (double)</p>

coded to Goals and Feedback.

Exclusion Criteria: Exclude statements that refer to the implementation team's (lack of) assessment of the progress toward and impact of implementation, as well as the interpretation of outcomes related to implementation, and code to Reflecting & Evaluating. Reflecting and Evaluating is part of the implementation process; it likely ends when implementation activities end. It does not require goals be explicitly articulated; it can focus on descriptions of the current state with real-time judgment, though there may be an implied goal (e.g., we need to implement the innovation) when the implementation team discusses feedback in terms of adjustments needed to complete implementation.

6. Learning
Climate

Definition: A climate in which: 1. Leaders express their own fallibility and need for team members' assistance and input; 2. Team members feel that they are essential, valued, and knowledgeable partners in the change process; 3. Individuals feel psychologically safe to try new methods; and 4. There is sufficient time and space for reflective thinking and evaluation.

Inclusion Criteria: Include statements that support (or refute) the degree to which key components of an organization exhibit a "learning climate."

Exclusion Criteria:

E. Readiness for
Implementation

Definition: Tangible and immediate indicators of organizational commitment to its decision to implement an innovation.

Inclusion Criteria: Include statements regarding the general level of readiness for implementation.

Exclusion Criteria: Exclude statements regarding the general level of readiness for implementation that are captured in the sub-codes.

1. Leadership
Engagement

Definition: Commitment, involvement, and accountability of leaders and managers with the implementation of the innovation.

Inclusion Criteria: Include statements regarding the level of engagement of organizational leadership.

		<p><u>Exclusion Criteria:</u> Exclude or double code statements regarding leadership engagement to Engaging: <u>Formally Appointed Internal Implementation Leaders</u> or <u>Champions</u> if an organizational leader is also an implementation leader, e.g., if a director of primary care takes the lead in implementing a new treatment guideline. Note that a key characteristic of this Implementation Leader/Champion is that s/he is also an Organizational Leader.</p>
2.	Available Resources	<p><u>Definition:</u> The level of resources organizational dedicated for implementation and on-going operations including physical space and time.</p> <p><u>Inclusion Criteria:</u> Include statements related to the presence or absence of resources specific to the innovation that is being implemented.</p> <p><u>Exclusion Criteria:</u> Exclude statements related to training and education and code to <u>Access to Knowledge & Information</u>. Exclude statements related to the quality of materials and code to <u>Design Quality & Packaging</u>. In a research study, exclude statements related to resources needed for conducting the research components (e.g., time to complete research tasks, such as IRB applications, consenting patients).</p>
3.	Access to Knowledge & Information	<p><u>Definition:</u> Ease of access to digestible information and knowledge about the innovation and how to incorporate it into work tasks.</p> <p><u>Inclusion Criteria:</u> Include statements related to implementation leaders' and users' access to knowledge and information regarding use of the program, i.e., training on the mechanics of the program.</p> <p><u>Exclusion Criteria:</u> Exclude statements related to engagement strategies and outcomes, e.g., how key stakeholders became engaged with the innovation and what their role is in implementation, and code to <u>Engaging: Key Stakeholders</u>. Exclude statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning, and code to <u>Networks & Communications</u>.</p>

IV. Characteristics of

Individuals	
1. Knowledge & Beliefs about the Innovation	<p><u>Definition:</u> Individuals' attitudes toward and value placed on the innovation, as well as familiarity with facts, truths, and principles related to the innovation.</p> <p><u>Inclusion Criteria:</u></p> <p><u>Exclusion Criteria:</u> Exclude statements related to familiarity with evidence about the innovation and code to <u>Evidence Strength & Quality</u>.</p>
2. Self-efficacy	<p><u>Definition:</u> Individual belief in their own capabilities to execute courses of action to achieve implementation goals.</p> <p><u>Inclusion Criteria:</u></p> <p><u>Exclusion Criteria:</u></p>
3. Individual Stage of Change	<p><u>Definition:</u> Characterization of the phase an individual is in, as s/he progresses toward skilled, enthusiastic, and sustained use of the innovation.</p> <p><u>Inclusion Criteria:</u></p> <p><u>Exclusion Criteria:</u></p>
4. Individual Identification with Organization	<p><u>Definition:</u> A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.</p> <p><u>Inclusion Criteria:</u></p> <p><u>Exclusion Criteria:</u></p>
5. Other Personal Attributes	<p><u>Definition:</u> A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.</p> <p><u>Inclusion Criteria:</u></p> <p><u>Exclusion Criteria:</u></p>
V. Process	
A. Planning	<p><u>Definition:</u> The degree to which a scheme or method of behavior and tasks for implementing an innovation are developed in advance, and the quality of those schemes or</p>

methods.

Inclusion Criteria: Include evidence of pre-implementation diagnostic assessments and planning, as well as refinements to the plan.

Exclusion Criteria:

B. Engaging

Definition: Attracting and involving appropriate individuals in the implementation and use of the innovation through a combined strategy of social marketing, education, role modeling, training, and other similar activities.

Inclusion Criteria: Include statements related to engagement strategies and outcomes, i.e., if and how healthcare professional and innovation participants became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of engagement efforts determines the rating, i.e., if there are repeated attempts to engage healthcare professional that are unsuccessful, or if a role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of healthcare professional - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well.

Exclusion Criteria: Exclude statements related to specific sub constructs, e.g., Champions or Opinion Leaders.

Exclude or double code statements related to who participated in the decision process to implement the innovation to Innovation Source, as an indicator of internal or external innovation source.

1. Opinion Leaders

Definition: Individuals in an organization that have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the innovation.

Inclusion Criteria: Include statements related to engagement strategies and outcomes, e.g., how the opinion leader became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage healthcare professional determines the rating, i.e., if there are repeated

attempts to engage an opinion leader that are unsuccessful, or if the opinion leader leaves the organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the opinion leader here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well.

Exclusion Criteria:

2. Formally
Appointed Internal
Implementation
Leaders

Definition: Individuals from within the organization who have been formally appointed with responsibility for implementing an innovation as coordinator, project manager, team leader, or other similar role.

Inclusion Criteria: Include statements related to engagement strategies and outcomes, e.g., how the formally appointed internal implementation leader became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage healthcare professional determines the rating, i.e., if there are repeated attempts to engage an implementation leader that are unsuccessful, or if the implementation leader leaves the organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the implementation leader here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well.

Exclusion Criteria: Exclude or double code statements regarding leadership engagement to Leadership Engagement if an implementation leader is also an organizational leader, e.g., if a director of primary care takes the lead in implementing a new treatment guideline.

3. Champions

Definition: "Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]", overcoming indifference or resistance that the innovation may provoke in an organization.

Inclusion Criteria: Include statements related to engagement strategies and outcomes, e.g., how the champion became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes

are coded here, the outcome of efforts to engage healthcare professional determines the rating, i.e., if there are repeated attempts to engage a champion that are unsuccessful, or if the champion leaves the organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the champion here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well.

Exclusion Criteria: Exclude or double code statements regarding leadership engagement to Leadership Engagement *if* a champion is also an organizational leader, e.g., if a director of primary care takes the lead in implementing a new treatment guideline.

4. External
Change Agents

Definition: Individuals who are affiliated with an outside entity who formally influence or facilitate innovation decisions in a desirable direction.

Inclusion Criteria: Include statements related to engagement strategies and outcomes, e.g., how the external change agent (entities outside the organization that facilitate change) became engaged with the innovation and what their role is in implementation, e.g., how they supported implementation efforts. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage healthcare professional determines the rating, i.e., if there are repeated attempts to engage an external change agent that are unsuccessful, or if the external change agent leaves their organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the external change agent here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well.

Exclusion Criteria: Note: It is important to clearly define what roles are external and internal to the organization. Exclude statements regarding facilitating activities, such as training in the mechanics of the program, and code to Access to Knowledge & Information *if* the change agent is considered internal to the study, e.g., a healthcare professional member at the national office. If the study considers this healthcare professional member internal to the organization, it should be coded to Access to Knowledge & Information, even though their support may overlap with what would be expected from

		an External Change Agent.
5.	Key Stakeholders	<p><u>Definition:</u> Individuals from within the organization that are directly impacted by the innovation, e.g., healthcare professional responsible for making referrals to a new program or using a new work process.</p> <p><u>Inclusion Criteria:</u> Include statements related to engagement strategies and outcomes, e.g., how key stakeholders became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage healthcare professional determines the rating, i.e., if there are repeated attempts to engage key stakeholders that are unsuccessful, the construct receives a negative rating.</p> <p><u>Exclusion Criteria:</u> Exclude statements related to implementation leaders' and users' access to knowledge and information regarding using the program, i.e., training on the mechanics of the program, and code to <u>Access to Knowledge & Information</u>.</p> <p>Exclude statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning, and code to <u>Networks & Communications</u>.</p>
6.	Innovation Participants	<p><u>Definition:</u> Individuals served by the organization that participate in the innovation, e.g., patients in a prevention program in a hospital.</p> <p><u>Inclusion Criteria:</u> Include statements related to engagement strategies and outcomes, e.g., how innovation participants became engaged with the innovation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage participants determines the rating, i.e., if there are repeated attempts to engage participants that are unsuccessful, the construct receives a negative rating.</p> <p><u>Exclusion Criteria:</u> Exclude statements demonstrating (lack of) awareness of the needs and resources of those served by the organization and whether or not that awareness influenced the</p>

	implementation or adaptation of the innovation and code to <u>Needs & Resources of Those Served by the Organization</u> .
C. Executing	<p><u>Definition</u>: Carrying out or accomplishing the implementation according to plan.</p> <p><u>Inclusion Criteria</u>: Include statements that demonstrate how implementation occurred with respect to the implementation plan. Note: Executing is coded very infrequently due to a lack of planning. However, some studies have used fidelity measures to assess executing, as an indication of the degree to which implementation was accomplished according to plan.</p> <p><u>Exclusion Criteria</u>:</p>
D. Reflecting & Evaluating	<p><u>Definition</u>: Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.</p> <p><u>Inclusion Criteria</u>: Include statements that refer to the implementation team's (lack of) assessment of the progress toward and impact of implementation, as well as the interpretation of outcomes related to implementation. Reflecting and Evaluating is part of the implementation process; it likely ends when implementation activities end. It does not require goals be explicitly articulated; it can focus on descriptions of the current state with real-time judgment, though there may be an implied goal (e.g., we need to implement the innovation) when the implementation team discusses feedback in terms of adjustments needed to complete implementation.</p> <p><u>Exclusion Criteria</u>: Exclude statements related to the (lack of) alignment of implementation and innovation goals with larger organizational goals, as well as feedback to healthcare professional regarding those goals, e.g., regular audit and feedback showing any gaps between the current organizational status and the goal, and code to <u>Goals & Feedback</u>. Goals and Feedback include organizational processes and supporting structures independent of the implementation process. Evidence of the integration of evaluation components used as part of "Reflecting and Evaluating" into on-going or sustained organizational structures and processes may be (double) coded to Goals and Feedback.</p> <p>Exclude statements that capture reflecting and evaluating that</p>

participants may do during the interview, for example, related to the success of the implementation, and code to Knowledge & Beliefs about the Innovation.

VI. Additional Codes

A. Code Name Definition:

Inclusion Criteria:

Exclusion Criteria:

B. Code Name Definition:

Inclusion Criteria:

Exclusion Criteria:

Appendix D Excluded theories, Frameworks and Models of implementation

Model	Reference	Primary exclusion reason
Diffusion of Innovation	(3)	Not focussed on implementation only
RAND Model of Persuasive Communication and Diffusion of Medical Innovation	(285)	Not focussed on implementation only
Effective Dissemination Strategies	(286)	Not focussed on implementation only
Model for Locally Based Research Transfer Development	(287)	Not focussed on implementation only
Streams of Policy Process	(288)	Not focussed on implementation only
A Conceptual Model of Knowledge Utilization	(289)	Not focussed on implementation only
Conceptual Framework for Research Knowledge Transfer and Utilization	(290)	Not focussed on implementation only
Conceptualizing Dissemination Research and Activity: Canadian Heart Health Initiative	(291)	Not focussed on implementation only
Policy Framework for Increasing Diffusion of Evidence-Based Physical Activity Interventions	(292)	Not focussed on implementation only
Blueprint for Dissemination	(293)	Not focussed on implementation only
Framework for Knowledge Translation	(294)	Not focussed on implementation only
A Framework for Analyzing Adoption of Complex Health Innovations	(295)	Not focussed on implementation only
A Framework for Spread	(296)	Not focussed on implementation only
Collaborative Model for Knowledge Translation Between Research and Practice Settings	(297)	Not focussed on implementation only
Coordinated Implementation Model	(298)	Not focussed on implementation only
Model for Improving the Dissemination of Nursing Research	(299)	Not focussed on implementation only
Framework for the Dissemination & Utilization of Research for	(300)	Not focussed on implementation only

Health-Care Policy & Practice		
Framework of Dissemination in Health Services Intervention Research	(301)	Not focussed on implementation only
Linking Systems Framework	(302)	Not focussed on implementation only
Marketing and Distribution System for Public Health	(303)	Not focussed on implementation only
OPTIONS Model	(304)	Not focussed on implementation only
A Conceptual Model for the Diffusion of Innovations in Service Organizations	(305)	Not focussed on implementation only
Health Promotion Research Center Framework	(306)	Not focussed on implementation only
Knowledge Exchange Framework	(307)	Not focussed on implementation only
Research Knowledge Infrastructure	(308)	Not focussed on implementation only
A Convergent Diffusion and Social Marketing Approach for Dissemination	(309)	Not focussed on implementation only
Framework for Dissemination of Evidence-Based Policy	(310)	Not focussed on implementation only
Health Promotion Technology Transfer Process	(306)	Not focussed on implementation only
Real-World Dissemination	(311)	Not focussed on implementation only
A Framework for the Transfer of Patient Safety Research into Practice	(312)	Not focussed on implementation only
Interacting Elements of Integrating Science, Policy, and Practice	(313)	Not focussed on implementation only
Interactive Systems Framework	(314)	Not focussed on implementation only
Push–Pull Capacity Model	(315)	Not focussed on implementation only
Research Development Dissemination and Utilization Framework	(316)	Not focussed on implementation only
Utilization-Focused Surveillance Framework	(317)	Not focussed on implementation only
“4E” Framework for Knowledge Dissemination and Utilization	(318)	Not focussed on implementation only
Critical Realism & the Arts	(319)	Not focussed on implementation only

Research Utilization Model (CRARUM)		
Davis' Pathman-PRECEED Model	(320)	Not focussed on implementation only
Dissemination of Evidence-based Interventions to Prevent Obesity	(321)	Not focussed on implementation only
Knowledge Translation Model of Tehran University of Medical Sciences	(322)	Not focussed on implementation only
Multi-level Conceptual Framework of Organizational Innovation Adoption	(323)	Not focussed on implementation only
Ottawa Model of Research Use	(324)	Not focussed on implementation only
The RE-AIM Framework	(320)	Not focussed on implementation only
The Precede–Proceed Model	(320)	Not focussed on implementation only
Facilitating Adoption of Best Practices (FAB) Model	(325)	Not focussed on implementation only
A Six-Step Framework For International Physical Activity Dissemination	(326)	Not focussed on implementation only
Pathways to Evidence Informed Policy	(327)	Not focussed on implementation only
CDC DHAP's Research-to-Practice Framework	(328)	Not focussed on implementation only
Practical, Robust Implementation and Sustainability Model (PRISM)	(329)	Not focussed on implementation only
Active Implementation Framework	(330)	Doesn't apply at system level
An Organizational Theory of Innovation Implementation	(331)	Doesn't apply at system, community, individual or policy level
Implementation Effectiveness Model	(332)	Doesn't apply at system, community or policy level
Promoting Action on Research Implementation in Health Services (PARIHS)	(333)	Doesn't apply at system or policy level and hadn't been applied to implementation planning
Pronovost's 4E's Process Theory	(334)	Doesn't apply at system or policy level
Sticky Knowledge	(335)	Doesn't apply at system or policy level
Consolidated Framework for Implementation Research	(122)	Meets criteria but doesn't provide an explanatory framework
Replicating Effective Programs Plus Framework	(336)	Doesn't apply at system, individual or policy level

Availability, Responsiveness & Continuity (ARC): An Organizational & Community Intervention Model	(337)	Doesn't apply at system, individual or policy level
Conceptual Model of Evidence-Based Practice Implementation in Public Service Sectors	(338)	Doesn't apply at system, individual or policy level

PARTICIPANT INFORMATION SHEET

A study to evaluate the HeLP-Diabetes website- can you help?

What is the study about?

- We want to find out how best to support patients to look after their diabetes and are interested to know what you think about HeLP-Diabetes and if it helps you with managing your diabetes.
- We are inviting people with type 2 diabetes through their GP practice or diabetes clinic.
- If you take part, you will be in the study until August 2015.

Why are we doing this study?

- Many people with type 2 diabetes need help and support to manage their condition well. We have developed HeLP-Diabetes, a website offering help and support for people with type 2 diabetes.
- We want to know what people think about HeLP-Diabetes and the way that it is delivered through the NHS. We're also interested to know if HeLP-Diabetes can help you with managing your diabetes.

We invite you to take part in the study:

- Before you decide whether to take part, it is important that you understand why the study is being done and what it will involve. Please read this information carefully. Discuss it with others if you wish. Take time to decide whether or not you want to take part.
- It is up to you to decide whether or not to take part. Saying no will not affect the care you receive from the NHS.
- Please contact us if you would like to ask any questions.

Why am I being asked to take part?

- We are looking for people aged 18 and above with type 2 diabetes who are registered at your general practice or diabetes clinic to take part.

What will I need to do if I take part?

- You can use HeLP-Diabetes whether or not you take part in this research study but if you do decide to take part:
- You will be asked to complete some questionnaires online about you and your diabetes. We will ask you to complete some of the same questions again at 3 months into the study and again at 12 months.

- Your use of HeLP-Diabetes (number of logins, pages visited etc.) will be automatically recorded by the computer.
- We may contact you during the study to ask you to participate in one or more interviews about your experiences of HeLP-Diabetes. This will be with the researcher and you can do this in person or over the telephone.

Possible benefits and disadvantages of taking part:

We think that people who take part in the study may benefit in two ways:

- Firstly, you will be able to use a free website about type 2 diabetes until 1st March 2016.
- Secondly, using the website may have a positive impact on your health. Previous studies have found that the health of people who have been given information about their diabetes tends to improve more than in those not given information.
- We think there is very little risk of harm in taking part. However, it is possible that some patients may worry as a result of reading information about the health of other people with diabetes. If this happens, please ask to talk with the researcher or your nurse or GP.

More about taking part:

Can I change my mind?

- Yes. You can decide to take part and then later change your mind without giving a reason. Your usual NHS care would not be affected. However, any information you had given until that point would still be used in the study results.

What happens when the study stops?

- When the research stops in August 2015 you will not be required to do anything further and can use HeLP-Diabetes until 1st March 2016. The NHS may make HeLP-Diabetes available to all patients with diabetes across the country. But that will depend on what the study shows and whether funds are available.

What will happen to my information in the study?

- All information you give will be treated in confidence. It will be stored on a secure computer, using only a study number to identify you. Only authorised people will be able to read the information.

Who is paying for and running the study?

- The study is being funded by the National Institute for Health Research (NIHR), which is funded by the government and is the biggest funder of research in the NHS.
- The study is run by University College London. The lead researcher is Professor Elizabeth Murray, who is a GP and a health researcher. The study is being managed by

Jamie Ross (Research Associate) and you should contact her if you have any questions.

What if there is a problem?

- If you took part in the study and felt unhappy about the way you were treated, you should contact the study manager, Jamie Ross (details below). If she cannot help, contact the lead researcher, Prof Elizabeth Murray (details below). If you remained unhappy, you could make a formal complaint through the NHS Patient Advice and Liaison Service (PALS) www.pals.nhs.uk
- In the very unlikely event that someone took part and became unable to make decisions for themselves, that person would not continue in the study.

Contact details:

If you have any questions about the study, please contact the HeLP-Diabetes study manager, Jamie Ross:

eHealth Unit
UCL Research Department of
Primary Care & Population Health
Upper 3rd Floor
Royal Free Hospital
Rowland Street
London NW3 2PF

Tel: 020 7784 0500 (ext 37073)

Email: Jamie.Ross@ucl.ac.uk

Or the lead researcher, Prof Elizabeth Murray can be contacted at the same address or on:

Tel: 020 7794 0500 ext 36747

Email: elizabeth.murray@ucl.ac.uk

[UCL departmental headed paper]

Centre Number:

Patient Identification Number for this study:

 CONSENT FORM

Title of Project: A study to evaluate the implementation of the HeLP-Diabetes online self-management programme for people with type 2 diabetes.

Please initial all boxes in this section to say that you agree to and understand the following statements:	Initial here
I confirm that I have read and understood the information sheet dated 05.12.2013 Version 3 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I am volunteering to participate in research to evaluate and improve HeLP-Diabetes and the way it's offered to patients through the NHS.	
My HeLP-Diabetes registration and usage data will be used anonymously for research purposes.	
I will be asked to complete questionnaires after joining the research and again at 3 months and 12 months.	
I may be asked to participate in one or more interviews with a researcher to discuss my experiences of using HeLP-Diabetes.	
The information I provide in interviews will be tape recorded and saved on a computer. Once the information has been transcribed, names and all other personal data will be destroyed in accordance with the Data Protection Act 1998.	
My participation is voluntary and I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
My GP may be informed of my participation in this research.	
All the information I provide will be confidential and that I will remain anonymous. However, if I disclose anything potentially dangerous to my health this may be reported	

to my GP or doctor.	
I agree to take part in the research.	

_____	_____	_____

Name of participant	Date	Signature
_____	_____	_____

Name of person taking consent	Date	Signature

[UCL departmental headed paper]

Staff interview information sheet. Date of issue: 31.10.2012

Staff interview information sheet. Version number: 1.0

HEALTH CARE PROFESSIONAL INTERVIEW INFORMATION SHEET

A study to evaluate the implementation of the HeLP-Diabetes online self-management programme for people with type 2 diabetes.

Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve for you. This information sheet will help you, so please take some time to read this information carefully and ask any questions you might have or if there is anything that is not clear. Talk to others about the study if you wish.

Part 1 of this information sheet tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Please ask if there is anything that is not clear.

PART 1.

Why are we doing the study?

Type 2 diabetes is one of the most common long term health conditions in the UK, affecting over 2 million adults. Many people with type 2 diabetes need help and support to live a healthy, happy life. The NHS recommends that every person with type 2 diabetes should have the opportunity to attend a course on diabetes when first told they have diabetes, and once a year thereafter. But not everybody who needs these courses gets them – either because there are not enough courses locally, or because the courses are hard to get to.

We think one way of helping people with diabetes get the support and information they need to live a healthy, happy life is through the web. We have developed a web-based programme offering help and support for people with type 2 diabetes called HeLP-Diabetes. We are now trying to implement the programme so that people who could benefit from it have easy access to it. We know that it is difficult to get new ways of working into routine practice and we are looking

for the best way of doing this. We are asking for your help with this. You can use the programme whether or not you help us with our research.

Why have I been chosen?

We are looking for healthcare professionals working in GP practices and diabetes clinics where the HeLP-Diabetes programme has been introduced.

Do I have to take part?

No. It is up to you to decide whether or not to take part in the research. Take as long as you need to reach a decision and discuss the study with the researcher before making a decision. If you do decide to take part, you will be asked to sign a consent form. Even after signing this form you are free to withdraw at any time without giving a reason. However, if you do withdraw after providing the research team with some information about you, that information will be kept as part of the study.

What will happen to me if I take part?

We will ask you to participate in one or more interviews about your experience of using the HeLP-Diabetes programme. This will be with the researcher and you can do this in person or over the telephone.

Will I benefit from taking part?

Not directly. You can use the programme (HeLP-Diabetes) whether or not you take part. But if you do take part you will know you have helped us work out how best to implement and disseminate the programme for other people to use in the future.

Are there any risks involved?

It is very unlikely that you will come to harm as a result of taking part in this study. The programme has been developed by a team of NHS doctors, nurses, dieticians, psychologists and researchers. It reflects current best practice in the NHS. The research procedures are also very low risk. You will be asked to take part in one or more interviews about your experience of using HeLP-Diabetes.

Do I have to take part?

No. It is up to you to decide whether or not to take part in the research. You do not have to make a firm decision now. If you agree to take part, you will be asked to sign a consent form to

confirm you wish to take part before you start in the study. You are free to withdraw at ANY time, without giving a reason. You can still use the programme without participating in the research. Even after signing the consent form you are free to withdraw at any time without giving a reason. However, if you do withdraw after providing the research team with some information about you, that information will be kept as part of the study.

What happens when the study stops?

When the research stops you will not be required to do anything further.

The HeLP-Diabetes programme may still be available for you to use, however, this is not guaranteed at this point and will partly depend on how many people use it. Following the research study amendments may need to be made to the programme, or the site may have to go offline for other reasons. More information on this will be made available on the HeLP-Diabetes programme at the end of the study period.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will the information I give in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

Can I withdraw from the study once I'm in it?

Yes. You can withdraw from the study at any time without giving a reason. However, any information that you have already provided will be kept in the study.

PART 2: Detailed information about the conduct of the study.

What will happen to the information I provide?

All information about you will be treated confidentially and in accordance with the Data Protection Act 1998. We will keep your personal identification data (your name, address) separate from the rest of the information about you in the study, which will only be identified by a unique participant identification number. The data will be stored online on a secure server which has been approved for clinical research. Only authorised persons (the research team and

the regulatory bodies that monitor researchers in the UK) will have access to your personal data.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should speak to the study researcher Jamie Ross who will do her best to answer your questions. If she cannot help, your concern will be passed to the Chief Investigator, Dr Elizabeth Murray, who has overall responsibility for the study. The contact details for both Jamie Ross and Dr Murray are below.

In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. Please make the claim in writing to Dr Elizabeth Murray who is the Chief Investigator for the research and is based at the e-Health Unit (UCL Research Department of Primary Care – full address below). The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

What will happen to the results of this study?

The results of this study will be submitted for publication in academic journals and presented at conferences. We hope they will influence NHS policy and lead to improved information provision for patients. We would be happy to send you a summary of the results – if you would like us to do so please fill in the 2nd page of the consent form.

Loss of Capacity

In the very unlikely and unfortunate event that someone who takes part in the study lost the ability to make informed decisions for him or herself, that person would not continue to take part in the study. Any information that we have received before such an event would be used in the study.

Who is organising and funding the study?

The study is being run by University College London. It is funded by the National Institute of Health Research. It is sponsored by the University College London.

The research team are: Dr Elizabeth Murray (General Practitioner and Researcher), Dr Kingshuk Pal (General Practitioner and Researcher), Dr Charlotte Dack (Psychologist and Researcher), Ms Jamie Ross (Psychologist and Researcher) and Ms Orla O'Donnell (Project Coordinator).

The content of HeLP-Diabetes has been written and developed by a larger team including people with Type 2 Diabetes, Specialist Diabetes Consultants, General Practitioners, Diabetes Specialist Nurses, Practice Nurses, Dieticians, Sociologists, Psychologists, a Web Designer and a Software Company. For more information about the team, please see <http://www.ucl.ac.uk/pcph/research-groups-themes/e-health>

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed by the [title] Research Ethics Proportionate Review Sub-Committee.

Is there an independent contact point where I can get general advice about taking part in research?

Yes. INVOLVE is a national advisory group that supports greater public involvement in NHS, public health and social care research. They provide advice and information on public involvement in research. You can find out more from their website: www.invo.org.uk You can contact them at: INVOLVE, Wessex House, Upper Market Street, Eastleigh, Hampshire, SO50 9FD or Telephone: 023 8065 1088

Is there a contact point where I can find out further details about the research study?

Yes. If you have any questions at all about the study or would like further information, please contact the study researcher, Ms Jamie Ross.

Who do I contact if I wish to take part?

If you are interested in taking part, have any questions at all about the study or would like further information please contact the Study Researcher, Ms Jamie Ross at the details below.

CONTACT DETAILS

Name	Ms Jamie Ross	Dr Elizabeth Murray –
Role	Study Researcher	Chief Investigator
Tel	020 7794 0500 (Ext: 37370)	020 7794 0500 ext 36747
Email	jamie.ross@ucl.ac.uk	elizabeth.murray@ucl.ac.uk

Address	eHealth Unit, UCL Research Department of Primary Care & Population Health Upper 3rd Floor, Royal Free Hospital, Rowland Hill Street London NW3 2PF
Fax	020 7794 1224.
Web	https://www.ucl.ac.uk/pcph/research-groups-themes/e-health

[UCL departmental headed paper]

Centre Number: Study Number:

Healthcare professional Identification Number for this study:

HEALTH CARE PROFESSIONAL CONSENT FORM

Title of Project: A study to evaluate the implementation of the HeLP-Diabetes online self-management programme for people with type 2 diabetes.

Name of Researcher: [Name of person taking consent]

Please initial all boxes in this section	Initial here
I confirm that I have read and understand the information sheet dated 31.10.2012 version 1.0 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that I am volunteering to participate in a research study evaluating the implementation of the HeLP-Diabetes online self-management programme for people with type 2 diabetes	
I understand that the purpose of the study is to inform and improve the implementation of HeLP-Diabetes in other practices / clinics	
I understand that I will be asked to attend one or more interviews with a researcher to discuss my experiences of using the HeLP-Diabetes programme. I agree to take part in these interviews.	
I understand that the information I provide will be tape recorded or saved on a computer and used for the purposes of this research study only. I also understand that once the information has been transcribed, names and all other personal data will be destroyed in accordance with the Data Protection Act 1998.	
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I understand that all the information I provide will be confidential and that I will remain anonymous.	
I agree to take part in the above study.	

Name of participant

Date

Signature

Name of person taking
Consent

Date

Signature

Appendix I Patient measures collected by online registration form

Type	Variable	Response options	Optional/ Mandatory	Date variable added to registration page	Verification
Registration details	Username	<ul style="list-style-type: none"> Free text Must be more than 3 characters, with no spaces, and using only 0-9 and a-z, A-Z. 	M	01.03.2013	Software checks that no one else has registered using this username.
	Password	<ul style="list-style-type: none"> Free text At least 6 characters and can include upper and lower case characters, numbers and special characters. 	M	01.03.2013	Participants asked to enter this twice and are given an indication of password strength using a 10 point colour scale and either the words Weak, OK, Good, Strong, Very Strong.
Contact Details	First name	<ul style="list-style-type: none"> Free text 	M	01.03.2013	
	Last name	<ul style="list-style-type: none"> Free text 	M	01.03.2013	
	Email address	<ul style="list-style-type: none"> Free text 	M	01.03.2013	Participants asked to enter this twice and the software checked that it was a valid email address.
	Telephone number	<ul style="list-style-type: none"> Free text 	O	01.03.2013	Software checks that the number entered is the

					correct number of characters and are all numerical digits.
Mobile number	<ul style="list-style-type: none"> Free text 	O		01.03.2013	Software checks that the number entered is the correct number of characters and are all numerical digits.
Date of birth	<ul style="list-style-type: none"> DD/MM/YYYY 	M		01.03.2013	
Gender	<ul style="list-style-type: none"> Single item, select one out of two options: Male Female 	M		01.03.2013	
Ethnic Group	<ul style="list-style-type: none"> Single item, select one out of eighteen options: Asian or Asian British- Bangladeshi Asian or Asian British- Chinese Asian or Asian British- Indian Asian or Asian British- Other Asian or Asian British- Pakistani Black or Black British- African Black or Black British- Caribbean Black or Black British- Other Mixed- Other Mixed- White and Asian Mixed- White and Black African 	M		01.03.2013	

Demographic details

	<ul style="list-style-type: none"> • Mixed- White and Black Caribbean • Other ethnic group- Arab • Other ethnic group- Other • Prefer not to say • White- English/Welsh/Scottish/Northern Irish/British • White- Irish • White-Other 			
	Highest educational attainment	<ul style="list-style-type: none"> • Single item, select one out of six options: • None • School leaver (e.g., CSE, GCSE, O-Level, NVQ1-2) • A-level or vocational equivalent (e.g. NVQ 3) • Degree or NVQ 4, HND or similar • Post-graduate degree or NVQ 5 • Not stated 	M	05.03.2014
	Date of diagnosis	<ul style="list-style-type: none"> • DD/MM/YYYY 	O	01.03.2013
	How long have you had diabetes?	<ul style="list-style-type: none"> • Single item, select one out of four options: • <1 year • 1-5 years • 5-10 years • 10-20 years • >20 years 	M	01.03.2013
Diabetes/clinical information	What would you most like help with for your diabetes?	<ul style="list-style-type: none"> • Select all options that apply: • Attending my appointments • Connecting with others • Cutting down on alcohol • Eating healthily 	M	01.03.2013

- Increasing my activity levels
- Living and working with diabetes
- Losing weight
- Managing my feelings
- Preventing complications
- Quitting smoking
- Taking my medicines
- Understanding my medicines
- Understanding what diabetes is

How is your diabetes managed?	<ul style="list-style-type: none"> • Single item, select one out of four options: • Lifestyle alone (i.e. diet and physical activity) • Lifestyle and tablets • Lifestyle tablets and insulin • Other injectables 	M	01.03.2013
GP/clinic name	<ul style="list-style-type: none"> • Free text 	M	01.03.2013
Have you ever been offered or referred to any diabetes self-management or education groups or classes (e.g. DESMOND)?:	<ul style="list-style-type: none"> • Single item, select one out of two options: • Yes • No 	M	19.08.2014 Specifically for patients who were from Camden
Are you currently attending or have you	<ul style="list-style-type: none"> • Single item, select one out of two options: • Yes 	M	19.08.2014 Specifically for patients

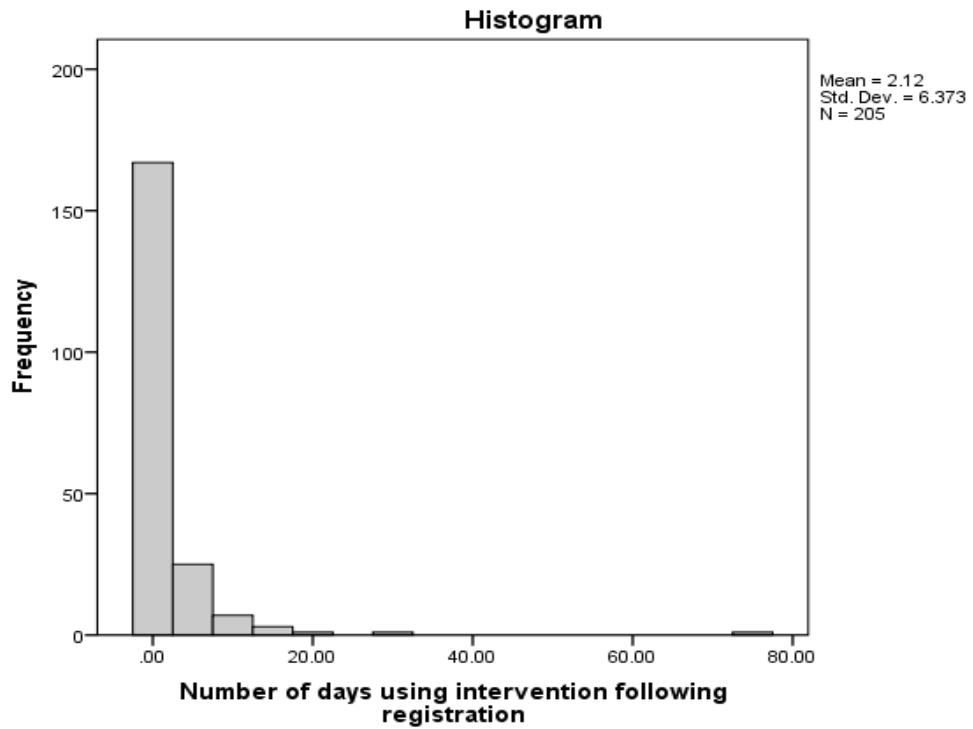
	attended any diabetes self-management or education groups or classes (e.g. DESMOND)?:	<ul style="list-style-type: none"> No 		who were from Camden
Internet access and experience	Internet access	<ul style="list-style-type: none"> Single item, select one out of two options: Home Public 	M	01.03.2013
	Use of computer	<ul style="list-style-type: none"> Single item, select one out of three options: Basic Intermediate Advanced 	M	01.03.2013

Appendix J Recoding of patient characteristic variables

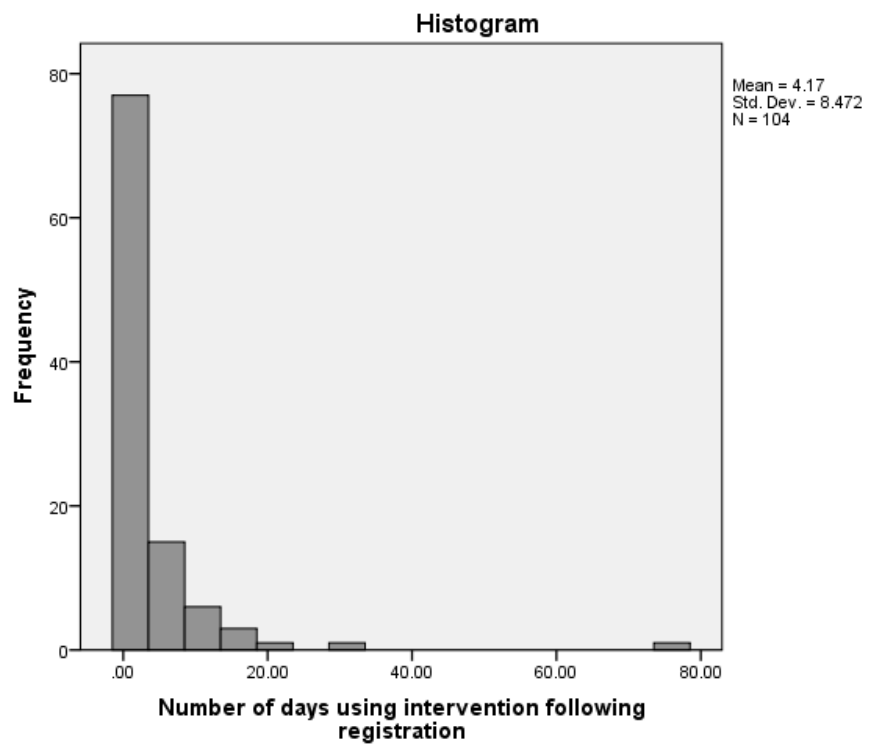
Variable	Original classification	Recoded to
Ethnic Group	White - English/Welsh/Scottish/Northern Irish/British	White British
	White - Irish	Non White British
	White - Other	
	Black or Black British - African	
	Black or Black British - Caribbean	
	Black or Black British - Other	
	Asian or Asian British - Bangladeshi	
	Asian or Asian British - Chinese	
	Asian or Asian British - Indian	
	Asian or Asian British - Other	
	Asian or Asian British - Pakistani	
	Mixed - White and Asian	
	Mixed - White and Black African	
	Mixed - Other	
	Other ethnic group - Arab	
Other ethnic group - Other		
Prefer not to say		
Duration of diabetes	<1 year	<1 year
	1-5 years	1-5 years
	5-10 years	5-10 years
	10-20 years	>10 years
	>20 years	
How diabetes is managed	Lifestyle alone (i.e. diet and physical activity)	Lifestyle alone (i.e. diet and physical activity)
	Lifestyle and tablets	Lifestyle and tablets
	Lifestyle tablets and insulin	Lifestyle, tablets and injectables
	Other injectables	
Education	None	None/school leaver
	School leaver	
	A-levels	A-levels or higher
	Degree	
	Post-graduate	

Appendix K Histograms representing distribution of intervention use

Histogram representing the distribution of the number of days patients used the intervention following registration (n=205)



Histogram representing the distribution of the number of days patients used the intervention following registration, excluding patients who didn't use it again (n=104)



Study Title: Evaluating the implementation of HeLP-Diabetes within the NHS

Thank you very much for expressing an interest in participating in our study. To ensure we collect opinions from a range of people about this topic and to help us make sense of the results we need to know a little bit about your background and experience. When reporting our results we will ensure you are not identifiable. If you are happy to take part in our study please complete this questionnaire.

For internal use only:	
Study ID: 13/EM/033	
Participant ID:	

Name:	
Guidance on preferences: how to contact you	
Address:	Telephone:
Email:	

How old are you?			
18-24	<input type="checkbox"/>	25-34	<input type="checkbox"/>
35-44	<input type="checkbox"/>	45-54	<input type="checkbox"/>
55-64	<input type="checkbox"/>	65-74	<input type="checkbox"/>
75+	<input type="checkbox"/>		
Are you male or female? Please tick relevant box:			
	Male	<input type="checkbox"/>	Female <input type="checkbox"/>

What is your role in looking after patients with type 2 diabetes? Please tick the box that best describes your role

GP Partner	<input type="checkbox"/>	Salaried GP	<input type="checkbox"/>
Diabetes Specialist Nurse	<input type="checkbox"/>	Practice Nurse	<input type="checkbox"/>
Diabetes Specialist Dietician	<input type="checkbox"/>	Management	<input type="checkbox"/>
Hospital Doctor	<input type="checkbox"/>	Commissioner	<input type="checkbox"/>
HCA	<input type="checkbox"/>	Receptionist/Admin	<input type="checkbox"/>
Other (please give details)			

How long have you been in your current role?

Years	<input type="checkbox"/>	Months	<input type="checkbox"/>
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What is your ethnic background?

Please tick 1 box or complete 1 section which best describes your ethnic background

White	British <input type="checkbox"/>	Black or Black British	Caribbean <input type="checkbox"/>
	Irish <input type="checkbox"/>		African <input type="checkbox"/>
Other white background (please write in)		Other Black background (please write in)	
Asian or Asian British	Indian <input type="checkbox"/>	Mixed Race	White and Black Caribbean <input type="checkbox"/>
	Pakistani <input type="checkbox"/>		White and Black African <input type="checkbox"/>
	Bangladeshi <input type="checkbox"/>		White and Asian <input type="checkbox"/>
Other Asian background (please write in)		Other Mixed race background (please write in)	

Other ethnic background Chinese <input type="checkbox"/>	Other ethnic background (please write in)	
How much experience do you have of using the Internet?		
Please tick 1 box which best describes your level of experience.		
Novice (e.g. never used the Internet before)	<input type="checkbox"/>	Basic (e.g. used the Internet a few times but not often) <input type="checkbox"/>
Experienced (e.g. used or currently use the Internet regularly)	<input type="checkbox"/>	Expert (e.g. work is to do with the Internet) <input type="checkbox"/>
Is there a computer linked to the Internet that you can use when you see patients?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Have you ever attended a diabetes education programme?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Have you ever used HeLP-Diabetes with a patient?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Have you ever used any computer programme to help manage patients with type 2 diabetes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

What is the current list size at your practice/ clinic? (if applicable)
How many of these patients have type 2 diabetes?

Appendix M Staff interview Topic Guide

1. Can you explain your job role to me?
2. Can you explain a little about the nature of this practice in particular?
 - number of doctors
 - healthcare professional
 - patients
 - How does it compare to other practices you've worked in?
3. What is the usual care pathway for someone with diabetes from diagnosis?
4. What are the biggest challenges for the practice in relation to diabetes?
5. What are your views on the role of the patient in taking care of their diabetes?
6. What is your role in supporting self-management?
 - a. How do you support it?
7. What services does the practice offer to patients with diabetes?
 - Does the practice refer patients to DESMOND etc. or any other structured education?
8. How do you decide upon new services to take on or endorse?
 - Who decides?
 - How are those decisions reached?
9. Initially you expressed an interest in HeLP-Diabetes, what was it that got you interested?
10. What value, if any do you think HeLP-Diabetes has in diabetes care in general?
 - a. How does it compare to other diabetes resources?
11. What did you think of HeLP-Diabetes after I came to demonstrate it?
 - a. How was that meeting received by the other healthcare professional?
 - b. Was there resistance from anyone? If so why?
12. How did you envisage HeLP-Diabetes being used in the practice/with patients?
13. Can you describe how you've introduced and used HeLP-Diabetes in the practice?
 - a. Who has done the work? How was this allocated? Are they supported?

14. How would you describe the success of HeLP-Diabetes in the practice?
15. What do you think the main barriers or facilitators are?
 - a. In what way, if any, has buy in from healthcare professional impacted on the implementation?
 - b. In what way, if any, have resources impacted on the implementation?
 - c. In what way, if any, have people's understanding of the value/utility of HeLP-Diabetes impacted on the implementation?
 - d. In what way, if any, has support from colleagues/ management impacted on the implementation?
16. How do you think we could make HeLP-Diabetes more workable in a practice like this one?
17. What do you think the role of technology like HeLP-Diabetes is within General Practice?

Appendix N Patient Interview Topic Guide

Diabetes and impact

1. How long have you had diabetes for?
2. How did you find out that you have diabetes?
3. How did you feel getting the diagnosis?
4. Can you explain what diabetes is?
5. What does having diabetes mean to you?
6. How do you feel about having diabetes now?
7. How serious would you say diabetes is for you?
8. How do you think others perceive your diabetes?
9. Do you talk to your friends and family about it?
 - a. Is it easy or difficult for you to talk to others about it?

10. Do you know anyone else with diabetes?
11. Where do you get support from for diabetes?
12. How do you manage your diabetes?
 - a. *How easy or difficult do you find it to manage your diabetes?*
 - b. *Any specific areas you feel you need help with?*
 - c. *How does diabetes affect your life?*
 - d. *What aspect of diabetes care is most important for you?*
 - e. *Are there any aspects of your diabetes that concern you?*

13. What is your role in looking after your diabetes?
14. Have you made any lifestyle changes in order to manage your diabetes?
 - a. *What changes have you made?*

15. Do you feel you know enough about diabetes?

Role of NHS

16. What is the role of the NHS in looking after your diabetes?
17. How often do you attend your GP?
 18. *How well does your GP/nurse support you with your diabetes?*
19. Have you attended any diabetes education or support groups? If not why not?
 - a. *What did you think of these?*
 - b. *Did they help you with managing your diabetes?*
 - c. *Would you want a refresher course or ongoing support or education?*
 - d. *Where do you get advice about managing your diabetes? e.g. internet, family, friends, peers, healthcare professionals*

HeLP-Diabetes

20. Can you explain what you think HeLP-Diabetes is?
21. How did you first hear about the HeLP-Diabetes website?
 - a. *Who introduced it to you?*
 - b. *How was it described to you?*
 - c. *How were you set up with a username and password?*
 - d. *Were you shown the website at the time of registration?*
 - e. *How did you find this process? What would make it better?*
22. Why did you decide to sign up to HeLP-Diabetes?
 - a. *Anything in particular that sounded interesting to you?*
 - b. *How important was the recommendation from your GP practice?*
23. Was there anything that made you unsure about using it?
 - a. *Did you feel confident that you could go home and use it on your own?*
24. Have you used HeLP-Diabetes since being registered?
 - a. *What for/ why not?*
 - b. *How often?*
 - c. *Where do you use it?*
 - d. *Have you had any help in using it?*
 - e. *Is there anything we can do that would help you use it more?*
 - f. *Has the way you use it changed over time (content looked at/ frequency of use/ style of use-booklet vs browsing)*
25. What are your impressions of HeLP-Diabetes?
 - a. *Any features you particularly like or dislike?*
 - b. *Which sections do you visit most?*
 - c. *Anything missing that you would like to see on it?*
 - d. *Have you experienced any difficulties in using the website?*
 - e. *What could we do to improve it?*
26. *Do you feel you have learned anything from using HeLP-Diabetes?*
27. Has using HeLP-Diabetes helped you with any specific aspect of looking after your diabetes?
 - a. *Which?*
 - b. *How has it helped?*
 - c. *Have you changed any behaviours?*
 - d. *What aspects have not been supported?*

28. We are interested in improving the way that HeLP-Diabetes is advertised and made available to people with diabetes through GP practices, do you have any suggestions for ways we can do this?

- a. *Were you given enough information about HeLP-Diabetes by your practice?*
- b. *Do you read any diabetes related websites/magazines? Do you attend any other healthcare services for your diabetes care? Would any of those services be good opportunities to introduce HeLP-Diabetes?*
- c. *Have you used/mentioned the website in appointments since being registered and if yes for what/how did it go etc.*

29. Have you received the fortnightly emails and newsletters for HeLP-Diabetes?

- a. *What do you think of them?*
- b. *Have they encouraged you to visit the website? Why/why not?*
- c. *Could they be improved?*
- d. *Other options – Telephone calls, personal emails?*

Information seeking and e-health

30. What do you think about the use of a website to help people manage their diabetes?

- a. *Positives/ negatives*
- b. *How does this compare to other diabetes support/education you've experienced?*
- c. *Would you use an app or a smartphone? If so which parts of the website would you use on the go?*

31. Where do you seek information from about your diabetes?

- a. *Role of the internet*

32. Do you have any final thoughts or comments on how we could improve HeLP-Diabetes and the way that it is offered to patients?

33. Is there anything else you would like to add?

How to sign up

1. Type the below address in your web browser:
www.help-diabetes.org.uk/signup
2. Enter your unique 'access code' which is located inside this leaflet
3. Create a username and password. (**Tip:** make a note of these)
4. Complete the questions about you and your diabetes. (**Tip:** type The Northern Medical Centre as the answer to 'GP Practice or Clinic Name')
5. Click the 'Register' button. You'll be taken to the 'Registration complete!' page.
6. You can now log in at the top right of the screen using the username and password you've just created.
7. You can now use HeLP-Diabetes whenever you like by visiting:
www.help-diabetes.org.uk

Useful information

Can anyone use HeLP-Diabetes™?

No. HeLP-Diabetes™ is not openly available to everyone at the moment. It is a new service that is only available to selected GP practices, diabetes clinics and patients. To use HeLP-Diabetes™ you must register using this leaflet.

I don't have a home internet access, can I still use HeLP-Diabetes™?

Yes, HeLP-Diabetes™ can be accessed from any computer with an internet connection. You can ask your health professional or the HeLP-Diabetes™ team for information about local places where you can connect to the internet.

Having trouble registering or using HeLP-Diabetes?

You can contact the HeLP-Diabetes™ team for any problems with using the website.

Contact details:

Tel: 020 7794 0500 (Ext: 37073)
Email: help-diabetes@ucl.ac.uk



The screenshot shows the HeLP-Diabetes website interface. At the top, there is a navigation bar with tabs for 'Understanding diabetes', 'Having healthy diabetes', 'Treating diabetes', 'Living & working with diabetes', 'Managing my feelings', 'My health record', 'News & research', and 'Forum & help'. Below this, there is a 'Diabetes self management programme' section with a video player titled 'Explaining Type 2 Diabetes'. A grid of topic links is visible, including 'Understanding diabetes', 'Having healthy diabetes', 'Treating diabetes', 'Living & working with diabetes', 'Managing my feelings', 'My health record', 'News & research', and 'Forum & help'. The website is branded with the UCL logo and the NHS logo.

What is HeLP-Diabetes™?

HeLP-Diabetes™ is a self-management website for people with type 2 diabetes that provides advice, support, information and tools to help you manage your diabetes.

Self-management is the most important part of diabetes care and can help people lead a healthy, happy life with diabetes whilst reducing the risk of other health problems. HeLP-Diabetes™ supports your self-management.

How was the HeLP-Diabetes™ website developed?

HeLP-Diabetes™ was developed at University College London by a team of GPs, psychologists, researchers, diabetes nurses, consultants, dieticians and most importantly people with type 2 diabetes.

What do I need to use HeLP-Diabetes™?

To use HeLP-Diabetes™ you will need an email address.

HeLP-Diabetes™ can help you with...

- What is type 2 diabetes?
- What is self-management?
- What happens if I don't control my diabetes?

Understanding Diabetes



- Increase your physical activity
- Taking medication
- Eating healthily
- Alcohol
- Smoking cessation

Staying Healthy



- How is type 2 diabetes treated?
- How is type 2 diabetes monitored?
- Information about medication
- Starting on insulin

Treating Diabetes



- Food
- Relationships
- Work
- Social Life
- Travel
- Driving
- Financial support

Living with diabetes



- Online CBT
- Access to diabetes specific Living life to the Full courses
- Advice about emotional well being and adjusting to life with diabetes

Emotional support



- An online diabetes care planning tool based on the Diabetes Year of Care
- Keep track of results
- Reminders and diary functions

Self-monitoring



- Moderated peer-to-peer forum
- Personal stories from the award winning Health Talk online website

Forum and Videos



- Updates on breaking news, new research findings and NICE guidelines
- Regular newsletter and email updates for users

The latest news and research



Here is your unique access code which you will need to sign up to HeLP-Diabetes™.

Instructions on how to sign up are on the back of this leaflet.

Your unique access code:

«code»

Appendix P Characteristics of practices/clinics who adopted HeLP-Diabetes

ID	List size	No. of people on diabetes register	QOF score (max=107)	No. of healthcare professional	% referred to diabetes structured education (QOF data)	Estimated number of patients with type 2	Months between adoption decision and study end	No. registered to intervention	% of eligible
A	11955	568	81.7	32	81.5	511.2	21	40	7.8
B	9814	386	101.8	24	75.0	347.4	20	40	11.5
C	6928	263	105.7	18	90.0	236.7	25	28	11.8
D	10027	427	107.0	27	87.0	384.3	20	15	3.9
E	5727	271	95.0	14	94.1	243.9	21	11	4.5
F	11945	521	94.5	26	85.2	468.9	21	11	2.4
G	3985	295	81.2	10	66.7	265.5	22	8	3.0
H	15273	356	107.0	36.5	81.3	320.4	13	7	2.2
I	12963	397	106.5	39	93.8	357.3	20	3	0.8
J	8472	243	103.4	19	75.0	218.7	23	3	1.4
K	5387	272	95.3	15	83.3	244.8	9	2	0.8
L	5448	284	94.5	21	93.8	255.6	24	1	0.4
M	6846	263	93.7	21.5	81.3	236.7	20	1	0.4
N	5565	257	103.9	9	57.1	231.3	20	1	0.4
O	3075	154	107.0	13	100.0	138.6	18	1	0.7
P	2472	135	92.6	10	100.0	121.5	14	1	0.8
Q	9939	299	105.1	22	94.4	269.1	21	1	0.4

R	6184	293	106.1	14	100.0	263.7	16	1	0.4
S*	1,849	83	102.42	7	75.00	74.7	7	0	0.0
T*	7,729	311	105.42	16	93.33	279.9	14	0	0.0
U*	6,846	263	93.72	18	81.25	236.7	24	0	0.0
V*	2,871	146	105.41	11.5	100.00	131.4	25	0	0.0
Hospital						882	18	29	3.3
Community						983	3	1	0.1

*Practices who adopted but did not use HeLP-Diabetes

Appendix Q Summary of implementation at each site

ID	No. patients registered to intervention (number registered by healthcare professional)	Implementation of registration methods	What introduction/training did the practice receive for HeLP-Diabetes?	Which healthcare professional were involved in the implementation	How was HeLP-Diabetes incorporated into practice?	Any identified facilitators to implementation	Any identified barriers to implementation
A	40 (39)	Adoption was agreed using the staff registration method. When the patient registration method was created leaflets were provided to the practice to use, but registrations remained mostly healthcare professional led.	Initial practice meeting with whole clinical team and practice manager. Training of two healthcare assistants who had been nominated to deliver HeLP-Diabetes. Initially I registered some of the patients in this practice until healthcare professional felt confident to take	Two healthcare assistants supported by practice manager	It became part of the diabetic clinics held by the two HCA's. Patients were asked if they were interested and then either registered on the spot or their details were noted and they were registered by one of the HCA's over the	Healthcare professional training. Strong sense of buy-in from the two HCA's who saw value in HeLP-Diabetes. Positive feedback they received from patients using it. Support from me	Time constraints within appointments Forgetting to offer HeLP-Diabetes to patients No real support or push for HeLP-Diabetes among other healthcare professional

over.

phone at a later
time.

in delivering it
early on.

The HCA used
HeLP-Diabetes
during
consultations as
a tool to explain
things to
patients.

Dedicated
diabetes clinics
where a number
of patients with
diabetes would
attend
appointments in
the same morning
or afternoon and
therefore HeLP-
Diabetes wasn't
as easily
forgotten.

Ongoing
communication
with me and
practice
healthcare
professional

HCA's thought
HeLP-Diabetes
was useful for

						their work in giving them more information about diabetes	
B	40 (38)	Adoption was agreed using the staff registration method. When the patient registration method was created leaflets were provided to the practice to use, but registrations remained mostly healthcare professional led.	Meeting and training with lead GP for diabetes, two practice nurses and HCA. Additional training provided to new HCA at a later date.	GPs, nurses and HCA.	Clinical healthcare professional would recommender the use of HeLP-Diabetes to patients and directly following their appointments would be sent to the HCA to be signed up. In cases where this wasn't possible, their details were taken and the HCA would phone up and register them at a later time.	Strong support and push for intervention by GP at practice Enthusiasm of HCA who enjoyed taking on this new role. Financial incentives (service support costs) GP asked for additional content to be added to HeLP-Diabetes for specific patients	Competing pressures for healthcare professional No buy in to intervention from one nurse Relied on GPs and nurses to remember to refer patients during consultations Numbers of patient registration dropped when the first HCA left the practice. A replacement wasn't appointed for a long time

							afterwards.
C	28 (28)	Adoption was agreed using the staff registration method. When the patient registration method was created leaflets were provided to the practice to use, but registrations remained healthcare professional led.	Initial practice meeting with whole clinical team and practice manager. Training of two practice nurses who had been nominated to deliver HeLP-Diabetes. Initially I registered some of the patients in this practice until healthcare professional felt confident to take over.	Two practice nurses and HCA	Initially I came to the practice on a weekly basis and registered patients who were sent to me by the practice nurses following their appointments during a regular diabetes clinic. When the nurses and HCA felt confident in registering patients themselves, they did the registrations as part of their routine appointments with patients.	Healthcare professional training. Strong sense of buy-in from the two HCA's who saw value in HeLP-Diabetes. Positive feedback they received from patients using it. Support from me in delivering it early on. Dedicated diabetes clinics where a number of patients with diabetes would attend appointments in the same morning	Not implemented within the wider practice and remained a nurse/HCA role only. HCA used intervention as a tool during consultations but often forgot to register patients. Saw it more as a resource for healthcare professional.

					The HCA used HeLP-Diabetes during consultations as a tool to explain things to patients.	or afternoon and therefore HeLP-Diabetes wasn't as easily forgotten. Ongoing communication with me and practice healthcare professional Financial incentives (service support costs) HCA used intervention as a tool to help her with appointments	
D	15 (13)	Adoption was agreed using the staff registration method. When the patient	Initial meeting with one GP who then informed other healthcare professional of intervention.	GP and reception healthcare professional	Paper copies of the online registration form were created and posted out to all patients	GP had a strong interest in diabetes and self-management and saw value in HeLP-Diabetes	Only the GP took ownership of HeLP-Diabetes and did not communicate about it with other

		<p>registration method was created leaflets were provided to the practice to use, these replaced the previous implementation method.</p>			<p>with type 2 diabetes on the register. Patients would return these and then, at a convenient time, reception healthcare professional would register patients on HeLP-Diabetes.</p> <p>Patient registration method leaflets handed out during appointments along with other diabetes related information.</p>		<p>healthcare professionals</p> <p>Time to register patients.</p> <p>Forgetting to mention HeLP-Diabetes to patients.</p>
E	11 (8)	Adoption was agreed using the staff registration method. When the patient registration	Initial meeting with two GPs and then training with the receptionist on registering patients	GPs and receptionist	Patients would be informed about HeLP-Diabetes by healthcare	New and enthusiastic GPs with an interest in diabetes, self-management and	Concerns HeLP-Diabetes was only available for duration of research study

		method was created leaflets were provided to the practice to use, but registrations remained healthcare professional led.			professionals and then registered at reception by the receptionist. The practice held a patient self-management evening where several patients were informed about HeLP-Diabetes and registered to use it.	patient empowerment Strong buy-in to HeLP-Diabetes by healthcare professional Demonstration of HeLP-Diabetes	Large healthcare professional turnover
F	11 (4)	Adoption was agreed using the staff registration method. When the patient registration method was created leaflets were provided to the practice to use which proved	Initial clinical meeting attended by GPs and practice managers. Subsequent training with 3 practice nurses, 3 HCAs and receptionists	Practices nurses, HCA and receptionist	Originally the receptionist took the lead on registering patients who were referred to him via the nurses and some GPs.	Training session especially the demonstration of HeLP-Diabetes Receptionist who was keen to undertake the role of registering patients	Following the initial meeting with staff the adoption of HeLP-Diabetes had not been well communicated by GPs to the nurses/HCAs, who were unaware at the training session

more successful than the staff registration method.

A practice nurse incorporated a reminder to the diabetes template within the practice to recommend HeLP-Diabetes.

The intervention discussed with patients during appointments with the practice nurses and HCA.

Once the patient registration leaflet was created these became the main strategy for offering HeLP-Diabetes to patients. Leaflets were handed out to patients by

Strong understanding of value of intervention from practice nurses
Big nurse/NCA team who worked closely together

Intervention kept at forefront of mind during diabetes appointments because of the reminder on the practice template

Feedback from patients about using it

that this was something they were expected to take on
GPs within the practice not involved in implementation, referrals for registration did not come from appointments with GPs
Receptionist left during implementation period

					the practice nurses and the HCA and any patients who require assistance in registering were helped by the receptionist.		
G	8 (0)	Initially, adoption was declined because the practice perceived there to be inadequate resources to deliver the staff registration method. This practice became the catalyst for the patient registration method and was the first practice to use the patient registration leaflets.	Initial practice meeting with one GP with training on registering at the same time	One GP	At the practice meeting the GP said that it would not be possible to implement HeLP-Diabetes within this practice as they had no healthcare professional or resources to do the registering. This was the catalyst for developing the patient registration	Keen GP with interest in technology and self-management Demonstration of HeLP-Diabetes patient registration method leaflets	Very small practice with limited resources No communication to other healthcare professional in the practice about HeLP-Diabetes

					method which was tested at this practice.		
					The GP would hand out leaflets to every patient following a diabetes related appointment		
H	7 (0)	This practice was introduced to HeLP-Diabetes when both models were up and running. They selected to use the patient registration method only.	Clinical meeting attended with demonstration of HeLP-Diabetes. No training as they opted to use patient registration method only.	Leaflets given to all healthcare professional to give to patients	Leaflets given to patients during appointments	All healthcare professional present at clinical meeting so all knew about HeLP-Diabetes	Difficult to establish contact with the practice about HeLP-Diabetes following the initial meeting.
I	3 (2)	Adoption was agreed using the staff registration method. When the patient registration method was created leaflets	Initial meeting with GP and two practices nurses with demonstration of HeLP-Diabetes. Subsequent training on	One practice nurse	Initially the practice nurses tried to register patients to use HeLP-Diabetes during routine appointments	Strong interest and belief in the value of HeLP-Diabetes by the practice nurse Two training	Large healthcare professional turnover with the practice nurse having to absorb workload of other nurse who left

		were provided to the practice to use. A combination of models were adopted.	registering and using HeLP-Diabetes with patients		but found it too difficult technically and too time consuming. They replaced the healthcare professional led model with the patient registration method when it was available	sessions provided Ongoing communication and support for the nurse	Competing pressures Competing services to offer to patients
						The practice nurse requested additional content be added to HeLP-Diabetes for a particular area of diabetes care she had no additional resources for, this was created.	Tasks associated with the research study overwhelmed healthcare professional Only the practice nurse involved in delivering intervenient with no other healthcare professional involved
J	3 (3)	Adoption was agreed using the staff registration method. When the patient registration method was created leaflets	Initial practice meeting with all partners Subsequent training with two practices nurses and HCA	Practice nurse	Intervention mentioned to patients during routine appointments and practice nurse signed	One practice nurse saw real value and need for intervention	Tasks associated with the research study overwhelmed healthcare professional Time needed to

		<p>were provided to the practice to use, but no patients registered in this way.</p>			<p>patients up to intervention</p>		<p>register patients</p> <p>Practice nurse not confident in registration procedure</p> <p>Practice nurse went on sabbatical for 12 months</p> <p>Intervention wasn't well communicated to other healthcare professional</p> <p>Other practice nurse wasn't engaged and did not see it as part of her role</p>
K	2 (0)	<p>This practice was introduced to HeLP-Diabetes when both models were up and</p>	<p>Initial meeting with all partners</p> <p>Training with practice nurse and HCA</p>	<p>Practice Nurse and HCA</p>	<p>patient registration method leaflets were given to the practice nurse</p>	<p>Partners and practice manager seemed very keen on intervention</p>	<p>Practice nurse and HCA did not see value in HeLP-Diabetes, did not think it would be</p>

		running. They selected to use the patient registration method only.			and HCA to give out to patients		suitable for any of their patients Even though senior healthcare professionals were engaged they did not encourage the practice nurse or HCA with implementing it
L	1 (1)	Adoption was agreed using the staff registration method. When the patient registration method was created leaflets were offered to the practice but they did not take up this offer.	Initial meeting with the practice manager to discuss HeLP-Diabetes. Training session with practice nurse and receptionist. I attended a patient evening to demonstrate HeLP-Diabetes to healthcare professional and patients but the practice did not have the screens set up properly and so the	Practice nurse and receptionist	It wasn't	Practice nurse saw value in	Practice manager wasn't engaged and did not respond to any further communication about HeLP-Diabetes GP said the practice was under too much pressure with additional changes they were implementing to take on anything

			demonstration did not work.				else
M	1 (0)	Adoption was agreed using the staff registration method. When the patient registration method was created leaflets were provided to the practice to use. In addition to this, the peer-led implementation model (described in Chapter 7) was offered to this practice but they declined.	Initial meeting with GPs at practice Training session with HCAs and reception healthcare professional	Reception healthcare professional	Initially the staff registration method was demonstrated to healthcare professional but this proved unsuccessful. Practice offered peer led registration method but declined. Patient registration method leaflets sent to practice but not used.	All healthcare professional appeared very interested in HeLP-Diabetes initially and could see value in it. GP lead for diabetes in the borough	Competing priorities No clear person to take responsibility for the implementation Those who agreed to adoption were not the same people as were expected to implement it. Time to register patients to use intervention Practice manager point of contact and no contact with healthcare professional who would be

							responsible for implementation
							Contact not maintained with practice healthcare professional
N	1 (1)	Adoption was agreed using the staff registration method. When the patient registration method was created leaflets were offered to the practice but they did not take up this offer.	Meeting and training with two GPs, Practice nurse, HCA and receptionist	Whole team	Whole team agreed to offer to patients during routine appointments and the HCA and receptionist would take responsibility for patient registrations	All healthcare professional very keen and saw value in HeLP-Diabetes	Practice had some very serious problems with their estate and closed down temporarily.
O	1 (0)	Adoption was agreed using the staff registration method. When the patient registration method was created leaflets	Meeting and training with GP, practice nurse, practice manager, assistant practice manager and receptionist	All healthcare professional	Originally it was planned that healthcare professional would mention intervention to patients and		Healthcare professional were not engaged with intervention, did not see the value in it

		<p>were provided to the practice to use, but no patients registered in this way.</p>			<p>assistant practice manager would register them. However this proved unsuccessful.</p> <p>patient registration method leaflets provided, but these were not given out by healthcare professional, instead they were left at reception for patients to take if interested.</p>		<p>GP was vocal in practice meeting that HeLP-Diabetes would not be suitable for their patients based on IT skills and age</p> <p>Healthcare professional did not recommend HeLP-Diabetes to patients</p> <p>Contact with practice was very difficult to establish and maintain</p>
P	1 (0)	<p>Adoption was agreed using the staff registration method but no patients registered in this way. When</p>	<p>Meeting and demonstration of intervention to practice manager, GP and practice nurse.</p>	Practice nurse	<p>List of all the diabetes patients created by the practice nurse and given to the receptionist so</p>	<p>Practice nurse and GP very interested in HeLP-Diabetes</p> <p>Practice nurse</p>	<p>Practice nurse did not think many patients would have computer/English language skills to</p>

		the patient registration method was created leaflets were provided to the practice to use.			that when they come in they can be asked whether they use the internet and would be interested in HeLP-Diabetes.	took ownership of intervention	use it
					Practice nurse mentioned intervention during routine diabetes appointments.		Practice nurse thought intervention was better aimed as an educational tool for healthcare professional
					Patient registration method leaflets given to interested patients.		Tensions between healthcare professional within the practice GP left during implementation period
Q	1 (1)	Adoption was agreed using the staff registration	Practice meeting with 5 GPs and 1 trainee doctor.	Receptionist	Receptionist was taking on additional HCA	Receptionist thought the registration	Adoption decision was made healthcare
							Practice nurse forgetting to mention intervention to patients

method. When the patient registration method was created leaflets were provided to the practice.

Subsequent training with receptionist on delivering HeLP-Diabetes.

duties and it was planned that she would sign newly diagnosed patients up to intervention.

process was simple and not time consuming

professional who did not take responsibility for implementation Receptionist did not see value in HeLP-Diabetes, wasn't sure why someone would use it

Receptionist thought intervention wasn't appropriate for the age of the patients she saw

Only one member of healthcare professional responsible for offering it to patients

No senior healthcare

							professional support
R	1 (0)	Adoption was agreed using the patient registration method.	Meeting attended with practice manager and all GPs	Unsure	Unsure	Unsure	Practice was going through a period of instability with healthcare professional turnover and difficulty in recruiting GPs. Unable to establish contact with the practice following the initial meeting.
Hospital	29 (3)	Adoption was agreed using the staff registration method. However, very few patients were signed up this way. When the patient registration method was created leaflets were provided to	Lead diabetes specialist nurse invited me to give a talk to all hospital healthcare professional before the implementation phase and explain HeLP-Diabetes. A meeting with all the diabetes specialist nurses followed which	Consultant. Diabetes specialist nurses. I also came to the clinic on several occasions to register patients in the waiting rooms.	Healthcare professional discussed HeLP-Diabetes with patients in appointments and gave leaflets out. The intervention was also used by one of the	Strong support and buy-in of HeLP-Diabetes by all healthcare professional Mail out of patient registration method leaflets My assisting patient registration	Very old computers and very slow internet connection made the staff registration method nearly impossible Competing demands within appointments

		the practice.	included training on registering patients.		nurse in their teaching course for HCAs in the borough on supporting patient self-management.	by canvassing the waiting rooms on several occasions	
					After the staff registration method proved problematic a mass mail out to all eligible patients was posted out with patient registration method leaflets which were accompanied by a letter from the consultant.	Ongoing communication with healthcare professional patient registration method leaflets	
Community	1 (0)	Adoption was agreed using the patient registration method.	Initial meeting and demonstration with Operational Lead for Intermediate Diabetes	HCA and community dietician.	Initially the HCA was to discuss HeLP-Diabetes with patients and	Strong support for HeLP-Diabetes by the Operational Lead for	The Operational Lead for Intermediate Diabetes Service

<p>Service, 2 diabetes specialist nurse and HCA.</p>	<p>assist them with registering if needed.</p>	<p>Intermediate Diabetes Service and the dieticians</p>	<p>left position shortly after implementation</p>
<p>After a change of healthcare professional a second meeting and demonstration was held with the community dieticians.</p>	<p>The patient registration method leaflets were given out at the end of the DESMOND course ran by the dietician (this strategy began to work well but did not fall within the time frame of the implementation study and therefore these patient registrations are not counted here).</p>	<p>Large healthcare professional turnover and reliance on agency healthcare professional Competing pressures Implementation was the responsibility of a part time HCA with no support from other healthcare professional</p>	