University of Southampton

Faculty of Medicine

Human Development and Health

The role of community pharmacy in supporting people with diabetes who have a history of repeated non-attendance at healthcare appointments

by

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Abstract

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Diabetes Mellitus is a chronic disease affecting an increasing population of people worldwide. The impact diabetes has on individuals, healthcare systems and economies is not insignificant and there is a wealth of literature demonstrating that if not managed optimally, the condition is associated with significant increased morbidity and premature mortality.

Diabetes management revolves around a number of self-care practices including, but not limited to, life-style changes (eg dietary changes and increasing activity levels), monitoring of blood glucose, taking medications and attendance at retinal eye screening. Regular attendance at diabetes healthcare appointments, such as the annual diabetes review, facilitates the optimisation of diabetes related parameters (eg. glycaemic exposure, blood pressure, cholesterol levels, renal function, weight) and serves as an opportunity to support and empower those living with diabetes. Repeated non-attendance at these healthcare appointments is associated with worse outcomes for an individual and can be deemed as a waste of increasingly stretched health resources.

The aim of this thesis was to explore the role of a hypothetical "community pharmacy diabetes support service (CPDSS)" in supporting those with diabetes who have a history of repeated non-attendance at diabetes healthcare appointments and sub-optimal glycaemic control. It was proposed that community pharmacy may be able to offer an alternative healthcare approach to those identified as being most susceptible to the deleterious effects of diabetes. Primary data collection included a systematic review exploring non-attendance at diabetes healthcare appointments and a literature review on community pharmacy and the role they have had in diabetes care to date. This was followed by two qualitative studies. The fist explored the views and opinions of healthcare professionals, including pharmacists and those involved in the care of those with diabetes towards a hypothetical CPDSS. The second study explored the views of individuals with diabetes for whom the CPDSS would be endeavouring to support.

There were a number of findings in this thesis. Non-attendance at diabetes healthcare appointments was found to typically stem from factors relating to three themes: patient-healthcare professional relationship factors, service-related factors and logistical barriers. Community pharmacy interventions to date have shown promise and community pharmacy have an appetite to offer more to those with diabetes. Furthermore, policy is moving in favour of

community pharmacy offering more clinical services. Nonetheless, significant barriers include being under-funded, the underappreciation of pharmacists' skill-set, both by the public and other healthcare professionals, and their limited digital integration with other healthcare services.

Based on the findings from this thesis, although there is a hypothetical place for community pharmacy in supporting those with diabetes identified as 'hardly reached,' at present their role and function may not be best suited to a hypothetical CPDSS intervention until some of the aforementioned barriers have been addressed. Nonetheless, with the changing landscape of the National Health Service and the introduction of Integrated Care Systems, it is likely only a matter of time before some of these limitations are overcome.

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Research Thesis: Declaration of Authorship

Print name:	Sarah Christine Ward Brewster

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I declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

I confirm that:

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Definitions and Abbreviations

ACE-I	Angiotensin Converting Enzyme Inhibitor
ACR	Albumin:Creatinine Ratio
BP	Blood Pressure
CARDS	Collaborative Atorvastatin Diabetes Study
CPDSS	Community Pharmacy Diabetes Support Service
DCCT	Diabetes Control and Complications Trial
DiRECT	Diabetes Remission Clinical Trial
EDIC	Epidemiology of Diabetes Interventions and Complications
eGFR	Estimated Glomerular Filtration Rate
GP	General Practitioner
GPhC	General Pharmaceutical Council
HbA_{1c}	Glycated Haemoglobin
HCP	Healthcare Professional
HOPE	Heart Outcomes Prevention Evaluation
HOT	Hypertension Optimal Treatment
LDL	Low Density Lipid
MRC	Medical Research Council
NDA	National Diabetes Audit
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NIHR	National Institute for Health and Care Research
PAM	Patient Activation Measure
PBA	Person Based Approach

Definitions and Abbreviations

PCNs	Primary Care Networks
PDF	Portable Document Format
QoF	Quality Outcome Framework
RPS	Royal Pharmaceutical Society
IDF	International Diabetes Federation
MeSH	Medical Subject Headings
MRC	Medical Research Council
WHO	World Health Organisation
UK	United Kingdom
UKPDS	UK Prospective Diabetes Study

Reflection- The impact of the COVID-19 pandemic

In March 2020, part way through my PhD, the country went into a national lockdown as a result of the COVID-19 pandemic. I was at the start of my primary data collection and the uncertainty of everything at the time was disconcerting. Globally there was a lot of panic alongside unanswered questions. Only with time has COVID-19 become more familiar and something we have adapted to live with.

In light of the increased pressure on healthcare services, in March 2020 I put my PhD on hold and returned to clinical duties for nine months. I used this time to reflect on my PhD project and considered how I would continue with my planned qualitative work. It was frustrating that courses and teaching sessions I had signed up to had to be cancelled, but having had already attended courses that I felt were the fundamental, these would have been nice extras to have supplemented my learning. With time, increasing numbers of resources became available virtually and I made use of these where possible.

To adapt to stringent national restrictions that prohibited people from meeting others outside of their household, I made minor amendments to my protocols to allow me to conduct my planned focus groups virtually. Whilst the process of obtaining ethical approval during the pandemic became more streamline and user-friendly, it still felt like an inconvenience at the time.

Prior to the national lockdown, in February 2020 I had begun the recruitment process for a qualitative study I had planned with university students. I used social media (Facebook and Twitter) and posters displayed across the Southampton University campus where permission was granted. Despite lots of people 'liking' and sharing my study over the course of a month, there were no expressions of interest. When the lockdown was subsequently announced, my supervisors and I felt that it was not appropriate to continue recruitment procedures for this study due to the unforeseen impact the pandemic and its restrictions were having on university

students at the time. The population I was trying to capture, young adults with diabetes, would instead be represented in my subsequent focus group work.

My other two planned qualitative studies were with healthcare professionals involved in the diabetes care pathway and with adults living with diabetes who had a recent history of repeated non-attendance at appointments and sub-optimal glycaemic control. On returning from clinical commitments in November 2020 and after ethical approval was granted for the minor study protocol amendments, I began recruitment into the two studies.

The pandemic helped people feel more comfortable using virtual platforms as it was becoming a popular means of communicating both formally and socially. Conducting my qualitative work this way was highly advantageous and efficient. It allowed for increased flexibility, avoided the need to book venues and was well accepted by participants. Furthermore, the 'record' function on virtual platforms was a way of recording the discussions and auto-transcribing them. The auto-transcriptions required significant editing but served as an efficient start to the transcription process.

Despite pressures in primary and secondary care being at an all-time high, recruitment into the qualitative study with healthcare professionals went well. I tried to be sensitive to people's competing demands and was also aware that discussing a hypothetical intervention may not have been well received during a time when so much was changing on a daily basis, however, this didn't seem to be the case. When listening to pharmacy podcasts and speaking to local pharmacists, I became acutely aware how neglected the healthcare professional group felt in the recognition and support (largely financial) they had received from the Government and public compared to other healthcare services. Nonetheless, this sense of feeling undervalued didn't appear to affect the enthusiasm of pharmacists who took part in the study or when discussing a hypothetical Community Pharmacy Diabetes Support Service (CPDSS).

As anticipated, recruitment into the study with people living with diabetes and a history of non-attendance proved challenging. Due to the strain on GP surgeries from the pandemic, their

capacity to help with recruitment and running database searches for eligible participants was limited. Of the surgeries that facilitated with recruitment, the response rate was low.

Dr Kat Bradbury joined my supervisory team in March 2021 to offer support with my qualitative work. She helped confirm what I had been learning and gave me confidence with the rest of my qualitative work and its write-up. To facilitate recruitment into the qualitative study with adults living with diabetes, I amended my study materials (participant invitation sheet and invitation letter) and offered a gift token to participants. Unfortunately, this did not result in many more expressions of interest, which I found surprising. Nonetheless, despite the low uptake (5% response rate), an adequate number were recruited that met information power calculations which I felt was a significant achievement.

Another pause in my PhD took place in August 2021 when I went on maternity leave for 12 months. At this stage I had completed my qualitative studies and written revised drafts of my chapters. I felt in a good place with my work and drew up a clear plan for resuming and completing my PhD on my return. Having been appointed a diabetes consultant post to start at the end of 2022, I organised my second progression review to take place whilst on maternity leave to make sure I was on track to complete my PhD in the months following my return.

Overall, I feel that the COVID-19 pandemic enhanced my learning and strengthened my PhD project. Whilst there were some inconveniences, it provided me with the opportunity to reflect on my work and encouraged me to invest time in becoming confident with virtual ways of working. It is important in research to adapt to changing circumstances. The COVID-19 pandemic gave me first-hand experience of this, which I believe has helped me develop into a stronger and more resilient researcher.

Chapter 1 Introduction

1.1 Chapter outline

In this chapter I present the relevance and rationale behind the work done for this thesis which set out to explore the role of a community pharmacy diabetes support service (CPDSS) to enhance diabetes healthcare engagement. I define diabetes and its accelerating prevalence before going on to describe the impact it has on those affected and the pressure diabetes imposes on economic and healthcare systems. The fundamental aspects of diabetes management are discussed along with supporting evidence from key landmark trials. This leads onto the role of the diabetes annual review and its associated care processes which serve as a means of standardisation to diabetes care. Following on, I describe the concept and importance of healthcare engagement in managing long-term conditions such as diabetes. Finally, I discuss diabetes care in the community with reference to the NHS Long Term Plan, followed by a section on the largely untapped expertise of community pharmacists, a highly skilled healthcare professional group with lots to potentially offer in supporting the delivery of diabetes care.

1.2 Diabetes Mellitus

Diabetes mellitus describes a chronic, metabolic disease characterised by elevated blood glucose concentrations, which over time, can lead to serious macro- and microvascular complications [1]. The main types of diabetes include type 1 diabetes, type 2 diabetes, monogenic diabetes, gestational diabetes and secondary diabetes.

Type 2 diabetes makes up 90% of all cases of diabetes and results from a combination of insulin resistance and impaired insulin secretion by the pancreatic beta-cells [2]. It usually presents in adulthood and there is a strong association with obesity, with some individuals being more genetically predisposed to the condition than others. Lifestyle modification is the cornerstone of management and can even help delay or prevent the onset of type 2 diabetes in those identified as being at increased risk.

Type 1 diabetes typically presents acutely during childhood or adolescence. It is the result of an underlying auto-immune process which culminates in the destruction of pancreatic beta cells. The affected individual is unable to produce adequate amounts of insulin, if any at all, and therefore treatment consists of daily insulin replacement [2]. The underlying cause of this auto-

immune response is not known and at present there is no way of identifying those at risk or preventing it from happening.

Monogenic, gestational and secondary diabetes are out of the scope of this thesis. To introduce them briefly, monogenic diabetes is rare, estimated to represent 1-2% of people diagnosed with diabetes, and is caused by a single gene mutation that is inherited in an autosomal dominant fashion. Gestational diabetes is defined as a new diagnosis of diabetes in pregnancy that resolves after delivery. It is associated with complications to both the mother and fetus and women with a history of gestational diabetes and their children are at increased risk of developing type 2 diabetes later in life [2]. Secondary diabetes is the consequence of another medical condition or the treatment of it. Management varies significantly depending on the underlying precipitant. Health conditions which may cause secondary diabetes include cystic fibrosis, polycystic ovarian syndrome and pancreatitis to name just a few. Treatments which may lead to secondary diabetes include certain medications (for example corticosteroids and immunomodulating agents) and procedures such as pancreatectomies.

1.3 The prevalence and incidence of diabetes

According to the 10th edition of the International Diabetes Federation (IDF) Diabetes Atlas, one in ten adults aged 20-77 years worldwide have diabetes and it is one of the fastest growing health challenges of the century [3]. The prevalence of diabetes (type 1 diabetes and type 2 diabetes combined with undiagnosed cases) in adults, estimated at 537 million people worldwide, has more than tripled over the past 20 years and is projected to rise by 46% to over 780 million by the year of 2045 [4].

More locally, in the UK the prevalence of diabetes has been estimated at 3.9 million [5]. 90% of this number is made of people living with type 2 diabetes, 8% with type 1 diabetes and 2% with rarer forms of diabetes. This figure does not include an estimated additional 1 million people thought to be living with undiagnosed type 2 diabetes. These statistics imply that diabetes affects one in fifteen adults living in the UK, and based on current trajectories, the prevalence is expected to rise to more than 5.3 million by the year of 2025.

1.4 The health impact of diabetes

Being one of the most prevalent chronic conditions worldwide, diabetes is also associated with significant disability, morbidity and mortality, and according to the World Health Organisation (WHO), now features as one of the top 10 causes of deaths worldwide [6, 7].

Diabetes is a major cause of macro-vascular disease (coronary artery disease, peripheral arterial disease and stroke) and is also associated with the development of micro-vascular complications (diabetic nephropathy, neuropathy, and retinopathy) [8]. It is the leading cause of blindness, end-stage renal failure, non-traumatic limb amputations, and cardiovascular morbidity and mortality in many parts of the world.

According to data from the 2017-2018 National Diabetes Audit (NDA) in the UK, people with type 1 diabetes are 3.5-4.4 times more likely to develop cardiovascular disease compared to someone without diabetes and the risk for people with type 2 diabetes is 2-2.5 times greater [9].

One in three people with diabetes have chronic kidney disease. Results from the 2017-2018 NDA report suggest that a person with type 1 diabetes is 17 times more likely to be in end stage kidney disease needing renal replacement therapy than a person without diabetes and a person with type 2 diabetes is 3.6 times more likely [9].

Nearly 6% of people with diabetes have foot disease including infection, ulceration and destruction of tissues of the foot [10]. Amputation is required in up to 1.5% of cases, with diabetes being the leading cause of admissions for amputations in the UK [9]. It has been estimated that a lower limb is amputated due to diabetes every 30 seconds [11].

In addition to the physical complications associated with diabetes, psychosocial outcomes are also negatively impacted by the disease, particularly in those with greater experienced diabetes burden [12]. Diabetes distress affects one in four people with type 1 diabetes and 1 in five people with type 2 diabetes, with greater distress contributing to an increased propensity to challenges with self-management, higher glycated haemoglobin (HbA_{1c}) values and reduced emotional well-being [13]. Living with diabetes can lead to diabetes burn-out and other mental health conditions including a doubling in the incidence of depression and an increased proclivity to disordered eating [14].

1.5 The economic impact of diabetes globally and in the UK

10% of global health expenditure is spent on diabetes [15]. The full economic impact is much greater, however, and includes both the direct costs associated with medical care in addition to a number of indirect social and productivity costs [16]. The latter typically relates to production losses from lost working days, reduced productivity whilst at work, labour force shortfall and deaths before retirement age (65 years) [17]. The financial impact on the individual should also not be forgotten as in some instances this can significantly impact an individual's ability to access the care they require.

Understanding the cost burden of diabetes is important, particularly when planning responses to address its rising prevalence. The total economic burden of diabetes worldwide in 2015 based on data from 180 countries was estimated at 1.32 trillion US dollars, with 35% of this value attributed to indirect costs [17]. Based on past trends, Brommer et al have projected this to rise to 2.48 trillion US dollars by the year 2030, with 31.5% of this figure being expected to be a result of indirect costs.

In the UK, a review by Hex et al in 2012 calculated the cost of diabetes during 2010/2011 as £23.7bn [18]. Of this, £9.8bn was a result of direct costs, representing approximately 10% of the NHS budget for England and Wales, with the remaining £13.9bn attributed to indirect costs. In the year of 2035/2036 the cost of diabetes is projected to rise to £39.8bn, £16.9bn in direct costs and £22.9bn in indirect costs. According to figures from NHS Digital for 2017/2018, 11.4% (just over £1,000 million) of primary care prescriptions were for medications to treat and manage diabetes alone [19].

A global systematic review conducted in the United Kingdom exploring the economic costs associated with type 2 diabetes, highlighted the concerning economic impact of diabetes on societies, health systems, individuals and employers [20]. Large differences in cost estimates across and within countries were identified. When considering the financial impact of type 2 diabetes at an individual level, people with relatively lower household incomes were identified as experiencing a greater relative cost burden from diabetes. Some studies found an increased cost with age and duration of diabetes, and employment probabilities of men were more often adversely affected than for women with type 2 diabetes in high income countries, although the reasons behind this were not explored. Two studies from the United States of America identified ethnic minorities as spending less on diabetes healthcare, but this was deemed to be based on differences in access to care between White and Black or Hispanic populations. This paper helps highlight the disparities in care and outcomes, and varying financial impact on those living with diabetes, both within countries and across the globe.

1.6 Diabetes management

The WHO describes health as “a state of complete physical, mental and social well-being”. As described earlier, diabetes is a multi-system disease with the potential to result in a number of adverse physical and mental health sequela. Management is complex, however, and a vast majority of it is the responsibility of the person with diabetes (or a parent or carer) and necessitates continued motivation and careful attention to lifestyle and behaviours.

Diabetes management relies on a number of self-care practices. These include, but are not limited to, lifestyle changes (e.g. healthy eating and engaging in regular exercise), taking medication including injectable therapies such as insulin, monitoring of blood glucose, attention to foot care and attendance at appointments including retinal screening. Empowering the person with diabetes to self-manage their condition is paramount and can reduce associated distress.

Based on current evidence, it is advised that those diagnosed with diabetes have a number of parameters monitored and optimised. Due to the associated increased risk of cardiovascular disease in those with type 1 diabetes and type 2 diabetes, optimisation of cardiovascular variables alongside support with glycaemic control is important to reduce morbidity and mortality associated with the condition.

1.6.1 The evidence behind supporting optimisation of clinical parameters in diabetes

1.6.1.1 Glycaemic control

The importance of intensive glycaemic control for protection against microvascular and cardiovascular disease in type 1 diabetes has been well documented [21, 22]. The Diabetes Control and Complications Trial (DCCT) was a multi-centre randomised controlled trial which ran from 1982-1993. It recruited over 1,400 people with type 1 diabetes aged 13-40 years with no history of cardiovascular disease or diabetes related complications. Intensive glycaemic control, aiming to achieve an HbA_{1c} within the 'normal' range of less than 42mmol/mol (6.0%), was compared with conventional care focusing on maintaining safe, asymptomatic glucose control. Those randomised to the intensive arm had a 76% reduced risk of developing retinopathy, 60% reduced occurrence of clinical neuropathy and were 69% less likely to develop the first appearance of neuropathy at five years compared to the conventional arm. Unlike the impact on microvascular disease, tight glycaemic control was not shown to have a statistically significant effect on macrovascular disease.

Despite its positive impact on microvascular disease outcomes, intensive glycaemic control was not without complications. The incidence of severe hypoglycaemia requiring third party assistance was approximately three times higher in the intensive arm compared to the control arm. In some instances, hypoglycaemia resulted in hospitalisation, seizure activity or hypoglycaemic coma. Nonetheless, overall mortality did not differ significantly between the treatment groups.

On completion of the DCCT, participants have continued to be followed up in an observational study - Epidemiology of Diabetes Interventions and Complications (EDIC). This has been running for more than 20 years and has demonstrated that in addition to a reduction in early-stage

microvascular complications, early tight glycaemic control also translates into significant reductions in severe complications several years on, and, unlike initial findings, reduced rates of cardiovascular disease. This legacy effect, also known as 'metabolic memory', is apparent even with a loss in the differences in glycaemic control between the two groups over time.

The UK Prospective Diabetes Study (UKPDS) was another landmark randomised control trial which recruited over 5,000 people with newly diagnosed type 2 diabetes between the years of 1977-1997 [23] . The primary aim was to determine the effect of intensive glycaemic control (target fasting blood glucose of less than 6mmol/l) to the conventional arm (fasting blood glucose of <15mmol/l). After lifestyle advice, individuals randomised to the intensive arm were further randomised to treatment with Metformin, Sulphonylureas or insulin to achieve the fasting glucose target of 6mmol/l or less. While intensive glucose control reduced all diabetes-related end points, it had no effect on mortality. Furthermore, like data from the DCCT/EDIC trials for type 1 diabetes, the relationship between glucose-lowering approaches and reduced incidence and/or progression of macrovascular complications was initially less clear [23, 24]. In fact, a UKPDS sub-study (Hypertension in Diabetes Study) showed that tight control of blood pressure (target BP less than 150/85mmHg) reduced diabetes-related morbidity and mortality, and unlike glycaemic control, had a significant impact on macrovascular disease as well as microvascular disease with strokes and heart failure reduced by half.

10 years later, however, the macrovascular benefit of glycaemic control emerged in post-trial monitoring [25]. Those randomised to tight glycaemic control during the study benefited from a risk reduction in myocardial infarctions (15%) and all-cause mortality (13%), despite the loss of between-group differences in HbA_{1c} within a year. Furthermore, continued reductions in microvascular risk were also seen. These findings indicate how long it can take to see a reduction in cardiovascular risk through glucose control in type 2 diabetes.

It must be considered that the way we diagnose, monitor and manage diabetes has evolved significantly since the DCCT and UKPDS trials. People identified as being at risk of type 2 diabetes are now encouraged to be screened for the condition, allowing for earlier identification and treatment of those affected. Those with type 1 and type 2 diabetes are now also offered a yearly diabetes annual review (discussed in next session) and yearly retinal screening, allowing increased opportunity to identify problems and intervene at an earlier stage.

Those living with type 1 diabetes in the UK now have access tools such as flash and continuous glucose monitoring to monitor their blood glucose more reliably and consistently, allowing earlier intervention as required. There is also increasing availability of insulin pumps to facilitate the administration of insulin, allowing more flexibility in dosing and timing. The treatment paradigms

for type 2 diabetes are radically different with a greater selection of medications, most of which also offer additional cardiovascular benefits without the same risks of hypoglycaemia.

Despite the advances in how we manage diabetes today, results from the DCCT/EDIC and UKPDS studies have been influential in the management of diabetes worldwide, encouraging a drive to intensive blood glucose control from the outset, even if tight control is lost with time. There is no threshold to the benefits of lowering HbA_{1c} and specialists advise reducing it to the lowest possible level at which frequent hypoglycaemic episodes do not occur.

1.6.1.2 Cholesterol, Qrisk calculators and the role of statins

The role of statin medication in both primary and secondary prevention of cardiovascular disease in those living with diabetes is well recognised [26, 27]. The Collaborative Atorvastatin Diabetes Study (CARDS) was a multicentre randomised placebo-controlled trial that recruited over 2500 people with type 2 diabetes aged 40-75 years with at least one cardiovascular risk factor (e.g. history of hypertension, retinopathy, microalbuminuria) but no history of a cardiovascular event or cardiovascular disease [27]. The study was terminated 2 years prematurely due to overwhelming benefit seen in those randomised to atorvastatin 10mg once daily. There was a 37% relative risk reduction in major cardiovascular events in those randomised to atorvastatin treatment compared to those taking the placebo, even when in the context of normal low density lipid (LDL) cholesterol level.

Various risk calculators are available to help understand an individual's risk of cardiovascular complications, although many underestimate the risk in those living with diabetes. Developed over 60 years ago, the Framingham risk calculator was one of the first cardiovascular risk assessment tools available and is still used today [28]. Based on data from the Framingham Heart Study conducted in North America, a predominantly white population with relatively few people with diabetes, it has the tendency to overestimate cardiovascular risk in Europeans and underestimate risk in people with diabetes, South Asian men and those who are socially deprived. The UKPDS Risk Engine is a type 2 diabetes specific risk calculator based on data from the UKPDS study, but due to its specificity for type 2 diabetes, it is not routinely used in primary care in the UK.

Another cardiovascular risk calculator is the Qrisk3 which is widely used in general practice in the UK today. It was initially developed for the UK population and is based on data from primary care databases, although has been shown to be the most accurate cardiovascular risk calculator across a variety of different population groups [28, 29]. It calculates a person's risk of having a myocardial infarction or stroke in the next 10 years. Over the years it has gone through various

iterations. The first Qrisk model was published in 2007 and was updated and followed by the Qrisk2 in 2008. Qrisk 2 included type 2 diabetes, rheumatoid arthritis, atrial fibrillation and chronic renal disease as risk factors for cardiovascular disease in additional to the traditional risk factors in the original model. Qrisk2 was then updated and re-calibrated on an annual basis to included type 1 diabetes amongst other conditions/parameters. Qrisk3 was subsequently developed in 2017 to take into account risk factors for cardiovascular disease identified in the 2014 NICE guidance on lipid management that weren't previously represented in Qrisk2.

The National Institute for Health and Care Excellence (NICE) guidance on risk assessment and reduction in cardiovascular disease, last updated in 2016, advises offering atorvastatin 20 mg daily for the primary prevention of cardiovascular disease to people who have a 10% or greater 10-year risk of developing cardiovascular disease according to their Qrisk score [30]. Considering new evidence on the side-effects and safety of statins, NICE are in the process of updating their guidance (expected publication date May 2023) to suggest that statins be considered as primary prevention in people with a 10-year cardiovascular risk score of less than 10% as part of a shared decision making process with an individual [31]. It is interesting to consider the impact this change in guidance may have on primary care resources. There are examples of community pharmacies successfully offering opportunistic cardiovascular disease screening, which could make them good candidates in supporting the delivery of the awaited update to the NICE guidance on cardiovascular risk and statins, particularly when trying to reach populations whose attendance at general practice is known to be low [32].

1.6.1.3 Blood pressure, renal function and the role of angiotensin converting enzyme (ACE) inhibitors

Blood pressure is important when considering the cardiovascular risk associated with diabetes [33, 34] . The Hypertension Optimal Treatment (HOT) randomised trial recruited over 18,000 people from 26 countries over the age of 50 years with diagnosed hypertension. Participants were randomly assigned to a target diastolic blood pressure with Felodipine given as the baseline therapy [34]. Additional agents were added as required according to a five-step regime. A 51% reduction in major cardiovascular events was seen in participants with diabetes mellitus randomised to the target group $\leqslant$80 mmHg compared with target group $\leqslant$90 mmHg, exemplifying the benefit of lowering blood pressure in those with diabetes and existing hypertension.

Another important trial demonstrating the value of BP control in reducing cardiovascular morbidity and mortality was The Heart Outcomes Prevention Evaluation (HOPE) study which recruited people over 55 years of age with existing or previous cardiovascular disease or diabetes

[33]. The arm randomised to receiving the Angiotensin Converting Enzyme (ACE) inhibitor, Ramipril, demonstrated a 22% relative risk reduction in the combined primary endpoint of cardiovascular disease, non-fatal myocardial infarction and non-fatal stroke. The results pertaining to the more than 3500 participants with diabetes were even more pronounced, with a 25% reduction in the combined primary endpoint. The benefits seen with Ramipril were felt to exceed the impact of lowering BP alone, and as a result of the positive findings, the study was stopped early.

Whilst the UKPDS study initially focused on glycaemic control, it later began to collect data on BP as it was recognised that the 43% of UKPDS participants had hypertension (≥160 mmHg systolic or ≥90 mmHg diastolic and not on any hypotensive therapy or patients already on therapy with a blood pressure of ≥150 mmHg systolic or ≥85 mmHg diastolic) and made up 70% of the study's cardiovascular endpoints. Results suggested that 'tight control' (aim of BP <150/85mmHg) with an ACE-inhibitor and/or B-blocker medication resulted in reduced risk of diabetes related deaths, complications, and progression of diabetic retinopathy [35]. Unlike with glycaemic control however, a legacy effect was not seen in the post-trial data and blood pressure control must be continued for the benefits to be maintained [36].

Studies such as HOT, HOPE and the UKPDS Hypertension study support the role of intensive BP control and the use of ACE-inhibitors in people with diabetes, particularly those with additional cardiovascular risk factors. Blood pressure is also important when considering renal disease, which people with diabetes are at increased risk of, as it directly influences the propensity to developing diabetic nephropathy. Renal impairment is the single strongest predictor of vascular disease, with albuminuria and estimated glomerular filtration rate (eGFR) being multiplicatively associated with cardiovascular and all-cause mortality [37]. Early detection of microalbuminuria through the measurement of urinary ACR is a harbinger of declining renal function. It should serve as an additional prompt to aggressively targeting BP, ideally with the use of reno-protective anti-hypertensive agents such as those that block the renin-angiotensin system (ACE-inhibitors or angiotensin 2 receptor antagonists) [38].

1.6.1.4 Weight-loss

With obesity being strongly associated with type 2 diabetes, weight-loss in those with the condition offers significant health benefits including the possibility of putting the disease into remission [39]. The Diabetes Remission Clinical Trial (DiRECT) was an open-label cluster-randomised controlled trial assessing remission of type 2 diabetes (remission defined as an HbA_{1c} of <48mmol/mol on withdrawal of all diabetes medications) following a calorie restricted primary care delivered weight loss programme compared to standard care. Results to date have shown

that 90% of those who lost 15 kilograms or more achieved initial remission. Furthermore, the DiRECT weight programme has resulted in sustained remissions at 24 months for more than a third of people with type 2 diabetes which is linked to the extent of maintained weight loss. Blood pressure, lipids and quality of life were also shown to improve with the intervention. Participants in the DiRECT trial all had type 2 diabetes diagnosed within the previous 6 years and it should be noted that remission, though still possible, is less likely after longer durations of disease.

With the DiRECT trial being delivered in primary care, using primary care staff and including a high proportion of participants from more socially deprived backgrounds, it is likely that the intervention is transferrable into routine clinical care [39]. Many weight-loss programmes show a regain in weight in the months to years that follow. The two-year follow-up from the DiRECT study has shown that the weight-loss achieved in the trial setting can be sustained. It is difficult to determine, however, whether such profound results can be achieved outside of the close monitoring and observation inherent to a clinical trial.

In light of the importance in glucose control along with optimisation of cardiovascular parameters such as weight, BP and cholesterol, regular monitoring of these alongside screening for diabetes complications including mental health conditions, can allow adjustments in treatment and care to be made to help preserve and promote health. This is the role of the annual diabetes review at GP surgeries which will be discussed in the next section.

Unfortunately, despite continued advances in diabetes care and the increasing availability of therapies with demonstrable benefits in terms of their effect on blood glucose and cardiovascular outcomes, there remains a significant mismatch between the recommended health targets and what is achieve by those living with diabetes [40]. Whilst with the correct use of diabetes and cardiovascular medications has been shown to be associated with a positive effect on health outcomes as described above, a review of the literature on medication taking revealed that on average, people only take these medications 72% of the time, and persistence is only 63% a year after their initiation [41]. This highlights the interplay between health behaviour and outcomes.

1.6.2 The annual diabetes review and the eight healthcare processes

In the UK, all people with diabetes are entered onto a national diabetes register, and, as stipulated by best practice national guidelines, should be offered structured education [42, 43]. The importance of initial and continued education is an integral part of diabetes care, helping to facilitate the acquisition of skills required to enable individuals to confidently self-manage their condition.

Following diagnosis, the ongoing support of a person with diabetes should include formal annual reviews with a clinician experienced in the condition. In England, this is typically the individual's General Practitioner (GP) or a practice nurse.

NICE recommends that the annual diabetes health checks in primary care should serve as an opportunity to monitor and manage the person's diabetes, aiming to reduce their risk of complications [42, 43]. To help standardise what is covered in these reviews, a set of eight annual measurements have been suggested by NICE which are eligible for Quality Outcome Framework (QOF) points.

QOF is a performance and payment incentive for GP practices in the UK to help them target their resources, but has come under a lot of scrutiny. Financial compensations are awarded to practices according to their level of achievement of a group of key indicators. QOF was first introduced in 2004 and has since undergone a series of reforms in intervening years [44].

Although the introduction of QOF resulted in an initial improvement in health outcomes for some of the included chronic conditions such as diabetes when it was first introduced, this improvement was not sustained and soon plateaued [44]. The introduction of QOF has been argued to 'crowd out' non-incentivised aspects of care- not dissimilar to other incentivised schemes operating in resource constrained environments, clinician focus inevitably gets shifted towards areas offering financial gains. Lower QOF achievement has been seen in more socially deprived areas leading to concerns the scheme encourages greater healthcare inequalities. General practitioners (GPs) have reported high or considerable pressure associated with meeting quality targets and have expressed concerns that the process driven tick-box targets do not support a holistic, patient centred approach [45].

The menu of QOF indicators for diabetes include an annual assessment and measurement of Body Mass Index (BMI), BP, HbA_{1c}, cholesterol, smoking status, foot examination, urine albumin:creatinine ratio (ACR) and serum creatinine [46]. The International Diabetes Federation's (IDF) European guidelines supports the integration of these activities into one patient visit. In the UK, the annual review in general practice offers the best opportunity to provide consistent regular foot examination and education to people living with diabetes [47].

In addition to the above, all individuals listed on the national diabetes register are offered yearly retinal eye screening. This is organised by the individual's local diabetes eye screening service and was first introduced to England in 2003, reaching nationwide coverage in 2008 [48].

The eight recommended care processes in addition to retinal screening are advised as part of regular reviews and assessments, as they are important markers of improved long-term

management in people with diabetes and are supported by landmark trials including the Diabetes Control and Complications Trial (DCCT) and the UK Prospective Diabetes Study (UKPDS) [49]. The percentage of eligible individuals having their annual review in any year is a useful indicator of quality of care. It has been suggested that once a patient attends their second or third consecutive review, they are more likely to continue to participate in subsequent years [50].

According to Public health England, the uptake of the NHS Diabetes Retinal Screening Programme between 2015-2016 was 82.8 per cent [51]. Uptake of the annual diabetes review and the associated assessment of the eight aforementioned health targets in England has been much lower according to the National Diabetes Audit (NDA)- 40.8% of patients with type 1 diabetes and 54.3% of those with type 2 diabetes complete all of the recommended care processes in 2018-2019 [52].

The future of QOF is uncertain. It has already been removed in Scotland and during the recent COVID-19 pandemic it has been relaxed in England. To date, QOF has incentivised primary care to undertake the diabetes annual review and collect data used in the NDA. If it is dissolved in the future, alternative means of sustaining data collection and quality improvements in diabetes care will need to be carefully planned [52].

1.7 Engagement in diabetes care

Healthcare engagement is required for the optimal management of long-term conditions such as diabetes and is associated with enhanced healthcare outcomes and experiences [53]. Low engagement levels are likely to contribute, in part, to the low uptake of the diabetes annual review and an individual's propensity to developing complications associated with the condition. However, healthcare engagement is challenging to define and quantify.

There are a number of varying definitions for patient healthcare engagement, but all share an underlying theme: "the facilitation and strengthening of the role of those using services as co-producers of health and healthcare policy and practice" [54]. It differs from patient activation which describes an individual's knowledge, skill and confidence in managing their health. Engagement also considers the individual's behaviour and external context including organisational and societal barriers.

It has been recognised that people with diabetes who are less engaged with their care are less likely to have optimal glycaemic control have an increased risk of complications and a greater propensity to non-attendance at healthcare appointments [55, 56].

There are likely to be a number of contributing factors and complexities under-pinning a person's willingness or ability to engage with their diabetes care. Treatment complexity is just one consideration. Factors impacting healthcare engagement may include patient related factors, healthcare professional factors, organisational factors and lay community-related factors [57].

There are limits to interpreting data and literature on engagement in diabetes, as there is no clear definition. Terms such as activation, non-attendance, non-adherence, reduced compliance and dis-engagement are frequently used, but do not always describe or depict the same underlying issues or challenges.

When referring specifically to avoidance of medication taking, it is frequently classified in the literature as being either 'intentional' or 'unintentional' in origin [58]. One could argue that this differentiation may also be applied to other aspect of healthcare engagement. People may choose intentionally not to take medication after a rationale decision-making process made by the patient where the pros and cons of following a treatment plan or medical advice are weighed. The patient then actively decides whether to follow them or not. This type of non-adherence is influenced by a patient's beliefs, cognition and understanding of the proposed intervention. Unintentional non-adherence is less influenced by understanding and beliefs, and is a result of unplanned behaviour (e.g. forgetting an appointment or to take their medicine).

Empowering and encouraging people to take responsibility for protecting their health is seen as the best way to ensure the sustainability of health systems, with the individual's role as an active partner in their healthcare [59]. Strategies to facilitate and support people to reflect on their experience of living with diabetes often leads to an enhanced awareness and understanding of the consequences of their self-management decisions. This concept of patient empowerment is fundamental when considering that individuals provide 98% of their own diabetes care by making their own decisions about their management on a daily basis [60].

Graffigna et al describe engagement as a process-like behaviour. It is not something that can be simply switched on or off, but exists more on a continuum [53]. A complex interplay between cognitive (what one thinks), emotional (what one feels) and behavioural (how one acts) factors influence health engagement, and without synergy between these three subjective dimensions, engagement can be difficult to achieve [53]. It has been proposed by Graffigna et al that 4 principal phases of healthcare engagement exist...

Phase 1-Occurs at the onset of a new health diagnosis

Phase 2- The individual perceives themselves as unwell, but delegates the responsibility of this to the healthcare system.

Phase 3- The patient follows the medical prescription and advice, but is not fully comfortable in managing independently and develops a strict and regimented set of behaviours.

Phase 4- Full engagement and co-producers of their condition and greater health.

Measuring a patient's engagement with their diabetes care objectively for research purposes is a challenge. Categorising people as either engaged or disengaged, as Graffigna et al argue, is also not a binary definition [53]. Furthermore, patients may engage with certain aspects of their care on an intermittent basis [61]. Attendance at diabetes appointments, measurement of baseline parameters such as HbA_{1c}, and adherence to prescribed treatments are all widely used, but only serve as surrogates for health engagement. To give an example, these endpoints do not consider those who are fully engaged and attending all appointments but for whom the prescribed treatments have not been optimised, or those who are self-managing without attending appointments but whose parameters are at target.

There are few assessment tools that take into account a patient's experience of their condition and the more subjective emotional and cognitive aspects of engagement. A majority of methods focus solely on the behavioural elements. Tools such as the Patient Activation Measure (PAM score) designed by Hibberd et al is a validated, commercially licensed tool which has been extensively tested, and addresses the wider concept of engagement [62]. By establishing a more holistic appreciation for an individual's level of engagement using tools such as the PAM score, more acceptable and appropriate support tailored to the individual patient can be offered to those living with diabetes. This is of particular importance when trying to reach out to those most disconnected with their existing diabetes care, but the PAM score is still not perfect with critics arguing that it neglects the psychological and emotional aspect of engagement [57].

1.8 The NHS Long Term Plan and Diabetes in the Community

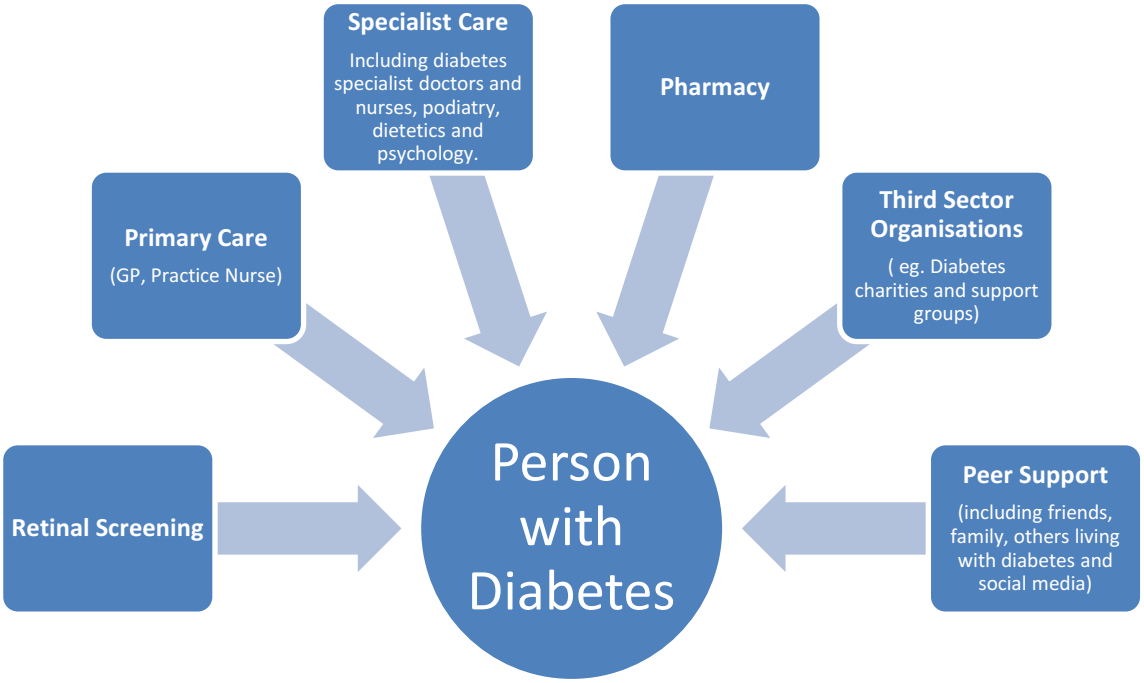

Figure 1 Natural communities of care to support those living with diabetes

There are a number of services and groups available to support people living with diabetes and individuals may have contact with all or only a selection of these at any one time. Some of the natural communities of diabetes care are shown in Figure 1.**Error! Reference source not found.** Although communication may exist between the groups or services depicted, the person with diabetes is best placed to take overall ownership of their condition and to be the central part of their care.

More than 75 per cent of people living with diabetes are managed in primary care [63]. On January 7th 2019, the NHS long-term plan was published, setting out a vision for the future of the NHS in 10 years' time [64]. The recommendations in the document prioritise prevention and public health and set to break down barriers between primary care, community services and hospitals, working towards a more integrated healthcare system. There is a particular emphasis in the plan on a selection of clinical priorities, and diabetes is one of these.

A key part of the NHS Long Term Plan are Primary Care Networks (PCNs), funded by a new investment of £4.5 billion. Each PCN is made up of local GP practices and community teams covering a population of approximately 30-50,000 people [64]. PCNs are expected to think of the wider health of their population. They are encouraged to focus on service delivery with a drive towards working with local partners, as 'Integrated Care Systems', to plan and deliver services which meet the need of their community.

As well as increased health service integration, the NHS Long Term Plan also calls for a push towards shared responsibility for health between healthcare professionals and patients, with a focus on moving away from a one-size fits all model towards more personalised care [64].

Whilst many aspects of the plan are celebrated, the details of proposals are variable, with some commitments viewed as ambitious, particularly within the constraints of funding available [65]. How the 10 year plan is affected by the more recent COVID-19 pandemic is yet to be seen.

With the increasing numbers of people living with diabetes and associated health co-morbidities, joined up working is becoming increasingly important. The NHS plan makes little reference to managing co-morbidities, but the drive to more integrated working and person-centered approaches will no doubt support those living with more than one health problem. Community pharmacists are an important part in a person's healthcare experience and have a unique role to play within PCNs and in helping to deliver the NHS Long Term Plan.

Providing increased support for diabetes in the community is hoped to reduce hospital admission rates and help people to stay well, supporting the concept of 'upstream prevention' referred to in the NHS Long Term Plan.

1.9 The role of community pharmacy

The Royal Pharmaceutical Society (RPS) believes that pharmacists have a crucial role to play in the support of people with long term conditions such as diabetes [66]. Pharmacists are regulated by the General Pharmaceutical Council and work across a variety of sectors including the community, hospitals, primary care, academia, the military and industry amongst others. This thesis focuses on community pharmacy. Most of the public will have a familiarity with community pharmacy as they have a large presence on the high street, with only a few community pharmacies operating as online or distance-selling pharmacies. In almost all regions of the UK, community pharmacies are the most accessible and available health care provider to the community [67]. They are owned and operated by one of three groups: sole traders (individual pharmacists who own and run a pharmacy), partnerships (two or more pharmacists own and operate one or multiple pharmacies) and body corporates (registered companies that own pharmacies) [68]. The majority of the population can access a community pharmacy within a 20 min walk from their household and, access is greater in areas of highest deprivation-the positive pharmacy care law [69].

Over the years pharmacy services have continued to expand from traditional dispensing roles to include more comprehensive clinical services and are recognised, along with other allied healthcare professionals, as key players in the delivery of the NHS long term plan [64, 70].

Pharmacy degrees and training are constantly evolving to reflect this, and by 2026, all graduates from a pharmacy degree will be independent prescribers.

Community pharmacy has a contractual framework with the NHS. This breaks down their services into 'essential services', 'advanced services' and 'locally commissioned services'. 'Essential services' are nationally set. All pharmacies must deliver them and they include the dispensing of medicines and medical devices, the safe disposal of medicines, advice of health living etc. 'Advanced services' are also nationally set, but are optional to those pharmacies meeting the minimum requirements. Examples include the 'New Medicines Service' which helps people understand new medicines they are started on and the 'Community Pharmacy Consultation Service' which allows other parts of the NHS to refer to pharmacy for some urgent care needs. Finally, 'locally commissioned services' are those that are set to meet the need of the local population and are funded by public bodies such as local authorities. In addition to publicly funded services, community pharmacies may also choose to offer private services such as travel health advice, the chicken pox vaccination service etc.

Diabetes and its associated co-morbidities is a prime example of a condition where individuals could benefit from increased support from the pharmacist. Collaboration with community pharmacy may help address some of the current challenges in achieving therapeutic targets for those with diabetes whilst enhancing the pathway of care to make it more whole.

Whilst the evidence to date supports increased integration of pharmacists into the care pathway for those with diabetes, there is a sparsity of studies specifically looking at the role of pharmacists in supporting those with diabetes who have had reduced engagement with the services currently available to them (e.g. not attending their annual diabetes reviews or retinal screening, or those who may need increased support to help them meet their therapeutic targets). These individuals are arguably most vulnerable to the complications and health burden associated with diabetes, but potentially also have the most to gain from an alternative supplementary intervention.

1.10 Aim and outline of thesis

The aim of this thesis was to explore non-attendance at diabetes healthcare appointments and to determine the suitability of developing an intervention in community pharmacy to address this behaviour.

The subsequent chapters of this thesis will describe the work done to explore the potential of a CPDSS to enhance diabetes healthcare engagement. I describe the theory, evidence and methods

used to understand the context and scope of such an intervention and to guide the early development process. A summary of the subsequent chapters of this thesis are as follows:

Chapter 2 is a systematic review of the literature on non-attendance at diabetes healthcare appointments. A version of this has been published in Diabetic Medicine.

Chapter 3 includes a narrative review of the literature describing the role of the pharmacists in the delivery of diabetes care. A version of this has been published in the Postgraduate Medical Journal.

Chapter 4 is a qualitative study. It explores the views and perspectives healthcare professionals have towards a hypothetical CPDSS to support people living with diabetes and a history of repeated non-attendance and sub-optimal glycaemic control.

Chapter 5 describes a second qualitative study involving people living with diabetes and a history of repeated non-attendance and sub-optimal glycaemic control. It set out to understand their perspectives of diabetes appointments, their experiences with community pharmacy and thoughts on a hypothetical CPDSS to support people like themselves with diabetes management.

Chapter 6 synthesises the data from the preceding chapters. It discusses the conclusions drawn and the evidence for a community pharmacy intervention to support people with diabetes, who evidence suggests, may be at greatest risk of adverse health outcomes.

1.11 My role in the research of this thesis

The text in chapter 2 is based on work that was published in Diabetic Medicine. Versions of chapter 3 and chapter 4 were published in the Postgraduate Medical Journal. I was the first author on all three of these papers and carried out this work for the purpose of my PhD which explains why the content of these chapters is similar to the published work.

As the first author on the systematic review described in chapter 2, I developed the review question, wrote the search strategy, screened abstracts (with another author, JB), assessed quality of the identified papers, performed data extraction, analysed the data and re-wrote manuscripts and submissions for publication.

For the review article described in chapter 3, as the first author I developed the review objectives, wrote the search strategy, reviewed the recent relevant literature identified by the search strategy, read around the broader subject area to put the findings into context and re-wrote manuscripts and submissions for publication.

As first author on the article on complex interventions in chapter 4, I reviewed the relevant literature, wrote the first draft, re-wrote manuscripts and submitted for publication.

For the qualitative work described in chapters 5 and 6, I wrote the initial application forms, including all supplementary documents, for both the University of Southampton Ethics and for Health Research Authority (HRA) and NHS Research Ethics Committee (REC) approval. I also dealt with subsequent revisions, amendments and submissions. I led study recruitment and organised and facilitated the virtual focus groups and one to one interviews. I edited the auto-transcription of these whilst listening to the audio-recordings to make sure that they were accurate and verbatim whilst removing personal identifiable data. Initial coding and thematic analysis was performed by myself and checked by JB.

Finally, the concluding chapter was written by myself to draw on the findings from the preceding chapters and to articulate the role of a hypothetical CPDSS to support people with diabetes who have a history of repeated non-attendance and sub-optimal glycaemic control.

Chapter 2 Non-attendance at diabetes outpatient appointments: a systematic review

2.1 Chapter outline

In this chapter I describe my systematic review on non-attendance at diabetes outpatient appointments which was published in Diabetic Medicine in March 2020.

2.2 Introduction and Background

Non-attendance at healthcare appointments is a significant problem across the world. According to NHS England's quarterly review ending March 2019, the overall non-attendance rate for general follow-up hospital outpatient appointments was 8% [71], with non-attendance rates appearing similar for people with diabetes compared to other chronic health conditions [72]. Non-attendance is associated with sub-optimal outcomes for the patient, and is a poor use of healthcare resources [73, 74].

Diabetes is a long-term condition associated with a number of complications, the incidence of which increases if the diabetes is not managed optimally [21, 75]. Despite significant advances, there remains a sizeable gap between advised and actual clinical outcomes achieved by people with type 1 and type 2 diabetes

Healthcare appointments are an opportunity for healthcare professionals (HCPs) to support individuals with diabetes with their self-management. Understanding the reasons why people do not attend outpatient appointments can help reveal barriers or personal determinants that also affect their ability to manage their condition.

It is unclear from observational studies whether poor appointment keeping is causally related to sub-optimal outcomes as non-attendance may stem, at least in part, from ill-health [76]. Regardless, non-attendance behaviour can serve as a marker for identifying those at risk of poor

outcomes, and who should be targeted with alternative care models or outreach services [76]. Steps taken to help people with diabetes attend more regularly could translate into better outcomes for the individual.

In 1998, a review by Griffin reported that there were relatively few qualitative studies exploring the beliefs and attitudes of people with diabetes towards clinic attendance. Contradicting the wider literature on non-attendance behaviour at the time, certain features such as socio-demographic characteristics were not associated with non-attendance at diabetes appointments. Griffin identified that interventions to address non-attendance at diabetes clinics were primarily aimed at providing reminders, with few organisational or patient-professional relationship interventions [74].

In a more recent review in 2016, Hynes et al reported how the experience young people with type 1 diabetes have during transition into adult care influences subsequent clinic attendance. Building strong patient-professional relationships to improve the perception of the value of attending appointments was important [77].

Over two decades since Griffin's review, there have been substantial changes to healthcare systems and diabetes care that may affect clinic attendance. It is therefore timely to re-consider the contributors, consequences, and potential solutions for non-attendance at healthcare appointments among adults and young people with diabetes.

2.3 Review Aim

This review summarises the literature on non-attendance at diabetes healthcare appointments. The objectives were three-fold:

1) To establish the features of missed diabetes healthcare appointments, the characteristics associated with those not attending and the impact on health outcomes.
2) To explore factors that influence attendance or non-attendance at diabetes appointments.

3) To describe interventions to improve attendance at diabetes appointments.

2.4 Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist was followed (see Appendix A.1 on page 151) [78].

2.4.1 Search Strategy

An initial scoping review was conducted using Google Scholar. This was followed by an online search of four databases, MEDLINE, CINAHL, Embase and PsychInfo using the EBSCO and OVID platforms to include articles from database inception to February 2019. The grey literature was not searched. Details of the review were registered with PROSPERO: Reference CRD42019128305.

2.4.1.1 Development of the search strategy:

When initially defining the search strategy following a scoping search using Google Scholar, preliminary piloting of search terms across four databases (Medline, Embase, CINAHL and PsychInfo) made clear that the chosen search terms were most encompassing.

To capture studies relevant to type 1 and type 2 diabetes, 'diabetes' was used as a generic search term to make sure that relevant papers were not missed. The exclusion criteria were subsequently applied to exclude studies that related to diabetes types other than type 1 or type 2 or that were pertaining to solely paediatric populations.

The search terms used by other reviews helped inform our search terms for 'non-attendance'. Using terms such as concordance, adherence and compliance captured the wrong behaviour when used across the databases. 'No show', 'absenteeism', 'attend*', 'non-appearance and 'default' identified papers of interest and were incorporated into the search strategy. 'No-show' was also included as a subject heading across the four databases to account for the variation in coding used by the search engines for terms used to describe the behaviour of interest.

2.4.1.2 Final Search Strategy:

To capture studies on type 1 or type 2 diabetes, the following search terms were used:

exp Diabetes Mellitus/ or

diabet*.mp.

To capture studies on non-attendance at appointments, the following search terms were used:

No-Show Patients/ or

no show or absenteeism or attend* or non-appearance. or default* mp.

2.4.2 Study selection: Inclusion/exclusion criteria:

Peer-reviewed papers conducted in all countries and of all designs were included if published in the English language and addressed one of the research questions. Non-attendance was defined as unexplained missed appointments and did not include cancelled or re-booked appointments. Articles had to be specific to outpatient diabetes appointments with a diabetes specialist doctor, general practitioner (GP) or nurse. Studies referring to people with diabetes other than type 1 or type 2 diabetes were excluded. Studies reviewing attendance at structured education, retinal screening, antenatal clinics, dietetic or podiatry appointments were excluded as attendance at these diabetes contacts is influenced by different factors, such as dislike of group sessions, differences in perceptions about healthcare vs. education and the response to an active diabetes-related complication.

The focus of this review was adults and young people with diabetes. Papers on transitional and young person clinics were included, as many of these studies incorporated adults, and the pattern of later attendance at clinics is often developed during early adulthood. Papers that solely included people aged <18 years were excluded.

One researcher (SB) ran the search with the assistance of a librarian. Two researchers (SB, JB) screened the study titles and abstracts identified from the search. Results were compared and discussed until a consensus was reached. All included studies were discussed by all authors. Figure 1 shows the PRISMA flow diagram of the article selection process [78]. One researcher (SB) cross-checked the references of included studies, which did not identify any additional articles.

2.4.3 Quality Assessment and Data Synthesis

Quality assessment and data synthesis was performed by one researcher (SB). The papers were assessed using the nine-item checklist developed by Hawker et al for appraising disparate studies (see Appendix 0 and A.3 on pages 153and 157) [79]. This tool was chosen to accommodate the diversity of study types assessed in one checklist, facilitating inter-study comparison. No studies were excluded based on quality. Data were extracted, summarised and tabulated by SB and discussed by all authors (see Table 2 at the end of this chapter). Findings were grouped according to the review aims and a narrative synthesis was undertaken. Due to the methodological, statistical and conceptual heterogeneity between studies, a meta-analysis was not performed.

2.5 Results

2.5.1 Types of studies identified and reported rates of non-attendance

34 studies of varying designs were identified (15 observational, 1 randomised control trial, 9 qualitative, 5 surveys, 4 service improvements). Sixteen were studies from the United Kingdom [80-94], four from Europe [77, 95-97], six from North America [76, 98-102] and eight from the rest of the world [103-110]. Six studies specifically focused on young adults in transition from paediatric to adult services, all of which had a mean participant age of >18 years (age range 15-30 years) [85, 86, 97, 103, 108, 111].

Reported baseline non-attendance rates at diabetes appointments were mostly between 10% and 30% [76, 80, 82, 83, 85, 87, 91, 92, 97, 99, 106, 107], but the extreme ranges were 8.3% [93] and

76% [86]. The means of quantifying non-attendance varied; some studies calculated the number of missed appointments as a percentage of total booked appointments [76, 82, 85, 87]. Non-attendance was also determined as the number of people missing more than one appointment in a defined period [83, 86, 88, 89, 91, 96-100, 103, 105, 107, 112] or when there was no record of HbA_{1c} measurement in primary or secondary care in the previous 12-15 months [92, 93]. Re-referred 'lapsers' made up 19% of the 'new patient' clinic load at one UK diabetes service [80] and appointment cancellations were only defined as a separate entity in one study where they occurred more frequently than non-attendance (18% vs 12%) [99].

The number of studies addressing each of the research questions is displayed in Table 1 with some studies addressing more than one aim.

Table 1: The number of identified articles addressing each of the research questions in the systematic review on non-attendance at diabetes outpatient appointments

Research question addressed	**Number of studies identified**
Characteristics of non-attenders or missed appointments and/or health outcomes associated with non-attendance	18
Reasons for non-attendance	9
Evaluation of an intervention	8

2.5.2 Features associated with missed appointments, the characteristics of non-attenders and the impact on health outcomes

Articles reporting on the features of missed appointments, the characteristics of non-attenders and the impact on health outcomes associated with missed appointments were predominantly observational in design. Longer gaps between appointments was a predictor for non-attendance

[107] but there was no seasonal variation in attendance rates [90]. A machine learning algorithm helped predict missed diabetes appointments at a Japanese hospital and found that 'how and when' an appointment was booked contributed more to attendance than the individual's clinical condition [109]. Factors with the strongest predictive accuracy of a missed appointment included making appointments on a Sunday, scheduling appointments for a Friday, a history of diabetic ketoacidosis in those with type 2 diabetes and a recent prescription of Rilmazafone (a water soluble benzodiazepine). Factors associated with reduced likelihood of a missed appointment included a history of treated Graves' disease, a previously kept appointment on Friday or booked on Monday.

Attendance may be influenced by the role of the referring HCP and the skill set of the receiving HCP [102]. Adults with type 2 diabetes referred by doctors across three healthcare centres in Chile were less likely to attend appointments than those referred by dietitians or nurses. Appointments with doctors, however, were better attended than with other HCPs. Some people preferred to see a doctor over a dietitian or nurse, but the majority expressed no preference.

2.5.2.1 Characteristics of non-attenders:

Table 3 summarises and compares findings across studies on the characteristics of people who are less likely to attend clinic appointments.

2.5.2.1.1 Age, gender and duration of diabetes.

Non-attendance was more likely in young adults [76, 89, 91-93, 95, 107] and older (age>70 years) individuals with diabetes [92], but this was not seen in all studies [76, 80, 88, 96]. The association of age persisted if transition clinic studies were excluded. Shorter duration of diabetes was associated with non-attendance [89], but age of diabetes onset [89] and duration were not predictive of attendance behaviours in other studies [80, 95]. Some [83, 91, 93, 107], but not all, studies [80, 86, 88, 89, 92, 95] found that men were less likely to attend.

2.5.2.1.2 Employment, socio-economic pressures and parenthood

A number of demographic factors including unemployment [96], financial pressures [76, 93], smoking [89, 91, 95, 96], increased alcohol intake [96] and parenthood, particularly being a single parent [89], were associated with non-attendance. In contrast, social deprivation was only mildly associated with non-attendance in one Scottish study [92].

2.5.2.1.3 Ethnicity and culture

Ethnicity was only reported in one study which identified people of Malay, Indian and other ethnic minorities as more likely to miss diabetes hospital appointments in Singapore [107]. Geographical location did not have a notable association with non-attendance despite different healthcare systems.

2.5.2.1.4 Illness perceptions and attitudes

A study in Thailand found no association between illness perception and diabetes clinic attendance [104]. A postal questionnaire of attachment styles found that in those without depression (88%), dismissive behaviour was most closely related to non-attendance at primary care reviews and people with fearful attachment styles were more likely to attend same day appointments [101].

2.5.2.1.5 Other associations

Other less well reported characteristics included the presence of other co-morbidities, attendance at diabetes education and insulin treatment in the context of type 2 diabetes. Apart from hypothyroidism, which was associated with lower non-attendance rates, the presence of other co-morbidities was not associated with missed appointments [95]. Non-attendance was associated with a lower co-morbidity score at a diabetes service in North California [76], although people with clinical levels of anxiety and/or depression were less likely to attend appointments [93]. Lack of therapeutic diabetes education and insulin therapy in the context of type 2 diabetes both increased the likelihood of non-attendance in Spain [95].

2.5.3 Health outcomes associated with non-attendance

Nine studies reported an inverse relationship between glycaemic control and clinic attendance [76, 80, 88, 89, 91, 93, 95, 97, 113], but this association was not seen in a retrospective review of diabetes services in Limerick, Ireland [96]. Associations with other biomedical outcomes were less well established. In studies that reported body mass index (BMI), higher BMI was associated with non-attendance in two studies [88, 91] but not others [80, 83, 95]. Higher blood pressure [83, 88, 95] and adverse lipid profile [83, 95] were more common in non-attenders when reported.

A study from Indiana, USA, reported that people with diabetes who did not attend primary care appointments were no more susceptible to subsequent hospital attendances over a 6 month period unless the person with diabetes was recently discharged from hospital and then missed their follow-up in primary care when re-attendance was more likely [112]. By contrast, another study, also from Indiana observed that emergency department attendances were more frequent in those who missed, or who had cancelled but re-scheduled an appointment [99].

The prevalence of diabetes related microvascular [80, 95] and macrovascular complications [80] was increased in non-attenders in the two studies that reported complications. Greater morbidity from diabetes related complications was also identified in white non-attenders aged >64 years at a hospital diabetes service in Wolverhampton, England [88]. Analysis of data from the Health Improvement Network (THIN) database, a UK longitudinal database with more than eight million patient records, found that non-attenders with type 1 diabetes had greater all-cause mortality after adjustment for demographic variables and other risk factors [91].

2.5.4 Reasons for non-attendance at diabetes appointments

Of the nine studies examining reasons for non-attendance, three were surveys [80, 83, 88] and six used interviews and/or focus groups [77, 81, 85, 94, 105, 110] .

2.5.4.1 Reasons derived from surveys

The main reasons given for not attending clinic according to patient surveys included: overcrowded clinics, prolonged waiting, lack of continuity, not seeing the consultant frequently enough, being too ill or too well to attend, non-specific personal reasons, and neglecting the diabetes [80, 83, 88]. When people with diabetes were asked to offer suggestions on how to improve services to facilitate attendance, these typically focused around clinic logistics [83].

2.5.4.2 Reasons for non-attendance derived from interviews and focus groups

The diabetes clinic is regarded as a valuable resource by young people with diabetes, healthcare providers [111] and ethnic minorities [81]. The importance attached to attendance was also evident in South Africa where people with diabetes claimed that attending assisted better self-management [105]. Rarely was non-attendance due to lack of motivation, perceived seriousness of the disease or perceived risk [81].

Snow et al proposed that three groups of people with diabetes exist: those who balance the costs, particularly the immediate obstacles to attending against the benefits, those who do not, and those who move from one group to another with time [85]. For the minority who do not consider the costs and benefits, attenders typically reported doing so out of routine, something instilled in them during childhood, whereas those with a period of non-attendance attributed it to a time of denial.

Three main themes emerged from the qualitative studies exploring the factors influencing attendance at diabetes healthcare appointments.

2.5.4.2.1 Illness perception, distress and coping strategies

Illness perception, diabetes distress and coping strategies all influence attendance patterns both positively [81, 111, 114] and negatively [110, 111, 114], in contrast to the earlier study from Thailand which found no association between illness perception scores and attendance patterns [104].

A sense of denial was described by young people missing appointments at a diabetes clinic in London, England, particularly when they felt their diabetes had become unmanageable [85]. According to young people in Ireland, distress-related diabetes negatively influenced self-management, which then either served as a motivator or a significant barrier to subsequent clinic attendance [111]. Denial was also a factor identified in adults with diabetes in Iran [110], and even when people with diabetes in South Africa were optimistic about their current health status, three-quarters expressed a belief that they were likely to develop health complications as a result of diabetes [105].

Focus groups and interviews with ethnic minorities from a diabetes clinic in London illustrated that handing over the responsibility of their health to someone else, notably family members, was a way of coping and managing their condition [81]. This coping strategy was most apparent for those who did not speak English, who relied on others for their attendance.

A Welsh study analysing interviews of non-attending adults with type 1 diabetes identified three groups based on their cognitive, emotional and coping strategies according to the health behaviour model [94]. The 'high fear' group use coping strategies to minimise anxiety rather than reduce health threat. The 'patient as the expert' group have strong internal control and are less likely to invite or accept advice from others. The 'low motivation' group, who despite appearing calm, perceive a health threat as externally visible and underestimate their risk.

2.5.4.2.2 Logistics and characteristics of the appointment/diabetes service

Appointment logistics were reported in all six qualitative studies. Bureaucratic problems and communication failures contributed to non-attendance [85] as did forgetfulness [105]. When asked, people with diabetes felt that appointment reminders would help boost attendance, with a telephone call being the preferred method of communication [105].

Barriers described by people with diabetes included lack of clinic flexibility [81], long waiting times [111, 114], meeting unfamiliar service providers [111], geographical location [81, 105], hassle

associated with travel to the appointment [81, 105, 110], parking problems [81], conflicting commitments such as work or other appointments [81, 85, 105, 110, 114], misunderstanding of appointment requirements [105], physical disability [110], financial difficulties [81, 105, 110] and a dislike for hospitals and/or doctors [114].

Semi-structured interviews in Iran recognised that some women described prejudice of their husbands, tradition and local customs as interfering with their acceptance of modern medicine and ability to attend appointments [110]. Issues with language and literacy was also a barrier for some in London, England [81]. Facilitators to attendance were less frequently reported but included timely test results, a reliable system of reminders, and practical information [85].

2.5.4.2.3 Relationships with the healthcare team:

The importance of positive relationships was well described [81, 85, 110, 111]. Semi-structured interviews with people not attending a young person's type 1 diabetes clinic in Ireland identified the relationship between the person with diabetes and HCPs as the predominant theme contributing to this behaviour [111]. Confidence and trust in HCPs was important to adults with diabetes in London [81], and young persons were most negatively affected by criticisms, particularly in relation to their HbA_{1c} and self-management [85]. The value of friendly, positive staff was appreciated by all as was emotional support and reassurance [85]. Short, impersonal appointments with unfamiliar HCPs negatively impacted relationships and thus attendance [111]. Outside of the UK, Heydarabadi et al also identified poor 'patient-doctor' relations as a barrier to attendance in Iran [110]. In Ireland, young adults with diabetes felt that collaborative relationships between them and HCPs helped foster engagement and also attendance [111].

A difference in opinion appeared to exist between those with type 1 and type 2 diabetes in London, England, regarding specialist care [81]. Those with type 1 diabetes perceived specialist care to be superior, whereas those with type 2 diabetes had less understanding of the different roles of GPs and specialists [81]. Campbell-Richards proposed that these varying opinions may influence attendance for some.

2.5.5 Interventions aimed at improving attendance or identifying those at risk of defaulting from clinic

Seven of the eight studies examining interventions to improve attendance were observational [82, 84, 87, 98, 100, 106, 108] and one was a randomised controlled trial (RCT) [103]. The types of interventions varied and included patient navigators [98, 100, 103, 108], web-based consultations [82], and strategies to improve appointment management, service structure and patient information [84, 87, 106].

2.5.5.1 Patient Navigators

Patient navigators provide personal guidance to patients, helping them negotiate their way through healthcare systems. They are not typically medically trained but serve as a single point of contact for an individual, and in some instances may serve as an advocate for them. Two of the four studies reporting patient navigators were from North America focusing on adults with diabetes [98, 100]. The other two from Australia [103] and Israel [108] were specific to people with type 1 diabetes transitioning to adult care. The role and skills of the patient navigator(s) varied across studies, but all reported improved attendance and clinical outcomes.

Weaver et al examined the effect of weekly phone calls by a navigator on new patient attendance at a diabetes clinic in Alabama [98]. The clinic was specifically for un-insured people discharged from hospital with a diagnosis of diabetes but without on-going care. The patient navigator was a registered dietitian and certified diabetes educator. The intervention significantly reduced non-attendance rates over a 6-month period. Attendance following a navigation call was associated with an average 22 mmol/mol (2%) decrease in HbA_{1c} from the time of hospital referral to first clinic appointment. Both patients and patient navigator reported the main barriers to clinic attendance were being resident in a shelter, difficulty in contacting the person with diabetes, non-English speakers, transport difficulties and hospitalisation at the time of the appointment.

In the study from Boston, US, Horny et al enrolled people with an elevated HbA_{1c} (>69mmol/mol, 8.5%) and a record of at least one non-attendance at a diabetes specialist clinic in a “safety-net”,

not-for-profit urban hospital [100]. The two patient navigators were non-clinical with no previous diabetes experience, but were selected for their communication skills. They received basic diabetes training and attended a course on patient navigation. There was a modest reduction in HbA_{1c} (-0.6 %, -6 mmol/mol intervention group vs. +0.5%, +5 mmol/mol control group) and non-attendance rates, but no reduction in hospital admissions or emergency department attendances.

An RCT assessed the effect of an appointment manager for those with type 1 diabetes transitioning from a tertiary paediatric clinic to adult diabetes services in Melbourne, Australia [103]. The patient manager acted as the point of contact between the two services and provided pre-appointment text messages and telephone calls. Missed appointments were automatically re-booked. Disengagement from services was defined as not attending a single adult appointment over 12 months. No improvement was seen in attendance or engagement at 12 months post transition, but an independent positive association was apparent at 12-24 months post transition (disengagement: 6% intervention arm, 49% control arm; number of clinics attended: 2.5 in the intervention, 1.4 in the control). Pre-transition attendance predicted post-transition attendance to a small degree, but both pre-transition attendance and the intervention did not have independent effects on HbA_{1c} after transition. In Israel, an improvement in mean HbA_{1c} (67mmol/mol, 8.3% to 57mmol/mol, 7.4%) and clinic attendance was demonstrated amongst people with type 1 diabetes one year after the introduction of patient navigators into a specialist transition clinic [108]. 80% of planned transition participants attended three or more appointments in the year post transition compared to 60% pre-transition, and 47% of those re-referred to the transition clinic after being lost to follow-up attended three or more appointments the year following transition.

2.5.5.2 Patient Information and service -restructuring

Keeping people with diabetes informed and improving clinic efficiency improves attendance rates [84, 87, 115]. Issuing an information pack on what to expect at an upcoming diabetes outpatient appointment in Merseyside, UK, reduced overall non-attendance rates from 15% to 4.6% [87].

This association was most pronounced for those who received a supplementary telephone call one week before their appointment (non-attendance 1.4% vs. 7.3% for those without the supplementary telephone call).

Wilson and Greenhalgh took measures to re-engage individuals lost to a young persons' service [84]. Letters of invitation put blame for non-attendance on the service, not the person with diabetes. The letter was followed by a supportive telephone call. The running of the clinic was radically changed. Staff were encouraged to be positive and non-judgemental, and a clinic nurse sat in the waiting room to put attendees at ease. Health promotion flyers/posters were made available, and diabetes nurse specialists were employed to offer flexible appointments. Non-attenders were phoned to check how they were, and another appointment re-booked. The intervention was not formally quantified, but patient satisfaction improved and there was positive feedback from those who had missed appointments for a number of years.

Ho undertook an extensive work-flow analysis to improve the efficiency of a tertiary diabetes centre in Singapore, which informed subsequent changes [106]. When asked, people with diabetes said that an acceptable appointment waiting time was 30-60min and so each doctor had their consultations timed and appointments scheduled to accommodate this. New patient communication sheets helped facilitate flow from one part of the clinic to another. Telephone reminders were made one week before an appointment, and clinic information sheets sent to individuals detailing the running of the clinic and any tests required beforehand. The changes improved patient satisfaction and attendance rates (non-attendance decreased from 30% to 21%). Turnaround time did not significantly improve.

2.5.5.3 Web-Cams

Vijayaraghavan et al assessed whether offering clinic appointments via Skype using a Webcam to all people attending a specialist diabetes clinic in Newham, London would be acceptable to people with diabetes and address non-attendance [82]. The quality improvement project successfully reduced non-attendance from 25% to 13% and was regarded by people with diabetes as being

accessible and user-friendly. Interviews, focus groups and questionnaires highlighted that the intervention improved accessibility and flexibility, saved time and cost, whilst improving the clinician-patient relationship. Participants felt more 'in control' of the consultation process, and described more attention being paid to them by the physician.

2.6 Discussion

Research exploring non-attendance at diabetes clinics is diverse. How non-attendance is defined and computed differs across studies, a finding not unique to this review [116]. Studies on characteristics of non-attenders provide conflicting information, but in most instances, non-attendance was more likely in young adults, those from a lower socio-economic background and those who smoke. The first two of these associations are in keeping with the current broader literature on non-attendance across medical specialities [116, 117]. The lack of an association between social deprivation and non-attendance in the paper by McCarlie et al was in contrast to other studies in this review and the wider literature and was thought to have possibly been explained by those in less deprived areas finding it more difficult to take time off work to attend or having better general health and therefore not feeling the necessity in attending. The day of the appointment and experience of the provider were two other factors also shown to have an impact on likeliness to attend according to this review and as seen in other specialities [116].

Of the studies included in this review, ethnicity was only reported in one. A recently published report by NHS England on reducing non-attendance in outpatient services stresses the importance of capturing details on ethnicity to better understand the barriers to non-attendance amongst certain populations and to make sure that all groups are given equal opportunities to access healthcare [117]. Details on ethnicity are important when designing an intervention to make sure that it is tailored to those it is intended to serve.

In accordance with Griffin's review, non-attenders typically have higher HbA_{1c} and a greater vulnerability to adverse health outcomes. Nonetheless, as described by Griffin, this association

cannot imply causation. As demonstrated in qualitative work by Snow et al, sub-optimal measures including HbA_{1c} can instil fear of being judged by HCPs, consequently leading to non-attendance [85].

The reasons for non-attendance are manifold and differ both between individuals and for any one individual. The influencing factors may also vary from one missed appointment to the next. Contributors given in surveys are more logistical in nature but interviews and focus groups have provided richer data on the self-determinants and complex interplay between the behavioural, emotional and cognitive issues that may be involved and should be considered when attempting to address non-attendance. Although qualitative work is limited, it has highlighted the importance of HCP-patient relationships and an individual's coping mechanism. Periods of denial may even be part of coming to terms with a chronic health condition, not unique to diabetes. Other barriers (personal, organisational, environmental, economic, social or service related) are well reported, all of which can have a more profound influence on attendance than the perceived benefit of appointments. Some of these are more amenable to change (e.g. clinic structure) than others (e.g. language barriers).

Despite the breadth of different countries represented by the studies in this review, the characteristics and outcomes associated with non-attendance and the underlying reasons for this behaviour show no particular geographical patterns. Perhaps this is a reflection of the few studies from low- and middle-income countries. Financial difficulties influencing attendance existed both in private and government funded healthcare systems, although details of the financial difficulties were not described. Cultural and language barriers were not widely reported but do exist. When assessing illness perception in Thailand, a majority of participants were Buddhist and were more likely to believe that their diabetes was a result of internal factors [104]. In Iran, local customs meant that women felt unable to attend appointments on their own [110]. In England, language barriers meant that people handed over responsibility of their condition to their family members [81].

Regardless of the underlying reason for non-attendance, with missed appointments being associated with poorer outcomes, the behaviour can serve as a way of identifying those most at need who may benefit from additional or alternative models of healthcare delivery. Various interventions have been tried across a breadth of long-term conditions to improve clinic attendance, many focusing on different ways to remind people about their appointments [118]. Those who simply forget an appointment are likely only a small proportion of all non-attenders, however, and unlikely to be exposed to the same health implications as those who do not attend for other reasons. Perhaps this explains the modest effect simple appointment reminders have had on attendance when delivered by post, telephone call or text message [118]. By contrast, informing people what to expect at appointments can be more effective, perhaps by reducing some of the perceived barriers to attending, fear of the unknown and also by helping people to feel more empowered. Diabetes services have started to use novel techniques to deliver this information, including online videos [119].

In keeping with Griffin's recommendations, over time there has been a gradual move away from blaming non-attenders, towards the design of interventions that are more supportive, informative and patient empowering. In addition to greater access to information, examples of this have included providing patients with points of contact (e.g. patient navigators), offering an alternative appointment medium (e.g. virtual clinics) and attempting to improve the running and logistics of services.

2.7 Study Limitations

Due to the low number of RCTs and the high number of observational and qualitative studies, a statistical analysis was not undertaken and a summary of findings was produced. The majority of studies used basic designs, retrospective methods and convenience samples. The participants were typically attending single hospital based clinics, potentially limiting the generalisability of findings. Transferability can be achieved with a rich description of the study context, but this was lacking in several instances. A number of studies used univariate analyses which fails to address

possible confounding factors. These limitations make it hard to determine the 'active ingredients' associated with any effects or outcomes seen.

The inclusion criteria in this review relied on non-attendance at diabetes appointments being a primary or secondary outcome. These criteria may have excluded studies reporting non-attendance when this was not a clear endpoint. Repeated appointment cancellation has been associated with more frequent emergency department attendances [99] but was not explored in this review and often overlooked in papers reporting on non-attendance.

Although the review focussed on adults with diabetes, we included studies that reported attendance at transition or young persons' diabetes clinics. We acknowledge that the reasons for non-attendance by teenagers living at home with parental support are likely different from older adults with diabetes. Nevertheless we believe that it was important to include these studies to avoid missing important findings that span all age groups. The mean age of participants in all the transition papers was over 18 years. Even in the study by McCarlie et al which included people as young as 12 years of age, most of the participants were older than 30 years of age, and the study also provided important information on people older than 70 years [92]. An association has been observed between attendance at transition clinics and attendance patterns in later life, providing relevant evidence about long-term non-attendance.

Some of the reported variation in non-attendance rates across studies reflects how they were quantified. When defined as a percentage of total scheduled appointments, this fails to identify those missing multiple appointments who may be most at risk of unmet health needs. The same problem is true when a single missed appointment is classed as non-attendance. Furthermore, in some instances, non-attendance may have been artificially elevated due to administration error.

Qualitative studies that performed interviews rarely discussed potential biases and reflexivity of the interviewer(s). Along with the surveys, they also did not share the reasons why some individuals declined to participate. These individuals are an important group as they are arguably most vulnerable to the potential consequences of missed appointments.

Finally, the grey literature was not reviewed in this study due to the time constraints of the PhD and because there is no gold standard method for searching the grey literature. Whilst this enabled a form of standardisation and ensured a consistent degree scientific rigour of the studies included, incorporating the grey literature can reduce the impact of publication bias- studies with null findings or from certain population groups that may be less likely to publish work in scientific journals.

2.8 Conclusion

Non-attendance at diabetes appointments is a complex behaviour that is likely influenced by the person with diabetes, HCP and service factors. Qualitative work suggests that perceived barriers to attending, relationships and coping mechanisms are important contributory factors. The health outcomes for those who frequently miss appointments is worse compared to people who attend regularly. Interventions to improve attendance are limited but these have started to move away from appointment reminders to clinic restructuring, better supporting people with diabetes in the transition to adult services, patient navigators and alternative appointment formats including virtual clinics.

Future work addressing the gaps in our understanding of non-attendance, looking deeper into the issues and personal determinants that influence this behaviour, is pertinent in view of the poor quality of the currently available evidence. Much uncertainty remains in spite of the conclusions reached. Interventions designed to address the problem are complex and should be informed by the local context, communication with relevant stakeholders and collection of relevant primary and empirical data. The Medical Research Council's framework for complex interventions provides an iterative structure to consult when designing and evaluating a complex intervention [120]. Using this in the process can allow for clearer identification of 'active ingredients' contributing to an effect and facilitate generalisability of an intervention across healthcare settings.

2.9 Implications for design of the design of the CPDSS manual

This review highlights the scale of non-attendance, its association with worse health outcomes and the complexity of non-attendance behaviour which is still at large, poorly understood. The review helps support the rationale for designing an intervention to address non-attendance behaviour, but also infers that any one single intervention component is unlikely to suite all -the interplay of factors driving non-attendance are not the same from one person to the next. An individualistic approach is likely key, and an intervention which is there to support an individual when they decide they are most at need. These considerations, along with what is learnt in the subsequent chapters of this thesis, help feed into the needs analysis of a hypothetical CPDSS intervention.

Table 2: Table of included studies in the systematic review of non-attendance at diabetes outpatient appointments

Author, Year, Citation Number	Study aim(s) relevant to this analysis	Participants	Number of participants/records studied and mean age of participants	Study design/Method	Location of study
Archibald et al (1992) [80]	To explore the demographics of non-attenders and the underlying reasons for defaulting.	All patients re-referred during one calendar year who had lapsed from follow-up for at least 12 months.	74 (37 non-attenders, 37 attenders). Mean age of non-attenders (SD): 49.9 ± 16.4 years Mean age of regular attenders (SD): 53.0 (12.4) years	Observational-Retrospective cohort. Questionnaire included.	Liverpool, England
Akhter et al (2012) [83]	To investigate the reasons for non-attendance, characteristics of non-attenders and possible service improvement strategies from the point of view of the person with diabetes.	People with type 1 diabetes who had not attended at least 1 appointment in the diabetes service over the preceding year, and who were aged >25yrs.	126 non-attenders Mean age (SD): 43.9 (12.7) years	Telephone survey	Cambridge, England
Alvarez et al (2018) [113]	To determine whether a relationship exists between HbA_{1c} and the frequency of attendance at scheduled appointments, having been referred from or to a particular speciality.	**Adults** (20-95 yrs) with type 2 diabetes from one of 3 family healthcare centres.	2290 patient records Mean age: 62.9 years (range 20-95).	Observational-retrospective cohort (descriptive and analytical study of patient records)	Chile, S. America
Campbell-Richards (2016) [81]	To understand why there are high rates of non-attendance at the Newham diabetes service in ethnic minorities in order to identify any unmet needs and inform non-attendance strategies.	People with diabetes and of African, Bengali, Pakistani or White ethnicity.	Focus groups: focus group for type 1 diabetes (n=3), type 2 diabetes focus group (n=2). Interviews: regular attendees (n=5) and non-attendees (n=5). Mean age not specified	Qualitative- Focus group and semi-structured interviews.	Newham, England
Casey et al (2012) [97]	To determine attendance rates at a dedicated young adult clinics and whether poor attendance is a predictor of adverse outcomes.	People with type 1 diabetes aged 18-25 years attending the Galway University Hospital diabetes service.	137 records Mean age (SD): 22.9 (1.96) years	Observational-Retrospective cohort	Galway, Ireland

Ciechanowski et al (2006) [101]	To determine behavioural and clinical characteristics of diabetes associated with depression and non-attendance at primary care reviews in a representative primary care population.	People with diabetes from 9 primary care clinics.	3923 patients Mean age (SD) of secure, dismissing, fearful and pre-occupied attachment styles respectively : 62.7 (12.8) years 64.3 (9.8) years 59.8 (14.6) years 63.8 (14.4) years	Observational: Retrospective cohort and a postal questionnaire	Washington, USA
Currie et al (2013) [91]	To determine if a diagnostic record of poor medication taking or appointment non-attendance was associated with all-cause mortality in people with type 1 diabetes.	Type 1 diabetes (all ages)	2946 records Mean age (SD) of adherent: 27.9 (19.2) years Mean age (SD) of non-attenders: 29.1 (17.4) years	Observational- Retrospective cohort (data extracted from the Health Improvement Network (THIN) database)	Across the UK
Dyer et al (1998) [89]	To examine factors associated with non-attendance at a diabetic clinic.	People with type 1 diabetes attending one of four major diabetes outpatient clinics or young persons' clinics , age >16 years at a hospital in Birmingham	259 records Mean age (SD) of attenders: 29 (9)years Mean age (SD) of Non-attenders : 27 (7) years	Observational-Retrospective cohort. Questionnaire sent to a subset of 83 patients.	Birmingham, England
Elders et al (2014) [93]	To establish the characteristics of adults with type 1 diabetes who disengaged entirely from diabetes care provision.	Adults with Type 1 diabetes. Those who were classified as disengaged had no recorded HbA_{1c} value in either primary or secondary care during the preceding 15 months compared to those who had.	2772 records Mean age (SD) of engaged: 44.8 (15.8) years Mean age (SD) of disengaged: 37.2 (13.2) years	Observational-cross-sectional	Grampian, Scotland
Garcia Diaz et al (2017) [95]	To measure the impact of glycaemic control on adherence to hypoglycaemic agents and to medical visits, and to explore factors that predict adherence.	Notes of historical cohorts of people with type 2 diabetes age >18yrs attending a hospital clinic in Lanzarote 2011-2016	639 records Mean age (SD): 62 (11.5) years	Observational-retrospective cohort	Lanzarote, Spain

Gill and Owens (1998) [90]	To establish the degree of non-attendance at the diabetes centre at the Walton Hospital, Liverpool. This included attendance rates at the 4 routine diabetes clinics and the 'special' diabetes clinics (new referrals, young persons, foot problems and antenatal).	Patients with appointments at the diabetes centre.	7015 appointments assessed Mean age not specified	Observational-prospective audit	Liverpool, England
Hammersley et al. (1985) [88]	To establish why people with diabetes did not attend, assess their medical supervision and compare their glycaemic control and prevalence of diabetes complications to people who attended hospital clinics regularly	White European people with diabetes aged >64yrs who did not attend their appointment between 1971-1981.	148 (74 non-attenders, 74 matched controls) Mean age of non-insulin dependent attenders: 56.7 years Mean age of non-insulin dependent non-attenders: 55.7 years Mean age of insulin users who attended: 47.7 years Mean age of insulin users who attended: 47.0 years	Observational-retrospective cohort. Questionnaire included.	Wolverhampton, England
Hardy et al (2001) [87]	To establish whether an information pack sent to people with diabetes 2 weeks prior to their appointment and a telephone call 1 week before reduced non-attendance rates of new referrals to the diabetes clinic.	New referrals to the diabetes centre compared to historical new patient controls	325 new patients following introduction of the intervention. Mean age not specified	Single centre, prospective, non-randomised controlled study.	Merseyside, England
Heydarabadi et al (2017) [110]	To identify and explain factors influencing non-attendance of people with type 2 diabetes to rural health centres.	East Health Centre people with Type 2 diabetes, family members of people with type 2 diabetes, healthcare professionals of people with Type 2 diabetes. All aged >27 years.	26 (14 people with diabetes, 6 health workers, 3 doctors and 3 members of the person with diabetes' families). Age range 27-60 years	Qualitative-phenomenological method. Semi-structured interviews.	Iran
Ho (2014) [106]	An intervention to improve patient turn-around time (duration of time the patient spends at the diabetes centre for an appointment)	N/A	N/A	Quality Improvement project.	Singapore
Horny et al (2017) [100]	To improve self-management, glycaemic control and improve efficiency of care with the introduction of patient navigators.	People with diabetes enrolled in the clinic with an HbA_{1c} >8.5% (69 mmol/mol) who had at least one non-attendance in the past year or if their health care	656: 234 (intervention), 422 (reference) 196 in each group matched on propensity scores. Mean age (SD) intervention group : 56.3 (13.6) years	Observational-Retrospective cohort study.	Boston, USA

		professional requested the service.	Mean age (SD) reference group: 55.7 (13.6) years Mean age (SD) intervention match sample: 56 (14) years Mean age (SD) reference matched sample: 56 (13.7) years		
Hynes et al (2015) [111]	To develop a theory explaining attendance at a hospital-based diabetes clinic.	Young adults with type 1 diabetes (18-25yrs) and service providers from one hospital-based diabetes clinic were interviewed	29 (21 young adults with type 1 diabetes and 8 service providers) Mean age: 22.4 years (range 16-28 years)	Qualitative-Grounded theory methodology. Data were collected through semi-structured interviews.	Galway, Ireland
Karter et al (2004) [76]	The relationship between missed appointments and glycaemic control.	People on the Kaiser Permanente N.California diabetes register who had at least 1 outpatient appointment during the year 2000, maintained continuous membership and medical plan drug benefits and who had an HbA_{1c} during the study period.	84,040 records Mean age (SD): 60.8 (13.5) years	Observational-Cross-sectional	N. California, USA
Kellett (1988) [96]	To follow patients at a newly formed diabetes clinic from 1982 to 1985 and establish non-attendance rates. Outcomes were compared between non-attenders and those who attended.	Diabetes clinic attendees	127 records Mean age (SD) of attenders: 35 (12.5) years Mean age (SD) of non-attenders: 34 (9.1) years	Observational-retrospective cohort	Limerick, Ireland
Kurasawa et al (2016) [109]	To predict a missed clinical appointment using a machine based learning algorithm	Records of people with diabetes attending a hospital diabetes clinic in Japan.	879 records	Observational: Development and validation of a machine learning algorithm.	Tokyo, Japan
Lawson et al (2005) [94]	To understand the reasons behind the decision not to attend a type 1 diabetes hospital clinic.	People with type 1 diabetes who had not attended their hospital apt for 18 months. Age >25 years.	12 participants Mean age not specified	Qualitative study. Interpretative phenomenological analysis of semi-structured interviews	Cardiff, Wales
Levy-Shraga et al (2016) [108]	To determine whether a dedicated transition clinic for emerging adults with type 1 diabetes can improve glycaemic control and visit attendance.	People with type 1 diabetes attending the transition clinic. Age 22.1 yrs±2.7	53 records Mean age (SD): 22.1 (2.7) years	Observational-retrospective cohort	Israel
Low et al (2016) [107]	To assess the magnitude and risk factors of missed appointments in the diabetes centre in a Singapore hospital.	People with diabetes attending the clinic June 2010-May 2012.	1610 records Mean age (SD): 56.7 (14) years	Observational-retrospective cohort	Singapore

Masding et al. (2010) [86]	To determine non-attendance rates at a transitional diabetes clinic and the characteristics of non-attenders.	People attending the Poole Hospital diabetes transition clinic (age 15-21yrs)	114 records: 53 records (Jan-Dec 2004); 61 records (Sept 2007-2008) Mean age 2004 cohort: 17 years (range 14-21) Mean age 2007-8 cohort: 18 years (range 15-20)	Observational-comparative retrospective audit from Jan-Dec 2004 and Sept 2007-Sept2008.	Dorset, England
McCarlie et al (2002) [92]	To consider the factors which may influence the uptake of routine diabetes care.	Patients on the Ayshire and Arran diabetes register with no record of HbA_{1c} or fundoscopy in the previous year aged >12 yrs.	9,026 records Mean age not specified.	Observational study-audit	Scotland
McComb et al (2017) [99]	To determine the prevalence and impact of appointment cancellation	Adults with diabetes age >18 yrs	7586 patient appointments Mean age not specified.	Observational-audit	Indiana, USA
Ngwenya et al (2009) [105]	To determine the factors influencing non-attendance with clinic appointments in people with diabetes at a Gauteng Hospital in 2007/2008	Consecutive non-attending people with diabetes (all >18 yrs. mean age 51.2 years)	76 people with diabetes Mean age: 51 years (range 18-85)	Qualitative-Face to face and telephone interviews of a convenience sample of consecutive non-attending people with diabetes prospectively recruited for the study. Interviews lasted approximately 7 min.	Pretoria, S. Africa
Nuti et al (2012) [112]	To assess whether no-shows to primary care are associated with increased risk of emergency department visits or hospital admissions among people with diabetes.	Diabetes age >18yrs attending outpatient clinics associated with an academic medical centre in Indiana.	8787 records Mean age not specified.	Observational-Prospective cohort.	Indiana, USA
Snow and Fulop (2012) [85]	To study the reasons for attendance behaviour from the patient point of view.	Type 1 diabetes aged 18-25yrs	102 patient records, 17 patient interviews Mean age not specified.	Qualitative-Semi-structured interviews/case studies of 17 purposively chosen patients (9 men, 8 women) based on attendance behaviours-7 as regularly attending, 5 with a record of intermittent attendance, 3 who had never attended within the survey period, 2 who were new to the clinic but had an extensive history of non-attendance. Interviews were 20-30min.	London, England
Thongsai (2014) [104]	To identify predictors of non-attendance and to investigate the influence of illness perceptions on attendance at diabetes outpatient clinics.	Thai people with type 2 diabetes age >18yrs.	442 participants Mean age: 60 years	Qualitative-Descriptive study. Illness Perception Questionnaire (IPQ) tool used for measuring patient perception of illness (but amended to be in Thai).	Phitsanulok, Thailand

Vijayaraghavan et al (2015) [82]	Hypothesised that web-based consultations would reduce cost per contact by reducing non-attendance rate, demonstrate improved health outcomes over time and reduce cost for the patient by reducing travel.	Patients attending a hospital diabetes clinic in Newham.	96 participants Mean age not specified.	Intervention with a qualitative study component. All people attending follow-up appointments with one of the consultants or one of the nurses were offered the online appointments. Intervention was followed by 28 online Questionnaires, 34 interviews (19 in depth and 15 face to face) and 5 focus groups.	Newham, England
Weaver et al (2019) [98]	To determine if providing patient navigation affects first appointment no-show rates and HbA_{1c} in uninsured patients with diabetes at a free clinic.	Uninsured people with diabetes aged >19yrs.	192 (96 in each cohort) Mean age: 42.6 years (range 19.1-79.7)	Quality Improvement Project.	Alabama, N. America
White et al (2017) [103]	To assess the effect of an appointment management intervention on clinic attendance and disengagement after transition.	Type 1 diabetes. Aged 17-19 yrs. Recruited from a tertiary paediatric clinic and scheduled for transition to adult services at one of eight centres in Melbourne.	120 patients Mean age (SD) over all : 18.8 (0.6) years	Randomised control trial. Patients randomly assigned (1:1) to usual care or the appointment assignment intervention using sequentially sealed opaque envelopes.	Melbourne, Australia
Wilson and Greenhalgh (1999) [84]	To follow-up all non-attenders to a young person's diabetes clinic (age 16-25 years)	People with diabetes attending the young persons' clinic.	Not specified.	Quality Improvement	Manchester, England

Footnote: Where type of diabetes has not been specified in column 3, this indicates participants with either type 1 or type 2 diabetes

Abbreviations: SD- Standard Deviations; HbA_{1c} – Glycated haemoglobin

Chapter 3 The role of community pharmacists and their position in the delivery of diabetes care

3.1 Chapter outline

In this chapter I describe my narrative literature review on the role of community pharmacists and their position in the delivery of diabetes care which was published in the Postgraduate Medical Journal in March 2020.

3.2 Introduction and Background

As described in the preceding chapters, diabetes is one of the most prevalent chronic conditions. It is associated with significant disability, morbidity and mortality, and the number of adults living with the condition worldwide is growing in a steep linear fashion [15]. The implications this has on healthcare services are considerable [121].

In most countries, people with diabetes are offered support from a multi-disciplinary team of healthcare professionals. Pharmacists are highly skilled and comprise the third largest group of healthcare professionals, but to date, are a largely untapped resource in the delivery of diabetes care worldwide [122]. With the growing number of people living with diabetes and the increasing strain on healthcare services, pharmacists are well situated to offer collaborative and complementary expertise alongside current models of care [66, 122].

3.3 Aim

To summarise the literature on the impact of pharmacy-led diabetes interventions. This will develop my appreciation for the expanding role of community pharmacists and their potential for greater integration into diabetes care. Although a global perspective is given where possible, I

have used the UK to illustrate the facilitators and barriers to the wider involvement of community pharmacists.

3.4 Methods

To provide a summary of the evolving pharmacy profession and services, their strengths and the challenges limiting increased inter-operability with other healthcare services, published data from key organisations and stakeholders were reviewed. This included, but was not limited to, the International Pharmacy Federation, the Royal Pharmaceutical Services, the Pharmaceutical Services Negotiating Committee, NHS England, the National Institute for Health and Care Excellence (NICE) and the Kings Fund.

To explore the literature on pharmacy-led diabetes interventions, an online search was carried out using three databases: Medline, Embase and Cinahl, from the date of database inception until September 2019. These databases were chosen as they are recommended and accessible through the University of Southampton. They are also routinely referred to in the reporting of medical systematic reviews including those pertaining to pharmacy. When adopting an approach that considered the time restrictions of the thesis, other smaller databases such as PsychInfo were not deemed likely to identify many additional papers. PsychInfo is an index of psychological sciences and was also felt to have less applicability to this review than the other databases used. Searches were restricted to English language. The following search strategy was used:

Diabet* adj1 (type one or type 2 or “insulin dependent” or type 2 or type two or “non-insulin dependent”)

AND

Pharmac* adj1 (care or clinical or community or service*) or exp pharmaceutical services/

AND

Education or “self-management” or “self-care” or intervention or “medication management” or Knowledge or “glycosylated or glycated haemoglobin” or “HbA1c” or “behavior change” or “behaviour change” or “glycaemic control” or “glycemic control”

3.5 Introduction to pharmacy

3.5.1 Pharmacists and the pharmacy workforce

Globally there are over 2 million licensed or registered pharmacists, equivalent to 5 pharmacists per 10,000 population [123]. Access to pharmacy services, however, varies widely between low- and high-income countries with 8.28 pharmacists per 10,000 population in Europe compared to 0.61 in Africa [123]. Pharmacists work across a variety of settings including hospitals, general practice, outpatients, industry, the military and prisons, but the majority (70%) are based in community pharmacies [123, 124].

Pharmacy training differs across the world, but typically comprises a four year Master of Pharmacy undergraduate degree followed by a pre-registration year [122]. Once registered, pharmacists may undergo further training to become more specialised and/or independent prescribers [125].

Other important members of the community pharmacy workforce include pharmacy technicians and pharmacy assistants who work alongside and under the supervision of licensed pharmacists. Pharmacy technicians help manage the supply of medicines and devices in a pharmacy. They also assist pharmacists with advisory services. To train as a pharmacy technician takes a minimum of two years and requires completion of a General Pharmaceutical Council (GPhC) approved qualification or apprenticeship pathway. Regular revalidation is a professional obligation for both pharmacists and pharmacy technicians. Pharmacy assistants are not regulated and formal qualifications are not a pre-requisite, but appropriate education and training is available and encouraged. Pharmacy assistants are able to help with the dispensing and supply of medicines

and medical devices, offer advice on their use and provide assistance to the other pharmacy professionals.

3.5.2 Commissioning of community pharmacy services

Rapid changes are occurring globally in how community pharmacies are remunerated, with less focus on dispensing and more focus on clinical services [126]. Payment methods and fees for pharmacy services vary widely across countries and between districts. Some services are reimbursed by government agencies or insurance plans while in other settings, services are paid directly by patients or funded by academic institutions. Regardless of the mechanism of payment, there has been a gradual shift towards quality-based reimbursement and less opportunity for business autonomy. For example, in England, where community pharmacies provide their services under the Community Pharmacy Contractual Framework, all pharmacies must demonstrate that they actively promote health and well-being, and through a structured framework, provide a breadth of public health services to empower people to self-manage their health [127]. Extra funding is available for pharmacists to undertake additional work [127]. Although this changes annually, for 2019/2020, checking that people with diabetes have had their annual foot check and retinal screening is one of the optional requirements to acquire additional revenue.

3.6 Strengths of community pharmacists

3.6.1 Trust and accessibility

Pharmacists are one of the most trusted professions worldwide alongside firefighters, nurses, teachers and doctors [128]. Different cultural, religious and socio-economic backgrounds are represented by the pharmacy workforce, and this wealth of diversity potentially minimizes the impact of any language or cultural barriers that may impact healthcare delivery [125].

Pharmacists are the most accessible health care provider in many parts of the world, and this access is typically greatest in areas of highest deprivation - the "positive pharmacy care law" [69]. In the UK, the majority of the population have a pharmacy within a 20-minute walk from their household [67]. Pharmacies have longer working hours than many other healthcare facilities and are accessible without registration, therefore offer a degree of anonymity, alongside a flexible, informal environment [122]. 90% of community pharmacies in England have private consultation rooms which makes them well equipped for more confidential discussions and services [122].

In England, adults visit a pharmacy on average 16 times a year, and those with diabetes are known to visit their pharmacist three to eight times more frequently than those without diabetes [129, 130]. There are 1.2 million health related visits each day across the 11,700 community pharmacies in England [122]. This frequency of access makes pharmacists well placed to recognise the early signs and symptoms of long-term conditions including diabetes, as well as helping to prevent these conditions and their associated complications.

3.6.2 Improving concordance with prescribed medication/ understanding prescribed medication

NHS England has recognised systematic support from community pharmacists in medication taking as a "high value intervention" for the reduction of cardiovascular disease in people living with diabetes [131]. Taking medication as prescribed correlates with positive health outcomes while not taking medication can be associated with therapeutic failure, hospitalisation and disease progression [132]. It should also be considered, however, that de-prescribing medications that are no longer relevant or causing harm is equally important [133]. Between 30% and 50% of the medicines prescribed for long term conditions are not taken correctly or are inappropriately prescribed, and this is where pharmacy interventions have been of particular benefit [134]. All prescribing can be associated with harm, but a recent cluster randomised controlled trial estimating the effectiveness, cost effectiveness and safety of pharmacy independent prescribers

across care homes in England, Scotland and Northern Ireland demonstrated that it was safe and well received with no adverse events or safety concerns identified [135].

The second Diabetes Attitudes, Wishes and Needs (DAWN) study in 2012 was the largest global psychosocial diabetes survey of its kind. It explored the perceptions and attitudes of more than 8,000 people with diabetes, 2,000 family members as well as nearly 5,000 health-care professionals across 17 countries [12]. The study revealed that more than a third of people with diabetes felt that their medication interfered with their life and that their treatment regimen was too complicated. Pharmacists are skilled at performing medication reviews, and their expertise is well suited to supporting people who are having difficulties with their treatment regimen. More than 55% of people with diabetes are worried about the risk of hypoglycaemia [12] . Pharmacists can provide individual education and advice on how to minimise this risk.

Better support and lower disease burden, in terms of complications, are both associated with more favourable outcomes with respect to well-being and quality-of-life [12]. Community pharmacists can provide additional support to what already takes place in existing diabetes healthcare services, and in doing so, help to reduce disease burden.

3.6.3 Scope for development of more integrated working

Globally, pharmacists are assuming more active clinical positions within inter-professional healthcare teams [126]. Their roles are expanding from traditional dispensing to include more comprehensive clinical services [123, 126]. Specialist pharmacy services are now being offered in more than 50% of countries and territories and include disease management programmes, clinical measurements and medicine usage reviews [123]. Pharmacists have also begun to integrate with primary care practices in England, and by 2020/2021, NHS England has made a commitment to have one pharmacist embedded in general practice for every 30,000 of the population [122].

The International Pharmaceutical Federation envisages a future of common patient databases and shared care protocols across care settings, developed collaboratively and based on best evidence

[126]. Digital integration is important for this and for pharmacy services to become better embedded into healthcare models, but is still limited in most countries [123].

3.6.4 Financial sustainability

Considerable cost savings can be achieved globally, across a breadth of settings by increased delivery of additional services in community pharmacy [136]. An independent report demonstrated that community pharmacy in England contributed an in-year benefit of £3 billion in 2015, with the activities in that year expected to accrue a further £1.9 billion in value over the next 20 years [137]. More work is required to understand which pharmacy services have the most substantive clinical benefits to patients whilst also delivering cost savings for healthcare budgets worldwide [136].

3.6.5 Response to a global Covid-19 pandemic

During the Covid-19 pandemic, community pharmacy have rapidly stepped up, adapting their services to support the healthcare needs of the public during unprecedented times [138]. Some have argued that they are the "unsung heroes on our high streets" [139]. In the UK, an increasing number of people visited their local pharmacy when they were unable to see their GP or their GP surgery had been operating a closed-door policy [138]. Many community pharmacies extended their working hours and expanded their services to accommodate social distancing and the evolving needs of the population. They took steps to support the most vulnerable in the society. Two notable examples have included their extended home delivery services for those having to self-isolate and putting measures in place to serve as safe places where victims of domestic abuse have been able to contact specialist domestic abuse services for support and advice [140].

During the initial peak of the virus in early spring of 2020, problematic behaviours including stock piling of medications led to supply problems that had to be addressed. Further adding to the challenges, the usually small and specialised team of community pharmacies also had to handle staff shortages, with 15% of staff in community pharmacy in April 2020 thought to have been

unable to attend work due to the coronavirus. How community pharmacy has responded to recent events reveals their commitment, adaptability and contribution to our health and social care system, particularly during a time of need.

3.7 Opportunities for community pharmacists in diabetes care

Government policies are beginning to recognise the value of community pharmacists in supporting the management of people with long-term conditions such as diabetes [126]. The frequent contact the public has with pharmacists is unique and this contact is greatest in those with long-term conditions, notably diabetes. The management of diabetes is complex, relying on self-care practices [141]. These include, but are not limited to, careful attention to lifestyle including diet, regularly attending healthcare appointments, taking medication(s), and in some instances, having to regularly measure blood glucose and inject insulin.

Empowerment is key to enabling people with diabetes to manage their condition and to adapt to various life circumstances [142]. For some, this journey can be more challenging. A healthcare appointment may not coincide with when an individual most needs help or support, and there are several reasons why an individual with diabetes may become 'hardly reached'. It has been well described that 'hardly reached' individuals are at increased risk of diabetes related complications [143].

The Royal Pharmaceutical Society has stated that pharmacists should be supported to play a greater role in the psychological and emotional support of those living with diabetes [125]. With their increased availability, accessibility and informal set-up, pharmacists have the potential to be there for individuals when they are most at need. With appropriate training, they are well positioned to notice 'red flags' such as acute foot problems, frequent hypoglycaemia, diabetes distress, and to refer to appropriate services if needed, whilst offering an alternative means of identifying and reaching out to people who are struggling.

3.8 Community pharmacy interventions in diabetes

Community pharmacy interventions have been trialled across a breadth of healthcare settings, covering a variety of chronic health conditions including asthma [144], chronic obstructive pulmonary disease (COPD) [145] and cardiovascular disease [146] amongst others. There is an expanding body of evidence exploring the role of community pharmacists in the delivery of diabetes care (**Error! Reference source not found.** and

Table 4). Despite varied settings, healthcare models and population groups, several systematic reviews have demonstrated the favourable impact community pharmacy interventions have on both clinical and patient-related outcomes (

Table 4) [147-155].

Table 3: Pharmacy diabetes intervention studies included in the review on community pharmacy

Paper	Type of Study	Participants	Intervention	Intervention Duration	Results
Ali M et al. Impact of community pharmacy diabetes monitoring and education programme on diabetes management: a randomized controlled study. Diabet Med. 2012;29(9):e326-33. **[129]**	Randomised Controlled Trial	Adults with type 2 diabetes 46 participants	Monitoring/counselling by a community pharmacist on six occasions over a 12-month period alongside an education programme on diabetes, its treatment and associated cardiovascular risk factors.	12 months	HbA_{1c} fell from 66 mmol/mol (8.2%) to 49 mmol/mol (6.6%) (P < 0.001) in the intervention group, compared with reduction from 65 mmol/mol (8.1%) to 59 mmol/mol (7.5%) in the control group (P = 0.03). Blood pressure fell from 146/87 to 126/81 mmHg in the intervention group (P = 0.01) compared with no significant change in the control group (136/86 to 139/82 mmHg). Significant reductions in BMI (30.8 to 27 kg/m^2, P < 0.001) and blood glucose (8.8 to 6.9 mmol/l, P < 0.001) were also observed in the intervention group as compared with no significant changes in the control group. Lipid profile changes were mixed. In the intervention group, improvements were seen in diabetes-related quality of life (P = 0.001), diabetes knowledge (P = 0.018), belief about the need for medication (P = 0.004) and reduced concerns regarding medication (P < 0.001).
Obarcanin E et al, Pharmaceutical care of adolescents with diabetes mellitus type 1: the DIADEMA study, a randomized controlled trial. International Journal of Clinical Pharmacy. 2015;37(5):790-8. **[156]**	Randomised Controlled Trial	Adolescents with type 1 diabetes 68 participants	Monthly structured pharmaceutical care visits delivered by pharmacists plus supplementary visits and phone calls on an as needed basis, for 6 months.	6 months	The improvement from baseline in HbA_{1c} was significantly greater in the intervention group than in the control group after 6 months (change from baseline −0.54 vs. +0.32 %, $p = 0.0075$), even after adjustment for country-specific variables ($p = 0.0078$). However, the effect was more pronounced after only 3 months (−1.09 vs. +0.23 %, $p = 0.00002$). There was no significant between-group difference in the number of severe hypoglycemia events. ($p = 0.1276$).
Lauffenburger JC et al, Impact of a novel pharmacist-delivered behavioral intervention for patients with poorly-controlled diabetes: The ENhancing outcomes through Goal Assessment and Generating Engagement in Diabetes Mellitus (ENGAGE-DM) pragmatic	Randomised Controlled Trial	1400 adults (age 18-64 yr) with type 2 diabetes	A telephone intervention by a clinical pharmacist consisting of a 2-step process that integrated brief negotiated interviewing and shared decision-making to identify patient goals and options for enhancing diabetes management.	12 months	Change in HbA_{1c} from baseline was -0.79 (SD:2.01) in the control arm and -0.75 (SD:1.76) in the intervention arm (difference:+0.04, 95%CI: -0.22, 0.30). There were no significant differences in adherence. In as-treated analyses, the intervention significantly improved diabetes control (-0.48, 95%CI: -0.91, -0.05).

Paper	Type of Study	Participants	Intervention	Intervention Duration	Results
randomized trial. PLOS ONE. 2019;14(4):e0214754. **[157]**					
Syarifuddin S et al, Impact of Pharmacist Intervention on Improving the Quality of Life of Patients with Type 2 Diabetes Mellitus. Open Access Macedonian Journal Of Medical Sciences. 2019;7(8):1401-5. **[158]**	Cohort Study	Adults with type 2 diabetes 45 participants	Education provided to the participants comprised lifestyle changes (physical activity and eating habit), adherence to the prescribed medications, and how to use and to store the medications.	3 months	The mean QOL (in the score) of the participants: before the intervention, 61.07 ± 15.13; after the intervention, 70.15 ± 14.23, there was a significant difference between groups with and without interventions, $p < 0.001$.
Withidpanyawong U et al, Family-based intervention by pharmacists for type 2 diabetes: A randomised controlled trial. Patient education and counselling. 2019;102(1):85-92. **[159]**	Randomised Controlled Trial	Adults with type 2 diabetes 196 participants	A pharmacist delivered educational sessions and encouraged family members to take an active role in self-management practices.	9 months	There was a greater reduction in glycated haemoglobin (HbA_{1c}) in the intervention group than in the control group (−1.37% and −0.21%, respectively; $P < 0.001$). Between-group differences in the improvements of low-density lipoprotein cholesterol (LDL-C) and blood pressure were found ($P < 0.05$). Higher scores in diabetes knowledge of patients, family support, medication adherence, self-management and self-efficacy were seen in the intervention group than in the control group ($P < 0.05$). Multivariable analysis showed family members who were spouses or women were strong predictors of improved glycaemic control.

Table 4- Table of review articles included in the review of community pharmacy

Study	**Type of Review**	**Number of studies included**	**Results**
Machado M et al, Sensitivity of Patient Outcomes to Pharmacist Interventions. Part I: Systematic Review and Meta-Analysis in Diabetes Management, Annals of Pharmacotherapy, 2007. 1569-82 p. **[150]**	Systematic Review and Meta-analysis	36 in total: -18 randomised controlled trials -9 non-randomised controlled trials -2 pre- and post observational cohorts -1 retrospective cohort study -5 chart reviews and -1 database study	Diabetes education (69%) and medication management (61%) were the most frequently used Interventions. Mean ± SD quality was 62 ± 11% (fair). Fifty-one (69%) study results were sensitive, Meta-analysis of data from 2247 participants in 16 studies found a significant reduction in hemoglobin A_{1C} levels in the pharmacists' intervention group (1.00 ± 0.28%; p < 0.001) but not in controls (0.28 ± 0.29%; p = 0.335). Pharmacists' interventions further reduced HbA_{1c} values 0.62 ± 0.29% (p = 0.03) over controls.
Collins C et al, Effect of pharmacist intervention on glycemic control in diabetes. Diabetes Research and Clinical Practice. 2011;92(2):145-52. **[148]**	Systematic Review and Meta-analysis	14 randomised controlled trials	Pharmacist intervention significantly lowered HbA_{1C} (*n* = 14 trials, WMD −0.76%, 95%CI −1.06 to −0.47) and fasting blood glucose (FBG) (*n* = 4 trials, WMD −29.32 mg/dL, 95%CI −39.54 to −19.10). A moderate to high degree of statistical heterogeneity was observed in these analyses (I^2 ≥ 44.1% for both).
Santschi V et al, Pharmacist Interventions to Improve Cardiovascular Disease Risk Factors in Diabetes. Diabetes Care. 2012;35(12):2706. **[151]**	Systematic Review and Meta-analysis	15 randomised controlled trials. -8 pharmacy only interventions -7 interventions with pharmacists in collaboration with other HCPs.	Pharmacist interventions included medication management, educational interventions, feedback to physicians, measurement of CVD risk factors, or patient-reminder systems. Compared with usual care, pharmacist care was associated with significant reductions for systolic BP (12 studies with 1,894 participants; −6.2 mmHg (95% CI −7.8 to −4.6)); diastolic BP (9 studies with 1,496 patients; −4.5 mmHg (−6.2 to −2.8)); TC (8 studies with 1,280 patients; −15.2 mg/dL (−24.7 to −5.7)); LDL cholesterol (9 studies with 8,084 patients; −11.7 mg/dL (−15.8 to −7.6)); and BMI (5 studies with 751 patients; −0.9 kg/m^2 (−1.7 to −0.1)). Pharmacist care was not associated with a significant change in HDL cholesterol (6 studies with 826 patients; 0.2 mg/dL (−1.9 to 2.4)).

Study	Type of Review	Number of studies included	Results
Antoine S-L et al, Improving the adherence of type 2 diabetes mellitus patients with pharmacy care: a systematic review of randomized controlled trials. BMC Endocrine Disorders. 2014;14(1):53. **[147]**	Systematic Review	6 randomised controlled trials	The outcomes of the analysed studies indicate that pharmacists could have an influential and important role in the respective health care system to improve adherence in patients taking oral type 2 diabetes mellitus medication. However, the heterogeneity of study populations interventions, adherence measures and outcomes in the included studies prevents a comparison as well as a generalization.
Pousinho S et al, Pharmacist Interventions in the Management of Type 2 Diabetes Mellitus: A Systematic Review of Randomized Controlled Trials. Journal of Managed Care & Specialty Pharmacy. 2016;22(5):493-515. **[160]**	Systematic Review	36 randomised controlled trials.	HbA_{1c} was evaluated in 26 studies, of which 24 reported a greater reduction in this outcome in the intervention group compared with the control group, with the difference in change between groups ranging from -0.18% to -2.1%. Eighteen studies assessed change in systolic blood pressure, of which 17 studies reported a greater improvement in this outcome in the intervention group, with the difference in change between groups varying between -3.3 mmHg and -23.05 mmHg. For diastolic blood pressure, a greater effect was also observed in the intervention group in 14 out of 15 studies, with the difference in change between groups varying between -0.21 mmHg and -9.1 mmHg. Thirteen studies described total cholesterol as an outcome measure, of which 10 reported a greater improvement in this outcome in the intervention group, with the difference in change between groups ranging from +18.95 mg/dL to -32.48 mg/dL. With regard to low-density lipoprotein cholesterol, a greater reduction in this parameter in the intervention group was documented in 12 out of 15 studies, with the difference in change between groups varying between +7.35 mg/dL and -30 mg/dL. Similarly, favourable data were reported on high-density lipoprotein cholesterol in the intervention group in 9 out of 12 studies that assessed this outcome, with the difference in change between groups ranging from -5.8 mg/dL to +11 mg/dL. Data on triglycerides were also reported in 12 studies, of which 9 reported a greater reduction in triglycerides levels in the intervention group, with the difference in change between groups varying between +12 mg/dL and -62 mg/dL. Overall, a beneficial effect on BMI was also described in the intervention group in 12 out of 14 studies. Of note, in all 6 studies that estimated the 10-year CHD risk among study patients, a greater improvement in the intervention group versus the control group was found. In addition, pharmacist interventions also had a positive impact on medication adherence and HRQoL in most studies that ascertained these outcomes. Finally, although only 3 studies conducted a cost-effectiveness analysis, pharmacist interventions proved to be cost-effective.

Study	Type of Review	Number of studies included	Results
Deters MA et al, Effective Interventions for Diabetes Patients by Community Pharmacists: A Meta-analysis of Pharmaceutical Care Components. Annals of Pharmacotherapy. 2017;52(2):198-211. **[161]**	Systematic Review and Meta-analysis	11 randomised controlled trials	The calculated meta-analytical effect of 640 analysed patients was a HbA_{1C} difference of -0.66%, with a 95% CI of -0.86% to -0.45%. The analysis revealed that most intervention elements had a significant positive meta-analytical effect on the HbA_{1C} values.
Fazel MT et al, Impact of Diabetes Care by Pharmacists as Part of Health Care Team in Ambulatory Settings: A Systematic Review and Meta-analysis. Annals of Pharmacotherapy. 2017;51(10):890-907. **[162]**	Systematic Review and Meta-analysis	42 randomised controlled trials (35 included in the meta-analysis)	The overall standardized mean difference (SMD) for A1C for pharmacist care versus comparison was 0.57 ($P < 0.01$), a moderate effect representing a mean difference of 1.1% (95% CI = 0.88-1.27). The effects for systolic blood pressure and low-density lipoprotein cholesterol were between small and moderate (SMD = 0.31 and 0.32; $P < 0.01$). The heterogeneity was high for all outcomes (>83%), indicating functional differences among the studies.
van Eikenhorst L et al, Pharmacist-Led Self-management Interventions to Improve Diabetes Outcomes. A Systematic Literature Review and Meta-Analysis. Frontiers in pharmacology. 2017;8:891-. **[163]**	Systematic Review and Meta-analysis	24 randomised controlled trials	Pharmacist-led self-management interventions included education on diabetes complications, medication, lifestyle, and teaching of self-management skills. Some studies focused on patient needs through a tailored intervention. No key components for a successful self-management intervention could be identified. Pharmacist-led self-management interventions improve HbA_{1c} levels with a mean of 0.71% (CI −0.91, −0.51; overall effect P < 0.0001) and had a positive effect on blood pressure (SBP −5.20 mm Hg (−7.58; −2.92), DBP −3.51 mmHg (−6.00; −1.01)), BMI (−0.49 kg/m2 (−0.79; −0.19)), lipids (total cholesterol −0.19 mmol/l (−0.33; −0.05), LDL-C mmol/l −0.16 (−0.26; −0.06), HDL-C 0.32 mmol/l (0.02; 0.61)), self-management skill development, and adherence to medication.
Bukhsh A et al, Efficacy of Pharmacist Based Diabetes Educational Interventions on Clinical Outcomes of Adults With Type 2 Diabetes Mellitus: A Network Meta-Analysis. Frontiers in pharmacology. 2018;9:339-. **[164]**	Network meta-analysis	43 randomised controlled trials	Network meta-analysis demonstrated that all interventions significantly lowered HbA_{1c} compared to usual care, but there was no statistical evidence from this study that one intervention was significantly better than the other for reducing HbA_{1c}. Pharmacist based diabetes education plus pharmaceutical care showed maximum efficacy for reducing HbA_{1c} (-0.86, 95% CI -0.983, -0.727; $p < 0.001$). Pharmacist based diabetes education plus pharmaceutical care was observed to be statistically significant in lowering levels of systolic blood pressure (-4.94; 95%CI -8.65, -1.23) and triglycerides levels (-0.26, 95%CI -0.51, -0.01), as compared to the interventions which involved diabetes education by pharmacist, and for

Study	Type of Review	Number of studies included	Results
			body mass index (BMI) (-0.57; 95%CI -1.25, -0.12) in comparison to diabetes education by health care team involving pharmacist as member.
Bukhsh A et al, Effectiveness of pharmacist-led educational interventions on self-care activities and glycemic control of type 2 diabetes patients: a systematic review and meta-analysis. Patient preference and adherence. 2018;12:2457-74. **[165]**	Meta-analysis	11 randomised controlled trials	Meta-analysis demonstrated that pharmacist-led interventions had a significant effect on lowering HbA_{1c} (−0.66; 95% CI (−0.83, −0.50); I^2=58.3%; P=0.008), in comparison to usual care. Self-care activities were assessed by using Summary of Diabetes Self-care Activities tool in eight studies. Overall meta-analysis of self-care activities for included studies demonstrated a significant effect of pharmacist-led interventions on improvement of self-monitoring of blood glucose (1.62; 95% CI (0.92, 2.32); I^2=70.5%; P=0.005), foot care (1.20; 95% CI (0.49, 1.90); I^2=95.0%; P<0.001), and overall diet (1.16; 95% CI (0.38, 1.93); I^2=64.2%; P=0.094).
Babar ZUD et al, Glycemic control through pharmaceutical care: a meta-analysis of randomized controlled trials. Journal of Pharmaceutical Health Services Research. 2019;10(1):35-44. **[154]**	Systematic Review	13 randomised controlled trials	The interventions included care plan development, medication reviews, patient education and counselling of patients with follow-up. All RCTs reported statistically significant reductions in HbA_{1c} in the intervention group (SMD = −0.97; 95% CI −1.21 to −0.73; P = 0.00001) as compared to the control group. Significant heterogeneity in SMD (χ^2 = 68.96) was observed.
Presley B et al, Pharmacy-led interventions to improve medication adherence among adults with diabetes: A systematic review and meta-analysis. Research In Social & Administrative Pharmacy: RSAP. 2019;15(9):1057-67. **[155]**	Meta-analysis	59 randomised controlled trials	Pharmacist-led interventions enhanced outcomes in patients with diabetes (standardized mean difference (SMD) -0.68; 95% CI -0.79, -0.58; p < 0.001). Sub-group analysis by intervention strategy, the type of intervention and outcome measures produced similar results. Further analysis showed that education, printed/digital material, training/group discussion, were more effective than other interventions.

Study	**Type of Review**	**Number of studies included**	**Results**
Soprovich AL et al, Systematic review of community pharmacy–based and pharmacist-led foot care interventions for adults with type 2 diabetes. Canadian Pharmacists Journal. 2019;152(2):109-16. **[166]**	Systematic Review	7 studies (2 were randomised controlled trials)	Six out of 7 studies reported significantly positive findings related to foot care practices.

Compared to diabetes interventions led by other healthcare professionals, those run by pharmacists have delivered at least comparable effectiveness in terms of lowering HbA_{1c}, and improving cardiovascular risk factors, self-management and medication taking [153, 155, 160, 167, 168]. Furthermore, improvements in HbA_{1c} are not always influenced by starting HbA_{1c} or the age of the participant [162]. The comparable effectiveness of pharmacist-led interventions compared with the same intervention delivered by other healthcare professionals is an important finding, particularly as role substitution can have profound implications for healthcare costs.

The positive impact of pharmacy interventions is not always clear, however. A 2018 Cochrane review on pharmacy services for non-hospitalised patients showed varying effects of pharmacy interventions on patient outcomes compared to usual care for long term conditions including diabetes, hypertension, hyperlipidaemia and depression [168]. Some services appeared to have little effect whilst others positively influenced clinically significant changes in important outcomes. The authors commented that the majority of included studies failed to report on potential harms associated with interventions (e.g. hypoglycaemia from glycaemic optimisation or hypotension from overzealous blood pressure lowering). Adverse events such as these are important when considering the overall impact and acceptability of an intervention.

In addition to the effect of pharmacy interventions on clinical outcomes, a recent Cochrane review looking at health-promotion interventions in the community pharmacy context suggested that an improvement in the behaviour of pharmacy workers can be seen, and that health promotion by pharmacists can have a beneficial effect on health-related behaviour and quality of life for pharmacy users [169].

A limitation to pharmacy interventions to date is that they are poorly described, thus limiting the ability to replicate them in future trials or service delivery. Furthermore, the heterogeneity in study populations, types of interventions and reported outcomes mean caution must be taken when drawing conclusions from reviews. I will now draw reference to community pharmacy

interventions that have been specific to type 2 diabetes and then go on to discuss pharmacy interventions that have particularly pertained to type 1 diabetes.

3.8.1 Interventions for type 2 diabetes

A significant majority of studies evaluating the effectiveness of pharmacy delivered interventions for diabetes have focused on type 2 diabetes. The duration of interventions has typically ranged from 3-12 months, while the follow-up period has ranged from 1 month to 4 years [155, 164]. There is conflicting evidence as to whether duration predicts effect [152, 154, 155] but it has been proposed that frequency of contact is most important [163].

The outcomes measured in diabetes pharmacy interventions worldwide have been varied and not always standardised, making interpretation of findings complex. Outcome measures have included HbA_{1c}, fasting glucose, self-measurement of blood glucose, blood lipids, body mass index, blood pressure, measures of diabetes self-care, medication adherence, diet, exercise and foot care [165]. Meta-analyses have found that interventions that combine diabetes education with pharmacy care have the greatest impact across a variety of health outcomes [155, 164]. Although positive effects have been demonstrated across health outcomes, a network meta-analysis of pharmacy delivered education interventions confirmed both clinically and statistically significant positive effects on HbA_{1c} , body mass index, blood pressure and lipid profiles [164].

A majority of pharmacy- delivered interventions to date have been reliant on face-to-face consultations with a pharmacist with a median duration of 45 minutes [152]. Although most intervention elements have demonstrated a significantly positive affect on HbA_{1c}, the most effective of these have been patient-centred and personalised and involved working across disciplines [152]. Goal setting and sending feedback or recommendations to the GP had the greatest effect in a systematic review; however, the details of the interventions are often poorly described, making translation of these findings into clinical practice in other settings challenging [152].

Intervention components that included reviewing blood glucose data helped empower people with diabetes; however, the measurements and assessments that had the most notable influence on HbA_{1c}, were those assessing current health status, patient health beliefs and current medication knowledge [152].

When considering patient-related outcome measures, pharmacy interventions have achieved statistically significant improvements in the quality of life for those living with type 2 diabetes, in part, by increasing diabetes knowledge and reducing concerns about diabetes medications [129, 158]. Although the evidence is limited, community pharmacists have also shown to be capable of providing a breadth of foot care interventions to people with diabetes, resulting in improved foot outcomes [166].

Whilst most interventions have focused on the individual with diabetes, family-based interventions by pharmacists for type 2 diabetes have also exhibited statistically significant reductions in HbA_{1c}, blood pressure and blood lipids [159]. This was most notable when the family member was a female care-giver or wife.

The training pharmacists receive for diabetes interventions differs significantly in duration between studies, with a median of 13 hours [152]. Topics covered during this training have typically consisted of information on the pathophysiology, diagnosis and treatment of diabetes, lifestyle advice and practical aspects of diabetes self-management [152]. There is large variation in the content and delivery of diabetes pharmacy interventions [163, 165], and whilst it is clear that a majority have had favourable effects, the granularity of their component parts are often poorly described, making it difficult to define the active and reproducible constituents [164].

3.8.2 Interventions for type 1 diabetes

Although there is less published evidence for interventions specific to type 1 diabetes, the available evidence suggests that interventions have proven effective [152, 156]. When tailored to adolescents with type 1 diabetes and elevated HbA_{1c}, Obarcanin et al. demonstrated that a multi-

disciplinary pharmacy care intervention could improve quality of life and HbA_{1c} without increasing the frequency of hypoglycaemia [156]. The 6-month intervention included monthly 60-90 minute scheduled visits with a pharmacist. Clinical data were recorded and assessments made to identify any problems or drug-related needs. Care plans were drawn up with the individual to incorporate at least one measurable goal and one problem-solving task. The participant's physician was kept informed and helped oversee the intervention. The effect was most noticeable after 3 months.

3.8.3 Tele-medicine interventions

Tele-medicine has proven to be feasible in the delivery of diabetes care, with modest benefit in lowering HbA_{1c} and improving other clinical outcomes with greater sustainability over time in comparison to usual care [170, 171]. Multi-disciplinary tele-medicine clinics including pharmacists have helped reach people with diabetes in more rural areas to good effect [171].

Lauffenburger et al trialled a behavioural pharmacist telephone intervention aimed at improving glycaemic control in those with an HbA_{1c} of >64mmol/mol (>8%) [157]. The pharmacists used brief negotiated interviewing and shared decision making to identify and set patient goals. The goals focused on either treatment intensification or addressing lifestyle factors. There was a significant reduction in HbA_{1c} when measuring 'as treated', but not when measuring 'intention to treat'. Only 30% or those approached accepted the initial pharmacist telephone consultation and 25% of participants were not ready to change the way they managed their diabetes. It was felt that a more thorough assessment of the participants' perceived or real barriers to disease management would have strengthened the intervention. The authors described the difficulty in delivering the intervention in the context of multiple co-morbidities. Other trials piloting pharmacy telephone interventions in diabetes care are in progress [172].

3.8.4 Limitations of published studies

Pharmacy based interventions are complex health endeavours that include several interactive and influencing factors, many of which cannot be measured. This complexity makes it difficult to pinpoint the active and reproducible ingredients contributing to an effect, or lack thereof.

A number of randomised controlled trials demonstrate a sizeable risk of bias when they have been assessed for quality. This has largely been a result of the randomisation process and deviation from the intended intervention due to lack of blinding of participants [152, 155]. Nonetheless, there is consistency across studies showing that community pharmacy interventions are capable of offering an additional strategy and skillset in the delivery of diabetes care which often leads to improved healthcare outcomes for those enrolled. However, to date there remains a lack of evidence of the long-term outcomes associated with pharmacy-led care.

3.9 Barriers to community pharmacy

3.9.1 The Murray Report

An independent review of community pharmacy clinical services in England published in 2016 by the Kings Fund, the Murray report, highlighted that renewed efforts should be made to make the most of the existing clinical services provided by pharmacists, particularly as the uptake of these had been poor [173, 174]. Three key thematic barriers were identified as contributing to the low uptake of the clinical services delivered by pharmacists. First, poor integration with other parts of the NHS, largely as a result of the limited capability of available digital platforms. Secondly, culture and behavioural issues in primary care around the role and identity of pharmacists, significantly slowing the mobilisation of the profession into healthcare models. Lastly, complex system designs including pharmacy contracts and commissioning routes are poorly understood, further disadvantaging the involvement of community pharmacy in the negotiation of evolving care models and more integrated working [173, 174]. These barriers are not unique to England and have been described in other countries [123, 175].

3.9.2 The public perception of community pharmacy services

A systematic review by Hindi et al exploring patient and public perspectives of community pharmacies in the UK identified two main themes, each of which had four subthemes (Figure 2) [176]. Public cognisance was used to describe the opinions and views of the public. These were influenced by four factors: awareness of the pharmacy services available, underlying perceptions, whether the public regarded physicians to have a supremacy, and promotional strategies encountered.

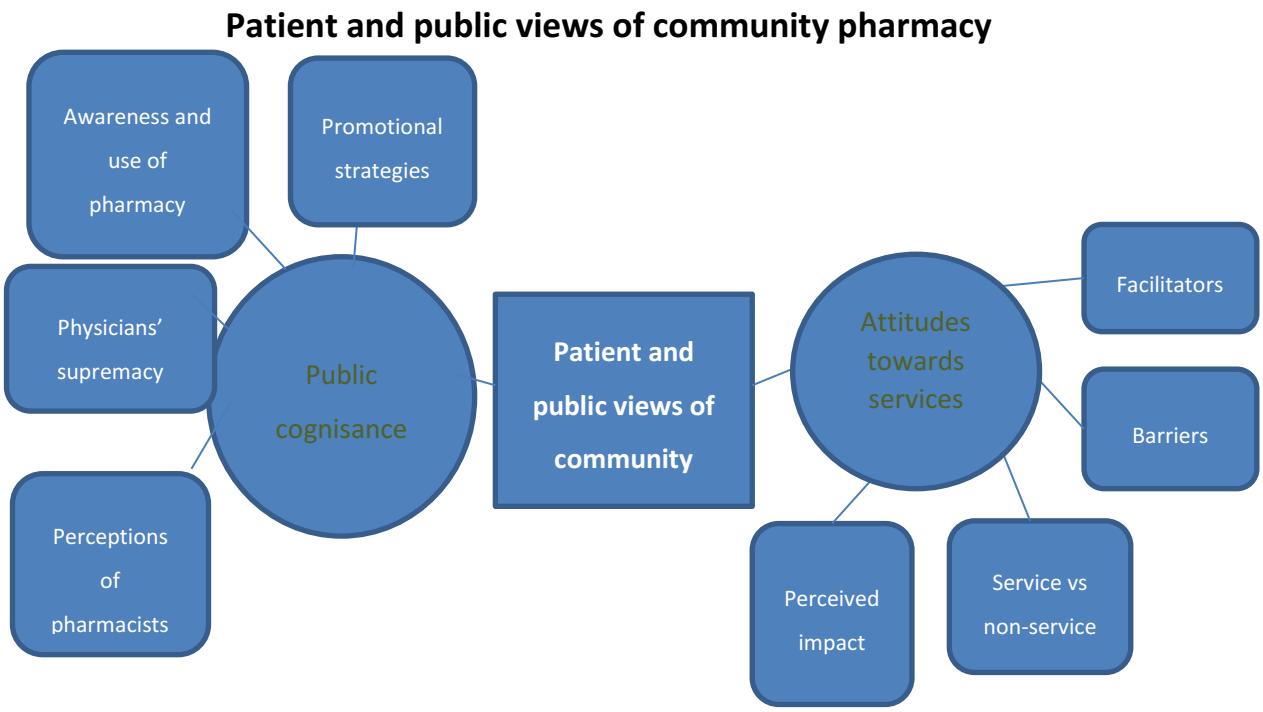

Figure 2- Thematic map of themes explaining patient and public perception of pharmacists- Adapted from Hindi et al 2017 [176].

There was a general unfamiliarity of the local pharmacy services available, which qualitative work attributed to limited publicity of services [176]. Perceptions of pharmacists were highest for activities linked to their traditional roles relating to medicines such as medicine reviews and advice, but lower for other services. Some studies reported public suspicion over the pharmacy commercial affiliations and financial incentives. The public's perception of their physician also had an influence on their confidence with pharmacists. Good relations with the physician reduced the

need to consult the pharmacist and vice versa. Some believed that a pharmacist's advice needed confirmation by a physician. Publicity was generally lacking, but few studies commented on how this could be improved. Word of mouth was deemed to be most effective in a questionnaire but focus group discussions did not reveal a preferable approach.

The public's attitudes towards pharmacy services was the second main theme. It depended on the perceived impact of pharmacy services, whether the individual had made use of them before and any barriers and/or facilitators to using pharmacy services. Facilitators included pharmacists' professionalism, ease of access and convenience, not needing an appointment, and feeling more comfortable and relaxed than with a physician. Barriers included lack of privacy, lack of access to medical records, inability to prescribe, poor communication with other healthcare providers, lack of continuity and limited pharmacist time. A significant proportion of the public did not know about the private consultation rooms available in many pharmacies, or if they did, had associated them with being used for substance misuse services.

Later focus group work by Hindi et al in 2019 explored the experiences and expectations of patients, pharmacists and GPs on the integration of community pharmacy into the primary care pathway for people with long-term conditions [177]. Increased public awareness nationally was deemed important, but difficult when different areas provide different services. High quality experience and word of mouth were deemed the most effective ways of publicising services. The main values added included freeing up GP time and easier access for patients. To be effective, it was felt that all staff in a pharmacy should be trained on a service, which should be as specific as possible. It was expressed that GPs would need incentivising to refer to community pharmacy, and pharmacists remunerated for their time. To avoid duplication of work and to strengthen communication, shared care plans were recommended with read/write access to care records. The importance of good safeguarding measures was stressed.

Evidence suggests that the public regard community pharmacy services as beneficial, but the clinical skills and capabilities of pharmacists are under recognised both by patients and physicians

[176]. Practitioners report strong mutual respect for pharmacists as allied health professionals, but communication between them could be strengthened [178].

3.9.3 Financial sustainability and representation of the community pharmacy sector in England.

Whilst the NHS would like an expanded role for pharmacy, financial policies to date have undermined this strategy, and for some time now, the economics of community pharmacy have been under pressure [179]. An independent report by financial advisors, Ernst and Young, commissioned by the National Pharmacy Association and published in September 2020, demonstrated that three quarters of English pharmacies are on the trajectory to being at a financial loss - approximately £43,000 per year within the next four years [138]. This has been the result of a combination of funding cuts made in the 2016 Community Pharmacy Contractual Framework, followed by the more recent five years of flat funding that was agreed for 2019-2024.

The precarious financial position of community pharmacy has been further intensified by inflation and the Covid-19 pandemic, forcing many pharmacies, particularly independent pharmacies, to close. During the first 5 months of 2020, 83 pharmacies closed (42 of which closed after March 23 when the Government imposed a nationwide lockdown) and 16 opened leaving a net closure of 67 pharmacies. This is close to twice the number of net closures compared to the first 5 months of 2019.

LPCs and the PSNC funded an independent review to explore their contractor representation- The Wright Review [180]. This came at an apt time in light of the real term income reductions seen in recent pharmacy contracts and the strains felt by the sector. The report was published in June 2020 and highlighted significant variations in performance and governance. It identified that satisfaction at all levels, PSNC, LPC and contractors could be improved and concluded with a set of 33 recommendations. These recommendations have prompted a lot of discussion amongst the pharmacy community but will hopefully lead to strengthened representation of a valuable workforce.

3.10 Limitations to this review

Firstly, this was a narrative review and not a systematic review. An initial scoping search identified recently published systematic reviews on pharmacy interventions in diabetes and therefore undertaking another one was not felt an efficient use of time or resources. With this in mind, some of the available literature on the subject may not have been represented in this piece of work. The search was restricted to articles published in English language. With community pharmacists working across the globe, interventions and work done in other countries is likely to have been under-represented. Whilst there could be learning from such studies, the way that community pharmacy operates outside of the UK is very different and so there would be limitations to the transferability of these findings. The grey literature was also not reviewed, but with increasing archiving of published work electronically, it could be argued that the amount of material in the grey literature is minimal. Furthermore, limiting this review to work that had been published maintains accuracy and a degree of scientific rigor. Nonetheless, pharmacists may be less likely to publish work in the recognised scientific journals searched in this review. Not including the grey literature can result in publication bias where only studies with positive findings are published. The decision to not review the grey literature or articles published in other languages was influenced by the time restraints of the PhD and the lack of a gold standard method for doing so.

Secondly, although the articles identified by the literature search were only screened by myself, a systematic approach was taken in order to identify relevant articles. A second reviewer from a different background (e.g a pharmacist) may have brought a different perspective and/or identified additional findings.

Finally, as a researcher I am aware of the inherent bias that I bring to this piece of work. I am susceptible to representing community pharmacy in a positive light, most notably because I am endeavouring to design a community pharmacy delivered intervention which I hope will help those living with diabetes. Furthermore, I have spent considerable time with pharmacists from a

variety of backgrounds, making efforts to better understand their current situation in the UK. I have attended Royal Pharmaceutical Society (RPS) meetings, joined pharmacy professional interest groups at diabetes conferences and listened to pharmacy related podcasts. This was all supplemented by interviews and meetings with pharmacists from the South Central local pharmacy committee and the Pharmaceutical Services Negotiating Committee (PSNC). These experiences have given me a good insight into how pharmacists view their current position and professional status. What started out as field work for my PhD led me to building relationships with this allied care profession, some of which I now regard as friendships. All of these experiences have inevitably drawn me to celebrating community pharmacy's skills and strengths, making me susceptible to confirmatory biases.

3.11 Conclusions and Summary

Optimal diabetes care relies on a number of self-management practices. Pharmacists are ideally positioned to support and empower people with diabetes, helping them to maximise their healthcare potential.

Community pharmacy interventions in diabetes and other long-term conditions have proven to be feasible, acceptable to those taking part, and capable of delivering improved health outcomes. It is important to ensure the fidelity of interventions before drawing conclusions from them. The active components of interventions can be challenging to decipher, but likely include person-centred approaches, goal setting, frequency of contact and availability of the pharmacist. The pharmacist being part of a multi-disciplinary team and able to communicate with the participant's GP has helped streamline care and improve efficiency.

Due to their accessibility and flexibility, community pharmacies are well suited to support and reach out to those with diabetes, particularly those who may be most at need. An increased public awareness of the skill-set and role pharmacists have to play is key to building public trust. With the response of community pharmacy to the current pandemic, the public has had more

contact with these allied care professionals than ever before. It is hoped that there will be an increase recognition in government policy to help alleviate some of the current financial pressures facing community pharmacy which otherwise may threaten plans to expand their clinical roles. Finally, measures need to be put in place to facilitate improved communication and collaboration with other healthcare professionals and services, so that pharmacists can offer a synergistic role, becoming more fully integrated and equipped to facilitate a more responsive and flexible healthcare system.

3.12 Future Work

To facilitate reproducibility, interventions need to be well described. The ideal composition of pharmacist-led interventions is not available yet. Whilst the current evidence supports increased integration of pharmacists into the care pathway for those with diabetes, there have been no studies published specifically looking at the role of pharmacists in supporting those with diabetes who are struggling to engage with the services currently available to them or who are 'hardly reached'. Although not exhaustive, this may include people with diabetes who have not been attending their clinical appointments, those not taking their medications, or those with multiple hospital attendances or admissions relating to their diabetes. These individuals are arguably most vulnerable to the complications and health burden associated with diabetes, but potentially also have the most to gain from an alternative supplementary intervention or healthcare service. Although there are likely to be varying reasons and self-determinants underpinning the aforementioned behaviours, pharmacists are in a privileged position to help explore these and offer support to these individuals.

Future work will need to build public recognition of pharmacists, whilst also improving communication between them and other healthcare professionals in order to deliver continuity and best care.

Chapter 4 Exploring the views and perspectives healthcare professionals have towards a hypothetical Community Pharmacy Diabetes Support Service (CPDSS) to support people living with diabetes who have a history or repeated non-attendance at appointments and sub-optimal glycaemic control – a qualitative study

4.1 Chapter Outline

The preceding chapters have focused on describing the impact the rapidly rising prevalence of diabetes worldwide is having on individuals and society as a whole. The concept of healthcare engagement has been discussed and the literature on non-attendance at diabetes healthcare appointments has been reviewed. The current position and role of community pharmacy has been considered and the next step in exploring the concept of a hypothetical Community Pharmacy Diabetes Support Service (CPDSS) intervention to support those with diabetes who are disengaged with their healthcare is to understand the views of key stakeholders. To complement what has been described so far and to involve and understand the perspective of key stakeholders in the potential intervention, two qualitative studies were performed.

The first qualitative study is described in this chapter. It explored the views and perspectives healthcare professionals have towards community pharmacy and a proposed CPDSS. It is important to understand this cohort's viewpoint when trying to consider a service that would require their input and 'buy in'.

The second qualitative study, described in the subsequent chapter of this thesis, recruited people with diabetes who have sub-optimal glycaemic control and a history of repeated non-attendance.

It set out to explore the attendance behaviours of the target population, their experiences and perceptions of community pharmacy and thoughts on a hypothetical CPDSS. In the design and development of any healthcare intervention it is best practice to involve the people it is intended to serve- "no decision about me, without me" [181].

A third qualitative study including university students with diabetes was originally considered. The previous systematic review on non-attendance in chapter 2 identified young adults as being more likely to not attend diabetes healthcare appointments. There were difficulties recruiting into this group, and with the subsequent COVID-19 pandemic, it was not deemed appropriate to continue with this third qualitative study due to the pressures and uncertainty that students were facing at the time. It was felt that the view of young adults with diabetes could still be represented in the second qualitative study. More detail on this can be found in the reflection section at the beginning of this thesis and in the concluding chapter (chapter 7).

4.2 Introduction

When considering an intervention to support people living with long-term conditions and multi-morbidity, it seems inherent to follow a process that considers their complexity. Regardless of the approach adopted in the early phase of intervention design, a detailed needs analysis is encouraged [182]. Considering a proposed CPDSS, it was deemed appropriate to supplement what was gathered from the previous review of the literature with the collection of primary data exploring the perspective and psychosocial context of the people who would be involved in the delivery of the intervention (chapter 4) or for whom the intervention endeavours to target (Chapter 5). This helps make sure that the resulting intervention is usable and engaging whilst being more attractive, persuasive and feasible to later implementation. A detailed needs analysis including the views of relevant stakeholders is crucial before one can even begin to consider whether an idea is appropriate or ready to enter the 'development' phase of complex intervention frameworks.

When conducting an analysis of the role of a hypothetical intervention, it is important to scrutinise the problem the intervention is endeavouring to address, its context and the actors involved. In the case of a hypothetical CPDSS, the perspectives of those that would be delivering the intervention are important at providing an insight into the capacity, attitudes and experiences of potential intervention deliverers. A qualitative approach was chosen to achieve this, as it allows for the emergence of novel findings and collection of rich detail.

4.3 Aims

Building on early scoping work and detailed reviews of the literature, the aim of this chapter was to explore the opinions and perspectives of general practitioners (GPs), practice nurses, diabetes specialists and pharmacists towards existing community pharmacy services and a hypothetical CPDSS. These healthcare professional groups are involved in today's delivery of diabetes care and are some of the key stakeholders that would be part of the development and later implementation of a potential CPDSS.

Ethics authorisation was granted for the qualitative work by both the University of Southampton's Ethics and Research Governance Online 2 platform and the Health Regulatory Authority's Research Ethics Committee (IRAS: 278035/ REC Reference: 20/SC/0065).

4.4 Methodology

When considering which research method to use to collect data, all research methodologies make two major types of assumption: ontological and epistemological. Ontology is concerned with the nature of reality and reflects what an individual interprets as constituting a fact. Epistemology is the basis of that reality, and the different ways of gaining that knowledge. There are many schools of thought within philosophy and it is important to consider one's research philosophy and reflexivity when planning and conducting research.

The three mainstream philosophical approaches are positivism, critical realism and constructivism. Each of these adopts different ontological and epistemological assumptions. A positivist assumes that reality is independent from human interpretation- only what can be objectively measured is regarded as real and valid. They prefer to use quantitative methods to produce findings. At the other extreme, constructivism assumes that all knowledge is socially and culturally interpreted and that it cannot be proven what is true and what is not true. Constructivists use qualitative methods to interpret, contextualise and understand reality. Lying between positivism and constructivism is critical realism which adopts a positivist ontology, assuming that concepts do exist, and a constructive epistemology that believes our knowledge of these concepts is determined by historical and cultural context [183].

It is important to consider one's research philosophy and reflexivity when planning and conducting research. Qualitative research is a recognised means of conducting a needs analysis in the design of complex interventions [182]. Unlike other methods such as surveys, it facilitates the collection of rich accounts and novel concepts without any prior assumptions.

Subjectivity and bias in qualitative research are inevitable but celebrated. Reflecting on my personal subjectivities, working as a medical doctor, I have generally held a positivist ontological stance which would favour quantitative research approaches. Over time, as I have been building my understanding of qualitative research with an increasing awareness of different philosophical views, I would now consider my philosophical stance more in keeping with a critical realist. This would suggest that I believe that a pre-social reality exists, but that we can only ever partially know it. As an example, if two people were to stand in a room and look out different windows, they would each be exposed to a different view or perspective of what the reality is, but they would both be observing the same reality.

4.4.1 Adopting a critical realist approach, I took a qualitative approach to the collection of data in both this study and that described in chapter 5.Study Design

The study design was an inductive qualitative focus group study. The key focus was to understand system level issues and how the aforementioned healthcare professional groups interact with one other. These perspectives would unlikely have been captured in individual interviews. Group discussions help explore and clarify the views of participants, something that can be more difficult in individual interviews [184]. The interplay between participants in a group discussion encourages ideas to be generated, reflected on and debated. The safety of a well-run group can also potentially draw contributions from naturally withdrawn or shy participants. For these reasons, focus groups were chosen as the preferred method for data collection.

4.4.2 Study procedure

4.4.2.1 Recruitment and sampling

Non-probability sampling was used to identify a purposive sample to ensure that the views of relevant stakeholders were represented. In light of the study aim, the purposive sampling was based on healthcare professional role and experience. E-mail invitations were sent to healthcare professionals using existing clinical networks including the Strategic Clinical Network, the Local Pharmacy Committee and the Local Medical Committee amongst others. As e-mail invites were sent via these clinical networks, it was not possible to ascertain how many people received them. I also recruited internally within the diabetes service I work for and therefore knew a few of the participants that were recruited through this means.

Those that expressed interest in the study were sent a participant information sheet and consent form. All participants were also invited to complete a brief demographic questionnaire collecting data on age, gender, ethnicity and occupation. This information was used to help understand the backgrounds of the participants which is important when considering transferability of study findings.

The concept of 'information power' was used to guide the decision on study sample size. According to Malterud et al, information power is an iterative process and considers five items: the study's aim, sample specificity, theoretical background, quality of dialogue and strategy for analysis [185]. The dimensions of these items and how they relate to sample size can be seen in Figure 3 [185]. The higher the information power (ie. studies with a narrow aim that ask a specific question, apply theory, have a strong dialogue and use case analysis), the smaller the sample size required.

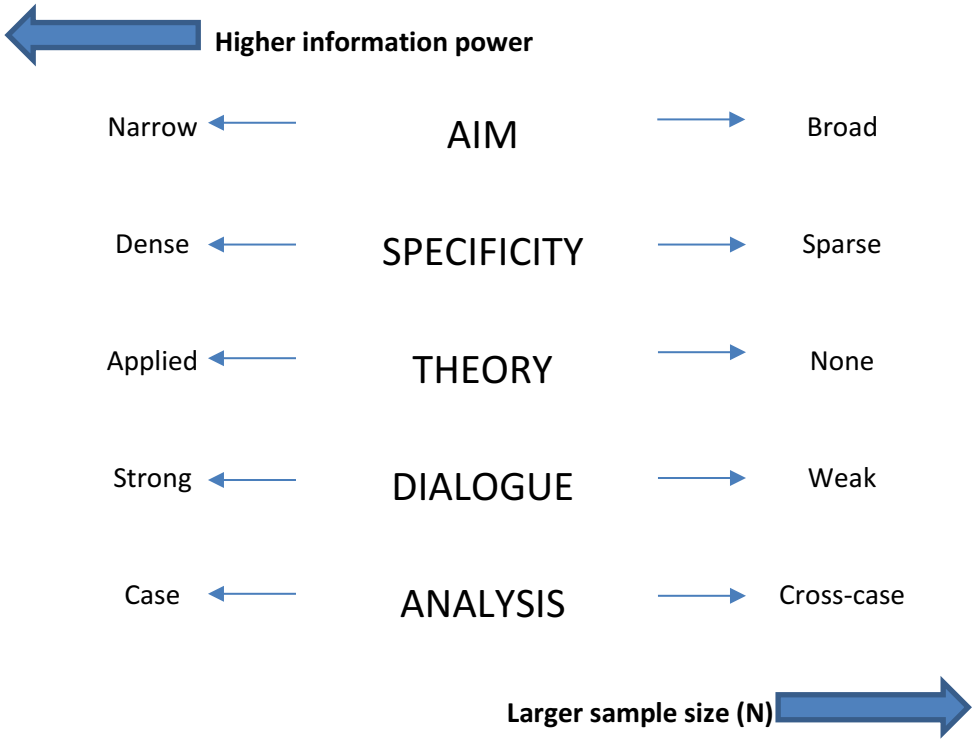

Figure 3 Information power- Items and dimensions (adapted from Malterud et al, 2015)

Considering each of the items of information power in turn and how they related to this study:

Study aim: The study had a narrow aim which set to answer a specific question, meaning fewer participants are needed.

Sample specificity: Specificity was dense due to the purposive sampling technique adopted and broad backgrounds of study participants. For example, some participants had worked across healthcare speciality settings (eg. working both as a diabetes specialist nurse and practice nurse). This allows for a smaller sample size.

Theory: The study was not based on specific theory therefore a larger sample size is typically needed. It was, however, informed by findings from the literature described in the preceding chapters which gave me insight into the possible issues that could be raised in the discussions.

Quality of dialogue: Strong and clear communication was achieved between myself as the researcher and the participants, helping reduce the number of participants required. The quality of the dialogue was likely facilitated by my shared healthcare professional background and because those who took part probably had an interest in the topic and/or views they wanted to communicate.

Analysis: This study was a thematic cross-case analysis as it aimed to uncover realistic and pragmatic interpretations of what different healthcare professionals think about a proposed CPDSS. Cross-case analyses typically require larger participant numbers.

From my reflections on the above, a provisional sample size of 15 participants was deemed appropriate. This is in line with work described by Maltread et al where a sample size of 10 informants was chosen for an interview study conducted by a novice researcher on a relatively broad subject matter but which was founded by theory [185]. As this study was not based on theory and trying to capture views from a breadth of healthcare professional groups, a larger sample size of 15 was felt appropriate. Information power is not intended to be a checklist for calculating 'N', which would be a realist approach and not in line with my epistemological position, but instead a series of items and dimensions to consider at each stage of the research process when appraising the number of informants required.

Data saturation is a concept that had previously been popular in helping determine sample size of qualitative studies and is defined as 'information redundancy,' or the point at which no new codes 'emerge' from the data [186]. Its application to qualitative research, notably thematic analysis, has been contested by eminent qualitative researchers including Braun and Clarke who argue that the concept of data saturation adopts a positivist approach which is not consistent with the values and assumptions of thematic analysis. Furthermore, codes and themes do not 'emerge' from the

data, they are constructed by the researcher who forms part of the research findings and is not distinct from them. For these reasons data saturation was not used to determine sample size in this study and the application of Information Power was deemed more appropriate.

4.4.2.2 Inclusion/exclusion criteria

4.4.2.2.1 Inclusion criteria:

-A healthcare professional (GP, practice nurse, pharmacist, diabetes doctor, diabetes nurse, diabetes dietitian).

AND

-Age >18 years AND Able to consent AND speak English.

4.4.2.2.2 Exclusion criteria:

-Those unwilling to take part.

-Those unable to consent or speak English due to the difficulty in orchestrating a focus group through an interpreter.

- Those not meeting the inclusion criteria.

These healthcare professional groups were chosen as they are routinely involved in the delivery of diabetes care and/or would be involved in the development and delivery of a proposed CPDSS. When considering the number of participants in each focus group, smaller groups have been reported to maximise discussion whilst maintaining order [187]. Small groups of two to six people facilitate more room for variation and disagreement and helps quieter individuals feel more comfortable.

4.4.2.3 Consent and the interview process

Verbal consent was gathered at the start of each focus group. Participants were reminded of the purpose of the study and that the conversation was going to be recorded to allow later transcription. After introducing themselves, participants were left to freely discuss their thoughts and opinions on a hypothetical pharmacy intervention to support people with diabetes and a history of non-attendance and sub-optimal glycaemic control. I had prepared a semi-structured interview template with open ended questions to help guide conversation (please see Appendix B.1 on page 161). This was piloted with a diabetes consultant and pharmacist prior to the first interview.

Involvement in the focus groups was voluntary and it was the participants' right to withdraw at any time if they changed their mind. After consenting there were no withdrawals in this study and most individuals partook out of goodwill, hoping that their experiences and ideas would be of help in the development of a service for those living with diabetes who may be most at need.

A total of three focus groups were carried out virtually. Each of these included no more than 6 participants in addition to myself as the researcher. An observer, Jack Colley (JC), from within the research team was also present for one of the focus groups to audit that study procedures were carried out appropriately. The focus groups were scheduled to run for a maximum of one hour. Longer than this on a virtual platform is not recommended as it can lead to fatigue and may have deterred busy HCPs from taking part [188]. Sessions were offered at lunchtimes and in the evening to facilitate attendance.

All focus groups were recorded and data stored in accordance with the Data Protection Act (2018). Audio files were auto-transcribed verbatim by the Zoom software. I edited the Zoom auto-transcriptions whilst listening again to the audio recordings, removing personal identifiable details and correcting any inaccuracies. The auto-transcriptions were most unreliable when people spoke quickly and on the odd occasions when more than one person was speaking at

once. Editing the auto-transcription shortly after each focus group helped my recall of the conversations.

4.4.2.4 The use of online video platforms in qualitative inquiries

Due to the COVID-19 pandemic that started at the time of my primary data collection, all focus groups had to be carried out virtually. Zoom was the chosen virtual platform as it had been approved by Southern Health's governance at the time and has end to end encryption.

Conducting focus groups using audio-visual tools has traditionally been challenging due to significant technical barriers including limited bandwidth and inadequate platforms [188]. This has improved significantly over recent years and further still as society has looked to online solutions during the restrictions put in place as a result of the COVID-19 pandemic.

Some of the major strengths of virtual focus groups and one-to-one interviews include their lower running costs compared to face-to-face meetings, their fast turn-around time and that participants do not have to factor in travel, being able to contribute from wherever they feel most comfortable that also has internet access. Furthermore, most virtual platforms now have recording capabilities, making the recording of the discussions more convenient for the researcher. The opportunity to conduct qualitative work virtually allowed me to continue my research during the COVID-19 pandemic when meetings in person were not possible due to national restrictions.

Critics of online focus groups argue that group dynamics in cyber space is more difficult, non-verbal inputs are lost and that it is difficult to ascertain whether participants are paying attention to the discussion- they may be carrying out other activities at the same time [188]. Furthermore, when a large number of individuals connect to a virtual call, not all attendees may be seen on the screen at once. Due to the small participant numbers in each focus group, these issues were either not encountered or felt to have interfered with data collection.

A significant limitation of conducting qualitative work virtually is the inability to pick up on body language in the same way that face to face meetings allow. As an example, if someone is tapping their foot with agitation or distress, this will not be seen virtually and therefore the cue not acted on. As humans, a lot of our interaction is through body language and this richness of communication is lost when interviews and focus groups are conducted virtually.

It is important to consider that using online platforms may preclude certain populations from being able to participate such as those without internet access or who have limited computer literacy. As this study was recruiting healthcare professionals, it was assumed that they would have access to the required technology. Most will require a computer and internet access to carry out their professional duties, particularly in light of the increased use of technology and remote consulting across healthcare settings resulting from the pandemic.

Whilst technological difficulties may interrupt the flow and dynamics of a focus group and negatively impact communication with and between participants, in some instances inconveniences like these may also unintentionally improve rapport as the researcher and participant(s) work together to try and resolve the issue [189].

To try and minimise digital exclusion and technological difficulties during focus group sessions, all healthcare professionals that expressed an interest in the study were offered a 'dummy run' beforehand to make sure that they were happy connecting virtually using Zoom. None of the participants requested this, suggesting confidence with using virtual platforms.Finally, when commenting on the pros and cons of conducting research virtually, it is important to reflect on how videoconferencing may affect participants' privacy. Whilst virtual backgrounds and turning off the video may enhance privacy, this can affect group dynamics and the flow of communication. Not doing so, however, may invade someone's personal space, especially for those who don't have headphones to use during the discussion [189]. All participants were given the option of turning off their camera and privacy was discussed before joining, although all participants chose to use their video function which facilitated the dynamics within the groups.

Unfortunately, due to the COVID-19 pandemic at the time of data collection, there was not an option to run the discussions face-to-face. The aforementioned strengths and limitations of virtual focus groups were considered in the discussion section.

4.4.3 Data Analysis

4.4.3.1 Rationale for using thematic analysis

Thematic analysis was used for data analysis as it provides a method for identifying, analysing and reporting patterns (themes) within data and can be applied flexibly across a range of theoretical frameworks [190]. A rigorous thematic analysis can produce insightful and trustworthy findings if carried out well. It is accessible to those new to qualitative research and allows for themes to be derived from the data in an inductive fashion. This study's inductive analysis aimed to understand the perceptions healthcare professionals have towards a hypothetical pharmacy intervention and to identify potential facilitators and barriers.

4.4.3.2 Steps of data analysis

Data analysis was done through three iterative cycles as described by Newell et al to make sure that the thematic analysis was performed in a methodical, step by step approach to enhance trustworthiness of the findings [191]. The software Nvivo (Release 1.0) was used to facilitate the sorting and organising of data [192]. During the first phase of data-analysis, transcriptions were independently read and re-read by myself and a fellow researcher, Jazz Bartholomew (JB), who has experience of qualitative research from her psychology background and delivering qualitative research as an assistant research portfolio manager at the Wessex Clinical Research Network. The aim was to become familiar with the data corpus and to determine the most important key features that participants raised about their perceptions of community pharmacy and a hypothetical CPDSS.

The second phase of data-analysis was about constructing initial codes. These identify features of the data that are of interest to the analyst and refer to 'the most basic element of the raw data that can be assessed in a meaningful way regarding the phenomenon' [190]. There are several different approaches, that if used in a disciplined way, can help ensure consistency when coding [191]. In this study a coding manual was created and codes that appeared most useful to the research question were applied to the rest of the transcripts (Please see Appendix B.2 on page 169). Coding manuals serve as a data management tool. They assist in interpretation by organising segments of similar or related data and help ensure a mutual understanding of what a code means when more than one person is involved in the data analysis process.

The third phase of data-analysis involved identifying codes that pertained to similar aspects of the data and clustering them together to form themes. Myself and JB worked independently but reconvened to discuss the coding manual and the developing analysis after each phase. We searched for deviant cases to make sure minority views were represented. The final codes and themes were discussed with an expert in qualitative methods, Kat Bradbury (KB), and were very slightly modified to enhance clarity and coherence,

4.4.3.3 Reflexivity

All qualitative studies are contextual which makes reflexivity important in displaying credibility and when trying to gather a deeper understanding of the work [193]. As part of my analysis I have reflected on my roles and identities and how they may influence each stage of the qualitative inquiry. I am a diabetes speciality registrar, trying to conduct a needs analysis on the role of a hypothetical CPDSS to support people with diabetes who regularly do not attend their healthcare appointments. My study questions, interpretations and findings have been influenced by my experiences, both personal and professional, my motivation for a qualification from my research and my pre-study beliefs.

4.5 Results

Three focus groups were conducted with 18 participants (5-7 participants in each group) which was deemed sufficient when reflecting on the items and dimensions of information power discussed in the study procedure. One individual expressed interest in taking part in the study but did not show up for the focus group session and had not given prior consent. Every group had representation from each of the relevant healthcare professional groups (GPs, practice nurses, diabetes specialists and pharmacists). Participant demographics are displayed in Table 5.

Table 5- Participant demographics

	Group 1	**Group 2**	**Group 3**
Number of participants	7	6	5
Occupation	Consultants = 1 Diabetes registrar = 1 DSN = 2 Pharmacist = 1 GP = 1 Practice Nurse = 1	DSN = 3 Pharmacist = 2 GP = 1	Consultants = 1 DSN = 2 Pharmacist = 1 GP = 1
Ethnicity	White Caucasian= 7	White Caucasian = 5 White Arab = 1	White Caucasian = 5
Age in years mean (range)	46.6 (29-60)	51.5 (38-61)	52 (39-67)

Abbreviations: Diabetes specialist nurse (DSN); General practitioner (GP)

Four themes were identified pertaining to the participants' views and perceptions of community pharmacy and a hypothetical CPDSS: 'Accessibility and relationships with the public'; 'Perceptions of community pharmacy and their integration with other healthcare services'; 'Resources and training'; 'Intervention content'. These are described below.

4.5.1 Accessibility and relationships with the public

Community pharmacies were seen to offer a unique healthcare environment that is easily accessible to the public. The convenience and choice they offer in terms of their locations, opening hours and more informal set-up compared to some other medical services were all deemed to be strengths that some participants felt would make them a suitable place to set up a diabetes healthcare intervention.

-"convenience is such a big thing and the idea that it's kind of much more 'on your terms' than any other access to the health service is really advantageous" (Practice Nurse A).

The frequency of contact that community pharmacies have with the public can foster an ideal environment for opportunistic conversations and continuity of care. When considering an intervention targeting those with diabetes and a history of non-attendance and sub-optimal glycaemic control, this was regarded as an important attribute that sets community pharmacy apart from other health services. Pharmacists felt their relationships with clients were key, and many valued providing a holistic service where the whole of the patient was considered, not just their diabetes. In line with these values, participants were keen that any new intervention should use language that supported a patient-centred relationship.

"I think you'll find pharmacists do quite a lot of soft negotiation with patients to try and encourage them to go and engage with whatever part of the system that they should be with… you do have to be very careful what you say to people, but don't underestimate the diplomatic skills of a community pharmacist. We'll see the patient, or their representative every month or every two months when they come in to pick up a prescription… that real continuity piece…Because they're your patients, you have quite a good rapport with them because you see them face to face a lot, a lot more probably than most other practitioners." (Pharmacist A)

"I think it (a CPDSS intervention) would have to be done in the right way because these people will be very defensive… you'd have to be really careful and non-judgmental with any questions... and don't talk about numbers" (Practice nurse A)

Considering a hypothetical CPDSS, some healthcare professionals were concerned that not all members of the public regard their experiences of community pharmacy positively and that the contact pharmacists have with the public may be threatened by people moving to online prescriptions and delivery.

"So we're moving much more interest in a 24 hour type picture where people will get their medications with often no human interaction at all… I have a concern for the high street pharmacist and the opportunity that they can build a relationship with patients. A lot of the patients that I look after tell me they've left their high street pharmacists, because the service they were having was slow or sort of not acceptable to them, even before COVID..." (General Practitioner B).

4.5.2 Perception of community pharmacy and their integration with other healthcare services

Pharmacy participants regularly discussed the clinical services they offer, their evolving contract that incentivises clinical services over their traditional dispensing role and some of the healthcare interventions that have taken place in community pharmacy including those pertaining to diabetes. Pharmacists felt that these factors strengthened their role in a potential CPDSS.

"So the government really wants community pharmacy to move away from purely supply, to actually delivering a lot more of this sort of clinical services" (Pharmacist A)

"… involved in a big project called 'Community Pharmacy Futures 2'... built around supporting patients with long term conditions including diabetes, not just with use of their medicines, but a whole holistic conversation ... think about a Patient's Activation Measure and their own personal

goals and what would mean something to them...It received a lot of very positive feedback."

(Pharmacist D)

Despite the expertise and breadth of services pharmacists' described offering, there was little recognition of this by most of the other participating healthcare professionals in the study.

"They don't really get involved in anything more than dispensing the meds and reminding us when we've made a prescription error, which is great" (DSN B)

The relationship that community pharmacists have with other healthcare professionals was seen as being more fragile than the relationship they have with clients and this was voiced both by pharmacists and other healthcare professionals in the study. This was reportedly due to their under-recognised role in offering clinical services and their inadequate integration with other healthcare services.

" they feel on the edge of the team a little bit" (DSN C)

"I think a lot of it is institutional cynicism" (Pharmacist E)

All categories of healthcare professionals in the study had concerns about the integration of community pharmacies with other healthcare services. At present the communication between pharmacies and other services was described as ad-hoc with pharmacists having limited read-write access to medical records. Pharmacists feel that they are 'sitting on a minefield of data' due to their regular contact with the public but have no formalised way of feeding back this information to GP records or other relevant services. Lack of technological integration between services was seen as one of the main limiting factors to efficient communication alongside institutional inertia, both of which healthcare professionals had concerns would impact a CPDSS if not considered.

"At the moment we have processes where the information comes down into pharmacy, which is all great, however, there is no real way of feeding that back up to make it a two way process ... IT

(information technology) is key, with whatever you do, the information flow has to be able to happen. One of my biggest concerns is that when I do refer patients on. I never get any feedback back" (Pharmacist E).

4.5.3 Resources and training

Pharmacists and the other healthcare professionals in the study expressed the need to adequately fund and resource a CPDSS, particularly in light of the current workload and financial pressures experienced by community pharmacies.

"I think you would have to be a paid intervention, if you wanted it to happen, to reimburse the pharmacies' time and I think that's going to be the key problem with it, is the time that pharmacists have to do it … In our area there tends to be one pharmacist and they are assisted by a number of technicians who are pretty busy for the whole time that they are open, it has to be said, there isn't much slack time in the community pharmacy setting around our area." (GP A)

In addition to adequate funding and staffing, appropriate training on the intervention would need to be offered to participating pharmacies, general practices and diabetes specialist services involved in the delivery of a CPDSS or the area that it is serving. Pharmacists in the study described the differing skillsets amongst colleague pharmacists, and therefore advised that if a CPDSS was to be piloted, it would be important to enrol pharmacies with an interest or background in diabetes care.

"…every pharmacy has a different speciality so it would be important to recruit pharmacies with an interest or experience in diabetes." (Pharmacist D)

4.5.4 Intervention content

When considering what a CPDSS intervention should include, most expressed a preference for a clear template for pharmacists to follow that still allows some flexibility so that a person-centred approach can be adopted. Participants agreed that there are likely a myriad of reasons

contributing to why an individual has a history of non-attendance and sub-optimal glycaemic control, and as such, the intervention would need to accommodate this.

"In an ideal world, you'd get some agreement on a kind of template, you know, template management plan that community pharmacists could use with resources and flexibility depending on the underlying issues…" (Practice nurse A)

There was a lot of discussion on how the patients recruited may respond to different approaches and it was agreed that being sensitive and non-judgemental with the language used was vital.

"… don't talk about numbers and don't be judgmental … I think it would have to be done in the right way because these people will be very defensive" (DSN D)

In terms of outcome measures to assess the effectiveness of the intervention, participants had very different views. Some felt these should be clinical outcomes (eg change in HbA_{1c}) whilst others felt that an improvement in a measure of engagement would be more suitable.

"I think there has to be very clear outcomes, for example, improvement in HbA_{1c}. So, what do you want to achieve? What are the processes to achieve them?" (GP A)

"More about engaging them with those steps in their care, rather than necessarily trying to show something like an HbA1c." (DSN E)

Despite these differing opinions, pharmacists described previous interventions incorporating a mixture of both and how these interventions were well received by all of those involved.

"We did have questions in there to check with them the things they are supposed to have accessed through the year- were they attending those appointments? If not, why not? … supporting these guys to make changes in their life. The project ran for a year … we had three major points through that year where several metrics were taken -height, weight etc. But in between if they were coming in, and so every 20 or every 56 days, it would just be very quick little chat with them to understand how they were getting on and if they had any questions or any queries or if they

wanted to review their goals, house how successful they were. So it really went very, very well and was satisfying for clients and professionals alike." (Pharmacist D)

Finally, when considering the frequency of contact a pharmacist would have with someone enrolled into a CPDSS, most participants felt that there should be a few scheduled face-to-face and/or virtual meetings, supplemented with ad-hoc contacts as necessary.

"You probably want to set the first of perhaps one or two contact points ... once we know that patients are sort of back on track if you like or engaged, then you know you can then drop that sort of engagement piece down and change frequency." (Pharmacist A)

4.6 Discussion

The current study set out to explore the views and perceptions healthcare professionals' have towards a hypothetical CPDSS to support people living with diabetes, specifically those with a history of repeated non-attendance at healthcare appointments and sub-optimal glycaemic control.

Normalisation Process Theory (NPT) helps recognise factors that promote and inhibit the routine incorporation and 'normalisation' of complex interventions into everyday practice [194]. Considering these in the early planning, design and development of complex interventions is important because if an intervention is not implemented successfully, it will not improve health or care. NPT is made up of four components which can be seen in Figure 4.

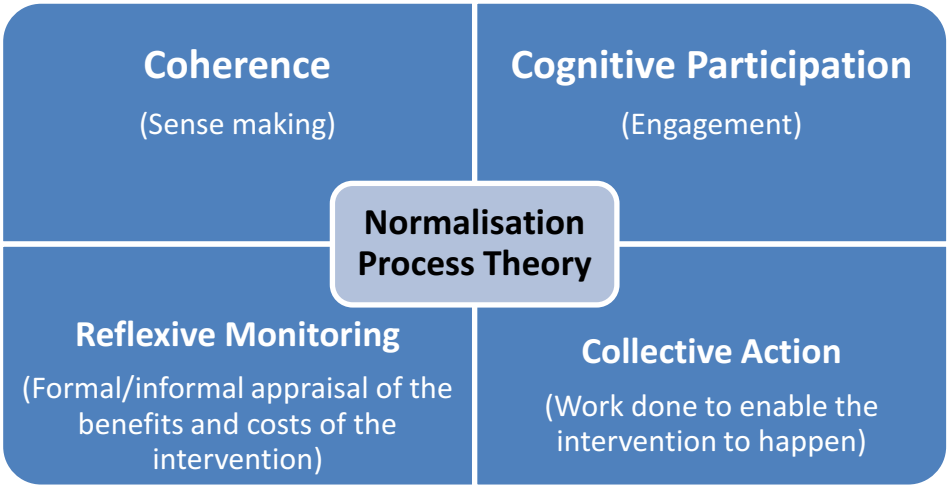

Figure 4 The four constructs of Normalisation Process Theory

Some key facilitators and barriers to a CPDSS were identified in this study. To first consider the facilitators and how they relate to NPT. All healthcare professionals agreed that the accessibility and frequency of contact pharmacies have with the public are features that make it a unique environment to set up an intervention for people with diabetes who have not been accessing other healthcare settings. Being distinct from other interventions gives meaning to a CPDSS which is important in the 'coherence' and 'cognitive participation' of NPT.

Pharmacists showed enthusiasm towards a CPDSS and likened it to other interventions or services that have been carried out in the community pharmacy setting previously. They felt it would fit into their evolving contracts which put more emphasis on clinical services over the dispensing of medicines. According to NPT, the pharmacists are 'sense-making' which is the work that people do when they are faced with a problem of operationalising a set of practices [194]. It is needed for interventions to 'normalise' in practice and is important when considering that pharmacists would be the stakeholders delivering a hypothetical CPDSS. The pharmacists participating in the study had a tendency to focus on the strengths of a potential CPDSS. They celebrated previous interventions they had been involved in and had an appetite for more integrated working.

When considering the barriers to a hypothetical CPDSS, non-pharmacy healthcare professionals, particularly those working in primary care, were more guarded and had a tendency to focus on

the limitations of community pharmacy and the hypothetical intervention. As suggested in the literature review in chapter 3, this likely stems from an under-recognition of pharmacists' skill-sets and the services they offer, instilling a lack of trust in their capabilities [195]. It may also result from the limited communication between the professions, typically as a result of poor technological integration. These issues have previously been shown to negatively impact the wider mobilisation of pharmacists into healthcare models worldwide [174]. If not addressed, these would exert a negative impact on healthcare professionals' 'cognitive participation' which may be experienced as limited readiness to commit and engage with a CPDSS.

It is clear that healthcare professionals, particularly those in primary care, would need to be made aware of what a CPDSS would deliver and how this would be different from routine care. They also need to be convinced that the target population would be accepting of pharmacists' involvement in their care. All healthcare professional groups in this study felt it important that a hypothetical CPDSS does not result in duplication of work or complicate what is already available to those with diabetes. It would be difficult to achieve 'coherence' according to NPT if the intervention is not perceived as offering benefit to those involved. 'Collective action' would also be compromised if the intervention were to lack compatibility with existing work practices or deemed to create more work for healthcare professionals, putting additional strain on limited resources (staffing, time and financial).

To overcome some of the aforementioned barriers and to understand how a CPDSS could compliment what is already on offer and strengthen diabetes care, regular stakeholder meetings during the development of a detailed intervention manual would be imperative and support the 'reflexive monitoring' component of NPT. Understanding the views of the target population through further qualitative work and including them as stakeholders in any future project development would be vital. It would be important to influence the perceptions of the wider population of healthcare professionals on the expertise pharmacists have to offer to help build working relationships and trust. This could be achieved through various networking events,

national campaigns and steps taken to strengthen the communication and integration between pharmacists and other healthcare services.

Healthcare professionals need to be comfortable that participating pharmacists in a hypothetical CPDSS would get the appropriate training and resources to effectively deliver the intervention. This may be facilitated by their involvement in the development and sourcing of relevant training materials.

More robust integration of pharmacists into existing healthcare models could be a way of allowing them to more effectively support diabetes management. Having the capability to share data and more efficiently communicate changes in a person's condition or management would potentially allow more joined up working. Participating pharmacists voiced how they ideally need to have read-write access to medical records so that their contribution is informed and communicated. This is of particular relevance when considering their increasing clinical role where they may make new diagnoses and prescribe treatments. They felt having read-only access significantly limited what support and feedback they could offer their primary care colleagues. The planning of a hypothetical CPDSS intervention would need to invest time exploring strategies to the more effective integration of pharmacists. With the changing NHS structure, the drive for improved digital and joined up working and the introduction of Integrated Care Systems, some of this deficiency in integration may improve with time.

Participants recognised that pharmacy resources (time and financial) are limited and would be further stretched with the introduction of a CPDSS. The pharmacy workforce is large so it is suspected that there would be an adequate supply of pharmacists to deliver a hypothetical CPDSS if adequate funding, recruitment and training were allocated. To encourage GP buy-in and to avoid tension from potential funding conflicts, it may be appropriate to incentivise participating GP surgeries which would also make them more likely to endorse pharmacy services and promote them to their patients.

Although pharmacists in this study had an appetite to undertake relevant training for a CPDSS, they recognised that not all pharmacists have an interest in diabetes, and this may be regarded as a barrier. To facilitate effective delivery of the intervention and the fulfilment of those delivering it, it would seem appropriate that a potential CPDSS considers recruiting pharmacies that have some expertise in managing the condition. With intervention specific training, this may not be strictly necessary, although a good familiarity with diabetes would help build the public's trust in the pharmacists' expertise and support all four components of NPT. With this in mind, training for a CPDSS should be standardised but allow some scope for tailoring components to meet the needs of the participating pharmacy. It is envisaged that many of the skills required by pharmacists will include behaviour change approaches which may not necessarily require diabetes specific knowledge beyond what is already included in their pharmacy curriculum. Having the latter and/or including some diabetes specific training may however build the public's confidence and facilitate more effective delivery of a hypothetical CPDSS.

Finally, some participants had concerns that the public may be moving towards online pharmacy services and thus the contact pharmacies have with the public may be threatened. Although not everyone was in agreement on this, a CPDSS should take this into account and how it may affect recruitment and participation in a CPDSS. As an example, there could be an option for pharmacists to leave a note advertising the hypothetical CPDSS to relevant people with diabetes that gets delivered to them with their medications. The target population of the hypothetical CPDSS are those with a history of repeated non-attendance. The systematic review on non-attendance in chapter 2 identified those from lower socio-economic groups as being more susceptible to missing appointments. It is likely that some of these individuals may also be digitally excluded, in which case, having the option of visiting a local pharmacy that is within walking distance from their home may be more accessible and appealing to them than digital alternatives.

Despite the concern that pharmacy services may be moving online, it should be considered that not all pharmacy encounters are for prescriptions. Many people visit their pharmacy for other services including picking up over the counter medications, flu vaccines etc. During the start of the COVID-19 pandemic when GP facilities were more difficult for people to access, many consulted their local pharmacist for healthcare advice. In England, people visit a pharmacy on average 16 times a year. This compares to the 51% of adults in England who have seen a dentist in the last 2 years [196] and only 24% of adults having visited their GP more than three times in a year [197]. These figures suggest that pharmacists' accessibility to the public and vice versa continues to be a strength, even with the additional offering of online and delivery services.

Due to the likely varying reasons and unmet needs of the target population, all healthcare professional groups felt that the content of a hypothetical CPDSS should be flexible and person-centred but still offer a clear pathway for the pharmacist to follow. The measurable intervention outcomes would need to be considered in detail as some felt that markers of engagement should be used whilst others suggested clinical parameters including HbA_{1c}. It is likely that a mixture of the two is required.

Advanced clinical services offered by community pharmacy in England overcome some of the barriers mentioned by being funded by Clinical Commissioning Groups (CCGs). Community pharmacies apply for the necessary funding to deliver the service if they meet the service specification criteria. These criteria typically include appropriate staffing allocation, specific training, and IT requirements/platforms and auditing of the service. There are clear Standard Operating Procedures (SOPs) to follow and whether a pharmacy offers the service is up to them. Being orchestrated more centrally and giving pharmacies choice may help address the reservations of other healthcare professionals and ensure standardisation, appropriate integration and best practice. These services have typically been informed by pilot studies, many of which were endorsed by Local Pharmacy Committees (LPCs) and/or the Pharmaceutical Services Negotiating Committee (PSNC) and funded locally or by the pharmaceutical industry. An

example of a currently available advanced service is the community pharmacy consultation service. GPs and the NHS 111 service can refer people with an expanding list of minor ailments directly to a participating pharmacy for a review and consultation. With community pharmacies taking on more clinical services, it seems likely that the public's perception will start to shift as they gain more personal experience of their capabilities.

This study has helped to understand the perspectives of the relevant stakeholders on a hypothetical CPDSS. Potential facilitators and barriers have been identified which have allowed the four components of NPT to be considered, helping to inform the needs analysis of a potential CPDSS. Many of the themes identified support the literature on community pharmacy interventions as described in chapter 3, particularly the accessibility of community pharmacy, the under recognition of the role and skill-set of pharmacists and the poor integration with other healthcare services. Novel findings included the appreciation healthcare professionals have for the accessibility community pharmacy offers and the ongoing enthusiasm community pharmacists have for delivering more clinical services, even after the recent escalation in clinical contact and workload as a result of the COVID-19 pandemic.

4.6.1.1 Strengths and limitations of this study

Following my extensive review of the literature, I have not found any other similar studies that have explored the views of healthcare professionals on a proposed community pharmacy delivered intervention to enhance engagement in people with diabetes who may be most at need. A strength of this study was that it included the participation of all relevant healthcare professional types in each focus group and credibility of the findings was enhanced by both myself and another researcher reviewing the transcripts.

Limitations include this being my first qualitative study, although I had support of an experienced qualitative researcher (KB), both during the implementation stage and whilst writing up the results.

A further limitation was the limited representation of different ethnic groups in this study. This, in part, reflects the predominantly white Caucasian population of West Hampshire where the study was conducted. Data from NHS Digital on the recording of ethnicity across different geographical areas in England showed that 84.4% of people in the West Hampshire CCG (Clinical Commissioning Group) geographical footprint identify themselves as British, Irish or any other white background and 9.8% of the population in this area has no known ethnicity recorded [198].

Despite a typically greater burden of disease, for some time it has been recognised that ethnic minority groups are under-represented in medical research [199]. The COVID-19 pandemic was a stark reminder of this where only 9.4% of participants in UK COVID-19 studies were from ethnic minorities [200]. Although the sample size in this study was deemed appropriate according to the principles of information power, the homogeneity of the participants and lack of ethnic minority representation limits the transferability of findings to areas with more diverse spreads of ethnicities. Whilst the representation of diversity is often important, the typical small sample sizes of many qualitative projects can make this challenging. Rather than stipulating ethnic minority representation in samples when attempting to enhance transferability, proliferation of the research is an alternative approach that can be taken and could be applied to this study to enhance its transferability to other communities [201].

Conducting qualitative work virtually has gained traction since COVID-19 and since conducting this study. Although running this study virtually may have increased participation due to increased convenience (both for participants and myself as a researcher), it was inevitably associated with a few limitations. Some of the dynamics experienced in face-to-face meetings are likely to have been lost, particularly as the subtle nuances of body language are missed. As people were asked to put their microphone on mute when not speaking, this may have inadvertently influenced people's readiness to contribute to parts of a discussion. Furthermore, I found that running the focus groups whilst also addressing technological issues (eg enabling participants to join from the waiting room etc) may have distracted me from the conversation taking place. Nonetheless, the

dialogue was strong in each of the groups with no significant pauses, and all of those involved appeared keen to contribute.

4.7 Conclusions

This study highlights a number of potential facilitators and barriers to a proposed CPDSS. Healthcare professionals want an intervention that is well integrated with other healthcare services, person-centred and flexible whilst still supporting a clear and structured pathway.

Barriers identified were the limited resources in pharmacy (both time and financial), under appreciation of the skill set and services community pharmacy have to offer, the likely varying needs of the target population and inadequate integration and communication with other healthcare services. Facilitators included the previous experience community pharmacy have had with delivering healthcare services and interventions, a shift in the pharmacy contract to offering more clinical services and the accessibility community pharmacy offers.

Adequate training would need to be offered to all healthcare professionals involved in a hypothetical CPDSS intervention, and the content and measurable outcomes of the intervention carefully thought through to ensure they are appropriate and acceptable to both the intervention users and deliverers.

To help further guide the needs analysis of a hypothetical CPDSS, it is important to recognise what the target population want, what they feel their needs are and their perception of a hypothetical pharmacy delivered intervention to support them. This is explored in the second qualitative study detailed in chapter 5.

Chapter 5 What do people living with diabetes who have a history of repeated non-attendance and sub-optimal glycaemic control think about their diabetes appointments and a hypothetical Community Pharmacy Diabetes Support Service (CPDSS)? – a qualitative study

5.1 Chapter outline

Chapters 1 and 2 of this thesis have demonstrated that non-attendance at diabetes appointments and sub-optimal glycaemic control adversely impact health outcomes. Community pharmacies have been involved in the delivery of healthcare interventions, including those pertaining to diabetes, and this has been discussed in chapter 3. Drawing from the findings described in these preceding chapters, it is proposed that there may be a role for a CPDSS to support people living with diabetes and a history of repeated non-attendance at appointments and sub-optimal glycaemic control. Chapter 4 discusses the concept of complex interventions and the importance of a detailed needs analysis including the views of relevant stakeholders. chapter five used an inductive qualitative approach to explore the perspectives of healthcare professionals on a hypothetical CPDSS to support people with diabetes who have a history of recent, repeated non-attendance at appointments and sub-optimal glycaemic control. To supplement the findings from this work, this chapter describes a second qualitative study that was conducted to explore the views of the target population that the CPDSS would endeavour to support. The primary data collection in this chapter and chapter 5 are important when following existing guidelines for good practice in intervention development which stress the importance of an extensive needs analysis in early intervention planning [202].

5.2 Introduction

Building on early scoping work, detailed reviews of the literature and a qualitative study with healthcare professionals,I next wanted to gather an insight into the experiences individuals have had with their diabetes appointments to explore why they had had a tendency to not attend them in the past. In addition, I wanted to get an appreciation for their thoughts on community pharmacy and the proposition of a hypothetical CPDSS to support them with their diabetes management. This is important when conducting a needs analysis for a potential CPDSS and will can help inform whether a CPDSS might be accepted by those it sets out to support, whilst revealing some of the barriers that may be affecting individuals' diabetes management and outcomes. A qualitative approach was chosen to allow for the emergence of novel findings and the collection of rich detail.

5.3 Aim

The aim of this chapter was to explore the opinions and perspectives of the target population that a hypothetical CPDSS intervention would be targeting -those with a history of recent and repeated non-attendance at diabetes appointments and sub-optimal glycaemic control.

Ethics authorisation was granted for the qualitative work by both the University of Southampton's Ethics and Research Governance Online 2 platform and the Health Regulatory Authority's Research Ethics Committee (IRAS: 278035/ REC Reference: 20/SC/0065).

5.4 Methodology

5.4.1 Study design

As describe in chapter 4, the study design was a qualitative focus group study but also included the option for one to one interviews to facilitate recruitment as required.

5.4.2 Study procedure

5.4.2.1 Recruitment and sampling

As detailed in chapter 4, a purposive, targeted sampling approach was adopted to make sure that the relevant stakeholders were represented. To accommodate the study aim, participants were recruited from the Southern Health Community Diabetes Service and local general practices. I screened the Southern Health Community Diabetes Service database for eligible participants and each of the recruiting GP surgeries screened their respective databases. Eligible participants were sent letters of invitation from their recruiting source and a participant information sheet with details of who to contact if interested in taking part. These documents can be found in Appendix C.1 and C.2 (pages 179 and 180). Those that made contact to express interest in the study were offered dates and times of focus groups to suite them. Only one person asked for (and was granted) a one to one telephone interview as they did not have access to a computer or the internet. All participants completed a brief demographics questionnaire to collect data on their type of diabetes, age, gender, ethnicity, occupation and smoking status. This information was used to help describe the sample but did not serve as criteria for purposive sampling. Earlier work in chapter 2 reported that smokers can be more likely not to attend appointments which is why this demographic characteristic was collected.

As introduced in chapter 4, the concept of information power was used to help determine sample size [185]. Considering each of the items of information power in turn and how they related to this study:

Study aim: The study had a narrow aim which set out to answer a specific question. This can reduce sample size requirement.

Sample specificity: Specificity was dense due to the purposive sampling technique adopted. Some of the participants also had broad backgrounds (eg. some participants had had diabetes for a

number of years and had experienced different services and community pharmacies). The specificity of the sample recruited reduces the need for a large sample size.

Theory: The study was not based on specific theory but was informed by findings from the literature described in the preceding chapters. When theory is not applied, this can increase the sample size requirement.

Quality of dialogue: In most instances strong and clear communication was achieved between myself as the researcher and the participants. This may have been facilitated by my background as a diabetes specialist who was therefore familiar with discussion points raised, the local diabetes services people referred to and the terminology or explanations for things that came up. Where participants had difficulty articulating themselves I was often able to clarify with them what they had meant. A good quality dialogue can help reduce the requirement for large participant numbers.

Analysis: This study used thematic analysis to uncover realistic and pragmatic descriptions of what people living with diabetes and a history of non-attendance and sub-optimal glycaemic control felt about their diabetes appointments and a hypothetical CPDSS.

From my reflections on the above, a provisional sample size of greater than ten participants was deemed appropriate.

5.4.2.2 Inclusion/exclusion criteria

5.4.2.2.1 Inclusion criteria

Diagnosed with type 1 or type 2 diabetes for at least five years

AND

Age 18 years or older

AND

A history of two or more missed diabetes annual review appointments in the last 5 years

AND

An HbA_{1c} of 70mmol/mol or above when last measured

To target those with a history of recent and repeated non-attendance at diabetes appointments, I identified those who had not attended two or more of their annual diabetes reviews in the last five years. An HbA1c >70mmol/mol was chosen as an inclusion criteria as the risk of severe complications from diabetes is most apparent in those with HbA_{1c} figures greater than this [203].

5.4.2.2.2 Exclusion criteria

-Those unwilling to take part.

-Those unable to consent or speak English due to the difficulty in orchestrating a focus group or one to one interview through an interpreter.

- Those not meeting the inclusion criteria (ie. have an alternative type of diabetes that is not type 1 diabetes or type 2 diabetes, has been diagnosed with type 1 diabetes or type 2 diabetes for less than five years, does not have a history of repeated non-attendance, has an HbA_{1c} of less than 70mmol/mol, is younger than 18 years of age).

5.4.2.3 Consent and the interview process

Verbal consent was gathered at the start of each focus group and before the telephone interview. Participants were reminded of the purpose of the study and that the discussion would be recorded to allow later transcription of the conversation. After introducing themselves, the conversation was guided by an interview schedule (please see Appendix C.3 on page 186).

Participation in the study was voluntary and it was the participants' right to withdraw at any time if they changed their mind. A gift voucher worth £20 was offered to participants to show appreciation for their time and contribution.

A total of four focus groups were carried out, all of which were done virtually. The use of online platforms has been discussed in chapter 5. In addition to the four focus groups there was also a telephone interview with an individual who did not have access to a computer or the internet. Focus group sizes ranged from two participants up to five participants in addition to myself as the researcher. The focus groups were scheduled to run for a maximum of one hour as longer than this on a virtual platform can lead to fatigue [188].

All focus groups and the one to one interview were recorded and data stored in accordance with the Data Protection Act (2018). Audio files were auto-transcribed verbatim by the Zoom software. I edited the Zoom auto-transcriptions whilst listening again to the audio recordings, removing any personal identifiable details.

To minimise technological issues and make sure that everyone was happy accessing the focus groups, I offered all participants a test video call which three participants then requested. Those with anxieties about joining on the day were encouraged to join early so that I could help with any issues. In the lead up and during each focus group I made sure I was accessible by email and phone in the event participants had problems. The safety netting placed helped participants feel more at ease and joining early allowed time for rapport to build in the groups.

5.4.3 Data Analysis

Thematic analysis was used as the method for data analysis as described in chapter 5. This approach provides a method for identifying, analysing and reporting patterns (themes) within data and can be applied flexibly across a range of theoretical frameworks [190]. This inductive analysis aimed to understand why people with diabetes and sub-optimal glycaemic control may not be attending appointments and their perceptions of a potential pharmacy intervention to support them with their diabetes management.

A coding manual was used to enhance consistency during the coding of the data corpus. Please see Appendix C.4 on page 191.

5.5 Results

A total of 263 eligible people were contacted across the three GP surgeries (186 people) and the Southern Health Community Diabetes Service (77 people). Of this, 14 people expressed an interest in the study and two people made contact to say that they were not interested. Of the 14 people that expressed an interest in the study, 13 participated overall. One participant expressed an interest in the study and completed the demographics form but did not turn up to the focus group session and could not be later contacted. Of the 13 participants that took part, three were from the Southern Health Diabetes Service and 10 from the GP surgeries. I did not know any of the participants that took part, but there was the potential that I might have through my clinical work for the Southern Health Diabetes Service.

The total sample size of 13 participants was deemed sufficient when reflecting on the items and dimensions of information power discussed in the study procedure. A majority of focus groups had a mixture of people with type 1 and type 2 diabetes and included both males and females. Most participants were aged over 50 years, were non-smokers and of white Caucasian ethnicity. There was an equal representation of males and females in the study. Participant demographics are displayed in **Error! Reference source not found.**.

Table 6: Participant demographics

	Focus Group 1	Focus Group 2	Focus Group 3	Focus Group 4	Telephone interview
Number of participants	5	2	2	3	1
Type of diabetes:					
Type 1	3	0	0	1	0
Type 2	2	2	2	2	1
Gender:					
Male	3	1	1	2	0
Female	2	1	1	1	1
Age in years:					
Mean (range)	53 (29-75)	59 (59)	69 (63-75)	65 (61-68)	70
Occupation:					
Blue Collar	1	0	1	0	0
White collar	2	0	0	1	0
Retired	2	1	1	1	1
Disabled	0	0	0	1	0
Smoking status:					
Non-smokers	4	2	0	3	0
Ex-smoker	1	0	2	0	1
Smoker	0	0	0	0	0
Ethnicity:					
White Caucasian	5	2	1	3	1
Asian	0	0	1	0	0

This study set out to explore two main topics- people's experiences of diabetes appointments and their thoughts and opinions on a hypothetical CPDSS. These will each be considered in turn.

5.5.1 Topic one: Diabetes appointments

Two overarching themes were identified as contributing to people's experiences of diabetes appointments: (1) appointment logistics and service-related issues; (2) relationships with healthcare professional(s).

5.5.1.1 Appointment logistics and service-related barriers.

Appointment logistics were a concern for a number of participants, particularly those in employment. Participants felt that the struggle to fit appointments around their work or other commitments often put them in a difficult and stressful position that left them feeling guilty and

frustrated. When individuals tried to re-schedule, they described having to wait several months for their next offered appointment and they attributed this to understaffing of diabetes services. The lack of flexibility and choice around scheduling of appointments influenced participants' likeliness of attending and some felt that a preferred solution was virtual consultations that inherently offer more flexibility.

"But if I call up and try to rearrange an appointment, that's say scheduled for April, and then end up having to wait to say October just because I can't make the morning. It's so hard. So when I get the letter I am always like 'oh God, I have to get this rearranged or got to take a day's holiday' or something like that. That tends to be the problem, not actually about the appointment is just the fact that there's obviously not enough DSNs to go around so you often have to take the appointment offered, which creates a bit of a Bedlam for work."

(Participant C, 29yr female, Type 1 diabetes)

"I would say, I had an appointment recently with my GP on the phone. Fantastic. I didn't need to see him and he didn't need to see me. We couldn't see each other anyway due to COVID. Actually, I think some of the changes that covid-19 has caused might be helpful. The more we can do electronically, with the more we can do video appointments rather than a real appointment."

(Participant I, 75yr male, Type 2 diabetes)

When people had problems out of hours or outside of their appointment, they were often left feeling unsure where to go to seek help. They felt services weren't always tailored to the individual or accessible when most needed.

"To me it feels like they ask you to come, and you go or don't go, as opposed to us reaching out to them to say. 'Hey, can I come and have an extra appointment with you, my 6 months is isn't up but, I've got an issue, can I come and see you?'… But it's that they pull us in as opposed to us pushing our way in if that make sense?"

(Participant H, 59 yr male, Type 1 diabetes)

Communication between the health service and the patient was deemed to be inefficient with some people being left unsure on the next steps in their care or follow-up. Communication between diabetes specialist centres and GPs was also commented on as being unreliable with the GP often not acting on the requests of the specialist team. Furthermore, some felt that using letters delivered in the post as the primary mode of communication was ineffectual and a waste of resources, preferring communication to be done digitally through e-mail, texting etc.

"They (diabetes service) contact them (GP surgery) and say 'can you sort out her prescription? Can you do this etc,' and every single time I get absolutely nothing from the doctors. I call my GP and then they go, 'Oh, no, we haven't heard from your diabetic nurse.' ... I literally feel like I'm on a hamster wheel and can't get off of it! I don't for one second doubt that the diabetes specialist nurse and the consultant are doing it because it's in the letters that I'm receiving."

Participant C, 29 yr female Type 1 diabetes)

"When I get a letter I think why did you send me a letter? Just send it to me electronically. It's such a waste of money"

(Participant E, 58 yr male, Type 2 diabetes)

One individual mentioned that he sees a private consultant for his diabetes care and that 'the system' struggled to acknowledge this, continuing to offer him appointments that he then cancelled or did not attend. Furthermore, he had been made to feel guilty for engaging with the private sector.

"…if you have private health care, you're sort of made to feel guilty ... I pay to have consultations with a doctor who I've known for twenty five years because I am on a pump. He works for the NHS but I have seen him privately for many many years. I continue to be offered diabetes appointments

on the NHS that I repeatedly have to cancel or not attend because they don't change their records."

(Participant H, 59yr male, Type 1 diabetes)

Finally, the frequently changing structure of diabetes and healthcare services was not appreciated by a number of participants who found it confusing and unsettling.

"I just thinks it causes total confusion and uncomfortableness when it's constant change and the NHS just seems to change everything every couple of years, all these different services and it's not good for us, for any of us I don't think."

(Participant F, 66yr female, Type 1 diabetes)

5.5.1.2 Relationships with healthcare professionals

Participants' relationships with healthcare professionals had a significant impact on their appointment experience and how they then valued it. Difficulties in the relationship resulted in frustration, an ambivalence about the process and a tendency to not want to attend appointments. Some participants didn't have confidence in the skill-set of healthcare professionals they had seen or felt that they were being given unrealistic goals to achieve which further threatened this relationship and their likeliness to attend appointments. A number of participants felt that they were 'told off' during their consultations and didn't appreciate this paternalistic approach.

"…one thing I feel is you tend to get told off a lot in these meetings which means I don't really want to go. I tend to feel like I'm back in class and you know, I'm sitting in front of my teacher who's marking my homework … Expecting you to have a blood sugar no lower than four and no higher than eight. That's an impossible target … and quite frankly, they're not going to tell me anything I don't know but it feels a bit like that."

(Participant B, 35yr male, Type 1 diabetes)

Although the majority had at some point experienced problems in their relationship or trust of healthcare staff involved in their diabetes care, there were occasions when it went well and the care offered was appreciated. People also had varying experiences depending on where they lived.

"But everyone's very kind and I have had an awful lot of input for the ups and downs I've had over the years so I'm very very supportive of the NHS in that respect."

(Participant F, 66yr female, Type 1 diabetes)

"I'm going back a few years, but like I say, this arrogant little so and so when I was living outside of Hampshire, he just didn't want to know half the time. Things have been better since I've moved from there though."

(Participant I, 75 yr male, Type 2 diabetes)

Continuity of care was deemed to be very important to many participants and they appreciated when they were treated holistically and made to feel empowered with the management of their condition.

"It's a roller coaster to be honest, but provided I've just got the one person to advise me I'm fine with it. I do believe that we all live with it and we manage it in our own way. When I get an appointment with someone new, I think 'Oh God, who am I going to get this time?' And this creates quite a lot of anxiety."

(Participant A, 70 yr female, Type 2 diabetes)

"… the more streamlined, the more you know that person and you'll see in the same person each time, then you do build up the trust and you don't start from the beginning and you don't actually mind them saying something to you that's a little bit sort of personal compared to someone that

you've never met before. I'd rather wait longer to have the appointment and then see someone who is good at giving me a personal answer and treat me as an individual and not as a diabetic"

(Participant G, 59 yr female, Type 1 diabetes)

One participant concluded with what she felt people with diabetes should be offered which draws on both themes described above:

"Certainly by what we said here today, we'd like it to be much more about continued care where we know where we go, what we get, when we get seen and we can contact people that we know who are on the end of the phone or on the end of you know, the video or whatever, as it's very very very hard for us as the person that lives with diabetes every day."

(Participant F, 66yr female, Type 1 diabetes)

5.5.2 Topic two: Perceptions of a hypothetical CPDSS

Codes identified from the data could be attributed to one of two main themes- the strengths and barriers to a hypothetical CPDSS.

5.5.2.1 Strengths

Frequency of contact was a strength. Most participants had a tendency to visit their pharmacy every two to four weeks, with only a couple of people opting to have their medicines delivered. A few participants did not trust pharmacy deliveries, particularly with the delivery of their insulin which needs to be stored at an appropriate temperature. All participants chose their respective pharmacies due to their locality and convenience.

""Yeah. Mine's (the pharmacy) a ten-minute walk away. Like you say like, they know you. It's also habit, it's always been the one I go to. I did the internet delivery once. I needed to get it delivered and the first time I did it, I found I wasn't in because it wasn't the time that they said it would be

delivered in the afternoon. Instead, it was morning and they left my insulin on the doorstep. I decided never again!"

(Participant C, 29 yr female, Type 1 diabetes)

Participants viewed community pharmacy as being very accessible and recognised that they have a large workforce, both of which would make them a good place to offer a healthcare intervention. They also felt that community pharmacy may have a role in helping to off-load some of the pressures of current diabetes services and may be most useful with supporting the data-gathering aspect of diabetes care.

"I think there's that regular contact. So it makes sense for pharmacists then to be your dispensary but also at the same time collect some basic information around you and then feed that back to the GP. I think that would be a really good use of their time... the data-gathering aspect of that would be very helpful I think and probably helpful for the diabetic clinics because that seems to be what they spend most of their time doing right now rather than diagnosing or giving advice. If you had this three-tiered approach: One off for the GP for when your leg is falling off or there's something seriously wrong and then the nurse/ the diabetic clinic for adjustments to treatment whether that's changing your insulin levels or what to do about ketones or whatever. It might be that then all the monitoring, the data-gathering, the looking after your day-to-day needs could go through the pharmacy."

(Participant L, 68 yr male, Type 1 diabetes)

5.5.2.2 Barriers

A significant barrier to a hypothetical CPDSS is the perception of pharmacists held by those living with diabetes. Pharmacists' skills-set and capacity to deliver a service for people with diabetes were questioned by some, with a general lack of trust in the wider incorporation of pharmacists into diabetes management.

"They don't know the ins-and-outs of everything like a DSN (diabetes specialist nurse) would know so it depends what they'd be offering really. I think you would have to have more trust in the pharmacist really to understand that they were doing it because they had the experience, etc, rather than just taking a box. The pharmacies are usually very busy anyway, so I can't imagine them having any more time than a doctors' surgery."

(Participant F, 66 yr female, Type 1 diabetes)

In contrast, some participants did have confidence in the competence of pharmacists but this usually pertained to their role in delivering medicine advice and other established services such as the flu vaccine. Their role during the COVID-19 pandemic was also appreciated.

"…as for their competence and confidence with medicines and the flu jab etc, no problem whatsoever."

(Participant H, 59yr male, Type 1 diabetes)

"But one thing I will say in fairness to the pharmacies, over the COVID-19 pandemic, I think they've been brilliant."

(Participant L, 68 yr male, Type 1 diabetes)

Many compared pharmacists to diabetes specialist nurses and didn't feel they had the same caring nature but were instead more commercially focused.

"If you think someone who's trained to be a nurse is trained to care for people, pharmacists are trained to sell you stuff. So it's a specific role, you know that nursing is very much a caring profession which pharmacy isn't."

(Participant M, 61yr female, Type 1 diabetes)

Participants voiced that they would not appreciate another layer to their current care which they felt would result in having to attend an increased number of appointments and risk receiving

conflicting advice to that given by other HCPs. Participants voiced that a CPDSS would likely lack efficiency and be at risk of 're-inventing the wheel', although if all diabetes care could be offered by pharmacists then their accessibility would be appreciated.

"No, I certainly wouldn't want another layer. Okay, if the pharmacist did everything, which is completely unreasonable, I appreciate, but if the pharmacist was the place to then it'd be great because it would be local, but that is unlikely to happen"

(Participant F, 66 yr female, Type 1 diabetes)

"I'm thinking that the one thing that would have to be considered very seriously is the efficiency of such a service … not re-inventing the wheel"

(Participant B, 35yr male, Type 1 diabetes)

A CPDSS would need to give pharmacists authority to make changes and communicate these to the GP whilst having access to health records, all of which participants didn't feel were currently the case.

"They need authority to make changes though, or to be able to communicate with those that have the authority in surgery."

(Participant H, 59 yr male, Type 1 diabetes)

Participants did not generally feel that there was a particular aspect of their management that a CPDSS could help them with other than one participant feeling they may have a role in data gathering as mentioned above. Although they would be happy for advice regarding vaccinations, medications and some more basic problems, they didn't have the confidence in pharmacists to get involved with their diabetes management. One participant felt that a CPDSS would be an example of privatisation of the NHS.

"Being a socialist all my life, I just see it (a CPDSS) as a privatisation of the NHS I'm sorry to say. And as far as primary care goes, that's going down the same route, or I think it seems to be. I think

we've already sold lots to the Americans in one area, so no, you know with our condition, it has to be taken care of by the hospital specialists and by properly trained specialist nurses."

(Participant L, 68 yr male, Type 1 diabetes)

5.6 Discussion

This was a study that involved people living with diabetes who have sub-optimal glycaemic control and a history of repeated non-attendance at diabetes appointments. It set out to explore their views on diabetes appointments and a hypothetical CPDSS, both of which are important when considering the role of a potential pharmacy delivered service to support individuals meeting these criteria.

My previous systematic review exploring non-attendance at diabetes appointments (chapter 2) suggested that the reasons for non-attendance are manifold and differ both between individuals and for any one individual [143]. In this study, participants described varying experiences when moving to different areas and depending on whether they were receiving NHS or privately funded care. Indeed, it is to be expected that everyone's experience of diabetes care will be different and vary over the course of their condition depending on their stage in life, where they are living, the service they are under and life circumstances to name a few.

Whilst one person's reasons for not attending appointments may differ from another's, some key contributors to non-attendance behaviour were identified repeatedly in the literature and further supported by this study. These include issues around appointment logistics, notably the lack of flexibility around appointments, and difficulties in the relationships with diabetes HCPs, particularly when there has been a paternalistic and judgemental approach to care or reservations about the skillset of a HCP [143]. The literature also suggested that illness perception, distress and coping strategies have a role in people's tendency to not attend appointments which seems possible, although these were not recognised as contributors in this study [81, 85, 105, 111].

Participants in this study wanted more support at times when they identified themselves as being most in need (eg outside of appointments or out of hours). They wanted to be treated holistically and made to feel empowered which they felt was best achieved when continuity and clarity of care could be offered. There was frustration when communication was sub-optimal, both between HCPs and between HCPs and people living with diabetes, which participants felt impacted treatment plans and the value of care offered. All of these factors were less prominent in the literature but had a tendency to affect participant's appointment experiences and to influence their perception of an appointment's value and therefore likelihood to attend.

Interventions to address non-attendance have typically focused on appointment reminders, care navigators, service re-structuring and the offering of virtual appointments [143]. Whilst all of these may have a positive impact, they don't fully address the aforementioned contributors to non-attendance. The ideal offering is likely different for everyone living with diabetes, although based on the findings of this work and my review of the literature, more flexible, convenient and patient-led approaches to contact with diabetes services would be appreciated. Care pathways and expectations should be clear and communication between healthcare professionals and also with people with diabetes should be fluent and timely. Continuity of care is challenging to achieve with the protean nature of healthcare systems and if flexibility in appointments is to be offered. However, a consistent ethos amongst diabetes teams can make sure that people with diabetes get consistent messages and support. Training staff to empower patients and move away from a paternalistic and blame culture is also important.

When exploring participants' perception of community pharmacy and a hypothetical CPDSS, the accessibility of community pharmacy was appreciated. All participants had a tendency to visit their local pharmacy more often than they did other healthcare providers and this was typically to pick up their prescriptions. Very few trusted their medicines to be delivered. Despite the regular contact with their local pharmacies, participants lacked confidence in pharmacists' medical advice, skill-set or underlying incentives and didn't feel they had a role in supporting them with

their diabetes care. This is in keeping with the wider literature which recognises that public cognisance and attitudes towards community pharmacy have been barriers to their wider incorporation into healthcare models/services [195] . Participants had concerns that local pharmacies do not have the capacity to deliver a hypothetical CPDSS and that such an intervention would lead to additional appointments for people with diabetes and a duplication of care. Participants didn't feel that pharmacists had the authority to make changes to their treatment, particularly with the limited access they have to medical records. These were all concerns voiced by healthcare professionals in the qualitative study described in chapter 4.

Although community pharmacies have been shown to have effectively delivered diabetes interventions in the past, as described in Chapter 3 and demonstrated in the qualitative work in this chapter and chapter 4, the public's perception of community pharmacy is that they are predominantly dispensers of medicines and commercial businesses that aren't part of the NHS. There is limited appreciation of their skill-set or ability to support diabetes care. These perceptions serve as significant barriers and would need addressing during the development of a hypothetical CPDSS.

The findings from this work and the preceding chapters suggest that there may be a place for integrating community pharmacy into the care of those with diabetes but that their role and function may not necessarily be best suited to a hypothetical CPDSS intervention. Instead, with improved communication and access to medical records, perhaps local pharmacies would be best suited to identifying and sign posting those they identify as being most at need and communicating this to the healthcare providers already involved in an individual's care.

There appears to be a gap between what community pharmacy has to offer and their appreciation by the public and other healthcare professionals. As more clinical services become consistently offered in community pharmacy (for example, medicines optimisation services, minor ailments services etc), and with the changing vision for pharmacy with the evolving

structure of health and care systems and service delivery models, public understanding of their ability will no doubt evolve [70].

5.6.1.1 Strengths and limitations

This study helps contribute to the limited qualitative literature on the reasons why people do not attend their diabetes appointments. To my knowledge, it is also the first study to explore the views of people with diabetes on a hypothetical intervention delivered by community pharmacy to support people with diabetes who may be most at risk of adverse health outcomes.

The population of interest in this study has a history of non-attendance where it may be implied, therefore, that recruitment can be challenging. With a response rate of 5%, the potential of non-response bias needs to be considered as non-responders may include individuals with very different views or circumstances to those who did respond.

The number of participants in this study met the minimum criteria according to previous information power calculations. During analysis, recurring themes were identified with limited additional information obtained in consecutive focus groups. This helped support the decision that adequate sampling had taken place.

All focus groups were small - two of the focus groups consisted of only two participants. Considering the difficulty recruiting this population, smaller groups allowed more flexibility in dates/times offered to participants. Non-attendance can be a sensitive issue to discuss and having smaller groups can be less intimidating for individuals sharing their experiences. Small numbers also allow more time for each participant to speak. The weakness of small focus groups is that participants may feel a pressure to speak and therefore say things for the sake of it to fill silences. They may also feel under the spotlight.

Although all focus groups and the interview had to be conducted virtually and not face-to-face due to the restrictions of the COVID-19 pandemic at the time of the study, two participants who had never used Zoom before had no difficulty accessing the focus group on the day. This was

after I had explained to them how to use Zoom and following test videocalls beforehand. Where an individual had no computer or internet access, a telephone interview was offered. These points suggests that computer literacy was not necessarily a significant barrier to participation in the study if people had the confidence to do so. Conducting things virtually may have in fact facilitated recruitment due to the convenience it offered for the majority. Nonetheless, as discussed in chapter 4, there are limitations of conducting focus groups virtually which also apply to this study. Furthermore, the limitations of the single telephone interview that took place include the added barrier that all forms expression and body language are lost. Speaking to this participant on the phone did however allow them to contribute when they otherwise would not have been able to due to digital literacy and mobility restrictions, factors that may very well interfere with an individual's ability to attend appointments.

A number of participants commented on how much they appreciated the opportunity the study gave them to speak openly and in confidence to others with similar backgrounds about their experiences of diabetes. Liaising with participants by email and phone beforehand and doing test video calls I felt improved my rapport with individuals and likely helped make them feel more at ease during the focus groups.

As previously discussed in chapter 2, the literature suggests that young adults, older individuals (age >70 years), smokers and people from lower socioeconomic backgrounds are more likely to not attend diabetes appointments. Some, but not all of these features were true of the participants in this study. Not unlike the population characteristics in West Hampshire where the study took place, there was a greater representation of people aged over 50 years and all participants were either non-smokers or ex-smokers. Details on socioeconomic background were not collected but according to the 2019 Index of Multiple Deprivation, Hampshire has 44 areas in the top 10% most deprived tier which is lower than a number of other regions [204]. The diversity of socio-economic backgrounds may however be inferred from people's category of occupation as displayed in **Error! Reference source not found.**.

The limited representation of ethnic minorities in this study must also be considered. All but one participant was white Caucasian. Although my systematic review on non-attendance in chapter 2 didn't consistently show that ethnicity was associated with attendance rates, it is likely that prevailing reasons for non-attendance differ between ethnicities and this should be considered when interpreting study findings and considering transferability. Although information power was met in this study, future work should endeavour to explore the views and perceptions of people living in other areas where the demographics differ and/or these different demographics should be targeted with different recruitment strategies.

5.7 Conclusions

This study highlights some of the factors affecting attendance at diabetes healthcare appointments which include issues around appointment logistics, service-related barriers and relationships with diabetes HCPs. These findings are in support of earlier work as described in the systematic review on this topic in chapter 2. Whilst an intervention to address non-attendance and sub-optimal glycaemic control may have an important role in improving long-term health outcomes, it must take into consideration the complex and broad spectrum of factors that underlie non-attendance behaviour. The role of a hypothetical CPDSS has been explored. Although people with diabetes appreciate the accessibility of their local pharmacies, the majority were guarded about what such a service would offer. They were concerned that it would add an extra layer to their care and were not convinced that pharmacists have the skill-set and capacity to deliver such an intervention. Some of these reservations were also articulated by healthcare professionals in the qualitative study in chapter 5. This study along with the findings from the other chapters serves as a needs analysis for a hypothetical CPDSS. Chapter 7 brings these together and considers the potential of proceeding with the next steps in intervention development.

Chapter 6 Overall discussion and summary of thesis

6.1 Chapter outline

This thesis set out to explore the potential role of a community pharmacy diabetes support service (CPDSS) to enhance healthcare engagement in those with diabetes who have a history of repeated non-attendance at diabetes appointments and sub-optimal glycaemic control. The chapters of this thesis represent a series of studies. The first of these critically appraise the literature. The aim of this was to better understand what is already known about non-attendance at diabetes appointments and to recognise the current position of community pharmacy and their previous involvement in diabetes interventions (chapters 1-3). The subsequent studies discussed in chapter 4 and chapter 5 used a qualitative approach to gather the views of key stakeholders including the target population and those who would be involved in the delivery of a CPDSS. The cumulative findings of all chapters have helped serve as a needs analysis for a hypothetical CPDSS and have been summarised in the sections below along with their implications for future research.

Midway through the course of this PhD the COVID-19 pandemic took place. Returning to clinical duties for a number of months had an inevitable impact on my thesis timeline, although gave me space to consider how to best proceed with my primary data collection. Due to national restrictions that were imposed at the time, it was necessary to make amendments to my qualitative study protocols and materials in order to conduct the fieldwork virtually. The nuances of this have been discussed in the preceding chapters.

6.2 Critical appraisal of the literature

6.2.1 Background

The prevalence of diabetes is growing, as is its impact on individuals, healthcare systems and society as a whole. Evidence to date has shown the importance of optimal control of glucose, blood pressure (BP) and cholesterol in reducing morbidity and mortality, although only 21.5% of those living with type 1 diabetes and 34.8% of those living with type 2 diabetes in England are meeting the recommended targets for these three parameters [205].

The National Institute for Health and Care Excellence (NICE) recommend that those living with diabetes have eight care processes (HbA1c, cholesterol, serum creatinine, BP, urine albumin, weight, foot examination and smoking status) assessed on an annual basis in additional to annual retinal screening [206, 207]. Many of these care processes were also advised in the 'National Service Framework for Diabetes' published in 2001. The Quality and Outcomes Framework (QoF), a pay for performance initiative introduced into the primary care contract in 2004, incentivises a diabetes register and the attainment of the eight aforementioned parameters in those living with diabetes [208]. Unfortunately, despite these recommendations and the QoF incentivisation, a majority of people living with diabetes are not having all eight care processes completed.

Not unexpectedly, during the early part of the COVID pandemic, care process completion declined nationally (27.4% of people with type 1 diabetes and 36.9% of those with type 2 diabetes had all 8 care processes in 2020-2021 compared to 42.3% and 58.5% respectively in 2019-2020) [209]. The greatest impact was on foot examination and weight measurement. Retinal screening was also negatively impacted. These findings are not surprising in light of the social distancing measures that were in place at the time.

More recent provisional data from the National Diabetes Audit from Jan 2021-March 2022 suggest that care process attainment is still not back to pre-COVID levels (32.8% of those with type 1 diabetes and 47.8% of those with type 2 diabetes had all eight care processes completed in

2021-2022) [205]. This is concerning as those that have fewer care processes completed are at increased risk of morbidity and premature mortality [210]. Work by Holman et al found that completion of five or fewer annual diabetes care processes in 2009 was associated with a mortality hazard ratio of 1.37 in people with type 1 diabetes and 1.32 in people with type 2 diabetes at seven years.

6.2.2 Non-attendance at diabetes healthcare appointments

Annual diabetes reviews with a healthcare professional serve as an opportunity to carry out and optimise the eight recommended care processes whilst offering support to people living with diabetes. Non-attendance at these appointments is therefore an important behaviour to address and better understand in order to combat its associated increased morbidity and mortality. My systematic review summarised in chapter 2 was published in Diabetic Medicine and received an award from Wiley publishers for being a 'most cited' paper in 2020/2021. This highlights the importance and interest people have in this subject area.

According to my review, reported rates of non-attendance at diabetes outpatient appointments vary, typically between 10-30% [143]. This variation is in part due to differences in how non-attendance is recorded and quantified. According to the findings of the systematic review in chapter 2, non-attendance at diabetes appointments has been associated with less favourable health outcomes [143]. This is not surprising given that healthcare appointments serve as an opportunity to complete care processes and the positive association between the number of measured care processes and health outcomes found by Holman et al [210]. Individuals who miss their healthcare appointments have been identified as being more likely to have higher HbA_{1c} readings and increased morbidity and mortality as a result of diabetes related complications. Despite this association, reasons for non-attendance are poorly explored and solutions have traditionally focused on logistical issues, neglecting the more complex factors that may underlie non-attendance behaviours (e.g. relationships with the healthcare professional, coping strategies, socio-economic factors etc) [143].

6.2.3 The role of community pharmacy

Diabetes care is multi-faceted and includes a broad array of different healthcare disciplines. These include but are not limited to general practitioners, diabetes physicians, diabetes specialist nurses, podiatrists, dieticians, educators, retinal screeners, ophthalmologists and renal specialists to name a few. To date, pharmacists are not routinely involved in the care pathway of diabetes but represent a highly skilled workforce well placed to offer additional support for people with diabetes. Chapter 3 highlighted the skillset of pharmacists, their evolving contract that puts more of an emphasis on clinical services over dispensing and demonstrated their involvement in diabetes healthcare interventions in the past. Despite this, there is an under appreciation of pharmacists' roles and skill-sets, both by the public and other healthcare professionals. These attitudes and perceptions have served as barriers to the wider integration of community pharmacy into both existing and evolving healthcare models.

In chapter 3, pharmacy-led interventions for diabetes were described. These typically focused on type 2 diabetes and lacked detail on intervention constituents. Most interventions relied on regular face to face and telephone appointments over a 3-12 month period and consisted of education delivered by a pharmacist, support with management queries and goal setting [195]. The interventions reported and discussed in chapter 3 proved feasible to deliver and accepted by those taking part. They were typically associated with reductions in parameters such as HbA_{1c}, BP, lipids, weight and improvements in patient-related factors including medication adherence and QoL scores.

Since writing and publishing chapter 3 of this thesis, additional diabetes pharmacy-led interventions have been reported. In keeping with previous studies, most of these have demonstrated favourable outcomes in terms of medication compliance and/or reduction in selected parameters associated with diabetes related morbidity and mortality (HbA_{1c}, BP, lipids etc) [115, 211-217]. Other studies have shown improved quality of life in those newly diagnosed with diabetes following education delivered by a pharmacist [218], a decrease in progression of

diabetic foot disease [219] and improved diabetes care co-ordination resulting in increased statin use and completion of retinal screening [220]. A study is also currently underway looking at a pharmacy intervention to reduce hypoglycaemia in those with type 2 diabetes on insulin [221]. All of the aforementioned studies were conducted outside of the UK where community pharmacy operates very differently. Outside of the UK many pharmacy services are funded privately or through insurance companies and not nationally commissioned. Nonetheless, community pharmacies across the globe share some common core principles, particularly relating to their accessibility to the public.

As identified in chapter 3, most of the recent published pharmacy interventions have been specific to type 2 diabetes with only one study identified as having recruited people with either type 1 or type 2 diabetes [220]. Typical follow-up in all studies was up to 12 months. These interventions continue to lack detail on intervention constituents and only one has clearly incorporated behavioural science [211]. The lack of detail may in part be a result of the word count constraints associated with published work, although often no formal intervention planning models/pathways have been referred to or followed when describing the various interventions.

In the United States, Sharp et al are conducting a randomised controlled crossover trial evaluating the impact of a joint health coach and pharmacist led mobile intervention for African-American and Latino adults with type 2 diabetes and sub-optimal glycaemic control [222]. Unlike previous studies, they clearly describe the details of the intervention and its related training. They combine face to face health coach appointments with virtual consultations with the pharmacist. The intervention focuses on a person-centred approach incorporating motivational interviewing, education and empowerment. The results of this study are pending, but it explores a novel approach to supporting a hardly reached population with diabetes in the United States of America.

The continued publications on pharmacy-led diabetes interventions demonstrates a global appetite for the wider implementation of pharmacists into diabetes healthcare models.

Considering that people living with diabetes are at increased risk of adverse health outcomes if they repeatedly miss appointments and/or are not meeting the recommended treatment targets, I proposed that there could be a role for a community pharmacy diabetes support service (CPDSS) to support these individuals. Their accessibility (extended hours, locations, opportunistic contact) could provide a more convenient and acceptable offering to those with a history of non-attendance at other diabetes appointments. Their input may also provide an alternative healthcare contact when there may have been a breakdown in relationship with other HCPs involved in someone's diabetes care.

6.3 Primary data collection- the views of relevant stakeholders

To understand the perspectives of relevant stakeholders I conducted two qualitative focus group studies. The first study sought the views and opinions of pharmacists and healthcare professionals involved in the care pathway of those with diabetes (eg. practice nurses, general practitioners, diabetes specialists etc). I had wanted to gather their thoughts on a hypothetical CPDSS to support those with diabetes identified as being most at need (those with recurrent non-attendance at diabetes appointments and sub-optimal glycaemic control). These healthcare professional groups would be key in the implementation and delivery of a CPDSS which is why they were selected.

The second qualitative study aimed to better understand the reasons people with diabetes may not attend appointments, their views towards community pharmacy and a proposed CPDSS. This is the target population of a proposed CPDSS which is why their input was important. Individuals from Southern Health NHS Foundation Trust, a secondary care diabetes facility, and four GP surgeries in Hampshire were invited to take part if they had a history of repeated non-attendance at their diabetes annual review (2 or more missed reviews in the last 5 years) and an HbA1c >70mmol/mol. It was proposed that individuals meeting these criteria may be those who would benefit most from an intervention that sat outside of the care traditionally offered to them. Whilst it was acknowledged that this population would be challenging to recruit due to

perceived lower levels of engagement, there have been very few qualitative studies exploring non-attendance at diabetes appointments, and to my knowledge, none looking at the views of this population towards community pharmacy and the role pharmacist may have in diabetes care.

6.3.1 Results of the qualitative studies

6.3.1.1 Non-attendance at health care appointments

To first consider the target behaviour of non-attendance. As anticipated, it was challenging to recruit people living with diabetes meeting the inclusion criteria to understand their reasons for repeatedly missing their diabetes appointments. Nonetheless, information power calculations were met, and themes apparent from the discussions that took place with the 13 participants. The study highlighted that non-attendance at healthcare appointments can stem from difficulties in the patient-healthcare professional relationship, service-related factors and logistical considerations, especially when having to arrange time off from work. Whilst these findings are in keeping with what has been reported in the literature, novel findings included that non-attendance sometimes stems from not feeling well supported when individuals have queries about their diabetes outside of their appointments, especially when their questions are 'out of hours'. The frequent changing of healthcare services was also deemed to be unsettling and confusing, whilst the lack of continuity with a service or healthcare professional was described as stressful, threatening the holistic approach to care desired by participants. People living with diabetes wanted to feel empowered but didn't always feel that this was supported by the professionals they encountered.

6.3.1.2 Perceptions of community pharmacy

People living with diabetes and HCPs had varying experiences of community pharmacy. Many participants were unfamiliar with the skillsets and additional services currently offered by pharmacists. There were concerns about pharmacies' limited resources (time, financial, staffing levels) which many felt could impact a potential intervention delivered in this setting. These

findings were in keeping with the wider literature summarised in chapter 3. Nonetheless, pharmacists in the study had optimism and enthusiasm for a diabetes intervention and felt that if adequately resourced, such an intervention could offer a lot of job satisfaction to the pharmacists involved, added value to patients and reduce work burden for GPs.

Healthcare professionals felt that the public were moving away from visiting their local pharmacies with a preference for online pharmacies and the delivery of medications. They discussed how this would threaten the frequency of contact community pharmacies have with the public and make it likely that high street pharmacies could start closing down. Although it is known that high street pharmacies are reducing in number due to financial strains (across England there has been a net loss of 310 pharmacies each year on average for the last two years [223]), people living with diabetes expressed a preference for collecting prescriptions in person over having them delivered. For some, visits to the pharmacy were much appreciated contact with others, especially during the isolating time of the COVID-19 pandemic. This exemplifies how healthcare professionals' concerns regarding online pharmacy services threatening the viability of high street pharmacies is a perception that is not shared by those living with diabetes. It also demonstrates how healthcare professionals' underlying assumptions may be wrong and therefore need addressing to ensure their engagement and confidence in a hypothetical CPDSS programme.

Although some participants in both studies regarded pharmacists as professional and helpful, others saw them for their dispensing role and would not consider asking them for additional support. All participants with diabetes chose their pharmacy based on convenience and locality. Whilst this is desirable in terms of accessibility, it may serve as a disadvantage should individuals not be prepared to travel outside of their locality to a pharmacy offering relevant expertise or healthcare service.

6.3.1.3 Views on a hypothetical CPDSS

When asked about a local pharmacy intervention to support people with diabetes, the views were mixed. People living with diabetes were concerned that it would add an extra layer to their care

which may result in conflicting advice and an increased number of appointments. Others would appreciate the continuity and support that it could potentially deliver. Participants were not confident what additional help could be offered to them in a CPDSS and did not feel that pharmacists had the authority to make changes to their management. Healthcare professionals and people with diabetes had concerns about duplication of work and difficulties with communication between pharmacists and other healthcare professionals, particularly with their limited technological integration and restricted access to medical records.

As described, healthcare professionals and people living with diabetes had reservations about a hypothetical CPDSS which largely stemmed from their perceptions of the pharmacy workforce and services. They also voiced concerns about community pharmacies' limited integration (largely technological) with other services. These issues would be important to address in a pilot CPDSS intervention and could be achieved by incorporating relevant stakeholder engagement, particularly during the early planning phase. These stakeholders would ideally include people living with diabetes for whom the intervention would be designed, healthcare professionals including pharmacists, diabetes charities and organisations, pharmacy organisations, and local commissioning bodies to name a few. There would also need to be investment into the technology used and careful consideration on how to best enhance the communication pharmacists have with other services and their access to medical notes.

6.3.2 Reflection on the qualitative studies

Despite the low uptake in the qualitative study with people living with diabetes, an adequate number were still recruited to meet information power despite the additional pressures of the COVID-19 pandemic. Due to the limited work to date exploring the views of people with a history of non-attendance at appointments, this study adds to our understanding of non-attendance behaviour which is important when it has consistently been shown to be associated with increased morbidity and premature mortality.

The pros and cons of conducting the two qualitative studies virtually were discussed elsewhere in this thesis. Prior to the COVID-19 pandemic, few studies had relied solely on virtual means of collecting primary qualitative data, but society's use of virtual technology has grown significantly and where appropriate, more research studies are relying on this means of data gathering. As the use of virtual technology continues to expand and advance, it is likely that the balance between its strengths and limitations will oscillate. With its evolution, certain barriers may be overcome but others inadvertently introduced.

As discussed in the reflection section at the start of this thesis, I had originally planned to conduct an additional qualitative study with university students. It had been envisaged that they would be a convenient and accessible population so I had not expected the lack of interest that I encountered. It would be interesting to explore this further and to better understand why this may have been. The issues of gift tokens to show appreciation for participation in research is a contentious one, but if offered, may have helped with recruiting this group. Surprisingly, offering gift tokens did not significantly facilitate the later stages of recruitment in the qualitative study with people with diabetes when added to the participation invitation letter. As there were young adults (age <30 years) with diabetes that took part in this latter study, it was felt that their views were represented even without the work with university students which had originally been planned. Nonetheless, it would have been interesting to have compared the findings.

6.4 Discussion of findings, conclusions drawn and implications for future research

This thesis has served as a needs analysis to understand the role of a hypothetical CPDSS in supporting those with diabetes and a history of repeated non-attendance and sub-optimal glycaemic control. In light of the data, this is an important population to target due to their increased risk of morbidity and mortality. A healthcare intervention, such as a CPDSS, that

endeavours to support these individuals would be 'complex' as recognised by the Medical Research Council's (MRC) guidance on complex interventions [202].

Complex interventions are those which contain several interacting components and are 'context-dependent' [224]. They typically incorporate a number of behaviours required by those delivering or receiving the intervention, target a number of groups or organisational levels, have a wide variability of outcomes and allow for a degree of intervention flexibility. Most healthcare interventions are, by definition, complex. The MRC framework for complex interventions was recently updated in 2021 in collaboration with the National Institute for Health and Care Research (NIHR) [225]. It serves as a framework to ensure the process followed in intervention development and evaluation is robust and explicit, enhancing transferability and likelihood of intervention success and reducing 'research waste'.

Before allocating resources and embarking on the development of a complex intervention, it is important to conduct a needs analysis to understand the context of a proposed intervention, the problem the intervention endeavours to address, to determine existing capacity and to engage with key stakeholders. This thesis served as an initial needs analysis which explored these factors.

A CPDSS to enhance engagement in those living with diabetes would need to address the multifaceted influences that contribute to non-attendance and the difficulties with attainment of recommended diabetes health indicators. As suggested by this thesis, to effectively do this a CPDSS would need to address service-related barriers including inadequate communication and technological integration between healthcare sectors, have a reliable and flexible way of seeing people, improve the public's cognisance of what pharmacists' can offer and incorporate behaviour change science whilst not endeavouring to replace what is already offered to those with diabetes. When developing a complex intervention, contextual factors must be carefully considered at every stage, and I would argue, are particularly important when conducting a needs analysis to help pinpoint barriers/facilitators that will play an important role in determining the

success of later implementation. Understanding these dynamic and inter-related factors can help planning groups focus their time and resources where they are likely to have most impact.

Lau et al provides a conceptual framework where contextual factors can be broken down into four themes/levels: external (e.g. policy, incentives), organisational (e.g. processes, resources, culture), professional (e.g. attitudes to change, professional role, philosophy of care) and intervention specific (e.g nature and characteristics of the intervention, complexity) [226]. This thesis has made headway into better understanding the context of a potential CPDSS in the West Hampshire area and factors in each of Lau's themes have been identified and broadly referred to below. Please see Figure 5 for a brief overview of the contextual factors relevant to a hypothetical CPDSS.

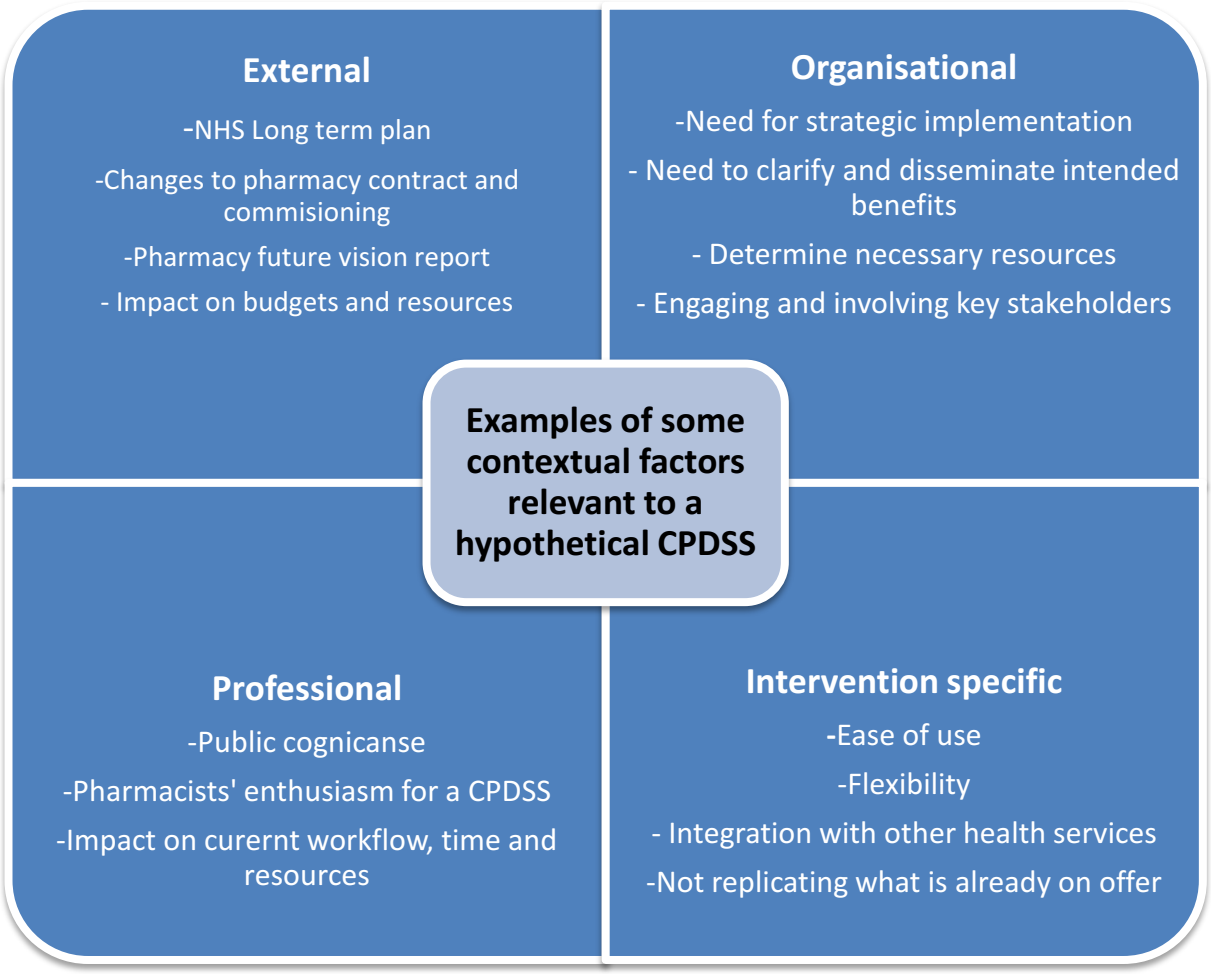

Figure 5: Examples of contextual factors relevant to a hypothetical CPDSS

External factors:

The NHS Five Year Forward View published in October 2014 discusses the need for 'greater use of community pharmacists', drawing reference to their incorporation into 'multispecialty community care provider' groups [227] . The subsequent 10 year NHS Long Term Plan published in January 2019, before the start of the COVID-19 pandemic, built on the policy platform laid out in the Five Year Forward View [64]. Diabetes is a focus area of the Long-Term Plan which commits to developing 'fully integrated community-based care' involving multi-disciplinary groups which are inclusive of pharmacists. This is an example of how policy is evolving to be more inclusive of pharmacists. There are also 'future visions' of community pharmacy which build on this and suggest how policy and commissioning of community pharmacy needs to change to maximise the potential of this workforce [70].

Organisational and Professional Factors:

Although pharmacists have great enthusiasm for a CPDSS and previous experience in delivering healthcare interventions, a significant barrier to a CPDSS is the appreciation the public (both people with diabetes and healthcare professionals) have for community pharmacies. They enjoy their accessibility but don't feel that pharmacists have the skill set to offer tailored diabetes advice. This is an example of both organisational and professional contextual barriers. People with diabetes could not see the added value of a CPDSS and were not keen on having another layer added to their care which they felt would result in additional appointment burden and the potential of being given conflicting advice.

Despite the large pharmacy workforce, healthcare professionals and people with diabetes identified the limited time and resources community pharmacies currently have. The integration of pharmacies with other healthcare services was also a great concern. Pharmacists have limited access to patient notes and formal means of communication with other services is limited. A CPDSS would need to adequately train the participating pharmacists and build public confidence in their skill set and expertise. It would need to be well funded, appropriately staffed, and would

have to find ways to enhance communication with other healthcare services, particularly the participants' GPs.

Intervention Specific Factors:

A CPDSS would offer an alternative care pathway that may be more acceptable to those identified as 'hardly reached'. It would need to avoid some of the short falls of current services that participants have described by adopting a person-centred and holistic approach, fostering strong healthcare-patient relationships and ensuring continuity. It would need to be flexible to minimise logistical challenges and would ideally offer support when the person needed it, not just restricted to allocated appointments or meetings. The intervention would need to be clear in its approach and work on shared goals so that participants feel they understand the process and expectations. These would all be important intervention specific factors.

6.4.1 Frameworks that may be relevant to the development of a Community Pharmacy Diabetes Support Service (CPDSS)

Considering that this PhD project was exploring the role of a hypothetical CPDSS intervention that attempts to influence changes in health behaviour, I reviewed approaches that incorporate behavioural science into intervention development. The Behaviour Change Wheel (BCW) and Intervention Mapping (IM) are two evidence and theory-based approaches that complement the MRC framework and incorporate models for anticipating and defining the likely influences on behaviour which can then be mapped onto appropriate behaviour change techniques. Both approaches have been widely used in healthcare intervention design, including those pertaining to diabetes [228, 229]. I will go on to describe both of these approaches in the next section below. Other approaches to complex intervention design include the 'Theory of Change' [230], 'Six steps in quality intervention development (6SquID)' [231], 'Realist complex intervention science' [232] and 'Action Research' [233]. These approaches are less well cited in the literature for behaviour change interventions pertaining to long-term conditions.

To complement theory and evidence approaches including the BCW and IM, the Person Based Approach (PBA) can also be incorporated. Through in-depth qualitative work, the PBA facilitates the understanding of an intervention's context and the people who will use it so that evidence and theory-based approaches can be more effectively applied [182]. Although most frequently used in digital interventions, it has not been designed exclusively for these. The benefits of incorporating the PBA approach into other evidence and theory-based frameworks, is that it goes beyond describing intervention content. It considers how the content is communicated to the user and facilitates early identification of problems with user engagement and participation, allowing issues to be addressed early and thereby minimising waste of resources.

6.4.1.1 The Behaviour Change Wheel (BCW)

The BCW by Michie et al consist of three phases or layers which offer a step-by-step guide to designing behaviour change interventions (**Error! Reference source not found.**). The first layer starts with the identification of behaviour(s) that need changing, prioritising them, and then selecting the few to target. This decision is made by considering likely impact, changeability and spill-over effect of each behaviour.

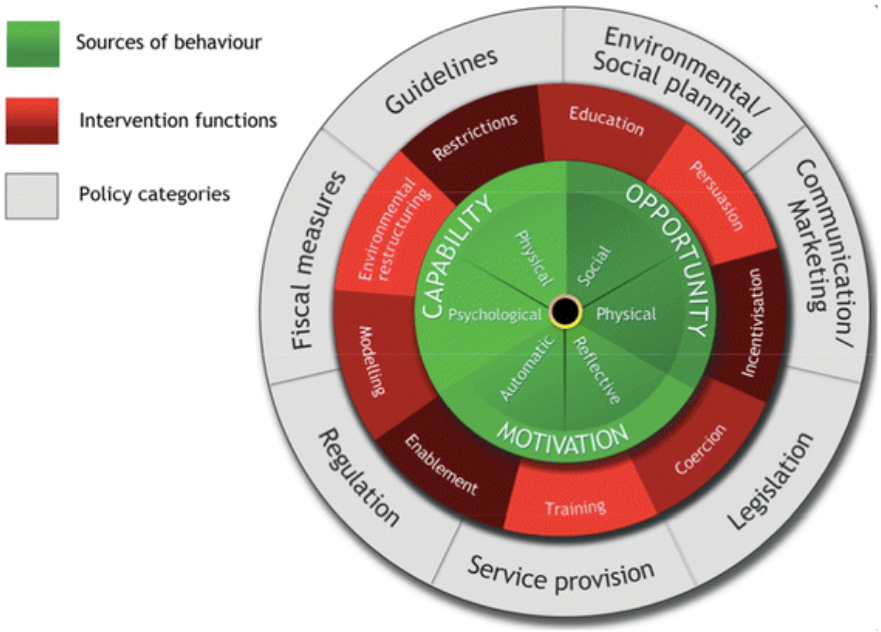

Figure 6- The Behaviour Change Wheel [229]

Once the target behaviour(s) have been chosen, researchers are encouraged to then use COM-B, which stands for Capability, Opportunity, Motivation and Behaviour, to help identify potential personal determinants to target which drive the behaviour of interest. COM-B maps onto the Theoretical Domains Framework (TDF) which divides behaviours into domains.

Following on from the COM-B analysis, the second layer of the BCW looks at identifying from a list of nine intervention functions, selected by expert consensus, the ones most relevant to the COM-B analysis which have shown to facilitate change in behaviour(s). Building from the COM-B analysis, its associated TDF domains and the intervention functions, the third layer of the BCW concerns identifying the relevant behaviour change techniques (BCTs). An extensive taxonomy of the most frequently used BCTs for each intervention function or TDF domain can then be consulted. These are irreducible, replicable and observable/measurable. Finally, once the behaviour change techniques have been identified and chosen, the most suitable mode of delivery can be decided.

Although a useful model, particularly for those less familiar with health behaviour interventions, the BCW assumes all behaviours are a result of personal determinants that fall into 'capability', 'opportunity' or 'motivation'. The flow from one model to the another in the BCW can be appealing, although the benefits of systemisation of intervention design has been debated, particularly with regards to the prescriptive nature of the taxonomy of behaviour change techniques [234]. It has been argued that systemisation risks creating a false sense of simplicity. There will always be variability in people, healthcare professionals, manifestations and situations, and it is this variability which contributes to the complexity of complex interventions [235].

6.4.1.2 Intervention Mapping (IM)

IM consists of six steps, each of which is divided into a number of tasks) [228]. The IM approach is cumulative with each step building on the previous, but the model also encourages an iterative approach, with researchers moving in both directions as new concepts and themes evolve.

Figure 7 Intervention Mapping [236]

By being less prescriptive, IM is more adaptive and arguably more encompassing, relying on fewer assumptions than other approaches to intervention development such as the BCW. In a recent taxonomy of approaches by O'Cathain et al, IM was the most comprehensive [237]. It has also successfully been used in healthcare interventions which have led to significant increases in the uptake of disease prevention programmes [238].

6.4.1.3 Similarities between the Behaviour Change Wheel and Intervention Mapping

Both the BCW and IM share many similarities. They both recommend a planning group, the use of empirical and primary data and an iterative approach to the development phase of intervention design.

Both models start by encouraging intervention developers to generate a list of target behaviours that the intervention will aim to change. To do this, they both encourage an attempt to identify all possible health behaviours contributing to the health problem of interest. Once these have been identified, both models ask that these behaviours are prioritised by considering their changeability and the likely effectiveness or suspected impact changing a given behaviour may have. The capacity of the developers and within the target population must also be part of this early decision process.

Once the target behaviour(s) are selected, the BCW and IM attempt to make these as specific as possible, breaking them down into their finer constituents whilst recognising that all behaviours are part of a wider ecological system. When deciding "what needs to change" in order to influence the target behaviour(s), both models consider the personal and environmental determinants that may have influence but do so using different techniques. As the interventions developers work through the two frameworks, the determinants of the behaviour are explored and the appropriate behaviour change techniques identified.

6.4.2 What a potential CPDSS could look like

Giving consideration to the findings of this thesis, an example of an abstract for a pilot CPDSS would be as follows.

6.4.2.1 Example abstract for a pilot CPDSS

Aim: To use a community pharmacy intervention to increase uptake at the diabetes annual review amongst individuals with a history of repeated non-attendance.

Method: This is a proof of concept study. GP surgeries in West Hampshire will be invited to take part in the CPDSS pilot. Those that agree to participate will be asked to screen their patient databases to identify individuals diagnosed with type 1 or type 2 diabetes and a history of two or more missed annual reviews in the preceding five years who also have an HbA1c of greater than 70mmol/mol. Individuals identified by the search will have electronic messages sent to their

named pharmacies, so that when next picking up their medications, they can invited by their pharmacy to participate in the pilot CPDSS. With their issued medication will also be an information leaflet on the CPDSS along with any necessary contact details. Those that agree to participate will be invited to an appointment with a pharmacist in their pharmacy. The intervention will take place over three months from the initial appointment. The frequency of subsequent contact and review will be agreed by the participant and pharmacist to take into account the individual's circumstances and goals. Pharmacists enrolled in the CPDSS will be given read-write access to the patients primary care records to allow effective communication. They will have also undergone training in the intervention to include the management and monitoring of diabetes, behaviour change and the availability of local services and resources.

Key outcomes: The primary outcome measure will be the acceptability of the CPDSS amongst individuals with diabetes, the community pharmacy team and primary care staff. This will be assessed by the uptake of the CPDSS by pharmacies, GP surgeries and individuals with diabetes, the number of participants completing the intervention and reported satisfaction/feedback from all those involved. As changes in attendance rates will take some years to be appreciated, other key outcome measures will include change in participant healthcare engagement score and number of participants completing the intervention.

As described in the example abstract above, a potential CPDSS in the future may include the identification of eligible participants from primary care records (those identified as having missed two or more annual reviews in the preceding five years and an HbA1c of greater than 70mmol/mol or no recent recorded HbA1c). An electronic alert would then be sent with the individual's prescription to their chosen pharmacy. When the prescription is issued, the pharmacist or pharmacy technician would offer the individual a brief consult at a mutually convenient date/time. Enough pharmacists would need to be trained in the intervention to enhance this offering. During the initial consultation, the pharmacists would probe to better understand the barriers to attendance and any issues with their diabetes or medicines

management. Ideally this would take place face to face in a pharmacy consulting room to enhance rapport and allow for any support that is less effectively offered virtually. The pharmacist would have a template to follow and a list of potential barriers and red flags to serve as a guide and prompt. Appropriate sign posting to local services would be encouraged, and as necessary, the application of suitable behaviour change tools could be applied and help tailor the support an individual is offered. The appropriate behaviour change techniques would need to be carefully worked through in the intervention development phase to make sure that they were evidence based and relevant. During the initial consultation, a measure of healthcare engagement could be assessed for later comparison.

After the initial face to face consultation, follow-up meetings would be arranged to be convenient and flexible for both the participant and pharmacist and would revolve around a person-centred approach with shared decision making. Continuity would be important, as this, along with lack of flexibility in appointment offerings, was something that people with diabetes reported as being a barrier to attendance in the primary data collection of this thesis. If in keeping with other pharmacy interventions delivered to date, the intervention duration would be 6-12 months, but as this is a proof of concept pilot, three months from the start of enrolment may be more acceptable to those involved. The principal outcome measures will include those that assess acceptability of the CPDSS. This should include feedback from all healthcare professionals and participants involved along with uptake and retainment in the CPDSS. Other outcome measures could differ between participants depending on their underlying issues, but a change in healthcare engagement level would be universal to them all, bearing in mind that changes in attendance rates may take some years to be noticed. Routine appointments in primary care would continue to be offered to participants, as the intervention would not seek to replace these, but support people in making better use of them and to supplement what they offer.

For any potential CPDSS to work, and before any further development or granularity to the constituents of such an intervention are considered, several things need to be achieved. There

needs to be a greater public cognisance of the role of community pharmacy and what they can offer, as stakeholder 'buy-in' is crucial to any intervention. Community pharmacy also need to be adequately resourced and more fluently integrated with primary care and the wider health care services. Whilst there is a growing expectation in NHS long term plans and various white papers that community pharmacy will offer more clinical services, the sector feels undervalued and is at cross-roads. If adequately funded, their potential is enormous. If, however, their funding continues to be cut in real terms, their sustainability is threatened as evidenced by the increasing closures of multiple pharmacies across the country.

In December 2022 a detailed report by the Kings Fund and the Royal Pharmaceutical Society was published on the 'vision for pharmacy professional practice in England' which builds on the Murray report from 2016 [70]. It lays out the vision for how patients and the public may experience community pharmacy over the next 10 years with particular detail to better integration with other healthcare teams and healthcare systems, supporting people to live well with the medicines they take and to enhance patient experience and access to care. It recognises the need for key enablers such as data, innovation, science and research; leadership, collaboration and integration and supporting pharmacists to work at the top of their abilities. With continued efforts such as these, it is hoped that the future of community pharmacy is a bright one.

6.4.3 Conclusion

Based on the findings from this thesis, although there is a hypothetical place for community pharmacy in supporting those with diabetes identified as 'hardly reached', the public's reservations towards community pharmacy and a potential CPDSS intervention would first need addressing, as would pharmacists' digital and wider integration with other healthcare services.

Whilst there may be a place for integrating community pharmacy into the care of those with diabetes, their role and function may not currently be best suited to a hypothetical CPDSS

intervention. Instead, with improved communication and access to medical records, perhaps local pharmacies would be best suited to identifying and sign posting those they identify as being most at need and communicating this to the healthcare providers already involved in an individual's care. Pharmacists are in a unique position to identify when people with diabetes may not be picking up their medications and/or to check if they have any unmet needs.

The pharmacy community has been campaigning for better appreciation and remuneration in their contracts. Their continued work will hopefully lead to better resourcing and recognition of their skills, and with time, a CPDSS may be more feasible and better accepted. Their contract has already started evolving with the support of policy to include more of a focus on clinical services over dispensing which is a step in the right direction.

With the introduction of Integrated Care Systems, there is a push for more integrated working and person-centred care. This agenda should hopefully further support the wider involvement of pharmacy in the management of long-term conditions including diabetes.

If the above can be worked on, integrating and involving pharmacists in routine diabetes care will likely build the confidence HCPs and the public have of pharmacists' expertise. To determine if this is the case, a repeat needs analysis could be conducted at a later date before considering proceeding with further stages of a hypothetical CPDSS to support those with diabetes most in need. If a repeat needs analysis shows a change in the public's perception and if resources are available, an extensive planning group including relevant stakeholders would need to be assembled and the initial steps of intervention development followed. Tools such as Intervention Mapping (IM) and the Behaviour Change Wheel (BCW) would be recommended to support the design phase of a CPDSS due to their previous application to behaviour change interventions.

Whilst progress on a hypothetical CPDSS may be some time away and dependent on further needs analyses, in the meantime it is important for clinicians involved in the care pathway of those with diabetes to consider some of the identified factors contributing to non-attendance

behaviour so that we can make every contact count and improve the experiences for those living with diabetes.

Appendix A Materials associated with Chapter 2

A.1 The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist [78].

	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	17
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	N/A (abstract not included in thesis)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	17,18
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	17,18
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	19
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	19
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	19
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	19
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	20

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	21
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	21
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	21
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	21
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	21

A.2 Hawker et al 9 point checklist for disparate studies [79]

1. Abstract and title: Did they provide a clear description of the study?

Good Structured abstract with full information and clear title.

Fair Abstract with most of the information.

Poor Inadequate abstract.

Very Poor No abstract.

2.Introduction and aims: Was there a good background and clear statement of the aims of the research?

Good Full but concise background to discussion/study containing up-to date literature review and highlighting gaps in knowledge.

Clear statement of aim AND objectives including research questions.

Fair Some background and literature review.

Research questions outlined.

Poor Some background but no aim/objectives/questions, OR Aims/objectives but inadequate background.

Very Poor No mention of aims/objectives.

No background or literature review.

3.Method and data: Is the method appropriate and clearly explained?

Good Method is appropriate and described clearly (e.g., questionnaires included).

Clear details of the data collection and recording.

Fair Method appropriate, description could be better.

Data described.

Poor Questionable whether method is appropriate.

Method described inadequately.

Little description of data.

Very Poor No mention of method, AND/OR

Method inappropriate, AND/OR

No details of data.

4. Sampling: Was the sampling strategy appropriate to address the aims?

Good Details (age/gender/race/context) of who was studied and how they were recruited.

Why this group was targeted.

The sample size was justified for the study.

Response rates shown and explained.

Fair Sample size justified.

Most information given, but some missing.

Poor Sampling mentioned but few descriptive details.

Very Poor No details of sample.

5. Data analysis: Was the description of the data analysis sufficiently rigorous?

Good Clear description of how analysis was done.

Qualitative studies: Description of how themes derived/respondent validation or triangulation.

Quantitative studies: Reasons for tests selected hypothesis driven/ numbers add up/statistical significance discussed.

Fair Qualitative: Descriptive discussion of analysis.

Quantitative.

Poor Minimal details about analysis.

Very Poor No discussion of analysis.

6. Ethics and bias: Have ethical issues been addressed, and what has necessary ethical approval gained? Has the relationship between researchers and participants been adequately considered?

Good Ethics: Where necessary issues of confidentiality, sensitivity, and consent were addressed.

Bias: Researcher was reflexive and/or aware of own bias.

Fair Lip service was paid to above (i.e., these issues were acknowledged).

Poor Brief mention of issues.

Very Poor No mention of issues.

7. Results: Is there a clear statement of the findings?

Good Findings explicit, easy to understand, and in logical progression.

Tables, if present, are explained in text.

Results relate directly to aims.

Sufficient data are presented to support findings.

Fair Findings mentioned but more explanation could be given.

Data presented relate directly to results.

Poor Findings presented haphazardly, not explained, and do not progress logically from results.

Very Poor Findings not mentioned or do not relate to aims.

8. Transferability or generalizability: Are the findings of this study transferable (generalizable) to a wider population?

Good Context and setting of the study is described sufficiently to allow comparison with other contexts and settings, plus high score in Question 4 (sampling).

Fair Some context and setting described, but more needed to replicate or compare the study with others, PLUS fair score or higher in Question 4.

Poor Minimal description of context/setting.

Very Poor No description of context/setting.

9. Implications and usefulness: How important are these findings to policy and practice?

Good Contributes something new and/or different in terms of understanding/insight or perspective.

Suggests ideas for further research.

Suggests implications for policy and/or practice.

Fair Two of the above (state what is missing in comments).

Poor Only one of the above.

Very Poor None of the above.

A.3 Quality risk-bias table of studies using the Hawker et al 9 point checklist for disparate studies

Author, year, citation no.	Type of study	Abstract and title	Introduction and aims	Method and data	Sampling	Data analysis	Ethics and bias	Results	Transferability/generalisability	Implication and usefulness
Archibald et al, 1992 [80]	Survey	Good	Fair	Fair	Fair	Fair	V.Poor	Good	Fair	Fair
Akhter et al, 2012 [83]	Survey	Good	Good	Fair	Good	Fair	V.Poor	Fair	Fair	Fair
Alvarez et al, 2018 [113]	Quantitative	Good	Good	Good	Good	Good	Fair	Good	Good	Good
Campbell-Richards, 2016 [81]	Qualitative	Good	Good	Good	Good	Fair	Fair	Good	Good	Good
Casey et al, 2012 [97]	Quantitative	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
Ciechanowski et al, 2006 [101]	Quantitative & survey	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
Currie et al, 2013 [91]	Quantitative	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
Dyer et al, 1998 [89]	Quantitative and survey	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good

Appendix A

Author, year, citation no.	Type of study	Abstract and title	Introduction and aims	Method and data	Sampling	Data analysis	Ethics and bias	Results	Transferability/generalisability	Implication and usefulness
Elders et al, 2014 [93]	Quantitative	Fair	Fair	Good	Fair	Fair	V.Poor	Good	Fair	Fair
Garcia Diaz et al, 2017 [95]	Quantitative	Good	Good	Good	Good	Good	V.Poor	Good	Good	Fair
Gill &Owens, 1998 [90]	Quantitative	Fair	Fair	Fair	Fair	Fair	V.Poor	Fair	Fair	Poor
Hammersley et al, 1985 [88]	Quantitative & survey	Fair	Good	Fair	Good	Fair	V.Poor	Good	Fair	Fair
Hardy et al, 2001 [87]	Quality Improvement	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
Heydarabadi et al, 2017 [110]	Qualitative	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
Ho, 2014 [106]	Quality Improvement	Good	Good	Good	Good	Good	V.Poor	Good	Fair	Fair
Horny et al, 2017 [100]	Quantitative	Good	Good	Good	Good	Good	Poor	Good	Good	Good
Hynes et al, 2015 [111]	Qualitative	Good	Good	Good	Good	Good	Poor	Good	Good	Good
Karter et al, 2004 [76]	Quantitative	Fair	Fair	Good	Good	Good	V.Poor	Good	Good	Good
Kellet, 1988 [96]	Quantitative	Good	Fair	Fair	Fair	Fair	V.Poor	Good	Fair	Fair

Author, year, citation no.	Type of study	Abstract and title	Introduction and aims	Method and data	Sampling	Data analysis	Ethics and bias	Results	Transferability/generalisability	Implication and usefulness
Kurasawa et al, 2016 [109]	Quantitative	Good	Good	Good	Good	Good	V.Poor	Good	Fair	Good
Lawson et al, 2005 [94]	Qualitative	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
Levy-Shraga et al, 2016 [108]	Quantitative	Good	Good	Good	Good	Good	V.Poor	Good	Good	Fair
Low et al, 2016 [107]	Quantitative	V.Poor	Good	Fair	Fair	Fair	V.Poor	Good	Fair	Fair
Masding et al, 2010 [86]	Quantitative	Good	Good	Good	Good	Fair	V.Poor	Good	Fair	Fair
McCarlie et al, 2002 [92]	Quantitative	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
McComb et al, 2017 [99]	Quantitative	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
Ngwenya et al, 2009 [105]	Qualitative	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
Nuti et al, 2012 [112]	Quantitative	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
Snow and Fulop, 2012 [85]	Qualitative	Good	Good	Good	Good	Good	Poor	Good	Good	Good
Thongsai, 2014 [104]	Qualitative	Good	Good	Good	Good	Good	Good	Good	Good	Good

Author, year, citation no.	Type of study	Abstract and title	Introduction and aims	Method and data	Sampling	Data analysis	Ethics and bias	Results	Transferability/generalisability	Implication and usefulness
Vijayaraghavan et al, 2015 [82]	Mixed	Good	Good	Fair	Fair	Fair	V.Poor	Fair	Good	Good
Weaver et al, 2019 [98]	Quality Improvement	Good	Good	Good	Good	Good	V.Poor	Good	Good	Good
White et al, 2017 [103]	Quantitative	Good	Good	Good	Good	Good	Fair	Good	Good	Good
Wilson and Greenhalgh, 1999 [84]	Quality Improvement	V.Poor	V.Poor	V.Poor	Poor	V.Poor	V.Poor	Fair	Fair	Poor

Appendix B Materials associated with Chapter 5

B.1 Participant Information Sheet- Healthcare Professionals

Study Title*:* What do healthcare professionals and people with diabetes think about a community pharmacy diabetes support service to enhance diabetes healthcare engagement?

Short Title: CPDSS- Qualitative (HCP and Ppl with Diabetes)

Researcher: Sarah Brewster

IRAS ID: 278035

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

If after reading the information sheet you are interested in taking part, please e-mail s.brewster@soton.ac.uk

If after reading the information sheet you decide not to take part, no further action is required.

This study has been reviewed and given a favourable opinion by HRA NHS Berkshire REC.

What is the research about?

Hello, my name is Sarah Brewster. I am a diabetes doctor working for Southern Health, currently doing a PhD with The University of Southampton. I am looking at designing a community pharmacy delivered intervention to enhance healthcare engagement in people with type 1 and type 2 diabetes, particularly for those who have become 'hardly reached'. To inform the design of the intervention, I am looking to explore the experiences GPs, practice nurses, and diabetes specialists have had with community pharmacy services, and the experiences of community pharmacists in delivering clinical services. I would like to know what healthcare professionals feel community pharmacy may or may not be able offer to support/help those with diabetes who may be struggling or most at need.

Why have I been asked to participate?

I would like to invite GPs, practice nurses, diabetes specialists (diabetes doctors, nurses or dietitians) and community pharmacists to participate in a small group discussion/focus group or one to one interview. If this is you, your participation in a one to one or group discussion will help me understand what healthcare professionals involved in the care pathway of people with diabetes think of community pharmacy services and how community pharmacy may be able to help support those with diabetes who may be most at need. This will guide the design and development of a proposed community pharmacy service aimed at supporting people with the diabetes who have become 'hardly reached'. Due to the Coronavirus pandemic, all interviews will be held remotely using Zoom.

What will happen to me if I take part?

This is a qualitative study. If you decide that you would like to take part, you will be invited to choose to take part in either a focus group (group interview/discussion) or one to one interview with a researcher held virtually at a date and time that suits you and the other participants accordingly. The group interviews/focus groups will typically have up to seven other participants in them along with myself and an observer. The other participants in the focus groups will also be healthcare professionals.

Depending on which you choose, before the scheduled date of the one to one interview or focus group/group interview, you will be e-mailed two forms. One of these will be a brief form asking you about your demographics which we will ask you to e-mail or send back to us. The other will be a consent form which we will ask you to read through prior to the virtual meeting. If you are happy with each part of the consent form then we will either ask you to sign it and e-mail it back to us or we will take verbal consent from you at the start of the meeting.

The discussions in the one to one interview or focus group that you are in will be audio recorded and transcribed by a researcher at a later date. All personal information will be kept anonymous. One to one interviews and focus group discussions are expected to last 30-60minutes in total. To respect the confidentiality of participants in focus groups, we ask that you do not share personal information about group members with others.

Even after consenting to take part, you are free to withdraw from the study at any point without having to provide a reason. Your decision whether to take part in the study, or not, will not affect your employment or other rights.

The information from the discussions in the focus group/one to one interviews will be used to help inform the development of a manual for a community pharmacy intervention aimed at people with diabetes who have been struggling with the management of their condition.

Are there any benefits in my taking part?

Your participation in the focus group/one to one interview study will provide valuable insights and information that will help inform the development of a service aimed at supporting those with diabetes who may be most at need. You will not be paid for your participation, but your time and contribution will be very much appreciated.

Are there any risks involved?

There are no foreseen risks associated with taking part in the study. The discussion topic is not expected to raise any sensitive issues or to cause any psychological distress. The contact details of the research team are available on this participant information sheet should you wish to discuss any concerns or problems pertaining to the study.

What data will be collected?

In order to keep in contact with you during the study to arrange the focus group meeting, your contact details will be stored for the duration of the study only. The focus group session will be audiotaped. You will not be asked to give any personal details during the recording. All personal data will be kept anonymous and the audiotape will be destroyed following transcription. All participant information will be added to an electronic data file and will be handled, computerised and stored in secure NHS computer systems ensuring compliance with General Data Protection Regulation (2018) in accordance with the Data Protection Act (2018). All study data will be stored on NHS premises in locked filing cabinets and on secure computer systems.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the Southern Health Research department or the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Your signed consent form will be kept locked in a secure filing cabinet on NHS premises as will the audiotape. The audiotape will be destroyed following transcription.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

If you are interested in participating, *please e-mail* **s.brewster@soton.ac.uk** *to express you interest and mention whether you would prefer to take part in a focus group discussion/group interview or one to one interview.*

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights or employment being affected.

If you wish to withdraw at any point, please use the contact details above.

If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

Where can I get more information?

If you would like further details or have any questions relating to the study, please get in contact with the researcher using the details provided above.

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the Southern Health Research Governance Co-ordinator, Andrews Trousdale.

Contact details

Andrew Trousdale

Southern Health Research Governance Co-ordinator

Address: Southern Health NHS Foundation Trust

Research & Development

Clinical Trials Facility

Tom Rudd Unit, Moorgreen Hospital, Botley Rd, West End

Southampton, SO30 3JB

E-mail: *Andrew.trousdale@southernhealth.nhs.uk,*

Telephone: 023 8047 5373

If the Southern Health research team are unable to address your concerns or you remain unhappy, please then consider contacting the Southern Health Patient Advice and Liaison Service (PALS)

Complaints and PALS,

Address: FREEPOST RSJL-JXSX-ATUE,

Southern Health NHS Foundation Trust,

5 Sterne Road, Tatchbury Mount,

Calmore, Southampton SO40 2RZ

Telephone: 023 8087 4065

Data Protection Privacy Notice

Southern Health conducts research to the highest standards of research integrity. As an NHS organisation, Southern Health has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual.

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to Southern Health's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the Southern Health is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, Southern Health is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. Southern Health will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the Southern Health Data Protection and Confidentiality Policy which can be found at: https://www.southernhealth.nhs.uk/_resources/assets/inline/full/0/44033.pdf

Thank you.

Thank you for taking the time to read the information sheet and considering taking part in the research.

If you are interested in participating, *please e-mail* **s.brewster@soton.ac.uk** *to express you interest and mention whether you would prefer to take part in a focus group discussion/group interview or one to one interview.*

B.2 Healthcare professional Interview guide

Introduction

Hi, my name is Sarah Brewster and I will be hosting today's group discussion. Thank you all for your participation in this.

As mentioned in previous correspondence, the session is expected to last no more than an hour.

The aim is discuss what your thoughts are on using community pharmacy to support people with diabetes who have been missing their diabetes appointments and/or who have an HbA1c >70mmol/mol.

The session will be recorded. All of your details will be kept anonymous during the later transcription process and after this, the file will subsequently be deleted.

Ideally I'd ask that you keep your microphone on mute but press 'unmute' when speaking to avoid interference. If you are happy to keep your video on, this will help with the group dynamics, but please feel free to turn it off at any point should you wish.

In the event you encounter any technical issues at any point, please let me know. Worst case scenario, sometimes leaving the group and re-joining it again can help.

Lastly, prior to today I sent around a consent form for you to look at. By joining the Zoom session I will assume that everyone is happy to proceed at this stage.

Has anyone got any questions before we begin and start the recording?

*****Press record*****

Ask everyone to introduce themselves, role and what capacity they see ppl with diabetes.

Topic One: Views and experiences of community pharmacy

-What have your experiences been with community pharmacists (positive and negative),

and for the pharmacists in the room, what have your experiences been of providing clinical services and working with allied healthcare professionals (barriers, facilitators).

-Why do you think people choose a particular pharmacy to visit? Convenient, friendly, reliable…..

Topic Two: Community Pharmacy intervention for ppl with diabetes

-When thinking about people with diabetes who have not been attending appointments, particularly those with an HbA1c >70, what do you think community pharmacy could offer?

-Strengths

- Barriers- how might these be overcome?

- What do you think might help people engage …?

-What would you see a community pharmacy intervention looking like?

-What do you think a pharmacy intervention needs to do to help get people back on track when they may be struggling?

How to invite ppl (Opportunistic, GP refers to pharmacy etc)

-Duration of an intervention

- Type and Frequency of contact

- Duration of each contact?

- What would it comprise?: Individualised goal-setting, education, MI, sign-posting, be a point of contact, review medications, review BG as relevant, liaise with GP.

- Additional apps or care tools?

Closing statement: Thank you all for your contribution to this group. Before we finish, does anyone have any other comments or anything additional that they would like to add?

B.3 Focus group coding manual- Healthcare professionals

Themes	Codes	Description	Example
Accessibility and relationships with the public	Holistic and personalised care	Mentions whether or not the pharmacist offers a person centred approach.	"Pharmacists who are interested in diabetes, they're interested in the individual, they really engage with a person and that's it working at its absolute best which is fantastic. " *(Pharmacist A)*
	Trusted form of medical support	Discusses the trust people have in pharmacists in terms of providing medical advice and support.	"…really value the expertise we give or they wouldn't be coming back." *(Pharmacist A)*
	Continuity and frequency of contact	Discusses the continuity of care that can be offered in community pharmacy as a result of frequency of contact with the public.	"We'll see the patient or their representative, if not the patient, you know, every month or every two months when they come in to pick up a prescription… that real continuity piece…. you could have an instance where you were speaking to somebody every year for four or five years….because they're your patients, you do have quite a good rapport with them because you see them

			face to face a lot, a lot more probably than most other practitioners. *(Pharmacist A)*
	Opportunistic relationships	Mentions the opportunistic contact that pharmacists can have with people and how this can be used to offer advice or support as needed.	"…very opportunistic conversations…with diabetics… every time we get script or every time we know somebody, we always ask them, ' how are you getting on with your medication?' " *(Pharmacist E)*
	Visible	Talks about the visibility of pharmacists and how this makes them accessible.	"…very easy to find and very easy to access." *(Practice nurse B)*
	Local/convenient	Discusses the locality and convenience of their local pharmacy.	"how many of them (community pharmacies) there are. I can think of, I don't know, probably three or four that would be in a short walk from my house." *(Diabetes Consultant A)*
	Physical environment	Mentions the front of house environment in pharmacies or the functions/facilities it offers.	"...the front of the shop is … dressed around self-care, you know, selling maybe blood pressure monitors…" *(Consultant B)*

	Non-physical environment	Talks about the feeling the pharmacy environment gives them.	"The appearance as you walk in, is that this is a place to make me feel better or good…." *(Consultant B)*
	Choice and high street presence	Discusses how people have the freedom to choose which pharmacy they visit.	"…element of choice that you have in a way that you don't say with your GP." *(Diabetes nurse C)*
	Opening hours	Mentions their opening hours.	"the fact that they are open, sort of a lot…." *(Practice nurse B)*
	Online pharmacies	Mention of people using online pharmacies and/or home delivery of medications and how this limits contact with local pharmacies.	"What I've noticed in the last six months. And this is sort of a flag, is that a lot of patients are moving away from Community pharmacists. More and more are using online pharmacy for their medications." *(GP B)*
Perception of community pharmacy	Relationship with other healthcare professionals	Discusses the relationship pharmacists have with other healthcare workers.	"… they feel on the edge of the team a little bit" *(DSN C)*

and their integration with other healthcare services.	Clinical Records	Discusses access and sharing of clinical records.	"…most of us are sitting on a mountain of data that we cannot share. We cannot improve because we're all working in isolation. If we share that data, not only would that improve my practice to help you, it will help the patient because that's who the record belongs to. *(Pharmacist E)*
	Communication	Talks about the challenges pharmacists have communicating with other healthcare professionals.	"one of my biggest concerns is that when I do refer patients on. I never get any feedback back" *(Pharmacist E)*
	IT services and platforms	Mentions the lack of infrastructure to efficiently communicate and integrate with other healthcare services and staff.	"...outside of that individual pharmacy, there's no way of capturing, there's no way of utilizing that information… we've got that information, but it's that handover, it's that passing it back." *(Pharmacist E)*
	Institutional Inertia	Discusses barriers to more joined-up working resulting from institutional inertia.	"There are huge institutional problems….Now the battle we had to get them (a secondary care trust) to use System One and to share with us, was not from the nursing staff at all. It was from the upper echelons and was immense. So, there is no easy fix at all, without a doubt. My ideal goal, and also thinking for secondary

			care, is that they use, that we all use systems that can be much better integrated with other records." *(GP B)*
	IT services	Mentions the role of IT in delivering pharmacy services.	"…remote consultation…. is not a thing of the future. It's here now." *(Pharmacist E)*
	Healthcare interventions	Discussion of various health interventions that have been trialled in community pharmacy.	"We've had, you know, several interventions offering brief advice and we've been commissioned not just to screen people, but then to go on and perform the intention." *(Pharmacist A)*
	Sign-posting	Talks about the role of pharmacists in sign-posting to appropriate health services when they are not able to offer the advice/support needed.	"…if we don't have any support service associated with that, we can signpost to the area that does, to the service that does smoking cessation." *(Pharmacist D)*
	Advice and clinical services	Mentions the role of community pharmacists in moving towards providing more clinical services.	"So the government really wants community pharmacy to move away from purely supply, to actually delivering a lot more of this sort of clinical services…" *(Pharmacist D)*

	Health and screening promotion	Talks about some of the health promotion and screening services offered in community pharmacies.	" Healthy Living Pharmacy was developed as a sort of a developmental model, and it's now, from the beginning of next year, it's actually a requirement as an essential part of our service- to make sure that we're more proactive and have very much identified the community pharmacy in the prevention agenda. In helping people to stay healthier for longer….. We will do sexual health services, there have been sort of screening for sexual health -Chlamydia is the usual one that's been screening. Also the morning after pill- EHC (emergency hormonal contraception).....One of the things you must have as a Healthy Living Pharmacies, is a health promotion zone." *(Pharmacist D)*
Resources and training	Resources	Discusses the lack of resources (eg time, financial, size of work force etc).	"Because there's usually only the one pharmacist. In our area there tends to be one pharmacist and they are assisted by a number of technicians who are pretty busy for the whole time that they are open, it has to be said, there isn't much slack time in the community pharmacy setting around our area."

			(Pharmacist C)
	Importance of training	Discusses reasons why appropriate training is relevant and important.	*"*It's all in the developing the team today to be more proactive because when locally enhanced services first came out, pharmacy signed up and didn't really do anything. We would provide the service if we were asked, but it was training people and encouraging them to actually offer those services and promote their services hear what somebody was saying to them, considering what it is they're coming in regularly to purchase from the medicines point of view which might indicate to you that there's something going on here in their lifestyle that you could help them with, and training and building that up. So that's the, I think the idea of trying to take advantage of being in the heart of the Community." *(Pharmacist A)*
	Future training	Talks about the future of pharmacy training.	"They are taught more these days and there is a big push now around the foundation year and everybody doing independent prescribing as part of that foundation year which is obviously a huge shift, from years ago, so everything's moving in the right direction but obviously everything takes time." *(Pharmacist A)*

	Variable skill-sets	Discusses the varying skills and capabilities amongst pharmacists.	"I've also been involved in the past in training community pharmacists, and it's quite interesting to know they know a lot about some things and not so much about other things…. *(Practice Nurse A)*
Intervention content	Language	Talks about the importance of using sensitive language when speaking to people enrolled into a proposed CPDSS.	"… don't talk about numbers and don't be judgmental…. I think it would have to be done in the right way because these people will be very defensive" *(DSN D)*
	Goal Setting	Mentions goal setting as a making up part of the content of an intervention.	"There would presumably be some kind of goal setting that might be, you book in to have an annual review at the surgery or you can have a blood test, or you can have your feet checked or you do some BP monitoring at home*." (Consultant A)*
	Training of pharmacists and awareness	Talks about the importance of training relevant stakeholders on the intervention (eg. Pharmacists, GPs etc)	" Providing pharmacists involved with sufficient training on the intervention would be crucial, as would raising awareness of the intervention amongst GP surgeries etc in the area." *(DSN B)*

	Measurements	Discussion on the sort of measurements that should be taken during a proposed CPDSS.	"I think you need to perform some sort of psychological assessment of them." *(DSN E)*
	Mode of delivery	Discusses how the interaction between the participant and pharmacist would be conducted (eg face to face, virtually etc).	"So some people will want to do face to face, particularly the older generation, you know, they want to come in and have a chat and they want to come in and see somebody, it might be their only trip out that day….whereas for other people who it's more difficult for them to get places or at certain times, they might prefer even more flexibility of doing things online. Being, for example, on a Saturday or Sunday or during an evening, I think, you know, having those options will capture more people." *(Pharmacist A)*
	Frequency of contact	Talks about the frequency of contact that would take place in a proposed CPDSS.	"You probably want to set the first of perhaps one or two contact points….once we know that patients are sort of back on track if you like or engaged, then you know you can then drop that sort of engagement piece down and change frequency." *(Pharmacist A)*

	Clarity and templates	Mention of materials that the pharmacist would have to support them in the delivery of a proposed CPDSS.	“In an ideal world, you'd get some agreement on a kind of template you know template management plan that community pharmacists could use with resources…” *(Practice nurse A)*
	Intervention recruitment	Discussion on methods of identifying and recruiting people with diabetes into a CPDSS.	“I wonder how much mileage there will be in patients identifying themselves… I wonder whether we allow patients to opt in if they want to, rather than it being another thing that they're offered, but don't attend.” *(Consultant A)*

Appendix C Materials associated with Chapter 6

C.1 Letter of invitation to participants- People with diabetes

Practice Headed Paper

Participant Address

Date

Dear -Potential participant's Name-

Are you interested in taking part in a research study run by Southern Health and the University of Southampton? Researchers there are wanting to understand how people feel in the lead up to their diabetes appointments with their diabetes doctor or nurse. They would also like to explore people's views of their local pharmacy. This information will help them to consider whether a service set up in local pharmacies may be able to help support people living with diabetes in addition to their usual care. Your views are important in helping improve diabetes care.

If you might like to take part, you can read more about the study in the information sheet that came with this letter. Once you have read the information sheet, if you would like to take part or if you have any questions, you can contact the main researcher, Sarah Brewster:

E:mail: sarah.brewster@southernhealth.nhs.uk or S.brewster@soton.ac.uk

Telephone # 07827 937 619

If you do not want to take part then you do not need to do anything else. We won't contact you again about this study.

Thank you very much for taking the time to read this letter.

Yours sincerely,

Dr -insert GP name-

C.2 Participant Information Sheet- People with Diabetes

Study Title*:* What do healthcare professionals and people with diabetes think about a community pharmacy diabetes support service to enhance diabetes healthcare engagement?

Study Title: CPDSS- Qualitative (HCP and Ppl with diabetes)

Researcher: Sarah Brewster

IRAS ID: 278035

We invite you to take part in this study

==========

It is up to you to decide whether or not to take part. Saying no will not affect the care you receive from your GP or diabetes service. This leaflet tells you why this study is being done and what it will involve. After you read it you can choose whether or not you want to take part. Please contact us if anything is unclear or you would like to ask any questions.

A brief summary of the study

- **This study is wanting to explore how people with diabetes feel about their diabetes appointments with their doctor or nurse. It also sets out to understand participants' views and experiences of their local pharmacies. This information will help the researchers understand if there may be scope for designing a service for people with diabetes that could be delivered by local pharmacies to support them with their condition alongside their usual care.**

- *If you take part, the study will involve a single group discussion with other people living with diabetes which will be held over Zoom. Alternatively, a one to one interview with a researcher can be organised and held over the telephone or using Zoom.*

- *The group discussion or one to one interview is not expected to last more than an hour and will be organised for a date and time to suite you.*

- *The study is being run by Southern Health NHS Foundation Trust and the*

What is the aim of the study and what is it about?

Hello, my name is Sarah Brewster. I am a diabetes doctor working for Southern Health, currently doing a PhD with the University of Southampton. I am looking at designing a

local community pharmacy delivered intervention to support people with type 1 and type 2 diabetes. To inform the design of the intervention, I am looking to explore the experiences people with diabetes have had at their diabetes healthcare appointments with their diabetes doctor or nurse. I would also like to understand what their experiences have been with their local pharmacies. The information from group or one to one discussions will help me to consider the role local pharmacies may have in providing additional care for people living with diabetes who may be most in need.

Why have I been asked to participate?

==========

You have been asked to take part as your GP surgery has recorded you as having either type 1 or type 2 diabetes and has noted that you may have missed 2 or more of your diabetes healthcare appointments in the past. Your experiences of diabetes appointments with a doctor or nurse are important to us so that we can try and make them better. We are looking to design a local pharmacy intervention to support people with diabetes in addition to their usual care and also want to know your thoughts on this.

What do I have to do if I participate?

==========

If you decide that you would like to take part, you will be invited to participate in either a focus group (group interview/discussion) or one to one interview with a researcher held at a date and time that suits you and the other participants accordingly. Due to the Coronavirus pandemic, all interviews will be held virtually using Zoom. The group interviews/focus groups will typically have up to six other participants with diabetes in them, along with myself and potentially an observer.

If you decide that you would like to get involved, before the group discussion or one to one interview you will be e-mailed two forms. One will be a brief form asking you about your demographics which we will ask you to e-mail or send back to us. The other will be a consent form. We will ask you to read the consent form before the scheduled meeting but will confirm verbal consent from you at the start of the meeting before any study related activity takes place.

The discussions in the focus group and one to one interviews will be video recorded and transcribed by a researcher at a later date. The videos will subsequently be deleted. All personal information will be kept anonymous during the transcription process. One to one interviews and focus group discussions are expected to last approximately 60minutes in total. To respect the confidentiality of participants in focus groups, we ask that you do not share personal information about group members with others. During the discussion,

you may use a pseudonym instead of your real name. Having the video function turned on during the discussion can add to the experience, but you may turn this off if desired.

What are the possible pros and cons of taking part?

==========

There is no direct benefit, but taking part will help us to try and improve the care offered to those with diabetes. In previous studies, people have enjoyed the opportunity to discuss their experiences with others living with diabetes in an open and friendly forum. To show our appreciation for your time and contribution we will offer you a £20 store voucher after all study procedures have taken place.

The main disadvantage of taking part are that it will take up some of your time. There are no foreseen risks associated with taking part in the study. The discussion topic is not expected to raise any sensitive issues or to cause any psychological distress. The contact details of the research team are available on this participant information sheet should you wish to discuss any concerns or problems pertaining to the study.

What will happen if I do not want to carry on with the study?

==========

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights or routine care being affected.

If you wish to withdraw at any point, please use the contact details below.

If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

How do I take part?

If you are interested or have any questions, please get in touch with the main researcher of this study, Sarah Brewster.

E:mail: *Sarah.brewster@southernhealth.nhs.uk or s.brewster@soton.ac.uk*

Telephone: *# 07827 937 619*

If after reading the information sheet you decide not to take part, no further action is required.

What data will be collected and will my data be confidential?

==========

In order to keep in contact with you during the study to arrange the focus group meeting, your contact details will be stored for the duration of the study only. The focus group session will be video recorded. You will not be asked to give any personal details during the recording. All personal data will be kept anonymous and the audiotape will be destroyed following transcription. All participant information will be added to an electronic data file and will be handled, computerised and stored in secure NHS computer systems ensuring compliance with General Data Protection Regulation (2018) in accordance with the Data Protection Act (2018). All study data will be stored on NHS premises in locked filing cabinets and on secure computer systems.

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the Southern Health Research department or the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential. The video recording will be destroyed following transcription.

What will happen to the results of the research?

==========

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

Who has reviewed the study?

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This study has been reviewed and given a favourable opinion by HRA NHS Berkshire REC.

What happens if there is a problem?

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If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the Southern Health Research Governance Co-ordinator, Andrew Trousdale.

Appendix C

Andrew Trousdale

Southern Health Research Governance Co-ordinator

Address: Southern Health NHS Foundation Trust

Research & Development

Clinical Trials Facility

Tom Rudd Unit, Moorgreen Hospital, Botley Rd, West End

Southampton, SO30 3JB

Email: Andrew.trousdale@*southernhealth.nhs.uk,*

Telephone: 023 8047 5373

If the Southern Health research team are unable to address your concerns or you remain unhappy, please then consider contacting the Southern Health Patient Advice and Liaison Service (PALS):

Complaints and PALS,

Address: FREEPOST RSJL-JXSX-ATUE,

Southern Health NHS Foundation Trust,

5 Sterne Road, Tatchbury Mount,

Calmore, Southampton SO40 2RZ

Telephone: 023 8087 4065

Data Protection Privacy Notice

==========

Southern Health conducts research to the highest standards of research integrity. As an NHS organisation, Southern Health has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual.

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to Southern Health's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the Southern Health is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, Southern Health is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. Southern Health will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the Southern Health Data Protection and Confidentiality Policy which can be found at:
https://www.southernhealth.nhs.uk/_resources/assets/inline/full/0/44033.pdf

Thank you.

Thank you for taking the time to read the information sheet and considering taking part in the research.

If you are interested in participating, *please e-mail* *sarah.brewster@southernhealth.nhs.uk* *or* **s.brewster@soton.ac.uk** *to express you interest.*

C.3 Semi-structured focus group & interview template: People with diabetes

C.3.1 Process:

Group discussion: ideally 2-8 in a group. To be held virtually using Zoom as the platform and making use of its recording and auto-transcribing function. Allow 1 hour for the group discussion to prevent fatigue.

One to One interview: Allow 30-60min. One researcher. May be over the phone or done virtually using Zoom.

C.3.2 Introduction:

Introduction –Explain the purpose of the focus group and how it will be conducted.

Good morning/afternoon, thank you for joining.

The aim of the focus group is two-fold. Firstly, I would like to explore with you your experiences of attending diabetes appointments in the past- what aspects have been good or not so good.

Secondly, I would like to understand your views on the pharmacies you have used and whether you would consider going to them for help/support with your diabetes.

Your contribution is very much appreciated as it will help us to develop an intervention to support people with diabetes.

The session will be recorded and later transcribed, but all identifiable data will be removed.

You should have all had a chance to read through the participant information sheet and consent form. I will take the fact that you have joined the meeting as implying consent to proceed.

Are there any other questions before we begin?

Recording now starts and participants get an alert to indicate this.

C.3.3 Ice breaker:

I would like to ask everyone in the room introduce themselves, and if comfortable to do so, to say what type of diabetes they have.

C.3.4 Interview Schedule and Prompts

Topic One: Health seeking behaviour/pathway and non-attendance at diabetes appointments

- **Card 1- Health seeking behaviour**

Q1

-Where do you go for extra support with your diabetes when you have problems?

Family, friends, online, pharmacy, support groups, GP or diabetes specialist service, nowhere…

Q2

-Why do you go there/to them?

Can you tell me more about that?

- **Card 2- Non-attendance**

Q3

-How do you feel when you know you are coming up to the time of your diabetes appointment?

Why is that?

Can you tell me what you think about that?

Q4

-Can you tell me about any things that have made it harder to attend appointments in the past?

That's very interesting. Can you tell me more about that?

- Can you tell me about anything that has made it easier to attend appointments?

- **Card 3- Value of diabetes appointments**

Q5

What value, if any, do you feel the various diabetes appointments offer you?

Opportunity to get advice, time to talk to someone who understands the condition, to review progress, to screen for complications and therefore hopefully prevent them, to get access to technology for managing diabetes, no value added…

That's interesting. Can you tell me more about that?

Q6

Could anything be done differently?

Topic Two: Views/experiences of community pharmacy

- **Card 4- Experience of community pharmacy**

Q7

-How often do you visit the pharmacy?

Q8

-Do you usually go to the same pharmacy?

Q9

-What makes you choose that pharmacy?

Eg) local, friendly, opening hours etc.

Q10

-What has been your experience with your local pharmacy? (positive and negative)

Q11

-Have you ever consulted your pharmacist for advice with your diabetes?

Topic Three: A pharmacy intervention

In addition to dispensing medications, pharmacists also offer additional services (for eg flu jabs, contraception advice, stop smoking services etc). Some of these will vary from pharmacy to pharmacy and depending on the time of year.

- **Card 5 Pharmacy interventions**

-In the past, pharmacies have run services to support people with diabetes to supplement their usual care.

Q12

a) Some of these services have…..

-helped the individual set and meet healthcare goals…*what are your thought on this?*

What do you like about this idea?

What do you dislike about this idea?

b) provided advice and education as and when needed…

What do you like about this idea?

What do you dislike about this idea?

c) offered tailored support depending on what the person needs…

What do you like about this idea?

What do you dislike about this idea?

d) been a point of contact when needing someone to speak to about diabetes…

What do you like about this idea?

What do you dislike about this idea?

e) sign posted to other services (eg weight-loss services)…

What do you like about this idea?

What do you dislike about this idea?

f) to help with the monitoring of BP, weight, blood sugars…

What are your thoughts on this?

What do you like about this idea?

What do you dislike about this idea?

g) to provide encouragement and motivation when needed…

What do you think about this?

What do you like about this idea?

What do you dislike about this idea?

Q13

-This support has been offered in many forms including face to face, over the phone and virtually.

What do you think about these?

Q14

-Thinking about all of the things we have spoken about in terms of what pharmacy can offer, what would you find helpful?

Can you tell me more about that?

C.3.5 Closing statement:

Thank you all for your contribution to the group. Before we finish, does anyone have any other comments or anything additional that they would like to add?

C.3.6 Closing comments: Thank you again for your time.

If you would like to receive a copy of the study results once they are finalised, can I please confirm your contact details. These details will be stored securely, separately from the transcribed interview to guarantee your anonymity.

If you would like to speak to me about your answers, please contact me: s.brewster@soton.ac.uk

C.4 Focus group coding manual- people with diabetes

Topic	Theme	Code	Definition of code	Example quote
Diabetes healthcare appointments	**Appointment logistics and healthcare service related issues**	Appointment flexibility	Discusses issues pertaining to booking and re-scheduling of appointments.	"Back when I was employed. It was a case of krikee, I've now got to look and get time off work. Yeah, you know and then you can take it as leave or make up time, for me, it was always like being between a rock and a hard place…. and you are left feeling guilty because you're not working around that team" *(Participant B, 35yr male, Type 1 diabetes)*
		Healthcare service resources	Mentions resources (eg time, staffing levels, financial etc) and how these impact delivery of care.	"They're overstretched, especially now with COVID so that's why I didn't go last time. With COVID, everybody's busy so I didn't bother." *(Participant D, 75yr male, Type 2 diabetes)* "I fully accept that and it's (healthcare services) overstretched underfunded" *(Participant L, 68 yr male, Type 1 diabetes)*
		Communication with the patient and other healthcare professionals	Discusses factors relating to how the diabetes healthcare professional communicates with them or other healthcare professionals involved in their care.	"the problem comes to me when I leave that room and information I've been given by my consultant or to the DSN doesn't seem to get back to my GP." *(Participant C, 29 yr female, Type 1 diabetes)*
		Changing healthcare structure	Refers to the structure of the healthcare system and how this impacts diabetes care or how that care is perceived.	"But where things are constantly changing, never mind the current situation and where things are currently, there has been reorganisation almost monthly. You think

				something's happening and then you then you find out, oh, we've had a meeting and you'll now have the vaccine. Can I know before it happens next time please. I know that it is not always possible though as there are quite a few of us who are diabetic.It's all of the chopping and changing." *(Participant F, 66yr female, Type 1 diabetes)*
	Relationships	Healthcare professional skill-set	Describes the perceived knowledge and skills of the healthcare professional involved delivering diabetes care.	"I know so much more about diabetes than the nurse that sometimes it feels like you're training or educating them and not all the time, but I felt like that sometimes." *(Participant H, 59 yr male, Type 1 diabetes)*
		Continuity	Continuity with a healthcare professional or healthcare service and how this impacts perception of care.	"It's a roller coaster to be honest, but provided I've just got the one person to advise me I'm fine with it. I do believe that we all live with it and we manage it in our own way. When I get an appointment with someone new, I think 'Oh God, who am I going to get this time?' And this creates quite a lot of anxiety." *(Participant A, 70 yr female, Type 2 diabetes)*
		Paternalism	Refers to being treated in a paternalistic fashion.	"…one thing I feel is you tend to get told off a lot in these meetings which means I don't really want to go" *(Participant B, 35yr male, Type 1 diabetes)*
		Perceived value of appointment	Discusses whether appointments are perceived as being worthwhile or not. Whether they offer value to someone's management and/or experience of living with diabetes.	"My appointments I find alright actually. I didn't initially cuz I was in a sense of denial when they first diagnosed me but since the last couple of years I have found them a useful event really and they're almost like a staging post to check

				up around how we're doing and a bit of a challenge." *(Participant B, 35 yr male, Type 1 diabetes)*
		Holistic and empowerment	Refers to being given empowerment to manage their condition and/or being treated holistically as a person and not just for the diabetes.	"one time I said to the DSN at the time, 'well, what do you advise?' She said to me 'whose diabetes is it?' When I said it was mine, She said 'right so are you going to come back to me every time you want to try to change the dose?' I took it well, but equally what I heard was, we're here to help, not to tell you what to do, which just I thought was fair enough. other people may feel differently but I thought yeah good point and that's something I've taken on to other places when people have, you know, various different contexts." *(Participant B, 35 yr male, Type 1 diabetes)* "We all have diabetes that we've all got very differently. I'm sure and we all handle it differently. So it's I fine as long as I'm seeing someone who actually is looking at me as a person rather than just as a diabetic." *(Participant C, 29yr female, Type 1 diabetes)*
Thoughts on a hypothetical CPDSS	**Strengths**	Frequency of contact	Discusses how often they visit their local pharmacy.	"We visit our pharmacists every 1-2 months. We don't see our GP or nurse that frequently." *(Participant H, 59 yr male, Type 1 diabetes)*
		Accessibility	Refers to ease of access to a pharmacy.	"Well I choose the pharmacy because it's literally just around the corner from my house. So it's just convenience. Pharmacies are very convenient"

				(Participant C, 29 yr female, Type 1 diabetes).
		Offloading diabetes services	Discusses how a potential CPDSS may help reduce the work load of other diabetes services.	"the data-gathering aspect of that would be I think very helpful and probably very helpful for the diabetic clinics because that seems to be what they spend most of my time doing right now rather than diagnosing or giving advice so that that would be that would make sense." *(Participant H, 59 yr male, Type 1 diabetes)*
		Size of workforce	Mentions pharmacy workforce numbers.	"There are more pharmacies and pharmacists than there are diabetic nurses." *(Participant H, 59 yr male, Type 1 diabetes)*
	Barriers	Skill-set	Refers to the skills and expertise of pharmacists.	"I wouldn't ask them for advice, because they can't give me advice. They're not qualified to do it." *(Participant K, 65 yr male, Type 2 diabetes)*
		Trust	Refers specifically to people's trust of pharmacies and/or pharmacy staff.	"I think you would have to have more trust in the pharmacist really to understand that they were doing it because they had the experience, etc, rather than just taking a box." *(Participant M, 62 yr female, Type 2 diabetes)* "…if the primary care doctors can't get it right to prescribe and tell you what to do with your diabetes, then what chance does the pharmacy have? They are at the bottom of the chain and primary care in the middle and they can't even get it right so." *(Participant L, 68 yr male, Type 1 diabetes)*

		Access to records	Access to medical records or patient information	" I would struggle to see how a pharmacist might be able to do that without having a lot of your records available to them. Personally, I don't care they can have access to all my records." *(Participant H, 59 yr male, Type 1 diabetes)*
		Capacity	Discusses capacity (in terms of time, staffing levels, financial constraints etc) of pharmacy and how this may impact a hypothetical CPDSS.	"The pharmacies are usually very busy anyway, so I can't imagine them having any more time than a doctors' surgery." *(Participant M, 51 yr female, Type 2 diabetes)*
		Authority	Refers to the ability of pharmacists to instigate a change in management or treatment plan.	"They need Authority to make changes though or to be able to communicate with those that have the authority in surgery." *(Participant B, 35 yr male, Type 1 diabetes)*
		Duplication of care	Discusses how a hypothetical CPDSS may lead to duplication of care already being offered elsewhere.	"It (A CPDSS) would likely add another layer of care so definitely not for me because as I said earlier, one place fine. Pharmacy does the pharmacy bit- it works. Great. It's when you get these multiple layers, I think it takes time, energy, money and personally upsets me on quite a few occasions so I don't like it. We don't need to re-invent the wheel or duplicate care."P *(Participant F, 66 yr female, Type 1 diabetes)*

Glossary of Terms

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