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The role of community pharmacy in diabetes prevention

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I am the vine; you are the branches. He who abides in Me and I in him, he bears much fruit; for apart from Me you can do nothing.

John 15 verse 5.

Abstract

The role of community pharmacy in diabetes prevention

By Thando Katangwe

Background

Diabetes Prevention Programmes (DPPs), comprising intensive lifestyle interventions, may delay or even prevent the onset of type 2 diabetes in Non-diabetic hyperglycaemia (NDH). Unfortunately, engagement with DPPs is variable with accessibility being a reported barrier; this may be addressed by community pharmacy involvement given its accessibility. The aim of this thesis was to explore the potential role of community pharmacy in diabetes prevention in England.

Methods

This thesis includes four studies; the first, a mixed methods study exploring engagement with the national DPP and eliciting views from people with NDH on the role of community pharmacy in diabetes prevention. The second, a qualitative study exploring views of healthcare providers and commissioners on the potential role of community pharmacy in diabetes prevention. The third, a questionnaire-based validation study. The fourth, a nominal group technique study designed to identify interventions most likely to facilitate successful implementation of community pharmacy-based diabetes prevention services (DPS). The studies were underpinned by the Behaviour Change Wheel framework which framed data collection, analysis and intervention development.

Results

The mixed methods study highlighted barriers to engagement in the national DPP including inconvenient location and session times and identified community pharmacy as a potential setting for delivering alternative DPS. The qualitative study and the subsequent validation questionnaire identified facilitators for the provision of community pharmacy-based DPS including the provision of integrated services in

primary care. The final study identified key interventions for ensuring engagement with (e.g. service promotion) and delivery of (e.g. training) community pharmacy-based DPS.

Conclusions

The thesis provides an overview of evidence underpinning the role of community pharmacy in the provision of accessible DPS and presents a model for implementation. The proposed model, which advocates integration of primary care services, aligns with the community pharmacy contractual framework and the National Health Service Long Term Plan.

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Glossary

BCW	Behaviour Change Wheel
BMI	Body Mass Index
CCG	Clinical Commissioning Groups
CPCF	Community pharmacy contractual framework
CVD	Cardiovascular disease
DPP	Diabetes Prevention Programme(s)
DPS	Diabetes Prevention Service(s)
FPG	Fasting plasma glucose
HbA_{1c}	Glycosylated haemoglobin
GP	General Practitioner
LPC	Local Pharmaceutical Committee
LTP	Long Term Plan
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NDH	Non-diabetic Hyperglycaemia
OGTT	Oral Glucose Tolerance Test
PCN	Primary Care Networks
IEC	International Expert Committee
IGR	Impaired Glucose Regulation
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
R and D	Research and Development teams
SPSS	Statistical Package for Social Sciences
STP	Sustainability and Transformation Partnerships
UEA	University of East Anglia
WHO	World Health Organisation

List of initials

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HF	Hannah Family
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SS	Sion Scott

Publications from thesis

- Katangwe T, Family H, Sokhi J, Al-Jabr H, Kirkdale CL,Twigg MJ (2019) **'The community pharmacy setting for the delivery of diabetes prevention programmes: Views and perceptions of stakeholders'** *Plos ONE* 14 (7) 2018: e0219686 https://doi.org/10.1371/journal.pone.0219686
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Chapter 1: Introduction

1.1 Prevalence, cost and aetiology of type 2 diabetes

Diabetes mellitus has been highlighted as one of the main non-communicable diseases responsible for the major health and development challenges of the 21st century (1). Globally, the prevalence of diabetes has nearly doubled from 4.7% in 1980 to 8.5% in 2014 (2, 3). In England, approximately 3.5 million people aged 16 years and over are estimated to be living with type 2 diabetes (diagnosed and undiagnosed), a prevalence rate of 7.7% (4). This is expected to rise to 4.4 million, which is 8.7% of the adult population, by 2035 (4). The management of type 2 diabetes and its complications poses a financial burden on the National Health Service (NHS) in England, currently costing £8.8 billion a year, almost 10% of the total budget (5).

Diabetes mellitus is a chronic endocrine disorder, characterised by hyperglycaemia resulting from inadequate secretion of insulin by the pancreas with or without insulin resistance (6). Diabetes mellitus is classified according to aetiology with type 1 and type 2 being the most common. Type 1, which usually develops in children and adolescents, constitutes 10% of people diagnosed with the condition (7). It occurs due to the autoimmune destruction of insulin producing pancreatic β-cells often triggered by exogenous factors such as food and viral infections in genetically pre-disposed individuals (6). Individuals diagnosed with type 1 diabetes require daily administration of insulin to regulate blood glucose (7).

Type 2 diabetes usually develops above the age of 40 (although it is increasingly diagnosed in younger people and even children). This thesis is focused on type 2 diabetes, which comprises almost 90% of all diabetes cases (6). Type 2 diabetes occurs due to a progressive development of insulin resistance and dysfunction of pancreatic β-cells leading to insulin deficiency and impaired glucose regulation (IGR) (6). The main symptoms of diabetes, polyuria (increased urine production) and polydipsia (increased thirst), occur due to osmotic diuresis secondary to hyperglycaemia (6). Hyperglycaemia may also cause blurred vision due to changes in lens fraction, and a higher infection rate (especially candida and urinary tract

infections) due to increased urinary glucose levels (6). The symptoms of type 2 diabetes, although similar to type 1 diabetes, are associated with a much slower and less marked onset due to the progressive nature of its development (6).

Sustained hyperglycaemia in diabetes mellitus can lead to the development of macrovascular and microvascular complications from atherosclerosis of the vessels (6). Macrovascular complications , including cardiovascular disease (CVD) (coronary heart disease and stroke) and peripheral vascular disease, are the major cause of death and disability in people with diabetes mellitus (8). The risk of developing such complications is twice as likely in people with diabetes mellitus compared with those without (9). Additionally, the risk of hospital admission for heart failure, myocardial infarction and stroke is respectively 73%, 55% and 34% higher among people with diabetes mellitus than those without (10).

Microvascular complications include nephropathy (kidney disease), retinopathy, and neuropathy (nerve damage) and result from damage to small blood vessels (6). It is estimated that 3 in 4 people with diabetes mellitus develop kidney disease during their lifetime with nearly 1 in 5 people possibly requiring treatment (11). Retinopathy, resulting from long term accumulated damage in the small blood vessels of the retina, can lead to blindness. Diabetic retinopathy accounts for approximately 14% of the main causes of blindness certifications in England and Wales and is the leading cause of preventable sight loss amongst people of working age in the UK (11, 12). The progressive loss of nerve fibres in people with diabetes mellitus, resulting from nerve dysfunction, can give rise to neuropathies which can affect up to 50% of patients (11). Chronic painful peripheral neuropathy, the most common type of neuropathy, is estimated to affect up to 26% of people with diabetes mellitus (13). This is a sensory neuropathy which reduces the sensation in the feet and lower limbs, contributing to increased rates of ulceration, infection and amputation (6, 13). In England there are higher rates of amputations in people with diabetes mellitus than those without, with over 7,000 people undergoing leg, foot or toe amputations each year (14). In 2010-11, the NHS in England spent an estimated £650 million on diabetic foot ulcers and amputations (15). Autonomic

neuropathy in diabetes mellitus may also give rise to other conditions such as diabetic impotence, bladder dysfunction and diabetic diarrhoea (6).

The risk of developing type 2 diabetes depends on multiple non-modifiable and modifiable risk factors. Non-modifiable risk factors include age, family history (first degree relative with type 2 diabetes) and ethnicity (6, 16). Type 2 diabetes has a strong genetic predisposition, with a 5-10% risk of development in children whose parents have the condition compared to 1-2% for type 1 diabetes (6). High risk populations include African, Hispanic or South Asian descent with Asia accounting for at least 60% of the world's population of people living with diabetes mellitus (17, 18). There is also a clear association between type 2 diabetes and modifiable factors such as being overweight or obese (19). Obesity accounts for approximately 80-85% of the overall risk of developing type 2 diabetes and together with physical inactivity, is estimated to cause a large proportion of the global diabetes burden (20, 21). It is suggested that an increase of 1kg/m^2 of Body Mass Index (BMI) and 1cm increase in waist circumference increases the risk of developing new-onset type 2 diabetes by 8.4% and 3.2% respectively (22). In England, almost 50% of the projected increase in prevalence of diabetes mellitus is attributed to the increasing prevalence of obesity which has risen amongst adults from 14.9% to 25.6% between 1993 and 2014 (23). By 2050 it is predicted that obesity will affect 60% of adult men and 50% of adult women (24).

1.2 Detection of type 2 diabetes

Diabetes mellitus is usually diagnosed using blood tests that measure plasma glucose levels or glycosylated haemoglobin levels (HbA_{1c})(16, 25). Plasma glucose can be measured using the fasting plasma glucose test (FPG) or the oral glucose tolerance test (OGTT). The FPG test requires individuals to fast for at least 8 hours prior to blood samples being taken. The OGTT also requires individuals to fast for at least 8 hours and then ingest a 75g oral glucose load prior to blood samples being taken (2, 6).

Glycated haemoglobin measures the amount of glucose carried by haemoglobin, a protein within the red blood cells which joins with glucose (26). Measuring HbA_{1c}, although more costly than blood glucose measurement, has an advantage of reflecting the average blood glucose concentration over a period of two or three months, rather than the momentary blood glucose concentration (26, 27). HbA_{1c} is estimated on a single non-fasting blood test but may vary with ethnicity, leading to either overestimation or underestimation of the result and could be inaccurate in the presence of haemoglobinopathies (28). Additionally, there are other conditions whereby the HbA_{1c} test cannot be used for diagnosis including suspected type 1 diabetes, children or young adults, gestational diabetes and people who are acutely ill (29, 30). In these conditions, glucose values fluctuate quickly and therefore HbA_{1c} measurements may not accurately reflect glycaemic exposure (29). However, to date, HbA_{1c} is the most convenient test used to measure blood glucose, requiring no fasting and providing measurements that reflect glycemic control over a 3-month period.

The internationally agreed criteria for diagnosis of diabetes mellitus is summarised in Table 1.1 (31, 32). In order to allow global comparison, the presentation of HbA_{1c} levels in this thesis adopts the International Federation of Clinical Chemistry (IFCC) standardisation of HbA_{1c} results which are expressed in mmol/mol (33).

Table 1.1 Internationally agreed diagnostic criteria for diabetic mellitus

		Diagnosis	
Diagnostic test	**Units**	**Normoglycemia**	**Diabetes**
FPG	mmol/L	<5.5	≥7.0
OGTT	mmol/L	<7.8	≥11.1
HbA_{1c}	mmol/mol	<42	≥48

1.3 Non-diabetic hyperglycaemia

Owing to the progressive loss of β-cell function associated with type 2 diabetes, where insulin production decreases over a sustained period of time, IGR may be detected before overt diabetes develops (6, 32). IGR is a term which refers to blood glucose levels above normal range but not high enough for diagnosis of type 2 diabetes (2, 32). It is therefore an umbrella term used to describe the presence of impaired glucose tolerance (IGT) and/or impaired fasting glucose (IFG) as defined by the World Health Organization (WHO) (25, 32).

IGT is a term adopted by the WHO in 1980 from the US national diabetes data group to denote a state of increased risk of progressing to diabetes (25). It is mainly associated with insulin resistance in the muscles and impaired insulin secretion (34). IFG, another term adopted by the WHO in 1999 from the American Diabetes Association (ADA) expert committee (25), describes the zone between the upper limit of normal fasting glucose and the lower limit of the diabetic fasting glucose (25). IFG is associated with impaired insulin secretion and impaired suppression of hepatic glucose output, hence its development is usually associated with an increased glucose secretion into the bloodstream from the liver overnight (35). Individuals diagnosed with isolated IFG have a fasting blood glucose that is higher than the normal range, but levels do not rise abnormally following an OGTT (35). It

is possible to have a diagnosis of both IGT and IFG. Both (IGT and IFG) are not clinical entities in themselves but are a risk factor for future diabetes mellitus and/or adverse outcomes (25, 32).

In recent years, other terms such as 'pre-diabetes' and 'non-diabetic hyperglycaemia (NDH)' (32) have been adopted as umbrella terms to describe IGR. The term 'pre-diabetes' was originally introduced by the ADA and is most commonly used in the USA (36). Although the term has not been widely accepted by other expert groups including the WHO, it has been adopted in health care systems and is widely referred to in research (37). WHO and the International Diabetes Federation, recommend using the term 'intermediate hyperglycaemia' in order to avoid stigma and potential anxiety about developing future complications associated with diabetes and to reflect evidence that a significant amount of people do not actually progress to type 2 diabetes. In the UK, the National Institute for health and Care Excellence (NICE) advocates the use of the term 'non-diabetic hyperglycemia' but recognises the use of terms such as pre-diabetes when referring to individuals with IGR. NICE is an executive non-departmental public body of the Department of Health in the UK which provides guidance, advice and information services for health, public health and social care professionals. Therefore, for consistency in UK terminology, this thesis primarily uses the term non-diabetic hyperglycemia (NDH) when referring to IGR. However, the term 'pre-diabetes', has also been adopted in the primary research undertaken for this study in order to reflect the language that may be used by healthcare professionals and patients.

Due to the progressive deterioration of β-cell function, undetected NDH could lead to the development of type 2 diabetes. There are currently 5 million people in England with NDH (38). It is estimated that the annual risk of progression to type 2 diabetes is >5 times in isolated IGT, 7 times in isolated IFG and >12 times in both IGT and IFG compared to normoglycaemic individuals (39). Evidence suggests that if NDH is detected before overt diabetes develops and intensive lifestyle interventions are implemented, the onset of type 2 diabetes may be delayed or

even prevented (40, 41). This thesis will primarily focus on the management of NDH in England.

1.4 Detecting non-diabetic hyperglecemia

WHO defines screening as '*a process of identifying individuals who are at sufficiently high risk of a specific disorder to warrant further investigation or direct action*' (42). To guide the selection of conditions that would be suitable for screening, the WHO commissioned a report on the criteria which warrants screening in asymptomatic individuals (Table 1.2) (43).

Table 1.2 Wilson and Jungner classic screening criteria

• The condition sought should be an important health problem
• There should be an accepted treatment for patients with recognized disease
• Facilities for diagnosis and treatment should be available
• There should be a recognisable latent or early symptomatic stage
• There should be a suitable test or examination
• The test should be acceptable to the population
• The natural history of the condition, including development from latent to declared disease, should be adequately understood
• There should be an agreed policy on whom to treat as patients
• The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole
• Case-finding should be a continuing process and not a "once and for all" project

The rising prevalence of type 2 diabetes worldwide, the substantial proportion of people who are undiagnosed, the long latent asymptomatic period in which the condition can be detected and the increasing prevalence of complications in newly diagnosed cases are some of the strong arguments for screening (42, 44, 45). However, in the past due to the lack of evidence evaluating the effectiveness of screening programmes in decreasing mortality and morbidity and the unknown

psychological and economic consequences of screening, it has been concluded that type 2 diabetes fulfils many but not all of the WHO criteria for population mass screening (46, 47).

In more recent years, evidence suggesting a greater risk of disease progression to develop type 2 diabetes in people with NDH has contributed to the growing interest in developing screening methods (40, 48-51). Additionally, concerns over the psychological impact and the cost-effectiveness of screening have been addressed by trials such as the ADDITION study, a pragmatic cluster randomised, parallel-group trail conducted in three European countries (Denmark, the Netherlands and the UK) (52). The study, which investigated the effect of early multifactorial treatment of type 2 diabetes after diagnosis by screening, also set out to test the feasibility of a primary care-based two-step screening approach for type 2 diabetes (53). Step 1 of the screening phase involved the use of questionnaires by participating general practices to randomly assess the risk of developing type 2 diabetes in registered patients aged 40-69 (54). In step 2, those identified as high risk were referred for a confirmatory blood test.

Although the early intensive management of patients with type 2 diabetes was associated with a non-significant reduction in the incidence of cardiovascular events and was not cost-effective compared to standard care, the study generated important findings for the identification and management of individuals identified with NDH (52, 54). The trial demonstrated that screening for type 2 diabetes is feasible in general practice and has limited short and long-term adverse psychological impact on study participants (52). Additionally, the study also found that screening for type 2 diabetes identified more people with NDH and high cardiovascular risk than those with overt diabetes (55). In Denmark for each person identified with diabetes, two were identified as having NDH (IFG and IGT) and six with high CVD risk (55). Approximately one in three people identified with NDH during the study developed type 2 diabetes within three and a half years (56, 57). These findings therefore highlighted a missed therapeutic opportunity, in the individuals who were identified as at risk, as they were not offered advice or

treatment as part of the intervention programme (58). A major recommendation from the trial suggested the development of systems to enable detection of both type 2 diabetes and high-risk individuals, including opportunistic screening and the development of preventative interventions (58).

1.4.1 National guidelines for detection of non-diabetic hyperglycaemia

National guidelines for the management of NDH have therefore been developed considering this evidence. Both NICE and European evidence-based guidelines for the prevention of type 2 diabetes recommend a two-stepped approach for the identification of individuals with NDH (32, 59). The first step involves the use of non-invasive screening tests to identify individuals at high risk whilst the second step involves a subsequent confirmatory blood test to identify those who may be suitable for intensive lifestyle interventions (32).

In England, the first step of the risk identification process is recommended for implementation in general practice settings and by other healthcare professionals including pharmacists, opticians and occupational health nurses (32). Whilst general practices employ the use of validated computer-based risk assessment tools to first identify individuals with NDH, community pharmacies use validated self-assessment questionnaires or signpost individuals to online validated self-assessment tools (32). Confirmatory blood tests (step 2) are currently recommended for implementation in general practice settings only (32). Other primary care settings, including community pharmacy, involved in step 1 of the screening assessments are advised to refer individuals identified as high risk to general practices for confirmatory blood tests (32).

1.4.2 Non-invasive tests (step 1)

In recent years, in order to reduce the number of individuals requiring invasive tests, a stepwise approach involving scores based on non-invasive information, has been recommended to initially identify individuals or population subgroups which may benefit from blood tests (60). Multivariate risk scores have been recommended in current practice guidance as a non-invasive way of identifying individuals with NDH (32, 61). Risk scores may be based on information available from routine clinical data (age, gender, body mass index and family history of diabetes) or collected by questionnaires completed manually or online (60). Risk scores based on routine health service data are also improved by adding commonly measured biochemical data e.g. FPG (60).

Due to the varying purposes of diabetes risk scores, including targeting prevention interventions to those at greatest risk, their validity has great implications (60). A systematic review examining evidence for the performance of diabetes risk scores in adults, recommended the use of risk prediction models that are validated within the population in which they are intended to be used, especially if ethnicities and countries differ from the derivation cohorts (60).

In the UK, NICE has recommended the use of validated risk scores such as the Cambridge risk score, the Leicester Practice Risk score and the QDiabetes score which use routine clinical data (32, 38). NICE also recommends the use of self-assessment questionnaires such as the Leicester Diabetes Risk Assessment Score and the FINDRISC which are available online or on paper (32, 38). This thesis focused on validated risk scores which have been recommended for use in the UK, the components of which are summarized in Table 1.3.

Table 1.3 Predictive variables for diabetes risk assessment tools

Variable	FINDRISC	Leicester Risk Assessment Score	Leicester Practice Risk Score	Cambridge Diabetes Risk Score	QDiabetes
Age	✓	✓	✓	✓	✓
Gender	-	✓	✓	✓	✓
Ethnicity	-	✓	✓		✓
Family history of diabetes	✓	✓	✓	✓	✓
History of prevalent/latent diabetes	✓	-	-	-	-
BMI	✓	✓	✓	✓	✓
Waist circumference	✓	✓	-	-	-
Physical activity	✓	-	-	-	-
Daily consumption of fruit and veg	✓	-	-	-	-
Townsend deprivation score	-	-	-	-	✓
Smoking status	-	-	-	✓	✓
Cardiovascular disease	-	-	-		✓
Prescribed steroids	-	-	-	✓	✓
High blood pressure or prescribed hypertensive medicine	✓	✓	✓	✓	✓

1.4.2.1 The Finnish Diabetes Risk Score (FINDRISC)

The Finnish Diabetes Risk Score is a self-assessment questionnaire which was developed and validated using two large, population-based cohorts in Finland (62). The questionnaire uses weighted scores from eight categories to detect the risk of developing type 2 diabetes within 10 years (62). The score ranks the risk as low (< 7), slightly elevated (7-11), moderate (12-14), high (15-20) and very high (>20). Having been validated in 8 independent cohorts, the FINDRISC is the most validated screening tool to date (60). It has also been found useful in identifying high risk groups that are most likely to benefit from intensive lifestyle interventions to prevent type 2 diabetes (63).

1.4.2.2 The Leicester Risk Assessment Score

The Leicester Risk Assessment Score is a validated assessment tool developed by Leicester University and University Hospitals of Leicester NHS Trust in England (64). The score was developed from FINDRISC to identify people who may have NDH and type 2 diabetes. The score is in the form of a questionnaire that can be completed without intervention by healthcare professionals (38). The questionnaire consists of seven questions whose score highlights a person's risk of developing type 2 diabetes in the next 10 years. It uses a points system to identity if a person is at low (0-6), increased (7-15), moderate (16-24), or high risk (>25) of developing type 2 diabetes. The Leicester Risk Assessment Score has been validated for use in a multi-ethnic population in the UK (64).

1.4.2.3 The Leicester Practice Risk Score

The Leicester Practice Risk Score was developed for use within primary care databases using the same data as that of the Leicester Risk Assessment Score (38). The main difference between the two scores is that the practice risk score does not include waist circumference as a component as this is not routinely available on primary care databases. The risk score has been recommended by NICE for use in general practice and other primary care settings to identify undiagnosed type 2 diabetes and those with NDH for suitable interventions (32). The Leicester Practice

Score, available as a software, calculates the risk score for all those aged between 18 and 75 years old excluding people with known diabetes, the terminally ill and those coded with gestational diabetes (65). The software may also be used for the analysis of OGTT/HbA_{1c}/glucose data in order to identify the number of people that have been screened and those who may have been missed, allowing practices to invite those at greatest risk for screening (65).

1.4.2.4 The Cambridge Diabetes Risk Score

The Cambridge risk score was originally developed to identify individuals with undiagnosed type 2 diabetes using data routinely collected in general practices (66). The score has been validated in a large cohort of people in the UK recruited from general practices in Wessex and Ely (60, 66). The score has also been validated for use in identifying those with NDH using a population-based prospective cohort (67). However, the study cohort used to develop the risk score were predominantly white, hence ethnicity is not included as a component variable in the model. Additionally, the cohort is unlikely to be a representative sample for all UK.

1.4.2.5 The QDiabetes score

The QDiabetes score is the first validated risk score to account for both social deprivation and ethnicity when estimating the 10-year risk of developing diabetes (68). The cohort study used to validate the score employed routinely collected data from 355 general practices in England and Wales to develop the score and 176 practices to validate the score (68). The predictive components rank the scores as low (0-10), moderate (10-20) or high (>20) risk of developing diabetes. The QDiabetes has since been updated to include new risk factors such as medical conditions (e.g. gestational diabetes and polycystic ovary syndrome), medication (e.g. atypical antipsychotics and statins) and blood glucose readings (FPG and HbA_{1c}) (69).

The risk scores selected by NICE for use in the UK have been identified above. However, the decision to use them largely depends on the setting where screening

is undertaken, the availability of clinical information and the population being screened. In clinical settings, where patient data such as blood glucose readings and medical histories are readily available, tools such as the QDiabetes score, the Leicester Practice Risk Score and the Cambridge Diabetes Risk Score could be used. However, it is important to ensure that tools used are appropriately validated for the population being screened (60). For example, the Cambridge Diabetes Risk Score, which has been developed for use in clinical settings and validated in a predominantly white population (34, 62, 70-72), has weaker discriminatory performance with regards to ethnicity (17, 18).

In non-clinical settings, more pragmatic tools which are accessible as online or paper-based tools (e.g. FINDRISC and the Leicester Risk Assessment Score) can be used.

1.4.3 Follow-up blood tests (step 2)

In 1979, the OGTT was the first test to be used to diagnose NDH (as IGT) (25). In 1999, due to the laborious nature of conducting the OGTT, WHO recommendations for the diagnosis of NDH expanded to include the FPG test (25).

In 2010, in keeping with the development of reference methods to standardise assays, the HbA_{1c} became the third test to be used to diagnose diabetes (HbA_{1c}) (mmol/mol or %)(27). The expansion of tests for identifying elevated glucose levels has led to the development of guidelines from NICE and the ADA that recommend the use of both FPG and HbA_{1c} for identifying people with NDH. The WHO recommends HbA_{1c} measurements only for the diagnosis of diabetes, provided the tests are quality assured, standardised to international criteria and there are no conditions that may prevent accurate measurements (27). However, although WHO acknowledge HbA_{1c} levels below 48 mmol/mol to indicate the presence of NDH, they have not committed to a specific lower cut-off point (73). Their position, which mirrors that of the International Expert Committee, is primarily based on the consideration that although the continuum risk of developing diabetes may be captured by the HbA_{1c} assay, the actual point where the risk begins or becomes clinically important is currently unknown. The International Expert Committee has, however, suggested people with HbA_{1c} level of 42-47 mmol/mol to be at a particularly high risk of developing diabetes and recommended them to be considered for preventative interventions. Current NICE, ADA and WHO recommendations for the detection of NDH are detailed in Table 1.4. In the UK, the standard diagnostic tests for NDH are HbA_{1c} and FPG, except where the test is considered inappropriate.

Table 1.4 Criteria for classifying non-diabetic hyperglycemia

		Guideline diagnostic criteria			
Test	**Diagnosis**	**NICE (32)**	**WHO (25)**	**ADA (74)**	**International Expert Committee (75)**
FPG (mmol/L)	IFG	5.5-6.9	6.1-6.9	5.6-6.9	
OGTT (mmol/L)	IGT	≥7.8 - <11.1	≥7.8 - <11.1	≥7.8 - <11.1	
HbA_{1c} (mmol/mol)	NDH	42-47	-	39-47	42-47 for the purpose of interventions

Globally, there is no agreed consensus on the range of FPG and HbA_{1c} levels that should be classed as NDH. Wide diagnostic ranges have the potential to increase the prevalence of NDH and consequently increase healthcare costs. Research suggests that a global implementation of ADAs definition of NDH (which is wider than that proposed by NICE and the International Expert Committee) could lead to approximately 50% of the Chinese adult population (over half a billion people) being diagnosed with NDH (76). The decision to implement lower cut-off points for NDH, should therefore consider the availability sufficient resources to cope with the increasing number of identified cases including sufficient evidence-based interventions (42, 77). WHO has advised consideration to be made whether local healthcare resources are sufficient to cope with the extra workload (2). It is therefore important that guideline recommended ranges for NDH do not create an unsustainable burden on healthcare systems and cause unnecessary anxiety about the complications of diabetes in those identified with NDH.

1.4.3.1 Accuracy of blood tests used to identify non-diabetic hyperglycemia

The OGTT, the first test to be used for diagnosis of NDH, has been considered (by some researchers and clinicians) to be the 'gold standard' test for identifying NDH (78). To date OGTT, has the most research evidence for predicting the incidence of

developing diabetes and coronary heart disease (76). Additionally, key randomised controlled trials that form the evidence base for interventions for people with NDH have been conducted in people with IGT (79-82).

In recent years, the expansion of tests for identifying NDH to include both FPG and HbA_{1c} has raised concerns with regards to the diagnostic accuracy of the tests. A meta-analysis conducted by Barry *et al.* challenged the diagnostic accuracy of using both the HbA_{1c} and FPG tests to identify NDH (78). The review, which aimed to assess the diagnostic accuracy of screening tests for NDH, found the HbA_{1c} test to be neither sensitive (mean sensitivity of 0.49 (95% CI 0.40-0.58)) nor specific (mean specificity of 0.79 (95% CI 0.73-0.84)) and found the FPG test to be specific (mean specificity of 0.94 (95% CI 0.92-0.96)) but not sensitive (mean sensitivity of 0.25 (95% CI 0.19-0.32)). The findings therefore suggested that using these tests to identify NDH could result in identifying (and treating) a population with an incorrect diagnosis of NDH while falsely reassuring another cohort of people with NDH that could benefit from intervention.

In considering this evidence, it is important to highlight that the meta-analysis measured the sensitivity and specificity of the HbA_{1c} and FPG tests using OGTT as the 'gold standard' (78). However, evidence shows that the OGTT test is poorly reproducible, with people identified with IGT in a first test having a 30% chance of a normal result on repeat testing (83). Additionally, although key randomised trials examining the effectiveness of interventions in people with NDH used the OGTT, the majority of the studies were undertaken at a time when newer assays such as HbA_{1c} has not been developed (79-81). Therefore, rather than consider the OGTT as the 'gold standard' or the most accurate test, it should rather be regarded as the test with the most available evidence to date. Arguably, there is a need to generate similar evidence for newer tests including the HbA_{1c} test.

Research evidence suggests that using both the HbA_{1c} and the FPG tests has potential to create heterogenous categories of NDH. For example, a study conducted using the ADA cut-off points in Chinese adults identified a prevalence of

8.3% of IGT, and 27.3% of IFG and 35% of those meeting the HbA_{1c} range for NDH (84).

With these findings, however, it is important to consider that current tests for diagnosing NDH identify three different types of glucose intolerances. The OGTT reflects the degree of insulin resistance in individuals, the IFG test measures glucose levels caused by excess liver glucose production and the HbA_{1c} test measures glycated haemoglobin. Therefore, rather than concluding tests to be 'inaccurate', consideration should be paid to the necessity of the categorisation of impaired glucose states. The IEC, for example, have suggested that perhaps dichotomous classifications, such as IFG and IGT, should be eliminated due their failure to capture the continuum risk in the sub-diabetic range (75). They have proposed the phasing out of these categorical clinical states as HbA_{1c} measurements replace glucose measurements.

In England, NICE recommends using both the HbA1c and the FPG for identifying suitable people for the intervention, provided the same test is used throughout the intervention (85). NICE cut-off points mirror IEC recommendations for identifying people suitable for intervention (32). Current screening interventions, that use both HbA1c and FPG to identify NDH, have the potential to generate some much-needed evidence with regards to associations between their use in detecting NDH and, the incidence of diabetes and the development of CVD complications.

1.5 Management of type 2 diabetes

The short-term management of type 2 diabetes aims to control blood glucose levels in order to alleviate symptoms of hyperglycaemia (6). The long-term management involves the minimisation of cardiovascular risk in order to delay and even prevent the development of complications and premature death.

In the management of type 2 diabetes, where obesity is a major risk factor, diet and physical activity interventions lie at the centre of improving disease outcomes (2, 20, 86). Exercise has been shown to significantly improve glycaemic control and reduce visceral adipose tissue, even without weight loss (87, 88). In those who are overweight or obese, a modest weight loss of 5-10% through increased physical exercise and calorie restriction has been associated with improvements in diabetes and cardiovascular risk factors (16, 89). Whilst diet and lifestyle changes are the mainstay treatment in the management of type 2 diabetes, the progressive loss of glycaemic control means that people with type 2 diabetes eventually require pharmacological treatment (16). Initial pharmacological interventions involve the combination of oral hypoglycaemic agents such as metformin and sulphonylureas and as the condition progresses patients may require insulin therapy (16).

The complexity of type 2 diabetes encompassing the multiple risk factors, complications, lifestyle choices, treatments and monitoring, makes structured self-management education the cornerstone in management (6). In the UK, NICE has recommended offering structured education with annual reinforcement and review to adults with type 2 diabetes and/or their family members or carers at and around the time of diagnosis (16, 90, 91)

1.6 Review of evidence for the management of non-diabetic hyperglycaemia

To develop an initial understanding of the current practice for the management of non-diabetic hyperglycemia (NDH) and the underpinning evidence, a non-exhaustive review of the literature was conducted. The literature review also aimed to identify gaps in the current management of NDH which could be addressed by community pharmacy. The focus of the search was therefore to identify both primary (e.g. randomised controlled trials) and secondary (systematic reviews and meta-analyses) evidence as well as identify relevant documents such as national guidelines and protocols for the management of NDH.

The search commenced with Google scholar and further expanded to databases such as MEDLINE and EMBASE. Relevant websites such as the National Institute for Health and Care Excellence, Public Health England, NHS England and Diabetes UK were also hand searched for key documents. Search terms consisting of key words and free text were used to conduct the searches without setting limits to study design, study outcome, comparator or peer reviewed journals. The terms used included key words reflecting impaired glucose regulation (e.g. nondiabetic hyperglycemia, pre-diabetes, impaired glucose tolerance and impaired fasting glucose), pharmacological and non-pharmacological interventions (e.g. metformin, orlistat, medication, diabetes prevention programme, diabetes prevention service, diabetes prevention study, lifestyle intervention, diet and lifestyle, exercise and physical activity).

The following sections highlight guideline recommendations for the management of NDH and examines key research evidence underpinning them. This thesis, reflecting current guideline recommendations, focuses on non-pharmacological interventions, particularly Diabetes Prevention Programmes (DPP). This is because overall research evidence has suggested non-pharmacological interventions to be more effective at reducing the risk of progression to type 2 diabetes than pharmacological interventions (78).

1.6.1 National guidelines for the management of non-diabetic hyperglycaemia

In England, following identification of people with NDH, NICE guidelines recommend the provision of intensive lifestyle interventions to prevent or delay the onset of type 2 diabetes (32). The lifestyle interventions are mainly targeted at modifiable risk factors such as obesity and physical inactivity and aim to achieve a prescribed reduction of initial body weight (usually 5-10%) (32). Similarly, the ADA recommend intensive behavioral counselling programmes targeting a weight loss of 7% and increased physical activity to at least 150 minutes per week (92).

Both NICE and the ADA regard lifestyle education as the cornerstone for the prevention of type 2 diabetes (16, 93). NICE recommends education to be offered as brief advice (one-off, 5-15-minute consultation) to individuals with a low to intermediate risk and as a major part of an intensive lifestyle-change programme in those with NDH (32). When delivered as part of an intensive lifestyle-change programme, education comprises of ongoing tailored advice on exercise and diet with the aim to lose weight (32). NICE also recommends established behaviour change techniques including information provision, goal setting, action planning and coping plans to be used when delivering intensive lifestyle-change programmes (32). This recommendation is in line with evidence which highlights effective behavioural change strategies such as counselling (group or individual) and goal setting as essential components in effective lifestyle-change programmes (94, 95). As well as dietary and exercise education, intensive lifestyle change programmes may also offer exercise sessions delivered in groups or one to one.

In the management of people with NDH, pharmacological treatment such as metformin and orlistat to manage hyperglycemia and aid weight reduction respectively are recommended as second-line options in those whom intensive lifestyle-change programmes have been unsuccessful (32, 59, 92). Pharmacological options are only recommended as first line in individuals who are unable to participate in intensive lifestyle-change programmes.

The development of national guidance for the management of NDH has been underpinned by extensive primary and secondary research examining the effectiveness of both pharmacological and non-pharmacological approaches. The following sections aim to discuss the evidence behind both pharmacological and non-pharmacological approaches including implementation into real life settings.

1.6.2 Pharmacological interventions

Evidence from systematic reviews has highlighted the benefits of using pharmacological interventions to reduce the risk of progression to type 2 diabetes

in individuals with NDH (48). Pharmacological treatments which have shown to be effective include metformin, glitazones, acarbose and orlistat (81, 96-98). The effects of pharmacological interventions, particularly metformin, have been examined in major randomised controlled trials such as the US DPP and the Indian DPP, where metformin achieved a relative risk reduction in the onset of type 2 diabetes of 31% and 26.4% respectively compared to standard lifestyle advice (81, 82). Metformin has also shown lower or similar effects to intensive lifestyle interventions in reducing the incidence of type 2 diabetes and no added benefit when in combination (49, 81, 82).

The choice to implement either an intensive lifestyle intervention or medication for the management of NDH should therefore consider individual characteristics and potential risks and benefits such as effectiveness and adverse events (48, 99). Whilst lifestyle interventions may be beneficial in motivated individuals, non-motivated individuals may benefit from pharmacological interventions (99). However, minor adverse events such as gastro-intestinal disturbances are of great importance if interventions are to be taken long-term (99). Additionally, appropriate dosage adjustments should be considered to minimise hypoglycaemic side-effects (82).

1.6.3 Non-pharmacological interventions

Systematic review evidence exploring the efficacy of non-pharmacological approaches such as lifestyle modification interventions, has highlighted diet and exercise as an effective combination for delaying or preventing the incidence of type 2 diabetes in people with NDH (41, 94, 100). A systematic review and meta-analysis conducted by Gilles *et al.* for example, demonstrated a 49% relative risk reduction in developing type 2 diabetes in trial intervention arms compared to control arms (49). This review has informed NICE guidelines on preventing type 2 diabetes and provided useful information on the impact of the interventions longer term.

Primary evidence underpinning the delivery intensive lifestyle-change interventions designed for the prevention of type 2 diabetes constitutes four major studies; the Finnish Diabetes Prevention Study, the Chinese Da Qing Study, the US DPP and the Indian DPP (79-82). The four studies, which assessed the effectiveness of diet and exercise modification, established intensive lifestyle modification interventions as an efficacious approach for delaying or preventing the incidence of diabetes in individuals with NDH (79-82). The trials also assessed the long-term effects of lifestyle-change programmes on the incidence of diabetes and explored how factors such as ethnicity may alter their effectiveness. A summary of research evidence for DPPs is provided below and the characteristics of interventions explored in the diabetes prevention studies summarised in Table 1.5.

Table 1.5 Intervention characteristics of major diabetes prevention studies

	The Chinese Da Qing study	The Finish Diabetes Prevention Study	The US Diabetes prevention programme	The Indian Diabetes Prevention programme
Year	1986-1992	1993 to 1998	1999 -2002	2002-2005
Country	China	Finland	USA	India
Study size	577	522	3,234	531
Study aim	To assess the long-term effects of intensive lifestyle interventions on diabetes risk, diabetes-related complications and mortality	To determine the effects of a lifestyle change program in preventing or delaying the onset of type 2 diabetes in IGT	To compare the efficacy and safety of intensive lifestyle interventions or standard lifestyle recommendations plus metformin or placebo in preventing or delaying the development of diabetes	To examine the influence of high insulin resistance in native Asian Indians on the effectiveness of diabetes prevention programmes
Population description	Men and women from the city of Da Qing.	High risk-groups (first degree relatives of patients with T2D)	68% women and 45% ethnic and social minority groups (African-American, Hispanic, American Indian, Asian American and Pacific Islander)	Middle-class population working in service organizations identified via workplace announcements and circulars and their families
Inclusion criteria	Age >25 with a positive screening test for IGT	Age (40-64); overweight (BMI >25) and IGT	Age >25; BMI>24kg/m^2; FPG-5.3 to 6.9mmol/l and OGTT-7.8 to 11.0mmol/l	Age: 35-55 years IGT
Screening	OGTT	OGTT	Risk score questionnaire plus an OGTT	OGTT
Interventions	Diet: advice to increase vegetable intake and reduce	Diet and exercise: Individualized dietary and exercise counselling to promote weight reduction (5% or	Intensive lifestyle intervention: Dietary advice to promote at least 7% weight reduction of initial body weight and a	Lifestyle modification: Dietary and physical activity: counselling

	sugar and alcohol intake and to promote weight reduction or Exercise: Goal was to increase leisure time physical activity or Diet plus exercise: As detailed above	more) including supervised exercise sessions	level of physical activity of at least 150min/week. Supervised exercise sessions twice weekly. or Metformin 850mg twice daily plus standard lifestyle education	or Metformin 250mg twice daily or Lifestyle modification plus Metformin: as above
Control	General diet and physical activity advice	General advice on diet and exercise	Standard lifestyle advice plus placebo	Not described
Intensity (Group and/or individual counselling)	Individual: initial counselling session by physicians Group: weekly for 1 month, monthly for 3 months and the once every 3 months	Individual: 7 face-to-face counselling (30 min to 1 hr) sessions in the first year, then once every 3 months Group: None	Individual: 16 initial sessions in the first 24 weeks and at least monthly thereafter Group: quarterly with each course lasting 4 weeks.	Individual: at baseline and every 6 months. Phone contact after 2 weeks and then monthly thereafter. Group: 6 × 2 h education sessions of varying content
Intervention duration	6 years	3.2 years	2.8 years	2.5 years
Primary outcome	Diabetes incidence, CVD incidence, mortality and complications	Diabetes incidence	Diabetes incidence	Diabetes incidence
Setting	Community health clinics	Five study centres in Helsinki, Kuopio, Turku, Tampere and Oulu	27 clinical centres	Community based intervention
Personnel	Physicians, nurses and technicians	Nutritionists	Registered dieticians	A physician, a dietician and a social worker.
Training	A 2-day training session each year on diet and exercise intervention instructions and examination procedures	Not described	Qualification in nutrition, exercise or behaviour modification.	Not described

1.6.3.1 The Chinese Da Qing study

The Chinese Da Qing study examined the effect of a six-year diet and exercise intervention by randomising 577 Chinese adults with IGT to either a control group or to one of three intervention groups (diet, exercise or diet plus exercise) (80). The study showed that diet alone was associated with a 31% reduction in the risk of developing type 2 diabetes, while exercise and combined diet plus exercise demonstrated a 46% and 42% reduction respectively. The 20-year follow-up study examining the long-term effects of the interventions showed that group-based lifestyle interventions over 6 years can prevent or delay diabetes for up to 14 years after an active intervention (101). The six-year active intervention (diet or exercise or diet plus exercise) which resulted in a 51% lower incidence of diabetes in intervention participants compared to control, demonstrated a 43% lower incidence of diabetes 14 years after the active intervention period and a delay in the onset of diabetes of approximately 3.6 years.

This study generated important findings with respect to the long-term effects of DPP. However, the six-year active intervention, does not mirror pragmatic interventions where often intervention duration could be limited by availability of resources.

1.6.3.2 The Finnish Diabetes Prevention Study

The Finnish Diabetes Prevention Study examined the effect of lifestyle interventions in preventing type 2 diabetes (79, 102). The study randomised 522 overweight participants with IGT to either an intensive lifestyle intervention (diet and exercise) or usual care for 3.2 years and followed them up for approximately 4 years. The aim of the intervention was to promote the reduction of dietary saturated fat and weight loss and to increase dietary fibre and physical activity. The lifestyle intervention, delivered using individualised dietary counselling and circuit resistance training sessions, demonstrated a 58% relative risk reduction during the active intervention period and a 36% relative risk reduction during the follow-up period compared to control. Each component of the intervention (weight loss,

physical activity, the reduction of total and saturated fat intake and the increase in dietary fibre) was shown to contribute to the risk reduction. Although the Finnish Diabetes Prevention programme generated some important findings, the generalisability of the data into real-world settings may be low. Important data which may influence the uptake of the programmes such as attrition rates were not reported in the published findings (79). Additionally, the methods of recruitment used in the Finnish Diabetes Prevention Study which included local advertisements, have not been shown to result in high programme participation (103).

1.6.3.3 The US Diabetes Prevention Programme

The US DPP, one of the largest randomised controlled clinical trials to date, was conducted in 3,234 adults with IFG and IGT (81). The study assessed the reduction in the incidence of type 2 diabetes following a lifestyle modification programme or metformin plus standard lifestyle advice over 2.8 years. The study showed that a lifestyle intervention with the goals of at least 7% weight loss and at least 150 minutes of physical activity per week, reduced the incidence of diabetes by 58% compared to control. The study also showed lifestyle intervention to be more effective than metformin, which reduced the incidence of type 2 diabetes by 31% compared to control. Findings from the follow-up study showed that during the 10-year study period the incidence of diabetes was reduced by 34% in the lifestyle intervention group and 18% in the metformin group compared with the control group (104).

The effectiveness of the DPP in a multi-ethnic population was also explored as part of the study. The study enrolled 68% women and 45% participants from ethnic and racial minority groups (African-American, Hispanic, American Indian, Asian American, and Pacific Islander). The study demonstrated that diabetes prevention interventions can reduce the incidence of diabetes with similar effects in men and women and in all racial and ethnic groups. However, resource limitations in real-world settings are a likely limit to the generalisability of the findings in the US DPP which offered a 16-week core curriculum, monthly group and/or individual sessions, long-term maintenance sessions and incentives. This has been highlighted

by variations in outcomes including weight loss in a number of studies focused on translating modified versions of the US DPP into real-world settings (105). Therefore, implementation of such an intervention should consider the effects of delivering modified versions of the US DPP on clinical outcomes, attrition and reach.

1.6.3.4 The Indian Diabetes Prevention Programme

The Indian DPP, a 3-year prospective community-based study, primarily aimed to examine the influence of diabetes prevention interventions on the progression to diabetes in Asian Indians with IGT (82). The study randomised individuals to a control group or three intervention groups (lifestyle modification or metformin or lifestyle modification plus metformin) and demonstrated relative risk reductions of 28.5%, 26.4% and 28.2% in the intervention groups respectively. The study demonstrated no net benefit in combining lifestyle modification and metformin. The rate of progression in Asian Indians, who often display relatively low BMI and high insulin resistance, was compared against previously studied populations (multi-ethnic Americans, Finnish and Chinese). Findings showed that although lifestyle modification significantly reduces the incidence of diabetes in Asian Indians, the progression of IGT to diabetes is higher in this ethnic origin. The progression rate of IGT, assessed in the control groups, was significantly higher in Asian Indians (18.3% per year) than the Finnish (6% per year), the Chinese (11.3% per year) and the Americans (11%) population.

Although the study generated important findings in Asian Indians, there was a lack of recommendations from the study to assist the modification of current clinical practice in order to address the increased progression of NDH in this ethnic group. Additionally, the control intervention was not described, making it difficult to generalise findings from this study.

1.7 The implementation of diabetes prevention programmes in real-world settings: evidence from translational studies

Systematic reviews and meta-analyses of translational studies have also reported the effectiveness of lifestyle intervention programmes in real world settings. A review conducted by Dunkley *et al.* demonstrated that translational DPPs have the potential to produce significant weight reduction in intervention arms by a mean 2.3 kg at 12 months follow-up.

However, despite the effectiveness demonstrated by intensive lifestyle programmes, intervention uptake and long-term adherence to behaviour changes remain a challenge in implementing DPPs into real-life settings (94). Evidence demonstrates that in order to engage target NDH populations, there is a need for intervention designs to focus on balancing both effectiveness (mostly determined by content) and participant experience (103). A thorough examination of current recruitment models, to develop strategies for achieving high programme reach, engagement and retention in lifestyle programmes whilst promoting long-term behaviour changes is therefore crucial (103). The following section discusses key intervention characteristics of translated DPPs with respect to their effectiveness, reach and potential impact.

1.7.1 Intensity, duration and mode of delivery

Adherence to guideline recommendations on intervention content, intensity and delivery has been associated with greater effectiveness of real-world interventions, particularly in achieving weight loss (103, 106). Additionally, evidence has shown DPPs with a high degree of contact to have greater potential for achieving positive outcomes (103).

To examine the implementation of DPPs into routine healthcare settings, studies have explored a number of modifications to original trial interventions such as intensity (number of sessions), programme duration and mode of delivery (103,

107). Most pragmatic studies have modified intervention intensity to offer fewer counselling sessions (105). Systematic review evidence shows that although such programmes' effectiveness in weight reduction may be low or moderate, diabetes risk reduction can be high provided they have a long duration (103). This is a promising finding especially where large populations can be reached but resources are limited (103). Another modification which has been explored and successfully adopted by national guidelines to limit resource requirements is the delivery of group-based education or telephone counselling as opposed to individual counselling (32, 103, 105, 107, 108). This modification is in line with evidence exploring the efficacy of type 2 diabetes education which has suggested that there is no difference in glycaemic control between group-based and individual education interventions (90, 91).

1.7.2 Personnel

The majority of pragmatic lifestyle intervention studies have used similar personnel to those in major randomised controlled trials (105). Such personnel primarily consisted of medical and allied health personnel, including physicians, dieticians, nutritionists, certified diabetes educators, nurses and nurse practitioners, health coaches and exercise physiologists (105). However, systematic review evidence has found that lay educators, with minimal training requirements, can achieve similar weight loss as medical and allied health personnel (109). Evidence proposes that training for lay educators should include minimum core competencies such as basic knowledge, organisational skills and empathy (109). The use of lay personnel in the delivery of DPPs may significantly reduce required resources and increase scalability of interventions thus reducing financial barriers to implementation (107, 110).

The use of lay personnel in the provision of DPPs has been investigated in the UK's Norfolk diabetes prevention study which used lay people diagnosed with type 2 diabetes as lifestyle mentors (111). The study, whose primary aim was to assess the effectiveness of a 40-month intensive diet and exercise intervention in reducing the progression to type 2 diabetes in people with NDH, also aimed to describe the

practicalities associated with recruiting, training and retaining individuals with existing type 2 diabetes to be diabetes prevention mentors (112). The study recruited and randomised 1,028 people with NDH to one of three arms (a control group or an intervention group with mentors or an intervention group without mentors). Although there are currently no published results for the effectiveness of the 40-month intervention, results for the secondary aim of the study have recently been published. The findings showed that lay members of the public with existing type 2 diabetes can be recruited, trained and retained as lay volunteer mentors to help support diabetes prevention in NDH. In the study, mentors were recruited through GP databases and assigned up to 7 participants. Their primary role was to work with health care personnel providing the intervention to support people with NDH through telephone calls scheduled once a month for the first 3 months and then once every two months until the programme ended. The mentors received group training delivered in the form of seminars over a 7-week period. The aim of the training was to provide up-to-date information on physical activity, diet, NDH and lifestyle related areas and the second was to develop key skills for the role. Additionally, the mentors received one-to-one practice work consisting of role play of telephone calls organised by the research team. The study successfully recruited and trained 104 mentors and had a withdrawal rate of 45% (n=47) at the end of the 3-year study period.

This research concluded that cost associated with diabetes prevention can be reduced, without compromising efficacy, by using non healthcare-professionals. However, without the primary clinical outcomes of the study being reported it is difficult to make informed judgements from the findings. Additionally, the extent to which healthcare personnel still played a role in delivering the intervention was not clearly described in the study, hence there is limited evidence to suggest the extent to which the implementation of such a delivery model would reduce healthcare resource requirements. The training package would need to be feasibility tested to investigate both the effectiveness and the cost-effectiveness of using mentors. The study described an intensive recruiting process which included four stages (screening, telephone interview, questionnaire and face to face interviews) which

could pose challenges in implementing in real-life settings. With almost half of the mentors withdrawing over the 3-year period of the study, this also raises questions about whether such a delivery model could be sustainable. More importantly, this delivery model would need to be evaluated to examine the impact of its implementation in different contexts in the UK, particularly in multi-ethic populations which are known to be at greater risk of developing type 2 diabetes (113). Therefore, although this study generated important findings with regards to the use of non-healthcare professional in diabetes prevention interventions, further research is needed before implementation of diabetes prevention models that include lay people with type 2 diabetes as mentors.

1.7.3 Settings and context

Based on the recognition that determinants of efficacy in trials might be fundamentally different from the vital characteristics necessary for implementation, evidence has also examined the impact of intervention characteristics such as the setting (103, 105, 114). Studies focused on the transferability of DPPs to real-world settings have explored four distinct settings including hospital outpatient, primary care, community and work/church (103, 105, 108-110). Whittemore *et al.* conducted a systematic review to assess the implementation of DPPs in different settings by evaluating factors such as efficacy, reach to the targeted population and adoption by providers (105). Hospital settings demonstrated ideal characteristics for the adoption and implementation of DPPs (105). This was attributed to the availability of facilities and resources which enable DPPs to be delivered with little adaptation from the original protocols. Additionally, since the hospital staff providing the programmes are often highly qualified, this setting showed the highest effectiveness in terms of weight loss. However, in terms of reach, the hospital outpatient setting displayed the least population diversity and had a high attrition rate. The review recommended the hospital setting as ideal for the delivery of DPPs for highly motivated and committed individuals.

Unlike hospital settings, primary care settings demonstrated a greater potential to reach adults of diverse ethnicity and had lower attrition rates. Primary care also showed the potential to implement and deliver efficacious DPPs. The review highlighted factors such as established relationships between participants and providers as well as the potential to manage co-morbidities that frequently occur in adults with NDH as beneficial attributes of the setting. However, the limited availability of key personnel that tend to deliver DPPs such as health educators, nurses and dieticians in primary care settings and the lack of space to facilitate the implementation of group-based care are amongst the challenges highlighted.

Church and work-based settings showed the greatest potential to reach adults with a diverse race and ethnicity. However, not only did programmes delivered in these settings face implementation challenges, but they also showed great variations in efficacy with some not achieving targeted weight reductions.

1.7.4 Potential impact of implementing diabetes prevention programmes in real world settings

In developed countries, attempts to halt the increasing prevalence of type 2 diabetes have led to the implementation of national interventions that identify people with NDH and treat them with intensive lifestyle interventions (115, 116). However, this approach has not been widely embraced due to concerns about the impact of providing nationwide DPPs.

Generally, there are two main approaches that could be adopted to prevent diabetes, including screen and treat interventions and the population-wide interventions (1, 117, 118). Central to both interventions is the promotion of healthy diet and exercise in order to reduce the rise in obesity (1). Population-wide interventions promote the prevention of obesity, healthy eating and physical activity by focusing primarily on policy reforms on food, transport, education, health and economics (1). Screen and treat approaches target subpopulations identified with NDH and offer them interventions aimed to prevent or delay the

development of type 2 diabetes (1, 78). This approach is favoured by national guidelines as it also promotes the early detection of individuals with undiagnosed type 2 diabetes (107). However, a prevalent perception amongst those in favour of the population-wide approach is that screen and treat addresses individual risk factors without considering wider social influences such as deprivation, local environments, food advertising and the affordability of healthy foods.

Whilst countries such as the USA and Australia have opted for screening and treating, other countries such as Finland have chosen a multi-level model by adopting both population-wide and the screen and treat interventions (32, 117). Countries such as Finland have thus demonstrated that one approach does not preclude the other. In England, despite some research evidence suggesting otherwise (78), Public Health England has also implemented a three-tiered (primary, secondary and tertiary) approach to diabetes prevention. The first tier, primary prevention, is a population approach which focuses on prevention of obesity by improving diet, increasing physical activity levels and obesity prevention through campaigns and introducing sugar tax policies (119). The second tier, secondary prevention, implements a screen and treat approach targeted at people with NDH (115). The tertiary approach focusses on improving adult diabetes services to reduce complications (7). This thesis focuses on the secondary prevention of type 2 diabetes which is the implementation of a nationwide programme known as the NHS DPP.

1.8 The NHS diabetes prevention programme

The NHS DPP is an evidence based, nationwide programme developed jointly by Public Health England, NHS England and Diabetes UK (40). The development of the programme was primarily based on findings of a commissioned systematic review which included 36 pragmatic lifestyle interventions for the prevention of type 2 diabetes in routine practice. The interventions ranged from diet only, physical activity or a combination of both. The findings of the review suggested that DPPs

can reduce the incidence of type 2 diabetes by 26% compared to usual care. The review also reported DPPs to be associated with an average weight loss of 1.57kg more than usual care. The NHS DPP is a 9-month intervention which identifies people with NDH (>18 years) primarily through retrospective screening of general practice databases and refers them onto a behavioural change intervention to reduce the risk of developing type 2 diabetes (120). Individuals with NDH can also be identified using validated self-assessment questionnaires or screening programmes such as NHS Health Checks by community pharmacists, occupational health nurses and community leaders. People identified through the latter route are then referred to their general practice for confirmatory blood tests (32). Both the HbA_{1c} and the FPG blood tests can be used for referral into the intervention and are recommended to be performed using venous blood. The NHS DPP aims to achieve three main goals including weight loss, improved diet and increased physical activity (121). The key measures of success for the programme are weight reduction, risk reduction (measured through blood glucose parameters at 12 months and beyond (HbA_{1c} or FPG)), reduction in the incidence of type 2 diabetes and retention of people on the programme. The characteristics of the intervention are summarised in Table 1.6 alongside NICE intervention recommendations.

Table 1.6 Summary of lifestyle change intervention characteristics recommended by NICE

	Setting	Providers	Delivery	Duration	Frequency	Contact time	Content	Behavior change techniques
NICE (32)	Primary care*	Primary healthcare teams and/or Dietary and lifestyle advice and support specialists**	Group based (10-15 people)	Intervention: 9-18 months Follow up: at least 2 years	Intervention: weekly or fortnightly (minimum 8 times over duration of the intervention) Follow up: every 3 months	At least 16 hours	Moderate-intensity physical activity (150 min/week). Weight loss to healthy BMI Diet modification - Increase consumption of dietary fibre and reduction in total dietary fat particularly saturated fat	Information provision Motivational interviewing to explore and reinforce participants' reason for change Goal setting; action planning; and relapse prevention
NHS DPP service specification (122)	Primary care*	Voluntary or private sector organisations	Face to face group setting (maximum 20 people)	9 months	Minimum of 13 sessions lasting between 1 and 2 hours and designed to support individuals to make positive lifestyle changes in order to achieve goals	At least 16 hours	Education (type 2 diabetes and its risk factors, weight loss and dietary information), Support to increase physical activity (e.g. by providing pedometers), Strategies for maintaining lifestyle changes(132).	The provider utilizes behavior change theory and techniques.

* Settings such as workplaces, leisure, community and faith centres and outpatient departments and clinics

**in the NHS, private, voluntary and community organisation

The programme is commissioned and funded by NHS England and is delivered nationally by framework providers who are selected through a national commercial procurement process conducted every four years (120, 123). The programme can be delivered by both primary care providers (e.g. community pharmacy and general practices) and non-healthcare providers (e.g. voluntary or private sector organisations) (124). The national procurement consists of a framework agreement that sets the cost of delivering DPP against national specification. NHS England work with Clinical Commissioning Groups (CCGs) to organise tender processes to procure the services to deliver locally specific DPPs.

NHS DPP providers receive staged payments based on the number of participants who complete defined milestones of the course. Thus, a key objective of the payment mechanism is incentivisation of providers to retain participants on the programme and to encourage completion. The milestones which determine the completion of a stage and relative payment include programme registration, attendance to initial face to face meeting and attendance to 25%, 50%, 75% and 100% of the planned course time. The implementation process began with a first wave of 27 areas in England in 2016 and achieved nationwide coverage in 2018. The programme was first delivered by private public health services providers including Reed Momenta, ICS Health and Wellbeing, Health Exchange CIC and Ingeus UK Limited (115).

1.8.1 Potential impact of implementing the NHS diabetes prevention programme

Systematic review evidence has shown lifestyle interventions to be a cost-effective strategy for the prevention of type 2 diabetes in individuals with NDH (49, 100, 125, 126). Furthermore, research evidence suggests screen and treat approaches to be cost-effective (127). However, there is a current lack of evidence demonstrating the impact of implementing nationwide screen and treat approaches such as the NHS DPP, particularly on long-term outcomes such as mortality, morbidity and cost on healthcare systems.

In 2016, an impact analysis performed to estimate the implications of implementing the NHS DPP on NHS resources and health outcomes formed the evidence base for implementing the programme (128). Suggesting lifestyle-change programmes to be cost-effective, the analysis estimated that the NHS DPP would achieve a net saving of £35 million over 20 years and cumulative direct health benefits of 18,000 Quality Adjusted Life Years relative to doing nothing. The analysis also estimated that over 5 years (2016-2021) the programme would prevent or delay approximately 4,500 diabetes diagnoses for every 100,000 people enrolled.

The impact analysis was based on assumptions of uptake and participant retention which are the central drivers of success of the NHS DPP. However, due to lack of available data, uncertainty in the likely uptake and retention rates in the NHS DPP remains a key risk in implementing the intervention nationally and a limitation in modelling its likely impact. Research evidence also suggests that the impact of DPPs could be undermined by poor engagement amongst people with NDH (78). Evidence from a meta-analysis has highlighted high withdrawal and attrition rates in DPP clinical trials, with only 27% of the identified population with NDH completing the intervention (78). Primary reasons for attrition identified by the meta-analysis were declining or withdrawal from the intervention and not being eligible for participation. Similar findings were also identified in a study evaluating an existing community-based DPP in England (129, 130). The study demonstrated low uptake (23% of the targeted population) following initial invitation letters mailed from 17 general practices which further decreased to 10% just before randomisation.

Qualitative research evidence investigating participation in DPPs or similar programmes has identified common barriers for uptake. Laws *et al*. who explored factors influencing participation in a practice based vascular disease prevention programme highlighted accessibility barriers such as transportation and geographical location (131). In addition, they highlighted challenges in organising group-based sessions suitable for most of the participants and identified the need for flexibility, including delivering nighttime, weekend or individual sessions and

offering telephone-based follow-up (131). Kullgren *et al*. who examined engagement of people identified with NDH through work-based screening identified primary reasons for not engaging as work and social commitments and accessibility of exercise facilities (132). Similar social barriers were also highlighted by a qualitative study conducted by Penn *et al.* which aimed to understand the experience of participants who maintained behaviour change following lifestyle interventions (133).

Both programme uptake and retention are therefore key determinants of the projected impact of the NHS DPP. A progress report on the NHS DPP has indicated that of those referred onto the programme, 49% attend the initial assessment meeting (128). Additionally, reports indicate that between 36% and 55% of people referred into the NHS DPP decline the intervention and between 26% and 50%, do not progress onto the group-based sessions (124). Qualitative research evidence highlights important barriers and facilitators that would need to be addressed by the current NHS DPP to ensure intervention uptake and retention. However, there is currently no published evidence investigating the barriers to uptake in the NHS DPP. Neither is there research investigating impact of delivering the programmes in alternative settings to increase uptake.

1.9 Exploring community pharmacy as a potential setting for delivering Diabetes Prevention Programmes

Systematic review evidence, exploring the implementation of DPPs in real world settings, has highlighted primary healthcare and community settings to have the greatest reach to people with NDH (103, 105). Furthermore, evidence suggests established participant/provider relationships and opportunities for the management of co-morbidities to play an important role in engaging with targeted populations in primary care settings (105). Globally, primary healthcare settings such as community pharmacy have been identified as suitable for delivering health promotional and disease prevention services (134). Community pharmacy's offering

convenient locations, extended opening hours (135) and the availability of a private consultation room, present an opportunity to support behaviour change interventions such as the NHS DPP by directly addressing some of the barriers to DPP uptake (135, 136). Additionally, potential facilitators to engagement with DPPs such as face to face interaction with professionals (3, 20) and continuity of providers (11, 21) are highly applicable to community pharmacy.

1.9.1 The community pharmacy setting

Over recent years, the traditional dispensing role of community pharmacists has developed towards the delivery of public health services such as diabetes screening, smoking cessation and weight reduction programmes (135-138). This is primarily due to the accessibility of community pharmacies (139). In England, there are over 11,688 community pharmacies which are estimated to provide health-related services to approximately 1.2 million visitors every day (139, 140). As the most visited NHS care setting in England, approximately 90% of the population has access to a community pharmacy within a 20-minute walk (141).

Accessibility of community pharmacies increases to over 99% in highly deprived populations including lower socioeconomic groups and ethnic minority groups (141). In these populations, obesity, the greatest modifiable risk factor of type 2 diabetes, has been shown to have the highest prevalence (19, 142). Evidence shows that general practices, the current primary route of identification of NDH, have a low uptake of diabetes screening services in highly deprived populations (32, 142). Therefore, with evidence demonstrating a higher accessibility in deprived areas than general practices, the community pharmacy is a potentially valuable setting for tackling existing health inequalities (114, 140, 143).

1.9.2 Community pharmacy personnel

Evidence suggests that DPPs can be successfully delivered by both healthcare and non-healthcare personnel (109). As the third largest healthcare profession in

England, the pharmacy workforce consisting of registered pharmacists, registered pharmacy technicians, non-registered dispensing and healthcare assistants, has potential capacity to deliver DPPs (144). Additionally, the proposed introduction of dispensing hubs and the widening of technicians' wider role on the national agenda, further serves in increasing potential capacity for the involvement of community pharmacy in delivering public health interventions.

The increased representativeness of the community pharmacy personnel to local communities also has potential to address current health inequalities. Research investigating uptake of DPPs in different ethnic backgrounds such as South Asians (145), Hispanic (146), Black Africans (147) and Bangladeshi (148) has highlighted language (145, 146, 148), social roles (145, 148) and poor cultural and religious understanding of healthcare professionals (135, 148, 149) as barriers to uptake. NICE recommends the use of local staff in delivering DPPs to overcome contextual factors such as language and other personal factors such as ethnicity, faith, culture or any disability. Community pharmacy personnel, who often tend to reflect local populations with respect to ethnicity, culture and language, could therefore play an important role in engaging hard to reach groups and thus maximize the impact of the NHS DPP (149).

1.9.3 Evidence for community pharmacy-based diabetes prevention programmes

Systematic review evidence suggests community pharmacy to be a potential setting for delivering public health interventions (150). However, despite such recommendations, there is a lack of evidence exploring the delivery of DPPs in the community pharmacy setting. Most studies investigating the role of community pharmacy in diabetes prevention have focused on diabetes screening rather than screen and treat interventions such as DPPs. For example, a study conducted by Ayoride *et al.* suggested diabetes screening interventions which include an element of education to be feasible and acceptable for delivery in community pharmacy (151). However, the study indicated that referrals made following screening in this setting to have a poor attendance rate. Similar findings were also highlighted by a

meta-analysis by Willis *et al.* which aimed to evaluate existing literature on community pharmacy-based screening interventions for type 2 diabetes and CVD (152). Whilst indicating such interventions to be feasible in the community pharmacy setting, the review highlighted that in those identified as being at high risk and referred to other services, a significant proportion do not attend follow-up appointment with their general practitioners (GPs). This evidence suggests that whilst uptake to screening may not be a problem in this setting, there is a need for research to focus on developing interventions that encourage attendance to early intervention.

The implementation of the DPP in community pharmacy has been investigated by Dhippayom *et al. (153)*. The study was conducted in pharmacies in Thailand and used a validated risk assessment tool and a follow-up FPG Point of Care Test (POCT) to identify people with NDH. For those identified as high risk, the intervention included a lifestyle education intervention based on guideline recommendations. The education intervention was delivered by pharmacists through leaflets and face to face consultations and consisted of information about lifestyle modification regarding diet, exercise and weight reduction.

The study identified potential diabetes and NDH in 12.7% and 28.4% (respectively) of all participants that were screened. The study also indicated poor attendance rates to referred services in those who had potential diabetes and suggested inconvenience as the primary reason for non-attendance. However, although the study suggested successful delivery of an education intervention in those identified with NDH, the one-off intervention does not mirror the ongoing lifestyle interventions provided in the NHS DPPs. There is, therefore, a need to explore the delivery of ongoing lifestyle interventions in the community pharmacy setting.

1.9.4 Guidelines for the management of non-diabetic hyperglycemia in community pharmacy

Public Health England has recognised the potential significant and sustainable impact that community pharmacy could make in reducing the risk of disease including diabetes (144). A potential key role of community pharmacy in delivering effective and impactful preventative interventions, supporting healthy living and reducing health inequalities has also been highlighted (154). NICE recommends the delivery of intensive lifestyle programs by primary health care teams which includes community pharmacies (32). The guidelines recommend community pharmacy teams to offer individual behavioral support for people with NDH in weight management by offering lifestyle interventions or referral to other behavioral support services where lifestyle interventions are not available in the pharmacy. However, despite NICE recommendations for the role of community pharmacy, routine primary care appointments or retrospective screening of general practice databases remains the primary route for identifying people with NDH (40, 120, 155).

In England, the only current involvement of community pharmacy in diabetes prevention is the delivery of screening programmes, such as the NHS Health Check (135, 137). The NHS Health Check is a nationwide risk assessment, awareness and management programme, offered free of charge to eligible adults aged between 40 to 74 years (156). Whilst the programme primarily aims to establish the risk of developing CVD, it also incorporates a diabetes filter whereby individuals at high CVD risk are offered diabetes FPG POCT (157). All individuals accessing the programme receive one-off tailored lifestyle advice from trained community pharmacy personnel and if identified as high risk, are referred to their GP for further testing.

The programme is primarily delivered in general practice and community pharmacy settings but can also be offered in other accessible settings such as workplaces and other community settings. Evidence evaluating the NHS Health Check has shown that community pharmacies successfully reach the targeted population, with higher referral rates to lifestyle services than those referred through other means (137, 158). However, although the programme can identify people with NDH, it is

currently not modified to enable direct referrals to the NHS DPP. Firstly, the programme does not offer venous blood tests (FPG and HbA_{1c}) which are required for referral onto the NHS DPP and secondly, it is only eligible to people age 40-74 with no existing cardiovascular risk, hence potentially excludes many people with NDH. The limitations to the use of the NHS Health Check as a referral pathway has therefore eliminated referrals from a potentially accessible setting (32, 135).

Therefore, despite the growing recognition that public health interventions delivered in community pharmacy should be integrated in a local primary care and public health network (144, 159), current pharmacy services do not offer pathways to current services interventions. Furthermore, at present there are no routine lifestyle interventions being delivered in the community pharmacy setting for people with NDH. In other countries such as the USA, where a large-scale implementation of a national DPP began in 2010, recommendations for further expansion have resulted in the development of clear guidance outlining the delivery of DPPs in accessible settings such as community pharmacy (160). In England, however, there are no clear guidelines for how community pharmacists could deliver lifestyle interventions for this population.

1.10 Summary

Evidence demonstrates a potential to delay or prevent the development of type 2 diabetes in people with NDH through DPPs (100). The current preferred method for identifying NDH is a two-step screening approach involving the use of validated risk assessment tools followed by confirmatory blood tests (32). National guidance recommends the delivery of intensive lifestyle interventions in those identified with NDH to delay or prevent the incidence of type 2 diabetes (32, 100). The impact and scalability of lifestyle interventions is largely determined by the reach of the programmes (105).

In England, the NHS DPP has been implemented to delay and prevent the incidence of diabetes in NDH. However, uncertainties in potential uptake and retention in the targeted population could negatively affect the projected impact of the programme. Qualitative research has highlighted accessibility as an important barrier to uptake in DPPs. With the primary care setting demonstrating the greatest diversity, NICE recommends the delivery of intensive lifestyle interventions in settings such as the community pharmacy (32). However, although evidence investigating the implementation of DPPs in community pharmacy settings has demonstrated screening interventions to be feasible, there is a need to investigate the delivery of follow-up lifestyle interventions or referral routes in this setting (152, 153, 161, 162). As such the research question for this thesis is: ***What is the role of community pharmacy in providing DPPs in England?***

1.10.1 Research aims

This thesis aims to characterise the current and potential role of community pharmacy in the prevention of type 2 diabetes and to explore community pharmacy as an option for the delivery of diabetes prevention services (DPS) in England.
*[In this thesis, the term DPS will be adopted to refer to potential diabetes prevention interventions that could be delivered in the community pharmacy setting. This term, rather than DPP, has been adopted since the role of community pharmacy in diabetes prevention in England is currently unclear]**.***

1.10.2 Research objectives

1. To identify the potential role of community pharmacy in delivering diabetes prevention services for people with non-diabetic hyperglycemia.
2. To describe acceptable intervention characteristics for people identified with NDH.
3. To identify the barriers and facilitators to implementing community pharmacy-based diabetes prevention services in primary care.

Chapter 2: The application of theory in exploring the role of community pharmacy in diabetes prevention

2.1 Introduction

The delivery of public health interventions such as DPPs usually require behaviour change at many levels (e.g. individual, organisational and societal) (163, 164). Behaviours may be those of healthcare personnel e.g. pharmacy technicians, or of the general population e.g. people with NDH, or of organisations such as CCGs. The development and implementation of effective interventions therefore require a clear contextual understanding of the problem being addressed, the behaviours driving the unwanted outcome and the processes that may usher in the desired outcome (165-168). For example, successful engagement with diabetes prevention interventions would require an understanding of the determinants of engagement and non-engagement in people with NDH. This information would in turn assist in identifying appropriate behaviour change interventions that would drive engagement. Similarly, the delivery of DPS by community pharmacy teams would require a thorough understanding of processes that would facilitate intervention delivery in this setting in order to implement behaviour change interventions that would enable the provision of these services.

Evidence suggests behaviour change interventions based on theory to be more effective than those that are not (169, 170). Theory not only guides the systematic understanding of targeted behaviours i.e. the problem being addressed, but also assists the development and implementation of effective interventions to influence and change behaviours (166-168, 171). Theory can be developed from existing literature and stakeholder perspectives (e.g. potential patients who may use the intervention and practitioners who may deliver the intervention) (172). Relevant existing psychological and social theories can also be used to develop theory led questions that need to be answered when conducting primary research such as interviews and focus groups with key stakeholders (78, 173). This research employed the use of existing literature, stakeholder perspectives and an existing psychological theory to thoroughly investigate the potential role of community pharmacy in diabetes prevention.

This chapter describes how theory has been applied to enhance the description of the role of community pharmacy in diabetes prevention, following the initial literature search (chapter 1). This process is outlined in two stages including:

1. Selecting a relevant theoretical framework
2. Application of the selected theory to current research

2.2. Selecting a relevant theoretical framework

Theory presents a systematic way of understanding behaviours. A theory can be defined as 'a set of interrelated concepts, definitions, and propositions that explain or predict events or situations by illustrating relationships between variables (174). By nature, theories are abstract without a pre-specified topic and only become useful when applied to practical topics and problems. Theories are made of constructs (key concepts of a given theory) and variables (the operational form of the constructs usually defining the measurement of a construct in a particular situation) (175). A number of theories may also be merged to assist the understanding a particular problem in a specified setting or context. These are known as frameworks (175).

Generally, there are two broad types of behavioural theory, explanatory theory and change theory (165). Explanatory theories largely seek to understand behaviour, often describing why a problem exists and identifying factors that contribute to a problem e.g. lack of knowledge or resources. Examples of explanatory theories include the Health Belief Model and the Theory of Planned Behaviour (176). Change theories guide the selection of behaviour change intervention(s) by identifying concepts that can be translated into intervention strategies and providing clarifications of why interventions are likely to be effective (165). Examples of such theories include the Diffusion of Innovations theory (177). Whilst these types of theories (explanatory and change) may have different emphases, they are often complementary and sometimes incorporated in one model (178).

Over the years, there has been a growing interest in the use of theories in health services research to understand behaviours and inform intervention design and implementation (179, 180). However, evidence shows significant variations in the application of theory in implementation research (181). These variations, which primarily occur due to the challenges with selecting appropriate theories and their practical application are discussed below:

- **Numerous existing theoretical models with little consensus**

  There are a large number of existing theoretical models (182), with most focusing on particular constructs (167). A 2015 scoping review by Davis *et al*. identified 82 behaviour change theories in the social sciences alone (183). Over the years several reviews have highlighted a lack of consensus between theories with similar constructs particularly with regards to the terminology used (184-187). Additionally, because most theories do not cover the full range of possible constructs, even with the combination of one or two theories there is a risk of excluding potentially important variables (188). For example, the Theory of Planned Behaviour and Health Belief Model, the two most commonly used theories in public health, between them do not address the important influences such as habit, self-control and emotional processing (189).

  To overcome these problems, psychologists have proposed integrative frameworks of theory that combine concepts and constructs from several existing theories and are subjected to rigorous testing across behaviors and situations and refined as necessary (190, 191). Frameworks, which incorporate a wide range of theories, allow researchers to capture and evaluate more behaviour determinants than they would with one theory alone. The Behavior Change Wheel and the Theoretical Domains Frameworks are examples of such integrated frameworks (188, 192). These frameworks will be discussed in more detail later in this chapter.

- **Lack of analysis to guide the choice of theories**

Research suggests that the potential effectiveness of evidence-based interventions increase with the number of theories used (170). However, due to the abundance of behaviour theories, researchers and intervention developers often face challenges with selecting the most appropriate theories. Additionally, whilst most existing theories used in health services intervention development are from a social science or psychological background, intervention developers often consist of researchers and healthcare personnel with no background in psychology or social science (193). This has, over the years, led to very little use of theory in intervention development, consequently leading to failed interventions (188). The few studies that have used theories, have shown no clear rationale for theory use and selection of constructs (168, 181). The lack of specification on how to select and apply appropriate theory poses challenges for intervention designers who are often non-psychologists (193).

What follows is a discussion of some of the most common theories used in the design and implementation of public health interventions. These common theories are: The Health Belief Model, The Theory of Planned Behaviour, The Stages of Change (Transtheoretical Model) and the Diffusion of Innovation theory. Newer frameworks that have been developed and adapted to resolve the challenges outlined above such as the Theoretical Domains Framework (171) and the Behaviour Change Wheel (188, 192) will also be discussed.

2.2.1 The Health Belief Model

The Health Belief Model (HBM), one of the first theories of health behaviour, was developed in the early 1950s by social scientists at the U.S. Public Health Service to help understand why people did or did not use preventative services offered by public health departments (165, 175). The HBM, derived from psychological and behavioural theory, suggests that components of health-related behaviour are a combination of 1) the desire to avoid illness and 2) the belief that a specific health action will prevent or cure illness. The model addresses an individual's perceptions of the threat/risk posed by a health problem (susceptibility, severity), the benefits

of avoiding the threat and factors influencing the decision to act (barriers, cues to action, and self-efficacy). There are six core constructs of the HBM:

1. **Perceived susceptibility:** Individual's subjective perception of the risk of acquiring an illness or disease.
2. **Perceived severity:** Individual's beliefs towards the seriousness of contracting an illness and disease as well as its consequences.
3. **Perceived benefits:** A person's perception of the effectiveness of advised actions to reduce risk or seriousness of impact.
4. **Perceived barriers:** A person's feeling on the obstacles to performing a recommended health action.
5. **Cues to action:** This is the stimulus needed to trigger the decision-making process to accept a recommended health action.
6. **Self-efficacy:** The level of a person's confidence in his or her ability to successfully perform a behaviour. This construct was added to the model recently in the mid-1980s and is a construct in many behavioural theories as it directly related to whether a person preforms a desired behaviour.

The HBM, which is explanatory and targeted at the individual level, has mostly been applied for health concerns that are prevention related and asymptomatic, such as early cancer detection and hypertension screening (194). Therefore, this model could be used in the present research to explain why some people at high risk of T2D engage and others do not engage with DPPs. However, there are several limitations to its use that could hinder its application in the present study. Firstly, the HBM does not take into account other individual determinants that could influence a person's acceptance of a behaviour such as attitudes or beliefs which have been shown to be important in determining the intent to perform a behaviour (195). This is an important factor for this research since in health concerns that are prevention related, an individual's beliefs could be as important or more important than overt symptoms. Secondly, because the HBM is also more explanatory, it does not suggest a strategy for change (165). Therefore, whilst the individual constructs may be useful for this research, the model would need to be integrated with other

models that account for environmental contexts and suggest strategies for change. Thirdly, because the HBM does not account for other behaviours that are performed for non-health related reasons (e.g. exercising for aesthetic reasons), it does not consider other influences such as social acceptability, environmental or economic factors that may prohibit or promote the recommended action. This therefore limits its use in the present study that is primarily exploring the potential role of community pharmacy in delivering diabetes prevention services in primary care.

2.2.2 Theory of Planned Behaviour

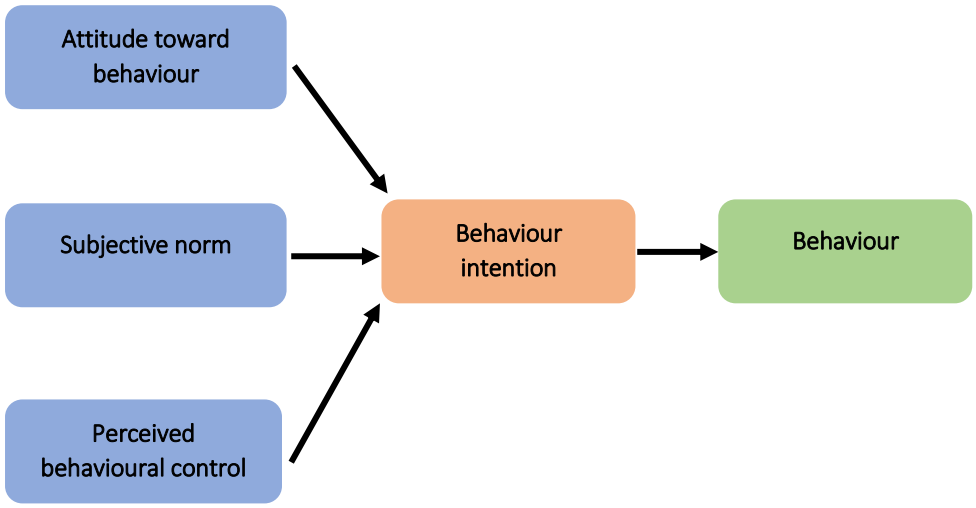
The Theory of Planned Behaviour (TPB), developed in the 1980s by Icek Ajzen, suggests that behavioural intention determines behaviour performance (196, 197). Intention is therefore the key component of the model and is defined *"as the cognitive representation of the person's readiness to perform a certain behaviour"* (198). The theory suggests that intention captures motivational factors that influence a behaviour and thus is an indication of the extent to which one is willing to try and the amount of effort one is prepared to exert to perform the behaviour.

The TPB initially started as the theory of reasoned action to predict an individual's intention to engage in a behaviour at a specific time and place journal of clinical epidemiology (199). The theory was developed to explain all behaviours over which people have the ability to exert self-control i.e. voluntary behaviour and was largely related to attitudes towards the behaviour. However, further research revealed that behaviour appeared not to be entirely voluntary and under one's control resulting in the addition of perceived behavioural control. With this addition the theory was changed to the Theory of Planned Behaviour (See Figure 2.1). The theory therefore has three main constructs that determine an intention towards performing a behaviour:

- **Attitude towards the behaviour:** the degree to which a person has a favourable or unfavourable evaluation of the behaviour of interest.

- **Subjective norms:** the belief about whether most people (peers or people of importance to the person) approve or disapprove of the behaviour. This also includes a consideration of social norms i.e. accepted behaviour that an individual is expected to conform to in a particular group, community or culture.
- **Perceived behavioural control:** an individual's perception/beliefs of the ease or difficulty of performing the behaviour of interest.

Figure 2.1 Theory of planned behaviour



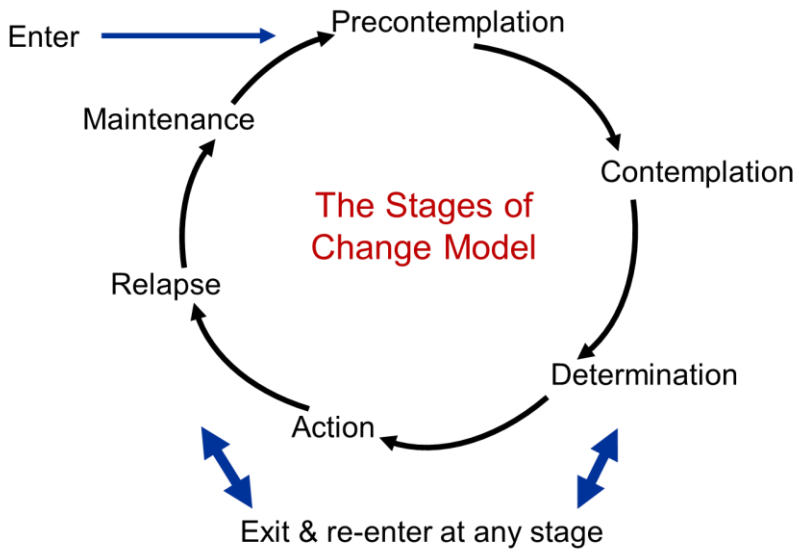
The TPB has been used to predict deliberate behaviour and explain a wide range of health behaviours and intentions including health service utilisation (200, 201). Although the TPB has shown greater applicability in public health than the HBM, its inability to consider environmental and economic influences has also limited its use (195). Its assumption that individuals have acquired the opportunities and resources to be successful in performing the desired behaviour regardless of the intention would therefore also limit its application in this research (195). Additionally, because the model also does not take into account other variables that factor into behavioural intention and motivation such as fear, threat, mood

and past experience, its use to explore engagement with diabetes prevention programmes would also be limited (195, 198). Like the HBM, the TPB is mostly explanatory and does not offer interventions to address behaviour. Therefore, although the constructs of this model are useful, it still needs to be integrated with components from other theories to make it a more functional model for this research.

2.2.3 Stages of Change (Trans-Theoretical) model

The Trans-Theoretical model (TTM) was developed by Prochaska and DiClemente and emerged out of studies comparing experiences of smokers who quit on their own with those of smokers receiving professional support (178). The model is based on three assumptions 1) behaviour change is a process that unfolds over time and involves a series of different stages 2) there are common stages and processes of change across a variety of health behaviours 3) tailoring an intervention to the individual's current stage of change is more effective than not evaluating readiness at all. Stages of change therefore forms the main construct of the model and proposes that people are at different stages of readiness to adopt behaviour change (see Figure 2.2). While the time a person can stay in each stage is variable, the tasks required to move to the next stage are not. Certain principles and processes of change work best at each stage to reduce resistance, facilitate progress, and prevent relapse. Those principles make up the three other constructs of the TTM i.e. decisional balance, self-efficacy, and processes of change.

Figure 2.2 Stages of change



Source: Boston University, School of Public Health.

Decisional balance: This construct has two elements, the pros and the cons. As individuals progress through the Stages of Change, decisional balance shifts in critical ways e.g. when an individual is in the pre-contemplation stage, the pros in favour of behaviour change are outweighed by the relative cons for change and in favour of maintaining the existing behaviour.

Self-efficacy: This construct reflects the degree of confidence individuals have in maintaining their desired behaviour change in situations that often trigger relapse. It is measured by the degree to which individuals feel tempted to return to their problem behaviour in high-risk situations e.g. in the pre-contemplation and contemplation stages, temptation to engage in the problem behaviour is far greater than self-efficacy to abstain.

Process of change: While the stages of change are useful in explaining when changes in cognition, emotion, and behaviour take place, the processes of change

help to explain how those changes occur. This construct consists of ten covert and overt processes that need to be implemented to successfully progress through the stages of change and attain the desired behaviour change. These processes result in strategies that help people make and maintain change. The stages of change and the potential strategies suggested by the process of change construct are presented in Table 2.1.

Table 2.1 Stages of Change model

Stage	Definition	Processes of change	Potential Change Strategies
Pre-contemplation	No intention of taking action within the next six months	Consciousness raising - increasing awareness about the healthy behaviour.	Increase awareness of need for change; personalise information about risks and benefits
Contemplation	Intends to take action in the next six months	Dramatic relief – emotional arousal about the health behaviour, whether positive or negative arousal. Self-re-evaluation - self reappraisal to realise the healthy behaviour is part of who they want to be. Environmental re-evaluation - social reappraisal to realise how their unhealthy behaviour affects others.	Motivate; encourage making specific plans
Preparation	Intends to take action within next 30 days and has taken some behavioural steps in this direction	Self-liberation - commitment to change behaviour based on the belief that achievement of the healthy behaviour is possible.	Assist with developing and implementing concrete action plans; help set gradual goals
Action	Has changed behaviour for less than six months	Social liberation - environmental opportunities that exist to show society is supportive of the healthy behaviour. Helping relationships - finding supportive relationships that encourage the desired change. Counter-conditioning - substituting healthy behaviours and thoughts for unhealthy behaviours and thoughts. Reinforcement management - rewarding the positive behaviour and reducing the rewards that come from negative behaviour.	Assist with feedback, problem solving, social support and reinforcement
Maintenance	Has changed behaviour for more than six months	Stimulus control - re-engineering the environment to have reminders and cues that support and encourage the healthy behaviour and remove those that encourage the unhealthy behaviour.	Assist with coping, reminders, finding alternatives, avoiding slips/relapses

The stages of change model has been applied in both individual behaviours such as the development of smoking cessation interventions (202) and organisational change such as informing practitioners' discussions with individual patients about engaging with screening tests (203). The key benefit of this model is that it provides suggested strategies for public health interventions to address people at various stages of the decision-making process. This can result in tailored interventions. In addressing our research problems, however, although this model could be used to assess the readiness of people at high risk of T2D to engage with diabetes prevention services, its lack of consideration for the social context in which change occurs may limit its application when considering the delivery of diabetes prevention services by community pharmacy teams. Overall, the theory is more targeted at individuals thus may not be very useful when considering organisational change in the community pharmacy or primary care.

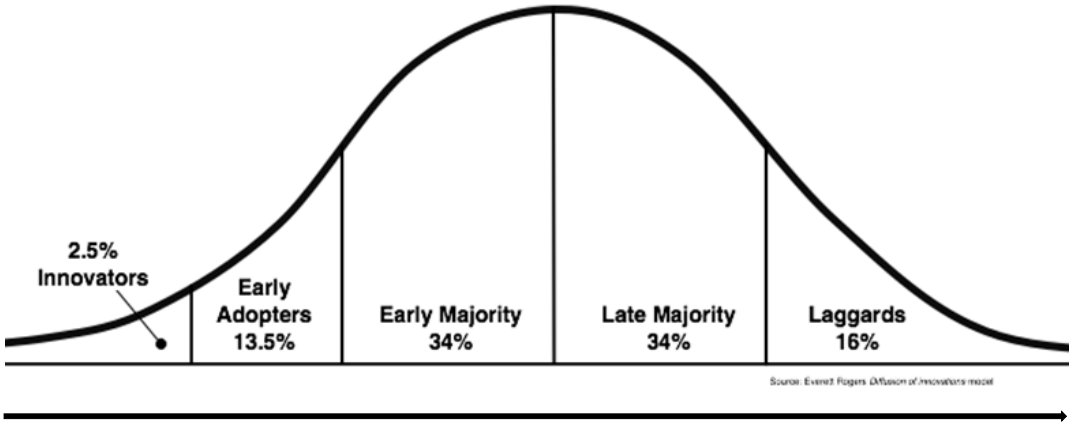
2.2.4 Diffusion of Innovation Theory

Diffusion of Innovation Theory (DOI) is a social science theory, developed by E.M. Rogers in 1962, to explain how an idea, product or behaviour gains momentum and diffuses (or spreads) through a specific population or social system over time (204). The theory has two concepts:

1. The outcome of the diffusion is that people adopt the new idea, behaviour or product with the key to adoption being a perception that it is new and innovative.
2. Due to people having different characteristics, adoption of the innovation does not happen simultaneously, rather that some people are more likely to embrace the innovation earlier than others (177).

The theory therefore stresses the importance of understanding the characteristics of the target population that will help or hinder adoption of the innovation when promoting it to the population. The theory therefore has five established adopter categories (see Figure 2.3), including suggested strategies to use to make the interventions appeal to them:

Figure 2.3 Diffusion of Innovation theory - adopter categories



Source: http://blog.leanmonitor.com/early-adopters-allies-launching-product/

1. **Innovators:** These people are venturesome, risk takers and take interest in new ideas. Because these people are likely to be ones that want to be the first to use try the innovation, very little needs to be done to appeal to them.
2. **Early adopters:** These are leaders whose awareness of the need for change makes them very comfortable adopting new ideas. Strategies that appeal to this population include how-to manuals and information sheets on implementation.
3. **Early Majority:** These are people who adopt new ideas before the average person but need some convincing to adopt a new idea. Strategies to appeal to this population include success stories and evidence of the innovation's effectiveness.
4. **Late majority:** These are sceptical of change and will only adopt an innovation after it has been tried by the majority. Strategies that appeal to

this population include information on how many other people have tried the innovation and have adopted it successfully.

5. **Laggards:** This constitutes the hardest group to bring on board due to their sceptical and conservative nature. Strategies that appeal to this population include statistics, fear appeals and pressure from people in other adopter groups.

The theory also has five main factors that influence adoption of an innovation and each of these factors is at play to a different extent in the five adopter categories:

1. **Relative advantage:** the degree to which an innovation is seen as better than the idea, programme or product it replaces
2. **Compatibility:** how consistent the innovation is with the values, experiences and needs of the potential adopters
3. **Complexity:** how difficult the innovation is to understand and/or use
4. **Triability:** the extent to which the innovation can be tested or experimented with before a commitment to adopt is made
5. **Observability:** the extent to which the innovation provides tangible results

The theory has been applied in various fields including communication and public health. Its application in public health including diabetes prevention emphasises that the most successful adoption of public health programmes result from understanding the target population and the factors influencing their rate of adoption (205). However, certain limitations to its use in public health that have been highlighted by research include concerns that the theory, including the adopter categories, do not have origins in public health and therefore were not developed explicitly to apply to adoption of new behaviours or health innovations (195). Additionally, because the theory works better with adoption of behaviours, its use in cessation or prevention of behaviours would likely be limited (195). Like most other theories the DOI also does not take into account individuals' resources or social support to adopt the new behaviour.

2.2.5 Integrated frameworks (The Theoretical Domains Framework and the Behaviour Change Wheel)

Newer theoretical models and frameworks have sought to overcome challenges in theory selection and application outlined earlier in this chapter. The development of the frameworks considered recommendations from leading psychological theorists suggesting the simplification of existing behaviour change theories and models in order to achieve consensus on behavioural constructs. Their development also particularly focused on increasing the ease of use of theory in the implementation of evidence-based practice which is often carried out by healthcare professionals and researchers with no psychology background. The Theoretical Domains Framework (193) and the Behaviour Change Wheel (188, 192) are two such frameworks that have been recently developed for this purpose.

2.2.5.1 The Theoretical Domains Framework (TDF)

The Theoretical Domains Framework (TDF), developed in 2005, is an integrative framework of theories of behaviour change which was developed through a consensus approach by a team of psychological theorists in collaboration with health services researchers and health psychologists (193, 206). The TDF was developed to address two main problems faced in the implementation of evidence-based practice:

1. The large number of possible theories and theoretical constructs developed within the social and behaviour sciences which often led to critical theories being missed.
2. The lack of a clear rationale for selecting theories and the suboptimal application of theory in implementation research.

Based on a recognition that research in the implementation of evidence-based practice is often applied by non-psychologists, the development of the TDF aimed to simplify and integrate the profusion of behaviour change theories and make theory more accessible to and usable by other disciplines. The TDF is therefore an

integration of 33 theories and 128 key constructs related to behaviour change which were identified in literature and synthesised into a single framework to assess implementation and other behavioural problems to inform intervention design (193, 206). The development process employed a six-stage consensus approach:

1. Identification of theories and theoretical constructs (a theoretical construct was defined as a concept specially devised to be part of a theory)
2. Simplification of constructs into overarching theoretical domains (a domain was defined as a group of related theoretical constructs)
3. Evaluation of the importance of the theoretical domains
4. Interdisciplinary evaluation and synthesis of the domains and constructs
5. Validation of the domains list by health psychologists
6. Piloting interview questions relevant to the constructs and domains with health services researchers

The resulting framework consisted of 12 domains, each with exemplar questions for use in interviews or focus groups to assist comprehensive theoretical assessments of implementation problems (193). Since the development of the framework, its use and development has been documented to advance the science and implementation research. In 2012, the TDF was revised and validated (191). This revision examined the frameworks' content validity and sought to confirm optimal domain structure (number of domains), content (component constructs in each domain) and labels (most appropriate names that best reflected the content of the validated domain structure). This exercise supported the refinement of the framework which resulted in 84 theoretical constructs sorted into 14 domains (191). Since its development, the TDF has been applied by research teams across several healthcare systems and in various countries including the UK to explain implementation problems and inform interventions aimed at behaviour change (191, 207, 208). The framework has mostly been applied to facilitate the understanding of healthcare professional behaviours (209). For example, the TDF has been used to understand prescribing behaviours amongst trainee doctors in

order to identify effective interventions to reduce errors (210). The TDF has also been used in a study investigating healthcare provider behaviour in performing assessments for rehabilitation following a stroke (211). In the above study, qualitative findings from focus groups with health professionals were mapped to the domains of the TDF and identified key behavioural influences such as 'beliefs about consequences' identified that could be targeted for implementation of appropriate interventions (211).

The TDF has several advantages to its use including the consideration of both individual (e.g. beliefs and motivations) and social/environmental factors. Thus, making it a useful tool for identifying barriers and facilitators that could be addressed to positively improve implementation outcomes. The framework is also a useful evaluation tool for assessing the effectiveness of interventions aimed at behaviour change (212). However, whilst the TDF is a useful framework for identifying and describing factors that influence a behaviour, it does not explain the relationship between cause and effect about a behaviour in a given context. The domain 'Nature of the Behaviours', which was removed following refinement of the framework to strengthen coherence, leaves the framework with no domain primarily dedicated to understanding the nature of behaviour. This domain, originally designed to identify 'what needs to be changed' in order for the behaviour to be performed, was useful in the provision of guidance on the extent of variation in the desired behaviour. Therefore, the elimination of this domain in the TDF, excluded constructs related to habit and experiences/past behaviours that could be key understanding targeted behaviours.

The rationale for removing the domain was that analysing the nature of behaviour is a different task to analysing influences on behaviour. Additionally, evidence suggested that previous studies that had adopted the TDF framework seldom used the 'Nature of the Behaviours' domain, meaning that behaviour analysis was not made as a basis of intervention design (213). Therefore, in order to perform a behaviour analysis prior to designing interventions, it has been recommended that the TDF be used alongside the Behaviour Change Wheel (BCW) (188, 192), a

complementary theoretical framework which characterises the target behaviour in terms of Capability, Opportunity and Motivation. It is suggested using the BCW allows intervention developers to start with a behavioural analysis to facilitate the selection of important domains to focus on when designing interventions. An example of this application was in a study examining antibiotic prescribing in long-term care facilities, where data from interviews with healthcare professionals were analysed using the COM-B model which is at the hub of the BCW to facilitate the understanding of factors influencing prescribing patterns prior to TDF mapping (214).

Another challenge with using the TDF is its accessibility to, and usability by, other disciplines. Although the framework was designed for simplicity of use by healthcare professionals and researchers with no psychology background, evidence shows that even amongst experienced health professionals who received some training on the TDF, challenges regarding the comprehension and independence of the domains still remain (215). Qualitative findings from a study exploring the experiences of using the TDF, showed that although the framework had been applied by healthcare professionals across different settings and disciplines including pharmacy, considerable variations in reported understanding of the frameworks domains and a perceived overlap between the domains exists (215). The reported difficulties in domain and construct interpretation were viewed by the participants to be due to unfamiliarity with psychology constructs and complexity of the TDF language thus leaving participants with a perceived need for underpinning knowledge in psychology (215).

In this thesis, a great importance has been placed on understanding the nature of behaviours as a basis for designing interventions. This is because the study is largely exploratory, and thus needing contextual understanding of the problem and behaviours being investigated. Therefore, although the TDF could provide a list of factors that could potentially influence behaviour, it was not used in this research as it does not fully explore the nature of behaviour (212, 216).

2.2.5.2 The Behaviour Change Wheel

The Behaviour Change Wheel (BCW) is a more recent integrative framework developed in 2011 to increase accessibility of theories to researchers or intervention designers without a psychology background (188, 192). The development of the framework began with a systematic literature search of databases and consultation with behaviour change experts to identify behaviour change frameworks. The development then proceeded to evaluate the identified frameworks according to three criteria: comprehensiveness, coherence and a clear link to an overarching model of behaviour. Below are brief descriptions of the criteria:

a) **Comprehensiveness:** An assessment of the number of intervention options covered by the identified frameworks. For researchers or intervention designers to identify the types of interventions likely to be effective, theoretical frameworks should cover the full range of available options. Ideally, the framework should also possess a logical system of selecting the most appropriate intervention from the available options.

b) **Coherence:** An examination of whether categories or concepts in a framework were all similar in type and specificity. Ideally theoretical frameworks should not include categories that are very broad and others that are very specific.

c) **A clear link to an overarching model of behaviour:** An assessment of whether frameworks provided a process for linking the model of behaviour to categories and specific behaviour change mechanisms. Research shows that insufficient attention is often given to analysing the nature of behaviour as the starting point of behaviour change interventions (217). The selection of effective interventions is primarily dependent on a thorough diagnosis of the behaviour in question to determine behaviour influences that are likely to be fruitful targets. Additionally, it is also important to establish how the behaviour analysis appropriately links to the possible interventions.

Two examples of frameworks that were included in the evaluation were MINDSPACE (218) and the Cochrane Effective Practice and Organisation of Care Review Group (EPOC)'s 2010 taxonomy (219). An evaluation of MINDSPACE, a framework consisting of nine categories/influences on behaviour highlighted a lack of comprehensiveness where the framework did not encompass all intervention types (188). The evaluation also highlighted the categories of the framework (influences on behaviour) to be a mixture of types of delivery, prompts and characteristics of target populations. Hence this framework, although widely used was highlighted to lack comprehensiveness and coherence.

The second example, EPOC, is a framework comprising 4 categories of interventions (Professional, Financial, Organisational and Regulatory), with each covering many intervention types to change health professional behaviour (219). An analysis of interventions within each category however demonstrated that because the categories were broad, they consisted of a mixture of different types of interventions at different conceptual levels (188). For example, the ‘professional category’ includes both individual (distributing educational materials) and organisational interventions (local consensus processes) and the 'financial category' includes individual and organisational incentives and environmental restructuring (changing the available products). Hence this framework also lacked coherence.

Overall, the evaluation of existing frameworks identified from the literature search highlighted a lack of comprehensiveness and coherence. Additionally, the frameworks also lacked a clear link between the model of behaviour to the overarching framework thus failing to provide guidance on selecting the most appropriate interventions. The development of the behaviour change wheel (BCW) was therefore intended to address this gap by providing a framework that achieved coherence whilst providing a system for intervention developers to apply theory and evidence to designing and evaluating behaviour change interventions (188).

The BCW is a synthesis of 19 frameworks of behaviour change found in the literature and is composed of a behaviour system/model at the hub, encircled by

nine intervention functions and then by seven policy categories (Figure 2.4) (188, 192). The framework proposes that in order to choose interventions likely to be most effective, one should start with a model of behaviour to assess the circumstances in which different interventions are likely to be effective as a basis for intervention design. For example, when designing interventions to promote healthy eating, the model of behaviour could be used to assess and identify influences on healthy eating such as availability of healthy foods in order to propose intervention that are likely to be effective. Therefore, at the core of the BCW is a theoretical model of behaviour known as the COM-B which is used to conduct an analysis of the behaviour in question. The COM-B model is based on the hypothesis that the interaction between ones' capability (C), opportunity (O) and motivation (M) can provide explanations of why a behaviour (B) is or isn't being performed (Figure 2.5).

Figure 2.4 The behaviour change wheel

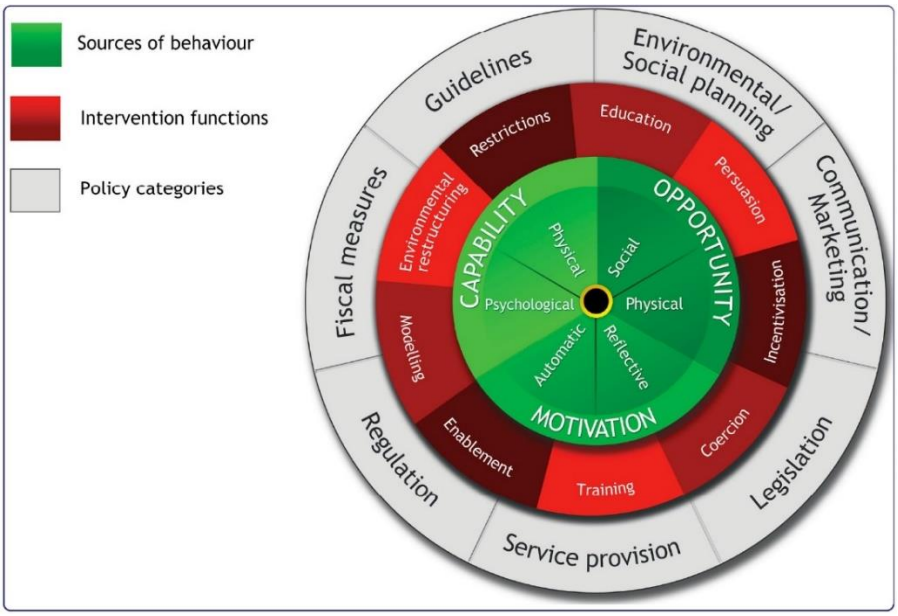
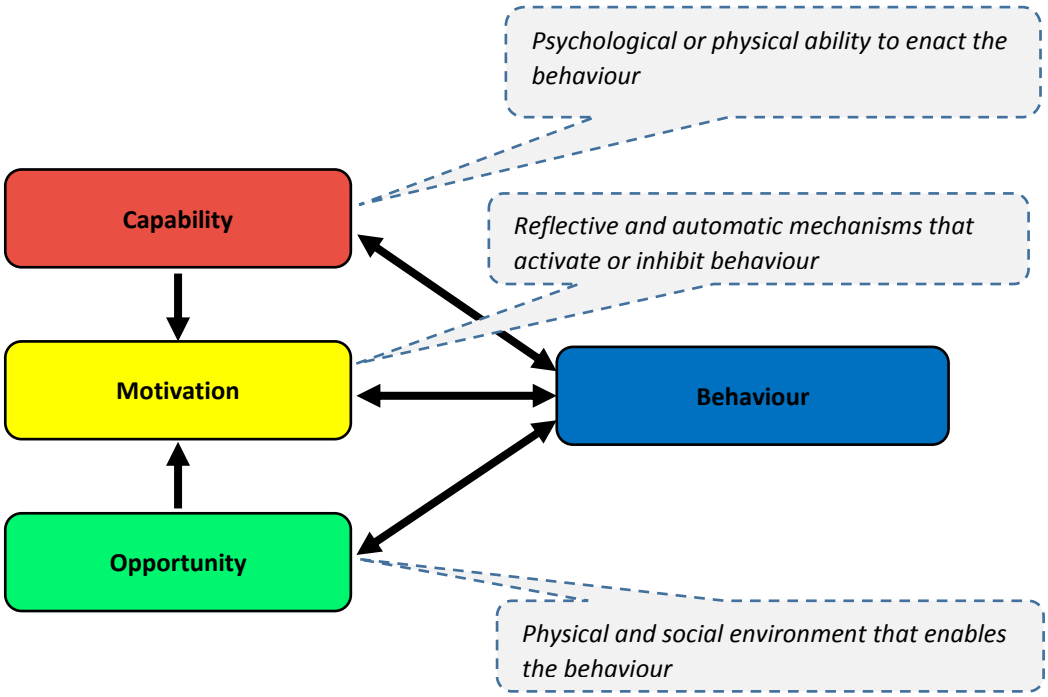


Figure 2.5 The COM-B theoretical model for behaviour change



Source: Michie et al. The Behaviour Change Wheel

The central principle of the model is that for any behaviour to occur there must be 'capability' to do it, there must be 'opportunity' for the behaviour to occur and there must be enough strong 'motivation' to perform it. These components are then divided to two types. Capability could be either physical (e.g. physical skills and strength) or psychological (e.g. knowledge). Opportunity can be physical (e.g. resources) or social (e.g. cultural norms). Motivation can be reflective (e.g. beliefs about what is good or bad) or automatic (e.g. processes involving wants or needs). The components also interact as illustrated in Figure 2.5. For example, increasing ones' capability and opportunity can increase motivation e.g. having a gym membership (opportunity) and knowing how to use a treadmill (capability) may increase motivation to use the gym. But motivation alone is not enough to use the gym if one cannot afford a gym membership and cannot use the equipment in the gym.

The theoretical analysis at the hub of the wheel therefore identifies sources of behaviour which could serve as fruitful targets for intervention. This analysis then guides the choice of intervention functions (or strategies) most likely to achieve behavioural change. The outer layer of the hub consists of nine broad intervention functions to choose from when targeting the identified behaviour targets (behaviour determinants or influences). Intervention functions are broad categories of means by which an intervention can change behaviour. These intervention functions, although largely broad can be used to select appropriate interventions as they are specifically linked to a taxonomy of 93 behaviour change techniques (188, 192, 220). The final outer shell of the wheel consists of policies that can be used to drive the selected intervention functions.

The BCW has been tested for reliability in two domains of behaviour change, tobacco control and obesity, where it was used reliably to characterise interventions within the Department of Health's 2010 tobacco control strategy (221) and NICE guidance on reducing obesity (222). These areas and documents were selected due to their importance in public health, their wide coverage of behaviour change approaches and the availability of evidence highlighting a lack of adherence to evidence-based guidelines by health professional behaviour (223-225).

This research adopted the use of the BCW to explore the role of community pharmacy in diabetes prevention. This framework was considered reliable for application in this research which is also addressing a public health concern. The BCW was selected due to its incorporation of both a system from which types of interventions likely to be effective can be identified (as it canvasses a comprehensive range of intervention options available) and a rational system for matching them to the behavioural target, the target population and the context in which the intervention will be delivered. The BCW was selected, rather than the TDF, due to its incorporation of a model to facilitate a formal behaviour analysis prior to intervention design (188, 192). Understanding engagement among people with T2D and barriers and facilitators for delivering interventions in a community

pharmacy setting was considered as central to describing the role of community pharmacy in diabetes prevention. Additionally, because the TDF was originally designed for healthcare professionals, it was felt that most of the constructs within its domains may not be wholly relevant when exploring engagement in people at high risk of developing T2D. Finally, considering the usability challenges of the TDF highlighted by research including the differences in comprehension and the perceived lack of independence of the domains, the framework was considered to have potential to pose challenges in exploring the multiple behaviours in this research (215).

2.3 The application of the Behaviour Change Wheel to current research

The following sections describe the application of the BCW to the present research which is exploring the role of the community pharmacy in diabetes prevention. This application followed the guidance provided by Michie *et al*. in the book entitled *'The Behaviour Change Wheel – a guide to designing interventions*' (192). In this guidance Michie describes three stages: 1) understanding the behaviour; 2) identifying behaviour options; and 3) identifying implementation options, which cover eight steps in designing interventions (see Table 2.2).

Table 2.2 Eight steps to designing behaviour change interventions using the Behaviour Change Wheel

Stage	BCW steps	Key questions being addressed
1. Understanding the behaviour	1.Defining the problem in behaviour terms 2.Selecting the target behaviour 3.Specifying the target behaviour 4.Identifying what needs to change	What is the problem you are trying to solve? What behaviour are you trying to change and in what way? What will it take to bring about the desired behaviour change?
2. Identifying intervention options	5. Intervention functions 6. Policy categories	What interventions are likely to bring about the desired change?
3. Identifying implementation options	7.Behaviour change techniques 8. Mode of delivery	What should be the specific intervention content and how should this be implemented?

2.3.1 Understanding the behaviour

Guidance for developing interventions recommends input from a variety of sources including existing literature and stakeholders to develop a strong theory of the problem being addressed (226, 227). In this research, gaps in the evidence base for the current management of non-diabetic hyperglycaemia with DPPs were identified through literature searches (Chapter 1). Additionally, the literature search explored the current role of community pharmacy in delivering public health interventions, specifically diabetes prevention services in England. In summary, this evidence suggested DPPs to be effective interventions for delaying and preventing the development of T2D amongst people at high risk (40). However, systematic review evidence did highlight high attrition and low uptake rates amongst the targeted population as key factors which could undermine the impact of the programmes (78, 192). Qualitative evidence highlighted work and social commitments, transportation and challenges in organising group-based sessions as key barriers for engagement. Evidence regarding the current role of community pharmacy in England highlighted the setting as potentially accessible for delivering diabetes prevention services but indicated that currently no services were being provided in this setting for people at high risk of T2D.

From this perspective the BCW was applied in this research to clearly define the broad problem identified from the existing literature which is poor engagement with DPPs amongst people with NDH. The BCW was also used to assess the community pharmacy setting as the potential solution for poor engagement with the current national DPP. This process involved four main steps: 1) defining the problem in behaviour terms; 2) selecting the target behaviour; 3) specifying the target behaviour; and 4) identifying what needs to change.

Step 1: Defining the problem in behavioural terms

This step aims to clarify the behavioural problem being targeted. It involves defining a behaviour in terms of the target group or population involved in the behaviour and concerning the behaviour itself, the location and relevant

behaviours. For the present study, three main behaviours identified from existing literature were defined in behavioural terms with respect to the type of the problem being targeted, the population involved and the location of the behaviour. These behaviours are summarised in Table 2.3.

Table 2.3 Defining the problem in behavioural terms

What behaviour?	1. Poor engagement with diabetes prevention services	2. Potential engagement with community pharmacy DPS	3. Delivery of DPS
Where does the behaviour occur?	Primary care or community settings e.g. general practices or community halls	Community pharmacy	Community pharmacy
Who is involved in performing the behaviour?	People at high risk of type 2 diabetes	People at high risk of type 2 diabetes	Community pharmacy teams

Step 2: Selecting the target behaviour

Behaviours are part of a system and do not occur in isolation. Since behaviours can occur within the context of other behaviours of the same or other individuals, it is important to consider other behaviours that the targeted behaviour might be dependent on. In this research, potential engagement with community pharmacy-based DPS, could largely be dependent on the engagement in the current NHS DPP as well as the availability of these services in the community pharmacy setting. Similarly, the delivery of community pharmacy based DPS could depend on the potential demand for the services, the need for the service in primary care and the likelihood of the service being commissioned. Therefore, all relevant behaviours were included in the COM-B analysis.

Steps 3 and 4: Specify the target behaviour and identifying what needs to change

Specification of selected behaviours in their context improves the quality of the behaviour analysis (192). The precision of the behaviour can be achieved by describing the behaviours in terms of 'who needs to perform the behaviour', 'what does the person need to do differently to achieve the desired behaviour', 'when will they do it', 'where will they do it', 'how often will the do it' and 'with whom will they do it'. Furthermore, identifying changes that need to occur in the targeted population or environment in order to achieve the desired change in behaviour is a crucial step that avoids wrong assumptions and determines intervention success. The present research applied the COM-B theoretical model, the hub of the BCW, to develop a more detailed description of the target behaviours and to conduct an analysis of what needs to change. The COM-B model was therefore used as a starting point for understanding the behaviours in the context in which they occur.

2.3.2. Application of the COM-B

Guidance for the application of the BCW recommends exploring the components of the COM-B model with multiple relevant stakeholders to develop a more accurate picture and strengthen the understanding of the behaviour (192, 226, 227). Obtaining a consistent picture of a behaviour and factors influencing it from more

than one source and using more than one method is thought to increase confidence in the analysis. Suggested sources of behaviour include the frontline healthcare providers and patients who perform the target and suggested data collecting methods include interviews, focus groups, direct observations and questionnaires.

Due to a lack of evidence in exploring engagement with DPPs in primary care settings in England, research was conducted involving mixed methods to obtain contextual evidence of key barriers and facilitators to engagement with the NHS DPP. Additionally, the studies also explored likely engagement with potential services in the community pharmacy setting amongst people at high risk of T2D. This was explored with key stakeholders including people at high risk of T2D, community pharmacy personnel, GPs and nurses. Similarly, in order to enhance the evidence base for the role of community pharmacy, both qualitative and quantitative methods were used to identify barriers and facilitators for delivering such interventions in this setting. This was explored with key stakeholders including community pharmacists, pharmacy technicians, dispensers, healthcare assistants, general practitioners, primary care diabetes nurses and commissioners.

This research employed the COM-B theoretical model to further enhance the understanding of behaviours relating to engagement and delivery of diabetes prevention intervention in a community setting in order to identify what needs to change (188, 192). As such, all primary research undertaken to explore stakeholders' perspectives employed the use of the COM-B theoretical model. The overall aim of conducting the studies was to identify the key components of the COM-B model that could serve as fruitful targets for intervention design. Therefore, the next four chapters of this thesis are dedicated to specifying the target behaviour and identifying what needs to change. A summary of the studies exploring the three key behaviours have been outlined in Table 2.4.

Table 2.4 Studies undertaken to understand the target behaviours

BCW steps	Thesis Chapter	Study and population	Behaviours covered		
			Engagement with NHS DPP	Engagement with potential community pharmacy DPS	Delivery of community pharmacy based DPS
Steps 3 and 4 specifying the target behaviour and identifying what needs to change	3	Questionnaire study A (People with NDH)	✓	✓	
	3	Qualitative study (People with NDH)	✓	✓	
	4	Qualitative study Practitioners and commissioners			✓
	5	Questionnaire study B Practitioners and commissioners			✓
	6	Nominal Group Technique study Practitioners and commissioners People at high risk of T2D		✓	✓

2.3.3 Identifying behaviour options

Steps 5 and 6: Intervention functions and policy categories

A COM-B analysis performed at the start of developing an intervention is key for reaching a behavioural diagnosis of what needs to change for the desired behaviour to occur. The next step is therefore to link this diagnosis to intervention functions and policy categories.

Intervention functions are broad categories of means by which an intervention can change behaviour. The term intervention function refers to the function that effective interventions are likely to serve rather than the intervention itself. This term, rather than intervention, is used because it is possible for an intervention strategy or behaviour change technique to serve more than one function. For example, a poster communicating the harmfulness of smoking may also include a picture of a person with damaged lungs. Therefore, although the poster may be designed to improve knowledge, it may also serve to evoke emotion that goes beyond the improvement of knowledge to persuasion. In the BCW framework intervention functions are further linked to policy categories that could support their delivery.

In the present research the COM-B analysis performed in Chapters 3-5 and finalised in Chapter 6 identify the change required for the desired behaviours to be achieved i.e. what to target in an intervention. Therefore, in this step, each COM-B component identified as relevant in bringing about desired change in the target behaviours was linked to intervention functions and policy categories which were likely to be effective in bringing about that change. This exercise has been documented in Chapter 6. The selection of the intervention functions and policy categories was guided by the APEASE criteria, which are criteria designed to assist in making strategic judgements as to what might be the most appropriate intervention and policies for the context (192). All behaviour change interventions operate within a social context, effectiveness alone is not an adequate consideration when designing an intervention. Therefore, the APEASE criteria

assisted the consideration of how other factors may affect the design of the interventions including affordability, practicability, effectiveness and cost-effectiveness, acceptability, side-effects/ safety and equity.

2.3.4 Identifying implementation options

Step 7 and 8: Behaviour change techniques and mode of delivery

Following the selection of intervention functions and policy categories, the next step in designing interventions involved selecting Behaviour Change Techniques (BCTs) which best serve intervention functions and the appropriate mode of delivery for the implementation of the intervention.

A BCT is therefore the active component of an intervention required to change behaviour. The characteristics of a BCT are that it is observable, replicable and an irreducible component of an intervention designed to change behaviour. An example of a BCT is goal setting, where an individual agrees to do a daily walking goal (e.g. walk for at least 30 minutes every day). The BCT taxonomy, a standardised language for describing the active ingredients of interventions has been identified in relation to particular types of behaviour such as physical activity, healthy eating, smoking, excessive alcohol use, professional practice and medication use (228-234). From these behaviour-specific taxonomies, BCTs have then been synthesised and refined in an internationally supported piece of work to produce BCT taxonomy (220). The taxonomy has 93 BCTs which have been organised into 16 groups including goals and planning, feedback and monitoring and social support.

In this research, following the recommendations of Michie *et al*., the selection of the BCTs started with identifying the most frequently used BCTs that are relevant to the intervention functions selected and considering their appropriateness in terms of how well they met the APEASE criteria in the context of the behaviour. As well as identifying appropriate BCTs, decisions were made about the mode of delivery of the interventions. Mode of delivery describes features of delivery such as face to

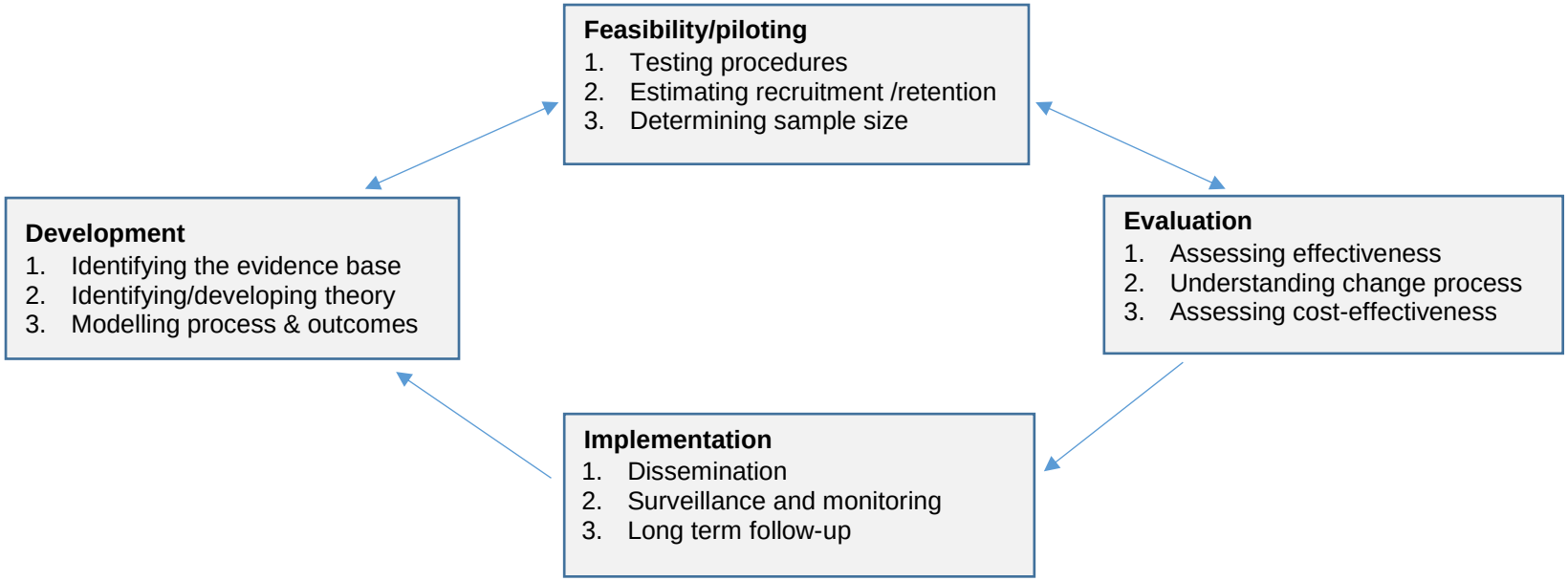
face, group-based or telephone-based interventions (235). However, because there is often less detail about the mode of delivery (e.g. face to face vs telephone) guidance for the application of the BCW recommends that mode of delivery is considered explicitly at this stage (192). Therefore, in this research the mode of delivery was considered in light of data collected from all studies (Chapter 3-6) and selected with consideration to the APEASE criteria.

2.4 The application of the Medical Research Council guidance to the current research

Public health is defined as '*the science and art of preventing disease, prolonging life and promoting health through the organised efforts and informed choices of society, organisations, public and private communities and individuals'* (236).To achieve this public health practitioners must first define the public health problem, assess the fundamental causes and determine the population most at risk. Secondly, practitioners must develop and implement evidence-based interventions or public health programs.

The Medical Research Council (MRC) have provided guidance on how to develop complex interventions such as DPS. The guidance comprises of a framework (Figure 2.6) (227) which proposes an iterative process of developing interventions consisting of four stages; 1) development, 2) feasibility testing/piloting, 3) implementation and 4) evaluation. In the present research that is exploring the community pharmacy setting as an option for delivering DPS, the focus will be on the 'development' phase of the framework which consists of three key stages:

Figure 2.6 MRC framework - key elements of intervention development and evaluation process



2.4.1 Identifying the evidence base

The guidance recommends undertaking or using a high-quality systematic review and reviewing the literature to identify the need for developing a new (or modified) intervention and the likely impact of behavioural change. This stage can also be supplemented by new research as demonstrated by Sinnott et al, who addressed gaps identified from their review of literature by conducting qualitative interviews with stakeholders (237).

In considering the application MRC framework in present research, a literature review (Chapter 1) has been conducted to identify the evidence base for the effectiveness of DPPs, gaps in the current interventions for NDH as well as the current and potential role of community pharmacy in diabetes prevention. Additionally, mixed-methods research will be conducted to supplement the literature search with more contextualised evidence regarding engagement with current national DPPs and the current use of community pharmacy services in a UK based population (Chapter 3, 4 & 5).

2.4.2 Developing theory

In the second stage, the MRC recommends the use of theory, suggesting that interventions that use theory are more likely to be effective than interventions that are purely pragmatic (226, 227). In cases where the rationale for intervention development is unclear, the MRC recommend developing a programme theory of how an intervention is likely to produce its effects. A programme theory assists the development of a theoretical understanding of the likely process of change by drawing on existing or new evidence (e.g. interviews and focus groups with stakeholders i.e. those targeted by the interventions and those delivering the intervention) and applying them to existing social and psychological theoretical models. The MRC recommends the use of social or psychological theorical models to identify the determinants of the target behaviour, to select appropriate behaviour change techniques and measures of change.

In the present study, the BCW, a theoretical framework for behaviour change and primary research (Chapter 3-6), was used to develop an understanding of the role of community pharmacy in diabetes prevention in England. The BCW was used to develop a thorough understanding of nature of behaviour of stakeholders including people with NDH (service users) and community pharmacy teams (service providers) in order to define the problem that is being addressed in behavioural terms (188). More importantly, an assessment of these behaviours has been considered in the context in which they would potentially occur i.e. the community pharmacy setting. Following the definition of the problem, the BCW has been used to identify the most effective interventions that could be implemented to address the problem (Chapter 6).

2.4.3 Modelling process and outcomes

In the third stage the MRC recommends a modelling process whereby implementation is considered at an early stage prior to a full-scale evaluation. This stage considers questions surrounding the targeted population (patients, the public, etc.), the population involved in the delivery of the interventions (national or local policy-makers, opinion leaders/formers, practitioners) and the setting. It also considers the barriers and facilitators for the delivery of the interventions.
In the present research, the modelling process and outcomes was considered throughout the research process by conducting primary research with key stakeholders and presenting the programme theory for development of community pharmacy-based DPS in a logic model at the end of the thesis (Chapter 7).

2.5 Conclusion

This research employed the Behaviour Change Wheel framework to develop an understanding of the influences behind engagement (or the lack of it) in diabetes prevention services. The framework was also used to explore the role of community pharmacy in delivering diabetes prevention services and gathered information to

assist the design of an effective intervention to enhance delivery in this setting. The research drew on existing evidence from literature (Chapter 1), supplemented by primary research with key stakeholders (Chapters 3-6), to develop a clear rationale for the intervention development and to identify effective intervention strategies to address behaviour change (Chapter 7).

Chapter 3: The community pharmacy setting for diabetes prevention: a mixed methods study in people with 'Non-diabetic hyperglycaemia'

Publications developed from this chapter:

Katangwe T, Family H, Sokhi J, Kirkdale C L, Twigg M J. **The community pharmacy setting for diabetes prevention: a mixed methods study in people with 'pre-diabetes'** (2020), *Research in Social and Administrative Pharmacy* **16 (8) 2020: 1067-1080** https://doi.org/10.1016/j.sapharm.2019.11.001

3.1 Introduction

In England, five million people are estimated to have NDH (32, 38). Evidence suggests that if individuals with NDH are identified and intensive lifestyle interventions are implemented early, the onset of type 2 diabetes may be delayed or even prevented (40, 41, 79, 81, 82, 101, 106, 109, 117). In England, the NHS DPP has been implemented in light of this evidence (40). The programme was first launched in 2016 despite evidence suggesting that its impact could be undermined by several factors including uptake (78). Qualitative research evidence investigating uptake in DPPs has highlighted accessibility, work and social commitments and practical challenges with organising group-based sessions to be amongst the common barriers for uptake (131, 132, 238).

UK guidelines recommend the delivery of DPPs by primary health care teams, including community pharmacy, as these settings have been associated with the greatest reach to the target population (32, 103, 105). However, although some community pharmacies deliver opportunistic screening and mainly refer to general practice services (135, 137), there are currently no routine lifestyle interventions being delivered in this setting for people with NDH and neither are there clear guidelines of how community pharmacy teams could deliver lifestyle interventions for this population. Therefore, with the current implementation of the NHS DPP underway, it is important to establish whether community pharmacy has a role in supporting implementation of the national programme. Additionally, there is a need to better understand the likely barriers and facilitators to engagement with the current programme in people with NDH in order to establish the context in which community pharmacy may play a role. Although previous research has identified likely barriers and facilitators to participating, DPP interventions delivered in the studies were dissimilar to the current NHS DPP and included factors likely to enhance participation. For example, Laws *et al.* describe an intervention with a significant involvement of healthcare personnel such as general practitioners, nurses and dieticians, a factor which was identified to influence study participation (131). Similarly, other studies have also described interventions which

included factors that potentially encouraged participation including social (partners) and external support networks (telephone calls from health coaches) (129, 130, 132, 238). Therefore, with the current NHS DPP delivered by mainly non-healthcare personnel and not including support networks and personalised support, it is important to establish contextual barriers and facilitators to participation in the programme.

The COM-B approach offers a theoretical model for identifying key factors influencing desired behaviour (i.e. engaging in DPPs) (188, 192). In this study, the COM-B was applied to understand two target behaviours: (1) people with NDH engaging in the NHS DPP and (2) people with NDH engaging with potential community pharmacy-based diabetes prevention services (DPS). Analysing these behaviours using the COM-B would help identify behavioural determinants and assist in developing future interventions that could enhance engagement of people with NDH in community pharmacy-based DPS through the application of the BCW.

3.1.1 Aims

To explore factors influencing engagement with the current NHS DPP and elicit views from people with NDH on the role of the community pharmacy in diabetes prevention using the COM-B to frame the data collection, analysis and future direction of interventions aimed at patients and healthcare professionals.

3.1.2 Objectives

1 To characterise participation in the current NHS DPP.

2 To describe the barriers and facilitators to engagement with the NHS DPP.

3 To describe the views and perceptions of people with NDH on the role of community pharmacy in diabetes prevention.

3.2 Methods

3.2.1 Study design and ethics approval

This research adopted a pragmatic epistemology and used mixed methods consisting of a questionnaire, a focus group and interviews to address the study objectives (239). Ethical approval was obtained from the Health Research Authority (IRAS project ID: 227930) before commencing the research. The study protocol can be found in Appendix 3.1, together with the ethics approvals (Appendix 3.2), ethics amendment approvals (Appendix 3.3) and research and development office approvals (Appendix 3.4). The study took place in Norfolk between November 2017 and May 2018.

3.2.2 Rationale for study design

This study adopted the exploratory sequential mixed method design whereby quantitative and qualitative data were collected sequentially in two phases (240). The questionnaire data were collected and analysed in the first phase. The questionnaire method was adopted following a literature search of factors influencing participation in DPPs which provided sufficient insight to enable the exploration of engagement in the current NHS DPP (131-133). The questionnaire provided the most efficient way, in terms of time and cost, to obtain data from a large sample of participants (241). In the second phase, qualitative (interviews and focus group) data were collected and analysed to get a deeper understanding of questionnaire responses with regards to influences on engagement with the NHS DPPs and the role of the community pharmacy in preventing type 2 diabetes (242). Using both interviews and focus groups also provided a degree of data triangulation.

Focus groups were the preferred data collection method as they are especially useful for confirming insights from a wide variety of participants (242). In this study, which enrolled participants with diverse experiences of engagement with the NHS

DPP and community pharmacy services, it was important for data generation to include an exchange of viewpoints and experiences in order to give participants the opportunity to reflect and consider their own standpoint in light of what they hear from others. Thus, in this study, the use of focus group discussions, which is thought to facilitate the refinement of individual responses, was viewed to be appropriate (242). Furthermore, the interaction of the researcher was felt to have less of an influence than in one-to-one interviews, allowing data and insights to be generated from a social context (242).

In order to provide a more accessible option to the studied population and encourage participation, an option of either face to face or telephone interviews was given as an alternative to attending a focus group (242). Semi-structured interviews were adopted rather than open-ended interviews to facilitate the gathering of focused subjective data (242).

3.2.3 Study terminology

The term 'engagers' as used in this study referred to participation sessions of the NHS DPP whether partial, current or complete whereas 'non-engagers' referred to participation in none of the sessions. This study therefore adopted five categories referred to as 'engagement status' to describe participant engagement with the NHS DPP and these included: dropped out ('partial engager'), attending ('current engager'), completed ('complete engager'), declined ('non-engager') and waiting for assessment ('non-engager'). These groups were adopted from the current classification of patients in the NHS DPP

3.2.4 Participant identification

3.2.4.1 Routine NHS DPP inclusion criteria

General practices: All general practices operating within the 27 areas selected for the initial implementation of the NHS DPP in England (Including Norfolk) were eligible to provide screening and referral services to the NHS DPP. Participating general practices were primarily required to identify eligible individuals for referral to the NHS DPP by performing retrospective screening of their databases.

People with non-diabetic hyperglycaemia: People with NDH are primarily identified for referral to the NHS DPP during routine primary care appointments or through retrospective screening of general practice databases. Eligible patients for referral were individuals who were 18 years or over and had an HbA_{1c} blood tests within the NDH range (42-47mmol/mol) in the last 12 months (32). Following identification, individuals were sent letters communicating their risk and inviting them to participate in the NHS DPP (243). At this point patients could voluntarily enrol onto the programme by contacting the providers via a telephone number highlighted in the referral letter. General practices kept track of individuals identified through screening based on feedback they received from NHS DPP providers.

3.2.4.2 Study recruitment

General practices: General practices were the participant identification site for the research. All general practices in Norfolk who were participating in NDH screening and referral to the NHS DPP were eligible for the study. Participating general practices were identified via the North Norfolk CCG, an NHS organisation responsible for the planning and commissioning of healthcare services for the local area.

At the time the study commenced the NHS DPP was undergoing implementation across Norfolk. Therefore, to ensure the recruiting of participants who had adequate experience with the NHS DPP, only practices that had been participating

in the NHS DPP for at least six months were invited to participate in the study. Participating general practices were reimbursed a one-off payment of £75 for identifying participants and posting questionnaires.

People with non-diabetic hyperglycaemia

Identification of eligible participants was performed by general practice staff by retrospective screening of databases. All patients who met the following inclusion/exclusion criteria were invited to participate:

Inclusion criteria

- Registered with a GP practice in Norfolk
- Referred to the NHS DPP in the previous 12 months

Exclusion criteria

- Non-English speaking
- History of type 2 diabetes
- Unable to give consent

Following identification of potential participants by general practices, envelopes containing a covering letter (Appendix 3.5) and a questionnaire (Appendix 3.6) provided by the research team were mailed to eligible participants. As part of the questionnaire, participants were given an option to express an interest in interview or focus group participation. Identification of participants was anonymous with the researchers not seeing any patient identifiable data until completed questionnaires were returned to the research team.

Once completed questionnaires were returned to the research team, participants who expressed willingness to be contacted for further research were identified. Selected participants received a covering letter (Appendix 3.7) and an information sheet (Appendix 3.8) which provided more information about the interviews/focus groups. Potential participants were given two weeks to read the information sheet

before making the final decision to participate in the research. Potential participants were then contacted by the research team to confirm participation and arrange a suitable time for the interview/focus groups. Following this, participants who opted for telephone interviews also receive a consent form (Appendix 3.9).

3.2.5 Sampling and sample size

3.2.5.1 Questionnaire

At the time of conducting the study, the NHS DPP was undergoing implementation in Norfolk, which was one of the first wave of 27 areas across the UK. North Norfolk and Norwich, consisting of 60 general practices in total, were the initial areas to start the screening and referral processes. Based on participation data provided by North Norfolk CCG we planned to approach all 9 practices that had completed the identification and referral processes within these areas. These practices had a recorded total of 1,570 patients who had received a letter inviting them to participate in the NHS DPP and had initiated first contact with the providers. Based on the assumption that, all 9 practices would participate in the study, we planned to post questionnaires to all 1,570 patients. Based on previous work which used a similar method of recruiting, a 10-20% response rate was expected, giving 150 to 300 questionnaire responses. Questionnaires were sent to all eligible participants regardless of their NHS DPP engagement status.

3.2.5.2 Interviews and focus group

Participants expressing willingness to be contacted for the qualitative element were identified from returned questionnaires. To gain the perspectives of both engagers and non-engagers in the NHS DPP, a purposive sampling method based on questionnaire responses was used to select participants (242). Selection of participants was primarily based on NHS DPP engagement status. Diversity was further sought by selecting participants according to employment status and community pharmacy use. The aim was to achieve maximum variation with regards to engagement with the NHS DPP and to obtain a diverse experience with community pharmacy service use. With respect to age, gender and employment, as

most participants were older, female and retired, balance was sought by specifically also targeting younger, male or employed participants.

The selection of participants was an iterative, ongoing process whereby selection criteria for subsequent interviews were constantly being modified to ensure intended diversity of participants was achieved. The selection of participants and data collection was therefore performed in parallel between December 2017 and April 2018. The number of interviews and focus groups conducted was based on participants' availability and data saturation (242). In this study data saturation was determined by the degree to which new data was expressed in previous data and thus had an emphasis on data collection rather than data analysis. Data saturation was therefore determined when there was no additional data expressed in new data (244). Participants were offered a £10 voucher as a thank you for participation and had their travel expenses reimbursed where applicable.

3.2.5.3 Under-representation of non-engagers following questionnaire responses

The focus of this study was primarily to address factors influencing engagement in DPPs. The study therefore sought to have a good representation of people who had not engaged with the current NHS DPP. In order to ensure that the views and perceptions of non-engagers were adequately considered a preliminary analysis on the questionnaire data was carried out to establish whether or not this population is adequately represented.

Where those who had declined to participate in the NHS DPP consisted of less than 20% of the questionnaire responses, efforts to increase the representation by specifically targeting this population were made by recruiting one or two new practices through which invitation letters (Appendix 3.10) were sent to all participants who had been invited to the NHS DPP. The invitation letter was only targeted at people who had declined participation in the NHS DPP despite being referred to it by their general practice. The envelope also contained an expression of interest form (Appendix 3.11) with a prepaid envelope. Five additional interviews

with non-engagers were sought to be undertaken when this underrepresentation was identified.

3.2.6 Data collection

3.2.6.1 Questionnaire

The questionnaire (Appendix 3.6) consisted of four sections which collected the following information: 1) demographics including NHS DPP participation, 2) feedback on the NHS DPP including accessibility, 3) community pharmacy use including general views on community pharmacy based DPS, and 4) expression to participate in further research. The first three sections consisted primarily of Likert scale questions and also included open ended questions in order to cover topics that had not been addressed by the closed questions. Respondents who had engaged with the NHS DPP were asked to provide comments on various aspects of the programme and those who had not engaged were asked to comment on influences behind their decision.

Questions exploring general views on potential engagement with community pharmacy based DPP were formulated by the research team (188, 192), to explore participants' views on the use of the setting for delivering DPS as well as willingness for participation. Questions exploring NHS DPP accessibility were based on previous qualitative research which had identified common barriers and facilitators to participation (131-133). The questionnaire, although primarily designed to validate accessibility barriers and facilitators identified from previous qualitative research within the context of the NHS DPP, also sought to explore other factors influencing engagement with the NHS DPP.

3.2.6.2 Interviews and focus groups

Interviews were conducted by the main researcher (TK) and lasted up to one hour. The focus group was conducted by two members of the research team (TK and MT/HA/SS) at the University of East Anglia (UEA) and lasted approximately 90 minutes. The focus group and interviews were digitally audio recorded and a semi-

structured topic guide based on the COM-B model (192) was used to facilitate the discussions (Appendix 3.12). Topics explored included experiences with NDH diagnosis, influences behind engagement or non-engagement, experiences with the NHS DPP or alternatives, experiences with community pharmacy services and views on community pharmacy delivering DPS. Written or verbal consent for focus group and interviews was obtained respectively (Appendix 3.9).

3.2.7 Data analysis

3.2.7.1 Questionnaire

Statistical Package for Social Sciences (SPSS) statistics (version 23; IBM Corp) was used for questionnaire data analysis. Medians (interquartile ranges (IQs)) were used to describe the data. Data was explored to identify the distribution of respondents' feedback on the NHS DPP, community pharmacy use and views on community pharmacy based DPS. To conduct inferential statistics on influences of NHS DPP accessibility on participation (location and session times), programme outcomes (weight and physical activity) and feedback on the programme (satisfaction and need of the programme) participants were separated into groups based on their engagement (i.e. engagers and non-engagers) (Kruskal-Wallis test and Mann Whitney U). Additionally, descriptive analysis (n (%) and Medians (IQs)) was performed to analyse data on community pharmacy use. Participants were again separated into groups based on their use of community pharmacy and general practice to conduct inferential statistics on their views on the involvement of community pharmacy in delivering DPS (Mann Whitney U).

3.2.7.2 Interviews and focus groups

Thematic analysis

Interview and focus group recordings were transcribed verbatim by a member of the research team (TK) or a paid transcription contractor, loaded in NVivo 11, and then checked for accuracy by listening back to the original recording. All written comments made on the open-ended sections of the questionnaires were transferred onto a Word document and combined with interview and focus group

data in NVivo for analysis. To provide an iterative process Braun and Clarke's six phases of thematic analysis was utilised (245). This approach was adopted because it can be used to analyse data from different types of communication media, providing a flexible approach to analyse data from both audio recorded interviews and focus groups (246). The activities involved in each step of the analysis are highlighted below:

Step 1: Familiarisation

The transcribed data were checked by re-listening to original recordings. The data were then read and re-read to gain an overview of the content and identify topics and subjects that were of interest and that were linked to the research questions.

Step 2: Inductive coding

The transcribed data were re-read and inductively coded. To aid the inductive analysis and provide a deeper understanding of the data, codes were discussed with another member of the research team (MT) and any disagreements resolved by consensus, referring to the transcripts and original recordings.

Step 3: Development of themes

Relationships between the codes were sought to develop subthemes and subsequent themes by two members of the research team (TK and MT). Any disagreements about the themes/subthemes were resolved by discussion, referring to the transcripts and original recordings.

Step 4: Reviewing themes

Transcripts were re-read to ensure that correspondence between the developed themes and the data. At this point iterative judgements were made in order to give a richer description of the themes.

Step 5: Defining themes

Each theme was given a name which captured the essence of the contents and a detailed analysis of each theme written. Transcripts were again revisited to develop

a richer description of the themes and to identify representative extracts to use in the written analysis. Extracts were selected to obtain a good representation of participant characteristics in terms of engagement and study involvement (questionnaire and qualitative elements).

Step 6: Reporting

A clear and concise narrative of the themes was written using extracts identified in step 5 as illustrative evidence of the themes. This ensured authenticity of the findings. Codes and themes generated from each phase contributed to the description to the role of community pharmacy in diabetes prevention.

COM-B analysis

To obtain a deeper understanding, codes of the themes associated with two target behaviours *i.e.* (1) people with NDH engaging in DPP and (2) people with NDH engaging with community pharmacy based DPS, were categorised as barriers and facilitators to facilitate further mapping onto the components of the COM-B model. Mapping was conducted according to the heuristic subdivisions of each of the components of the COM-B model where Capability can be either 'physical' (e.g. physical skills) or 'psychological' (e.g. knowledge) ability to perform the behaviour; Opportunity can be 'physical' (e.g. Resources) or 'social' (e.g. interpersonal influences); Motivation may be 'reflective' (e.g. beliefs about what it good or bad) or 'automatic' (e.g. processes involving wants and needs).

Mapping processes were conducted with reference to the target behaviours and aided by discussion amongst the research team (247). The process involved mapping coded interviewee narratives to relevant COM-B categories. However, where there was overlap between COM-B categories, discussions were held amongst the research team and interviewee narratives mapped to the COM-B category relevant to the "primary determinant". The 'primary determinant' was considered as the starting point / root cause of a barrier or facilitator.

Mapping was conducted by the main researcher (TK) and then discussed with another member of the research team (MT). The final mapping was then re-analysed independently by another member of the research team with expertise in psychology and using the COM-B (HF). Any disagreements were resolved by consensus following discussion with two other members of the research team (TK and MT).

3.3. Results

3.3.1 Questionnaire: NHS DPP

Nine hundred and sixty-two questionnaires were posted via five general practices which agreed to participate resulting in 181 (18.8%) responses. Participants' demographics and NHS DPP engagement status are summarised in Table 3.1. The majority of the respondents were white 176 (97.8%) and almost half reported to have either completed the programme or were still attending sessions. A quarter of respondents reported to be waiting for an initial assessment following contact with the service providers.

Table 3.1 Questionnaire participant characteristics

Characteristics	N	Measure	Classification	Responses
Replied	962	n (%)		181 (18.8)
Female	180	n (%)		103 (57.2)
Age (years)	180	Mean (sd)		69.0 (10.0)
Employment status	181	n (%)	Employed Student Retired Unemployed	41 (22.7) 9 (5) 127 (70.2) 4 (2.2)
NHS DPP engagement status	167	% (95% CI)	Waiting Attending Dropped-out Completed Declined	25.7 (19.1, 32.2) 24.6 (18.1, 31.1) 9.6 (5.1, 14.1) 25.1 (18.5, 31.7) 15.0 (9.6, 20.4)

Feedback on the NHS DPP is summarised in Table 3.2. There were significant differences between the groups in terms of convenience of programme location and session times with a general trend being towards agreeing or strongly agreeing for those who were attending, had completed or had dropped out of the programme compared to those who had declined or were waiting for an initial assessment (Kruskal-Wallis test: $p < 0.001$ (($X_2 = 38.69$, df = 4) and $p < 0.001$ ($X_2 = 29.99$, df = 4) respectively).

Table 3.2 Feedback on the NHS DPP

Questionnaire statement (Median (IQ))*	Waiting n=24	Attending n=38	Completed n=41	Dropped-out n=15	Declined n=20	Result
The location of the programme was convenient for me	3 (3,4.75)	4 (4,5)	5 (4,5)	4 (4,5)	3 (2,3)	<0.001 **
The times that the sessions were offered were convenient for me	3 (2, 5)	4 (4,5)	5 (4,5)	3.5 (2,4)	3 (2,3.5)	<0.001 **
I found attending the sessions as a group helpful	-	4 (4,5)	5 (4,5)	4 (3,4)	-	0.019 **
The programme has helped me or is helping me to lose weight	-	4 (4,5)	4 (4,5)	4 (2,4)	-	0.075 **
The programme has helped me or is helping me to exercise more	-	4 (3,5)	4 (3,4.75)	4 (2,4)	-	0.045 **
Please indicate your level of satisfaction with the programme	-	4 (4,5)	5 (4,5)	3 (2,4)	-	0.001 **
I feel like I need the programme	3 (3,4.25)				2 (2,3)	0.014 ***

*Likert scale: strongly disagree (1), disagree (2), neither agree nor disagree (3), agree (4), strongly agree (5)

** Kruskal-Wallis Test

*** Mann Whitney U

There was also a variation between 'non-engagers' (waiting for an initial assessment and declined) with regards to feeling the need to attend the programme. Those who had declined agreed to feeling that they did not need the programme (Mann Whitney U, p=0.014) whilst those who were waiting had no strong views about whether they needed the help of the programme.

Overall feedback on the NHS DPP from 'engagers' (attending, completed and dropped out) was positive. There was little variation in feedback about programme outcomes, with most respondents reporting the programme to have successfully helped them in achieving weight loss and increasing physical activity. However, overall satisfaction with the programme and views concerning the helpfulness of group sessions varied amongst the three groups with responses being less positive amongst people who had dropped out of the programme.

3.3.2 Questionnaire: community pharmacy

Most participants reported taking prescribed medication (88.6% (156)). In total, 59.5% reported collecting their medication from community pharmacy rather than dispensing GPs (practices that dispense medicines they prescribe to patients living remotely from a community pharmacy). Ninety three percent of participants on prescribed medication collected their medication in person. A larger proportion of respondents (82.8%) who collected medication from the community pharmacy reported visiting the pharmacy more frequently, i.e. either once a month or most days, than those who collected medication from dispensing doctors (54.1%). Most of the respondents who collected their medication from a local community pharmacy reported a shorter travel distance (90.4%; 1-2 miles) compared to those collecting their medication from dispensing general practices (44.3%; +3 miles).

Table 3.3 summarises the reported use of community pharmacy services by respondents. Most respondents reported using community pharmacy for either over-the-counter services, information/advice or screening services. Just over a

quarter of respondents reported to have either never heard of or used any of the listed community pharmacy services.

Table 3.3 Community pharmacy services use

Which community pharmacy service have you used before?	Service description	Intervention % (n = 157)
Over the counter advice	Clinical advice on non-prescription medicines for a range of minor illnesses, such as coughs, colds, fungal infections, and aches and pains. This advice also includes diet and lifestyle recommendations and signposting to more appropriate services including general practice for more serious conditions.	29.7 (47)
Blood Pressure check	A blood pressure screening service.	25.3 (40)
NHS Health check	A screening service designed to predict the 10-year risk of developing heart disease and offer lifestyle advice and intervention where necessary. The check is for adults in England aged 40-74 and consists of a combination of BMI measurements, blood pressure, blood glucose and cholesterol screening, diet and physical activity information.	19.0 (30)
Cholesterol check	A cholesterol screening service.	17.7 (28)
Health leaflets	Free health-related leaflets on various conditions including diabetes and hypertension as well as advice on healthy living advice.	16.5 (26)
Diabetes check	A diabetes screening service (random or fasting plasma glucose test).	14.6 (23)
Smoking cessation	A one to one service delivered by trained pharmacy advisers that provides a range of proven smoking cessation methods. The programme provides information and advice on stopping smoking, as well as professional support, during the first few months following cessation.	4.4 (7)
Weight loss programme	A service delivered by trained pharmacists to support patients to lose weight through the provision of diet and lifestyle advice, goal setting and motivating patients to change their behaviour.	1.3 (2)
Other	Other services including seasonal influenza vaccination services and medicine related services (e.g. medicines use reviews).	4.4 (7)
None/never heard of these	N/A	28.5 (45)

Table 3.4 illustrates responses relating to the role of community pharmacy in diabetes prevention. People who collected medication from community pharmacy were more inclined to think that community pharmacy was capable of delivering DPS (p=0.023). Most respondents agreed that they would consider using community pharmacy for DPS and would be motivated to utilise community pharmacy-based DPS. There was no significant difference in participants' motivation (p=0.076) and consideration (p=0.124) to use community pharmacy for DPS between people who collected their prescriptions in community pharmacy and those who collected their medication in dispensing doctors.

Table 3.4 Views on potential engagement with and delivery of community pharmacy diabetes prevention services

Questionnaire statement	All participants N = 162	Collects prescribed medication from community pharmacy N=90	Collects prescribed medication from dispensing GP N=54	p-value Mann-Whitney U
		Median (IQ)		
I think community pharmacy is capable of providing a diabetes prevention service	4 (3,4)	4 (3,4)	3 (3,4)	0.023
I would consider community pharmacy (as an option) for a diabetes prevention service	4 (3,4)	4 (3,4)	4 (3,4)	0.124
I would be motivated to attend a pre-diabetes screening or prevention service provided by the community pharmacy team	4 (3,4)	4 (4,4)	4 (3,4)	0.076

3.3.3 Interviews and focus groups

One hundred and four respondents (57.5%) expressed an interest in the qualitative element of the study. With most participants opting for interviews, one focus group consisting of six participants and 10 telephone interviews were conducted. Table 3.5 presents the demographics of the 16 participants purposively sampled to participate in the qualitative element. Included in the table is also a participant identification key for the illustrative quotes.

There were slightly more females than males and more were retired than employed. There was an even distribution across those who had engaged with the NHS DPP (completed or attending (n= 6)) and those who had declined or dropped out (n=7). The sample also included participants who were waiting for initial assessment (n=3). As a preliminary analysis of questionnaire responses indicated a response rate from those who had declined of less than 20% of the respondents, an additional general practice was recruited to identify five additional interviewees who had not engaged with the NHS DPP. However, there was no response from these individuals.

Table 3.5 Characteristics of interview and focus group participants

Characteristic	N	Measure	Classification	Responses
Age (years)	16	Mean (sd)		68.4 (5.6)
Female	16	n (%)		9 (56.3)
Employment status	16	n (%)		
			Employed	4 (25)
			Retired	12 (75)
Engagement status	16	n (%)		
			Attending	3 (18.8)
			Completed	3 (18.8)
			Waiting	3 (18.8)
			Dropped out	2 (12.5)
			Declined	5 (31.3)
Community pharmacy use	16	n (%)		
			About once a month	4 (25)
			Once every two to three months	1 (6.3)
			Two or three times a year	8 (50)
			Never	3 (18.8)

Key for illustrative quotes:

FG = focus group participant, I= interview participant, Q= participants' response to open-ended questionnaire sections. All participant identifiers include a questionnaire reference number and NHS DPP engagement status.

One hundred and forty-four participants (80%) responded to the open-ended sections of the questionnaire and these responses were included in the analysis. The thematic analysis produced four main themes 1) Perceptions of non-diabetic hyperglycaemia 2) Factors influencing engagement in the NHS DPP 3) Feedback on the NHS DPP and 4) The role of community pharmacy in non-diabetic hyperglycaemia. Two themes ('Factors influencing engagement in the NHS DPP' and 'The role of community pharmacy in non-diabetic hyperglycaemia') were identified as closely linked to the target behaviours ('people with non-diabetic hyperglycaemia engaging in DPP' and 'people with pre-diabetes engaging with community pharmacy based DPS') respectively. Tables 6 and 7 present the mapping of the codes associated with these two themes to the components of the COM-B model.

3.3.3.1 Theme 1: Perceptions of non-diabetic hyperglycaemia

Participants expressed a lack of awareness of NDH prior to diagnosis. Reactions following diagnoses were mainly that of shock particularly due to positive self-perception about diet, lifestyle and lack of family history. Those who were not shocked were clearly able to relate the diagnosis to risk factors such as age, weight, family history, co-morbidities and poor dietary choices. Whilst a few participants were not concerned with the diagnosis and had made the conclusion that the risk of developing diabetes was not serious, others highlighted the need for earlier interventions, prior to a formal diagnosis of pre-diabetes, to address poor lifestyle behaviours before they became an issue.

'I know I'm a wee bit overweight but not extortionately and we have a very healthy diet in so much as we eat plenty of fruit and vegetables… nobody else in my family is diabetic so it did take me by surprise that I could be going that way' [I-017, attending]

'I think you drift into bad habits and if someone says to you your blood sugars are increasing every time you might find it easier to amend your habits earlier on in the

process rather than go and say 42 [meaning HbA_{1c} reading] now this is what you need to do' [FG-025, waiting]

3.3.3.2 Theme 2: Factors influencing engagement with the NHS DPP

There were several factors that influenced participation in the NHS DPP following diagnosis of NDH. Table 3.6 summarises barriers and facilitators to engagement mapped to the COM-B, along with illustrative quotes. The table also consists of summary phrases for each identified barrier and facilitator together with the descriptions of Capability, Opportunity and Motivation. The target behaviour linked to this theme was 'people with pre-diabetes engaging in DPPs'.

Table 3.6 A COM-B analysis of factors influencing engagement with the NHS DPP

COM-B components with definitions	Mapped codes		Illustrative quotes
	Barriers	**Facilitators**	
Physical capability - physical skill, strength or stamina to perform the behaviour	Co-morbidities		"*My level of exercise has been hampered by other health problems*" [Q-98, completed]
Psychological capability - knowledge or psychological skills, strength or stamina to engage in the necessary mental processes			
Physical opportunity - opportunity afforded by the environment involving time, resources, locations, cues, physical affordance	Location Transportation	Location	"*I don't drive, so one of the questions I asked him* [GP] *where do these sessions take place, because if I need to go to* [location] *or somewhere to do it, it's not easy you know. It adds another several hours to the day for me*" [I-19 declined]
	Session times Social/work commitments		*"It was a bad time of the day you know, effectively I lost a day's work by the time I got up there and got back"* [I-81, dropped-out]
Social opportunity - opportunity afforded by interpersonal influences, social cues and cultural norms that influence the way that we think about		Employer support	*"It is quite a commitment though. I work full time and I've been very lucky in that my employers let me go every week"* [FG-91, completed]
	Healthcare professionals' influence		" *I said 'do I need to do this prevention programme?, because I am quite happy to do it if you think it is advisable', and he [GP] said, 'well I'm not sure it's going*

things e.g. the words and concepts that make up our language			*to do you a lot of good, you're already eating healthily and you're losing weight'"* [I-19 declined]
Reflective motivation - reflective processes involving plans (self-conscious intentions) and evaluations (beliefs about what is good and bad)	Self-help (existing knowledge of dietary management)		"*I think from my own diet management really I seem to have got myself back within the bounds or within the figures I should be*" [I-115, dropped-out]
	Group-based sessions		*"I am not one for being in a mixed crowd, I'd rather be on my own"* [I-29, declined]
	Perceiving no additional benefit from the programme	Perceiving positive health benefits from the programme	*"I have a general idea you know. I listen to the radio and I watch television and you hear from programmes there about how to cope with diabetes and how to make your lifestyle better, so I thought what am I going to gain by doing some yet another class as it were"* [I-40, declined]
	Family history	Family history	*"My brother has it [type 2 diabetes]. It's a nuisance and it affects him in a way which I thought well I don't want to be in that situation. In fact, I thought I am not going to be in that situation full stop."* [I-18 completed]
		Perceiving online information sources to be less reliable	"*In a way I was happy to wait for more expert advice, because whilst I obviously used internet and google to check things out, you get a lot of information, some of which is conflicting. So it's not always the best source*" [I-18 completed]
		Weight loss	*"I've got to be fair and say I went more with the idea of trying to lose some weight than actually preventing diabetes. I've got to be honest about that"* [I-42, completed]

		Saving NHS money	"It's *a dreadful thing to think that I might be costing the NHS money because I am ill-disciplined, and that is really why I want to take it more seriously*" [FG-32, waiting]
Automatic motivation - Automatic processes involving emotional reactions, desires (wants and needs), impulses, inhibitions, drive states and reflex responses.		Fear of diabetes and complications	*"To be honest, I would hate to be diabetic. If I had to give myself injections, I just don't know how I could handle that. I know people who have had it affects other parts of your health and that frightens me"* [I-17, attending]

Capability

Physical ability to participate in sessions of the NHS DPP, particularly group exercises, was identified as a key enabler for engaging with and completing all programme sessions. To this end some participants described being hindered by co-morbidities such as arthritis and only engaging in the educational elements of the programme.

Opportunity

Programme location, session times and transportation, contributed to both facilitators and barriers to engagement. Participants felt that session times, which run during working hours, were more accessible for those without work commitments. Social influences on uptake arose from a variety of networks including employers where some participants described employers allowing them to have time off work to attend sessions of the programme. Other participants, however, described making decisions to engage based on advice sought from healthcare professionals, particularly GPs and nurses. Some of these participants described practitioners advising them against participating based on their beliefs of the benefits of the programme and the availability of spaces on the programme.

Motivation

A variety of reflections influenced lifestyle changes and engagement with the NHS DPP. Participants' perceived own ability of making dietary changes and increasing physical activity, without intervention from the NHS, influenced some to disengage from the national programme. These participants described making changes which had resulted in positive outcomes such as weight loss, lower HbA_{1c} and blood pressure. Group-based sessions also appeared to be a deterrent to some who acknowledged this to be attributable to personal preference.

Participants described making decisions to engage with the programme based on perceived potential health benefits as well as perceived reliability of alternative sources of help such as online information. Participants' beliefs about the consequences of type 2 diabetes, which were mainly based on family history or

other observations, also influenced engagement. Whilst some participants with a family history of type 2 diabetes were more inclined to engage with the national programme others felt that their experience with the condition had given them enough information and knowledge to support them in making lifestyle changes and therefore chose not to engage. Emotional responses to diagnosis, particularly fear of diabetes and complications, served as motivators to making lifestyle changes or engaging with the programme. Participants also described being motivated by self-conscious intentions and goals such as losing weight or improving prognosis of co-morbidities such as arthritis. Finally, one participant in particular felt strongly that their reason for wanting to engage with the help offered by the NHS DPP was influenced by their view of the role of the NHS and that they should be doing everything they can to prevent additional burden to the health service.

3.3.3.3 Theme 3: Feedback on the NHS DPP

Feedback from participants who engaged with the national programme, including those who had dropped out, largely reflected the 'one size does not fit all' notion with some giving positive feedback and others giving negative feedback on the same aspects. Participants who had attended some sessions or had completed the programme described the location as accessible and session times as convenient whilst those who hadn't engaged had opposing views including a lack of flexibility in programme delivery. Participants who had attended some sessions of the programme gave largely positive feedback and expressed positive outcomes achieved including raised awareness in making healthy dietary choices, weight loss, increased physical activity and reduced HbA_{1c}. Some participants also reported positive outcomes with comorbidities such as blood pressure and arthritis. In terms of delivery, participants felt that the programme was well presented by knowledgeable non-healthcare personnel and felt that delivery was consistent throughout its duration.

"Well the location was very good for a start, it was very near the doctors and I go to the surgery so it was convenient for me" [I-7, attending]

"I thought that the people that presented it, without being doctors, nurses, pharmacists whatever, did a very good job and I'm tempted to think they might also use a language that's closer to that used by the participants than a medical professional" [I-18, attending]

Participants also expressed the usefulness of resources offered by the programme including written materials and props which helped them to gain a better understanding of NDH and dietary choices. However, some expressed a preference for simple written materials instead of the book provided by the programme. Negative experiences appeared to centre on the notion that the duration of the sessions was too long, with some describing the 2-hour sessions as 'heavy going'. Some participants also commented on aspects of the programme such as exercise sessions that seemed irrelevant to them due to their age and co-morbidities. Group activities also received both positive and negative feedback with participants liking activities such as weighing and others not taking to some of the activities. Most participants who completed the programme seemed to have a richer appreciation of the support and encouragement that the group-based sessions provided.

"Only attended one session. Found it was very long, unnecessary and rather patronising" [Q161, dropped-out].

"*In the group I attended most of the people were 60 plus so the activities/exercise provided I think were for that age group and not mine*" [Q-1, completed].

"A big benefit of the course was the group meetings. It wouldn't have meant anything to me if it hadn't have been for that. I actually look forward to going every week and listening to what other people have done that week; what they found easy what they found difficult. I thought that was brilliant I think that interaction was what made it for me" [FG-91, completed]

3.3.3.4 Theme 4: The role of community pharmacy in non-diabetic hyperglycaemia

Participants discussed characteristics of services that could be delivered in the community pharmacy including a one to one alternative option of the NHS DPP. Participants who had completed the programme also felt that community pharmacy could be useful for providing post-intervention monitoring services to support maintenance of positive clinical outcomes. Suggested characteristics of the types of services community pharmacy could deliver are summarised in Table 3.7. Barriers and facilitators for engaging with community pharmacy-based DPS in particular NDH screening and prevention programmes were also identified. Barriers and facilitators mapped onto the COM-B are presented in Table 3.8. The table also presents summary phrases of these factors and highlights those that have been taken forward for further COM-B analysis. The related target behaviour in this theme was 'people with non-diabetic hyperglycaemia engaging with community pharmacy based DPS'.

Table 3.7 Potential intervention characteristics of community pharmacy-based services

Type of service*	Illustrative quote
One to one option	*"Possibly useful alternative to group sessions"* [Q-166, dropped-out]
Support after NHS DPP	*"I would welcome continuing support after the programme completed"* [Q-152, completed]
HbA_{1c} monitoring	*"If technology is moving away from having to send blood samples away and having to wait days for them to come back to the surgery… if modern equipment is able to do that in a pharmacy setting maybe there's an opportunity that might work"* [FG-11, attending]
Private screening services	"*If there'd been some way I'd have even paid for it to monitor my health in some way, which is where I was thinking you know community pharmacy if you could pay them to test you when you're 35 (HbA_{1c})"* [FG-25, waiting]

* Links forward to chapter 5, table x (Questionnaire study) and chapter 6, table x (Nominal Group Technique study)

Table 3.8 Barriers and facilitators to engaging with community pharmacy-based diabetes prevention services

COM-B components with definitions	Mapped codes		Illustrative quotes	Summary phrase
	Barriers	**Facilitators**		
Physical capability- physical skill, strength or stamina				
Psychological capability - knowledge or psychological skills, strength or stamina to engage in the necessary mental processes	Knowledge of appropriate healthcare pathways		*"There are just so many avenues you can get medical advice through nowadays, and it gets very confusing"* [Q-25, waiting]	**A.** Knowledge of support options
	Lack of awareness of community pharmacy services	Promotion of community pharmacy services	*"I'm not aware of all the different things that chemists do, I didn't think they probably would measure your cholesterol and things like that I suppose it's possible"* [I-7, attending]	**B.** Awareness/promotion (patients and public)
Physical opportunity - opportunity afforded by the environment involving time,		Convenient	*"It sounds like a convenient way for people to access screening and advice on how they can best avoid developing full blown diabetes"* [Q-94, attending]	*****Accessibility (location) Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 3a)

resources, locations, cues, physical affordance		Accessible location	*"An excellent idea. Closer to home is a huge improvement. No long 1hour+ on cold wet days - that's 1hr minimum - on my trip into [location]"* [Q-48, declined]	*Accessibility (location) Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 3a)
	Confidentiality and privacy concerns		*"Would there be a private room available or enough space if it's a course and privacy and confidentiality. I hope it wouldn't be held or reviewed at the shop counter"* [Q-103, unknown participation status]	**C**. Suitable consultation rooms (privacy and confidentiality)
		Shorter waiting times	*"Probably far quicker than waiting for doctor's appointment. Prevention screening services? Excellent idea if carried out by professionals targeting specific ailments include "Wellman Clinic"* [Q127-waiting]	*Accessibility (shorter waiting times) Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 3c)
	Busy Uncertainty regarding appointments		*"Not sure if this would work as they always seem to be quite busy, unless it was done in appointment system"* [Q114-completed]	*Accessibility (appointments) Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 3d)
	Space challenges		*"I feel the group setting is a good way forward for a prevention service and I am not sure if this can be provided by*	*Suitable consultation rooms (space)

	Inability to deliver group-based sessions		*community pharmacy with limited space"* [Q-110, completed]	Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 5)
	Lack of access to medical records		*"I think the doctors have more accessibility to medical records for contacting people but the community pharmacy is always there for excellent advice"* [Q-26, completed]	*Access to patient medical records Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 6)
	Understaffed	Extra resources e.g. 2 pharmacists	*"I don't feel that community pharmacies have the resources to provide an effective diabetes prevention services as this would require lengthy consultations to cover the many aspects involved"* [FG-11, attending]	*Resources Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 7b)
	Funding cuts	Funding	*"I think community pharmacy I think would be it's not so much a commercial thing if you want would probably be a better option I'd love to see it but it's going to take a lot of investment in time people and money"* [I-18 completed]	*Funding (resources) Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 7b)
Social opportunity - opportunity afforded by interpersonal	Division between pharmacy and the rest of the	Diabetes prevention	"*You've got all sorts of people who have become involved with the surgery who weren't before…same with the pharmacist, if it was within that*	**D.** Integration (collaboration with GP)

influences, social cues and cultural norms that influence the way that we think about things e.g. the words and concepts that make up our language	medical profession	services must be linked to GP	*environment and they were all linked together and they had that interaction I think people would probably have more confidence"* [FG-11, attending]	
	Little or no experience of using community pharmacy services		*"I haven't really had any experience with pharmacies…well I guess I'd have to trust them [to deliver DPS]. As I say I have no experience of ever going to them before, so I can't judge them on no experience"* [I-115, dropped-out]	**B.** Awareness/promotion (patients and public)
	CP underutilised in England		*" If you go abroad I mean in other countries the pharmacist is usually the first port…even in European countries where you don't pay for healthcare necessarily you go to a pharmacist you get advice"* [FG-25, waiting]	**B**. Awareness/promotion (patients and public)
	Prefers GP or nurse due to established relationship and cultural norms		*"Rather see the practice nurse as I know her"* [Q-65, waiting]	**E.** Healthcare professionals
Reflective motivation - reflective processes involving plans (self-conscious intentions) and evaluations	Negative experiences with other services delivered in community pharmacy	Positive experiences with other services delivered in community pharmacy	*"Having to wait at least 30 minutes in my pharmacy to collect prescriptions, they seem very disorganised with no system. I feel they would not be capable of providing this service efficiently"* [Q-104, declined]	**F.** Experience (receiving other community pharmacy services)

(beliefs about what is good and bad)	Sceptical about community pharmacy being able to deliver DPPs		*"It is so detailed and comprehensive [NHS DPP] that I'm finding it difficult how a local pharmacy is going to be able to provide that sort of advice, service and encouragement"* [FG-11, attending]	*Feasibility Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 10)
		DPPs can be delivered by any trained personnel	*"I mean these courses were given by people who weren't doctors or pharmacist and hadn't had that amount of training, but they were trained to deliver this course and that was fine. I didn't need to have somebody who's got a degree"* [FG-42, completed]	*Training* Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 1)
	Qualifications	Training Pharmacists' knowledge and qualifications	"*The staff are very capable for my use so far, and I see no reason why with training they [community pharmacy staff] would be unable to do so [deliver DPS]"* [I-29 declined]	*Training* Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 1)
		Potential to save GP time	*"That could actually save the doctors an awful lot of time and especially the climate at the moment is that hospitals doctors surgeries are at bursting point…it would be very useful for a chemist to take some of these more*	*General practice benefits Explored under the behaviour *'delivering community pharmacy-*

			simple things which are very important to the body on board and free the public from standing in queues and free the surgeries from having too many people to attend to" [I-7, attending]	*based diabetes prevention services'* (Ref 23)
Automatic motivation - Automatic processes involving emotional reactions, desired (wants and needs), impulses, inhibitions, drive states and reflex responses		**Community pharmacy monitoring service would give patients peace of mind**	"*I think to be able to go in for peace of mind cos I know sometimes I feel that if I've gone too long and not eaten my blood sugar goes down*" [I-13, declined]	*Patient centred services (accessibility) Explored under the behaviour *'delivering community pharmacy-based diabetes prevention services'* (Ref 3)

*Links forward to Chapter 4, Table 4.3

A-F links forward to Chapter 6

Capability

Generally, participants who were unable to engage with the current national programme due to various accessibility factors (e.g. time commitments) expressed a lack of knowledge of where to access alternative help. Therefore, with most participants also expressing a lack of knowledge about current community pharmacy-based public health services, it was felt that people with pre-diabetes would need to be informed about DPS provided in this setting to enable them to engage. Experiences with current community pharmacy services were largely medicine related and involved information provision or counselling. Apart from influenza vaccinations, there was a general lack of awareness of non-medicine related services, including diabetes screening, offered in this setting. Generally, due to the lack of awareness of current community pharmacy services and its public health role, participants felt that community pharmacy based DPS would need to be promoted sufficiently to the targeted population for it to be successful.

Opportunity

The community pharmacy setting was identified by the participants as accessible and convenient, particularly in terms of location and ease of making appointments. Participants felt that there is an opportunity for community pharmacy to deliver NDH screening and monitoring services with some expressing their willingness to attend and even pay for the services. Participants felt that the DPS delivered in this setting would be most appropriate for regular community pharmacy users due to established relationships.

A number of barriers that would have to be overcome to deliver the services such as lack of access to medical records, time, funding and staff resources were also identified. Whilst some participants felt that, due to space challenges, community pharmacy would be unable to deliver group-based sessions, others discussed concerns about privacy and confidentiality, which were mainly based on the set-up of community pharmacies and the tendency for advice to be given over-the-counter.

Most participants felt that the integration of community pharmacy DPS with general practice services could increase acceptability of service users. Participants also felt that delivering DPS in this setting could potentially decrease GP workload and thus decrease waiting times at general practices. Other participants who were less keen on the idea of community pharmacy delivering DPS explained that the service would be better provided by the general practice alone due to their increased access to medical records and familiarity. However, some participants acknowledged their views were based on pre-conceived ideas of the role of community pharmacy and reservations about them providing services that traditionally would be otherwise provided by general practices.

Motivation

Motivations to access community pharmacy based DPS were largely reflective, where participants described basing decisions on their experiences and beliefs. Most respondents felt that delivering NDH screening and DPPs through community pharmacy was a good idea with some expressing that the setting could provide an alternative for those who do not like the group-based setting. Those who had either completed the national DPP and had managed to revert their HbA_{1c} levels to normal ranges expressed that this setting could be useful for providing follow-on support and monitoring and would give them peace of mind due to ease of access.

Participants acknowledged that community pharmacy has the potential to deliver DPS but considered appropriate training and qualifications of personnel delivering services as key determinants for enhancing their motivation to engage. This indicated that participants were comfortable with the community pharmacy personnel delivering DPS as they felt it could be delivered by anyone providing they had the appropriate training. This aligned with other participant views about non-healthcare professionals delivering the NHS DPP successfully.

Willingness to participate in community based DPS was largely influenced by participants' experience with other services in this setting, with those who had negative experiences with prescription services strongly opposing the concept of

community pharmacy delivering diabetes prevention interventions. Additionally, some participants who had attended the national DPP were sceptical about community pharmacy being able to deliver DPS. These participants expressed that having attended the current national programme, which from their experience was a lengthy and comprehensive service, they were finding it difficult to envisage community pharmacy delivering a similar programme.

3.4 Discussion

This research highlights that a one-size fits all approach should not be applied when delivering the DPP and that alternative delivery approaches should be explored to maximize reach (131). Factors influencing engagement identified by this research not only highlight a potential role for community pharmacy in addressing accessibility barriers but could also inform pathways for signposting people with NDH into better suited DPP settings. This study also identifies important facilitators in the Capability (e.g. training) and Opportunity (e.g. time) domains of the COM-B theoretical behaviour change model that could be targeted when designing and implementing NDH interventions that could be delivered by community pharmacy teams.

The experience of being diagnosed with NDH, largely described as a feeling of shock by the participants in this study, and the subsequent motivation to make lifestyle changes, highlights a timely opportunity for the provision of suitable interventions. Previous research has highlighted NDH as a 'window of opportunity' for healthcare professionals to support those identified to implement lifestyle changes (248). This research demonstrates scope for community pharmacy teams to deliver DPS for people diagnosed with NDH following screening as an alternative option to the current national programme. Community pharmacy was seen by people with NDH as a potentially accessible and convenient option, particularly for regular service users. Previous research exploring views and perceptions of the public towards community pharmacy screening services and its public health role has shown

similar findings, identifying accessibility and convenience as positive aspects of community pharmacy (249-251). However, in line with previous research, our findings have shown that although the community pharmacy setting could be a favourable choice for people who are employed and regular service users (252, 253), engagement could be hindered by lack of awareness of community pharmacy services and poor perceptions of the role and expertise of community pharmacy teams (249, 252, 254). Additionally, strong views of pharmacists as drug experts (255, 256), preference for general practice settings by patients and lack of GP endorsement have also been highlighted by research as common hindrances to community pharmacy services uptake(253).

In 2016, a review of community pharmacy clinical services in England highlighted similar behavioural constraints for accessing community pharmacy services including lack of awareness and expectation of the clinical care that pharmacy can and could deliver by patients, the public and other health care professionals (257). The report highlighted that raising awareness of community pharmacy services as well as increasing public perception and experience is central to changing behaviours. The review recommended building local peer relationships with other healthcare providers and using patient groups to raise awareness to people with different cultural backgrounds and age groups (257).

This study demonstrates that engagement with community pharmacy based DPS could be influenced by perceptions of community pharmacy teams' capability (in terms of training and qualification) to deliver such services. Although this research indicates that regular community pharmacy users are more inclined to perceive community pharmacy to be capable of delivering DPS, the findings show that most people with NDH would be willing to engage with services in this setting if community pharmacy teams received appropriate training. A systematic review examining the beliefs and attitudes of consumers towards pharmaceutical public health, has shown similar findings suggesting that although most service users view pharmacists as appropriate providers of public health advice, they have mixed views on pharmacists' ability to do this (258). The review also found high

satisfaction rates amongst those that had experienced community pharmacy based public health services and recommended the provision of training to increase pharmacists' confidence in providing these services.

Other intervention characteristics such as programme content and delivery, seemed to influence retention of people with NDH following initial engagement. Characteristics such as session times and duration, were among factors identified by our study to influence those who dropped out of the national DPP. This reflects findings of the ComPoD study which evaluated an existing community-based DPP in parts of England (Exeter and Birmingham) and reported a similar proportion of people who had declined or dropped out (129, 130). The ComPoD study reported, amongst those willing but unable to engage with the programme, inconvenient session times as barriers. Previous qualitative research which identified organising suitable session times for a group as a challenge for providers identified the need for session time flexibility in programme delivery and ensuring sufficient physical access including transportation and parking (131).

Finally, as this research suggests motivation to be an important factor influencing participation in DPPs, the provision of DPS in alternative settings to such as community pharmacy, which primarily serve to increase opportunity for engagement, could indirectly enhance motivation (188, 192, 259, 260). This study also identified motivational factors such as patients' perceptions of their ability in making health changes and perceived reliability of alternative support options, as factors that have the potential to influence to engagement with the DPPs. Such factors would therefore need to be taken into account when considering the primary targets of the NHS DPP. It is also important that patients motivated to make lifestyle changes without the support of DPPs are well provided with evidence-based information and resources.

3.4.1 Strengths and limitations

This is the first study investigating influences of participation in NHS DPP and exploring the role of community pharmacy in diabetes prevention. Demographic characteristics, which largely consisted of an elderly population, including a small proportion of employed people and fewer men than women, sufficiently represented that of Norfolk which largely consists of a white British population with a relatively older age profile compared to the rest of England (261). Participation demographics reflected both national NHS DPP figures and previous research which demonstrate increased uptake with age and a significantly lower attendance in men (131, 133, 262-264). Additionally, participation rates reflected local figures which demonstrate a 56% (95% CI 53 to 60) uptake rate (attendance of initial session) since initiation of the programme in June 2016 (264).

The mixed method, exploratory design enabled triangulation of findings to gain views of a wider NDH population. Using a theoretically informed approach to investigate the role of community pharmacy in diabetes prevention in this research presents a potential to inform development and implementation of services for people with NDH in this setting. The findings could also inform possible screening methods for signposting patients into better suited DPP settings.

One of the limitations of the study was the lack of diversity thus providing a limited perspective from people of other ethnic backgrounds. Additionally, the exclusion of non-English speakers could have also created a literacy and language barrier to participation in both the NHS DPP and in this study, thus limiting the generalisation of findings to subpopulations (145). Another limitation was the low response rate to the questionnaire study which limited the number of questionnaires included in the analysis. With the majority of respondents constituting those who had expressed some interest in participating in the NHS DPP, social desirability may also be a bias in the responses received (265) i.e. the data is likely to represent people likely to be engagers in health initiatives than those unlikely engage with the programme.

The use of an unvalidated questionnaire incorporating agree/disagree Likert scale, a scale which research suggests achieve results with lower reliability and validity due to acquiescence and cognitive burden, also poses a limitation in this study (266).

3.5 Conclusions

Community pharmacy is an acceptable setting for the delivery of DPS and could be a possible alternative for people with work and social commitments, regular community pharmacy users and those seeking alternatives to the current national programme. This research outlines factors that could influence the implementation of services in this setting with regards to engagement. Opportunity to engage with community pharmacy-based DPS services could be based on its accessibility. Therefore, if community pharmacy were to provide DPS with flexible session times, which is possible given their extended opening hours, this could present a potential role for the setting in addressing some of the current barriers to engagement. Patient perceptions of the capability of community pharmacy to deliver acceptable DPS could be influenced by knowing that community pharmacy teams are appropriately trained to deliver the services. In order to enhance motivation for people with NDH to engage with DPS, community pharmacy teams would need to build trusting relationships with this population and ensure endorsement by healthcare professionals such as GPs and nurses.

This chapter provides evidence to inform development of an intervention as per the aims of the COM-B model in the BCW. The barriers and facilitators mapped to the COM-B components of this research were taken forward to describe the role of community pharmacy in diabetes prevention. Further work presented in Chapter 5 and 6 seeks to refine these barriers and facilitators to assist the linking of the outcomes through the Behaviour Change Wheel (203, 207), to develop appropriate interventions and strategies that could increase participation in community pharmacy-based services.

Chapter 4: The community pharmacy setting for diabetes prevention: views and perceptions of stakeholders

Publications developed from this chapter:

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4.1 Introduction

Intervention accessibility has been identified as an important influence for engaging with DPPs (131-133). Research investigating engagement with the NHS DPP has identified similar barriers, including lack of transportation, inconvenient location and session-times (Chapter 3). Such barriers may be addressed by community pharmacy involvement given its accessibility (Chapter 3).

In England, however, with NDH primarily identified through routine primary care appointments or retrospective screening of general practice databases, the role of community pharmacy in the delivery of DPPs remains undefined (120, 155). Additionally, although community pharmacy delivers opportunistic screening interventions, there are no direct referral pathways to the NHS DPP from this setting (137), nor are there routine lifestyle interventions being delivered for people with NDH. Therefore, with the NHS long term plan advocating involvement of community pharmacists in primary care networks for case finding and treating high risk conditions (115), it is important to establish a clear role for community pharmacy in delivering interventions for people with NDH. Additionally, there is a need to better understand the likely barriers and facilitators to delivering public health interventions in this setting.

To date, with majority of qualitative research focusing on exploring barriers and facilitators to engagement from the perspective of people with NDH (132, 145, 146, 238), very few studies have explored the views of those delivering the interventions. Successful delivery of community pharmacy based DPS would require behaviour change from those delivering the interventions. Therefore, the study presented in this chapter focusses on behaviours of healthcare personnel that would be involved in delivering community pharmacy based DPS including GPs, pharmacists and commissioners (131) to inform the potential role of community pharmacy in the management of NDH within the primary care context. The study applied the COM-B theoretical model to understand the target behaviour 'the delivery of DPS by community pharmacy teams' (188). Analysing this behaviour

using the COM-B was intended to assist in identifying behavioural determinants which could serve as fruitful targets for community pharmacy-based interventions that could facilitate the successful and sustainable delivery of DPS.

4.1.1 Aims

To explore the community pharmacy setting as an option for delivering DPS by eliciting views of stakeholders and using the COM-B to frame the data collection, analysis and future direction of interventions aimed at patients and healthcare personnel.

4.1.2 Objectives

1. To characterise the current and potential role of community pharmacy in the prevention of type 2 diabetes
2. To describe the barriers and facilitators to delivering DPS in the community pharmacy setting

4.2 Methods

4.2.1 Study design

This is a qualitative study that adopted a pragmatic epistemology to explore the study aims and objectives. The research employed semi-structured interviews and focus groups to explore views of multiple stakeholders including community pharmacy teams, GPs, nurses and commissioners (267). The study took place in Norfolk, UK, between January and March 2018.

4.2.2 Ethics approval

Ethics and governance approval was obtained from the Health Research Authority (IRAS project ID: 233631) and the Faculty of Medicine and Health Sciences Research

Ethics committee at the UEA before commencing the research. The study protocol can be found in Appendix 4.1, together with the ethics approvals (Appendix 4.2), ethics amendment approvals (Appendix 4.3) and research and development office approvals (Appendix 4.4).

4.2.3 Rationale for study design

A pragmatic and exploratory research design was used to address this research topic in which very little research had previously been undertaken (267, 268). Pragmatism, a philosophy that recognises that there are different ways of interpreting the world and research, suggests there to be multiple realities and hence that no single point of view can ever give the entire picture (269, 270). Pragmatic research therefore seeks to use whatever combination of methods necessary to find the answers to research questions.

Exploratory research is often used to tackle research topics on which little or no previous research has been done (267). It is usually undertaken in a preliminary stage of an investigation to gain background information, produce insights of the situation being developed and generate ideas (267, 268). Since there is currently very little research investigating community pharmacy as a setting for the delivery of DPS, an exploratory research design was deemed appropriate.

A mixture of focus groups and interviews was adopted. Focus groups were viewed as central to exploring the research topic in this group of participants who often work as a team to deliver services (242). However, to provide flexibility to potential participants and thus encourage participation, the interview option was made available to GPs, nurses and commissioners. This option also supports honest in-depth accounts of experiences and opinions thus was considered suitable for obtaining accounts about community pharmacy and community pharmacy teams from other primary care team members and commissioners (242).

4.2.4 Study setting

This study was set in primary care, specifically community pharmacy and general practice settings (271). General practices are private healthcare businesses whose role is to provide healthcare to local communities. Although the majority of general practices work to NHS contracts, follow NHS guidelines and see NHS patients, they do not compete for patients, or profit in the way competitive providers of healthcare do. General practices consist of multidisciplinary teams including general practitioners, nurses, pharmacists and healthcare assistants. These teams are responsible for both looking after patients with chronic illness and health promotion. Community pharmacies are also private healthcare providers working to NHS contracts in providing medicine related services such as dispensing and counselling. As part of their contract, community pharmacies also provide health promotion services such as smoking cessation programmes.

In England, local health promotional services provided by both general practices and community pharmacies are commissioned by CCGs and local authorities (272). CCGs are groups of general practices which come together in an area to commission the best services for their patients and population. These groups therefore buy services for their local community from any service provider, including community pharmacy, which meets NHS standards and costs. Commissioners are usually supported by Clinical Support Units with external support, specialist skills and knowledge and may also consult Local Pharmaceutical Committees (LPCs), who represent all pharmacy contractors in a defined area, on services that could potentially be provided via community pharmacy.

This study involved multiple stakeholders involved in both the provision and commissioning of local health promotional and preventative services in order to obtain a more complete perspective on a potential role of community pharmacy in delivering DPS in primary care.

4.2.5 Study Participants

Eligible participants were community pharmacy personnel, GPs and nurses working in Norfolk, UK. Community pharmacy personnel included pharmacists and registered technicians and healthcare assistants involved in the delivery of public health services (273). GPs, nurses and other pharmacists were only eligible if they were working for general practices participating in NDH screening and referral to the NHS DPP and had a special interest in diabetes. Individuals involved in commissioning and negotiating services for community pharmacy in Norfolk were also eligible to participate in the study. These included individuals working for the CCG, the LPC, NHS England, Public Health England and the East of England strategic clinical network.

4.2.6 Participant identification and approach

4.2.6.1 Gatekeeper consent

Community pharmacy: Gatekeeper consent was sought from area managers (responsible managers for a group of pharmacies in a defined area) of multiple pharmacies or pharmacist managers for independent pharmacies. Area managers/pharmacist manager were sent an e-mail (Appendix 4.5) asking them to circulate an invitation letter (Appendix 4.6) and a participant information sheet (Appendix 4.7) to pharmacists in their area/store. Where gatekeepers were unable to do this, consent was sought from the gatekeepers to contact community pharmacies via telephone before sending research documents to interested persons.

General practice: GP practice participants were approached through the Norfolk and Suffolk Primary and Community Care Research and Development teams (R and D) office (Appendix 4.5). These are teams set up in each CCG to support research that aims to develop new treatments and knowledge for better healthcare. Research information, including an invitation letter (Appendix 4.6) and a participant

information sheet (Appendix 4.7), was e-mailed to practice managers by the R and D officers asking them to forward it to GPs and nurses in their practice.

Commissioners: Commissioners were identified through the Norfolk and Suffolk Primary and Community Care Research and Development (R and D) office and/or existing contacts with CCGs and Local Pharmaceutical Committee (LPC) (Appendix 4.5). Potential participants were approached via e-mail which included an invitation letter (Appendix 4.6) with an attached participant information sheet (Appendix 4.7).

4.2.6.2 Expression of interest and follow-up

Individuals who were interested were asked to complete an online expression of interest form (Appendix 4.8) which contained options for their availability. Participants were given two weeks to respond to the e-mail and followed up either via e-mail (Appendix 4.9) or a follow-up telephone call. All participants who volunteered to participate in the study were sent a reminder e-mail at least three days before the interview or focus group (Appendix 4.10).

4.2.7 Sampling

The study aimed to conduct two focus groups and a maximum of 12 interviews. For community pharmacy participants, initial recruiting involved convenience sampling followed by purposive sampling. This was to ensure a good representation of community pharmacy personnel from various chains and independent pharmacies. Participants were therefore selected to obtain a diversity of views using job titles and workplace representation (242). The size of the focus groups consisted of five to eight participants to ensure a group composition that facilitated a rich discussion (242).

Convenience sampling was used to recruit commissioners, GPs and nurse participants whilst ensuring representation of practices in Norfolk. All GPs, nurses and commissioners opted for the interview option rather than the focus group

option, hence focus groups were only conducted with community pharmacy participants. The number of interviews conducted was determined by availability of participants and data saturation. In this study data saturation was determined when there was no additional data expressed in new data (244).

4.2.8 Incentives and reimbursement

Participants involved in focus groups and interviews conducted outside of working hours were reimbursed for travel costs and received a £30 voucher for participating. General practices were reimbursed at £80 per hour for GP time and £23.21 per hour for nurses' time for interviews conducted during working hours in line with advice from the Norfolk and Suffolk R and D team. Participating commissioners offered to participate without payment. Refreshments were provided for the focus groups.

4.2.9. Data collection

4.2.9.1 Data collection procedure

Semi-structured interviews were conducted at the UEA or participants' workplace by the main researcher (TK) and lasted up to a maximum of 30 minutes. Focus groups were held at the UEA and facilitated by the main researcher (TK) and another member of the research team (MT/HA) and lasted approximately 60 minutes. Both interviews and focus groups were digitally audio recorded and a semi-structured topic guide was used to facilitate the discussions. Written consent was obtained for both the focus groups and interviews (Appendix 4.11).

4.2.9.2 Topic guide

A topic guide facilitated the conduct of both interviews and focus groups, and this is summarised in Table 4.1. The full version can be found in Appendix 4.12. The topic guide was designed to gain information about the current and potential role of the community pharmacy in diabetes prevention. It also explored the main barriers and facilitators of delivering a community pharmacy-based DPP. It was developed based on a review of the literature and discussion among the research team and

underpinned by the COM-B model proposed by Michie *et al.* (192). However, the structure was not restricted to this in order to allow emergence of unanticipated topics. The topic guide was tailored to the appropriate healthcare professional group or commissioner, but the key issues remained the same.

Table 4.1 Topic guide summary

Research topic	Issues discussed
Background	Current job role and work experience
Non-diabetic hyperglycaemia (where applicable)	Experience and challenges with the management of patients with NDH Engagement with the delivery of current NDH services
Community pharmacy services	Experience and views about current community pharmacy services Views on current primary care based public health services e.g. NHS Health Checks Current challenges and impact of services
Community pharmacy-based diabetes prevention	Views on the role of community pharmacy in diabetes prevention (screening and lifestyle interventions) Capability: barriers and facilitators for using community pharmacy personnel to deliver services e.g. skills and training Opportunity: barriers and facilitators for using the community pharmacy setting for the delivery of DPS Motivation: barriers and facilitators for community pharmacy teams delivering DPS as part of the primary care team

4.2.10 Data Analysis

4.2.10.1 Thematic analysis

Interviews and focus group recordings were transcribed verbatim by the main researcher (TK) or a paid contractor. The transcripts were then uploaded to NVivo 11 and checked for accuracy by listening back to the original recording. To provide an iterative process of analysis Braun and Clarke's six phases of thematic analysis, a method for identifying, analysing and reporting themes within data was conducted (274). This approach was adopted because it can be used to analyse data from different types of communication media, providing a flexible approach to analyse data from both audio recorded interviews and focus groups (275). Processes taken to conduct thematic analysis in the study were similar to those presented in Chapter 3.

In summary, the transcribed data was re-read and inductively coded by the main researcher (TK). The coding process was then discussed with another member of the research team (HA) to assist the development of themes. Relationships between the codes were sought in order to develop subthemes and subsequent themes by the main researcher (TK) and another member of the research team (HA). Subthemes and themes were then reviewed by another member of the research team (MT). Any disagreements were resolved by consensus following discussion, referring back to the coded and original transcripts. Transcripts were again revisited to develop a richer description of the themes and to identify representative extracts to use in the written analysis. Extracts were selected to ensure a balanced representation of participant characteristics in terms of engagement with the NHS DPP and study involvement (questionnaire, focus groups and interviews). Theme descriptions and extracts were discussed by the main researcher (TK) with another member of the research team (MT).

4.2.10.2 COM-B analysis

To facilitate the COM-B analysis of the target behaviour, themes associated with the target behaviour (i.e. the delivery of diabetes prevention services by

community pharmacy teams') were identified by the main researcher (TK) and another member of the research team (MT). Respective codes from the themes were then separated into barriers and facilitators and mapped onto the three categories of the COM-B. Mapping was carried out independently by the main researcher (TK) and two other members of the research team (HA and MT). Following this the mapping was further analysed by another member of the research team (HF) who has a psychology background and experience in using the COM-B. Any disagreements were resolved by consensus, referring to the coded and original transcripts.

4.3 Results

Two focus groups with community pharmacy participants and nine interviews with GPs, nurses and commissioners were conducted. One focus group consisted of a mixture of four pharmacists and three technicians and the other consisted of four pharmacists and one pre-registration pharmacist. Participant characteristics are summarised in Table 4.2. Thematic analysis identified five main themes, and these were as follows: 'Management of non-diabetic hyperglycaemia and associated challenges', 'The community pharmacy setting', 'Awareness of community pharmacy services', 'Relationships and communication' and 'Delivery of community pharmacy services'. The first theme sets the context for the current management of people with NDH in primary care which is largely carried out in the general practice setting and the subsequent themes relay the factors associated with the delivery of DPS in the community pharmacy setting. What follows aims to provide a commentary on the first theme along with illustrative quotes to provide context and a COM-B analysis of the subsequent themes with respect to the target behaviour i.e. the community pharmacy team delivering the DPS.

Table 4.2 Participant characteristics

Characteristic	Total (N=21) N (%)
Gender	
Female	16 (76.2)
Profession	
Pharmacist (registered)	8 (38.1)
Pharmacist (pre-registration)	1 (4.8)
Pharmacy technician	3 (14.3)
General practitioner	3 (14.3)
General practice pharmacist	1 (4.8)
Nurse	3 (14.3)
Commissioner (pharmacist)	1 (4.8)
Commissioner (non-healthcare professional)	1 (4.8)
Place of work	
Pharmacy chain	9 (42.9)
Independent pharmacy	3 (14.3)
General practice	7 (33.3)
Commissioner (Local Pharmaceutical Committee-non-healthcare professional)	1 (4.8)
Commissioner (Commissioning Support Unit - pharmacist)	1 (4.8)

4.3.1 Thematic analysis

4.3.1.1 Theme one: Management of non-diabetic hyperglycaemia and associated challenges

Despite the implementation of the NHS DPP, there was a variation in its utilisation by participants working in general practices who described using different risk management protocols and expressed a variety of associated challenges. GP and nurse participants described providing diet and lifestyle advice using, but not limited to, leaflets and face to face or telephone consultations. Personnel responsible for annual monitoring and reinforcement of lifestyle advice also varied and included healthcare assistants, nurses and GPs. Although most GPs and nurses felt that patients were largely receptive to their advice, some felt unable to deliver personalised support due to time constraints. These participants relayed that the overwhelming numbers of people with NDH identified in their practices had led to reactive rather than proactive screening and management.

"When pre-diabetes first became a thing we went from being really proactive about it, thinking gosh we've got to stop these people from becoming diabetic and we were talking to them bringing them in for face to face consultations. Then we realised it was too many people and we couldn't sustain that. So now we send them a letter which is a bit of a cop out" [P15-GP]

Experience with referral to the NHS DPP was varied amongst GP and nurse participants who largely welcomed the programme as a referral option that saved them time and allowed them to focus on management of other conditions. Although some participants mentioned receiving positive feedback from patients who had engaged with the programme, most seemed to have very little knowledge about the content of the programme.

"It is a good option I do feel because of the time element and obviously we're really busy in primary care. Whilst I would always offer that time to the patient equally if

they say, 'yes I will go on the diabetes prevention', that does then reduce that, not burden, but it transfers that responsibility over" [P18-Nurse]

Nurse participants felt that uptake amongst their patients was low and was largely affected by location of the programmes and transportation means. Some participants felt that the programme could have better uptake if it was being delivered within their practice due to familiarity and location. Apart from accessibility factors, other barriers to participation included social and work commitments, group-based sessions and patients' perceptions that they had adequate knowledge and capability to make changes themselves. From experience with their patients, some participants felt that engagement was noticeably low amongst people with co-morbidities and those from low socioeconomic backgrounds.

"The other thing is a lot don't like groups…the minute I found that I say oh you know it's a group session, they say, 'oh no I don't want to go, I don't do groups" [P16-Nurse]

4.3.2 COM-B analysis

Four themes: 'The community pharmacy setting', 'Awareness of community pharmacy services', 'Relationships and communication', and 'Delivery of community pharmacy services' all contributed to various degrees in the Capability, Opportunity and Motivation domains of the COM-B analysis. What follows is a brief description of each theme and the results of the COM-B analysis in relation to the target behaviour 'community pharmacy teams delivering DPS'. The separation of the codes in each theme into barriers and facilitators and mapping to the COM-B is detailed separately in Table 4.3 together with the descriptions of Capability, Opportunity and Motivation. The codes in each COM-B component have been given a summary phrase which will be taken forward for further research in chapters 5 and 6.

Table 4.3 COM-B analysis of barriers and facilitators to delivering community pharmacy-based diabetes prevention services

COM-B components with definitions	Mapped codes		Illustrative quotes	Summary phrase*
	Barriers	**Facilitators**		
Physical capability – physical skill, strength or stamina		Practical training	*"I think if the CCG is commissioning a service then they should be able to provide us with the practical training"* [P4-Pharmacist]	1a. Training (practical)
Psychological capability – Knowledge or psychological skills, strength or stamina to engage in the necessary mental processes	Inadequate training to deliver services	Knowledge of support staff Consultation skills Coaching and behaviour change skills	*"I think we need to be very mindful that when we're training our staff it's not just about how you use the equipment. We have to up-skill them on consultation skills as well, because if people are to be utilising us more, they also need to feel that they're getting quality service"* [P8-Pharmacist]	1b. Training (theoretical knowledge) 1c. Training (communication skills)
	Maintenance of knowledge/skills is important		*"You need the skills to be concentrated because if like say for example in the past we* [GP practice] *used to provide smoking cessation services, but we felt that we were not dealing with enough number of services so that our skills would remain at a high level"* [P14-GP]	2b. Experience (service delivery)
Physical opportunity – opportunity afforded by the environment involving time, resources, locations, cues, physical affordance		Accessibility	*"It's about access as well. I think access is very important because I've had customers, they would have gone to the GP otherwise if we weren't closer… one of them had to go in a wheelchair on the bus to go all the way to the surgery whereas they could just leave the house go in the wheelchair to the pharmacy and have it* [Flu vaccination]	3a. Accessibility (location)

			done and then go home, so for them it's easy access" [P1-Pharmacist]	
		CP setting well placed to deliver pre-diabetes services	*"How easy would it be to actually do things like mass screening in community pharmacy and the answer is really really easy…community pharmacy could be picking up pre-diabetics and you know giving the intensive lifestyle advice, weight management etc. you know that's such a piece of cake*" [P20-Commissioner]	3b. Accessibility (setting)
		CP screening for NHS DPP could deliver faster referrals than surgeries	*" I think it could only be a good thing for everybody because the delay in patients getting appointments in a busy practice means that if they are able to go via the pharmacist then they would get the referral quicker than perhaps waiting for an appointment to see somebody here to then be referred into the system"* [P18-Nurse]	3c. Accessibility (shorter waiting times)
		Appointment systems with shorter waiting times than general practice Walk in services	*"Actually, booking appointments, I think, works for a lot of people even if they have to wait ten minutes. I think that's better than what they have to wait at the doctors surgery's"* [P12-Pharmacy technician]	3d. Accessibility (appointments)
		A time-flexible alternative	*"I think it's again going back to individualisation…some patients would chose not to engage in the prevention programme, they may feel I don't want to go to my GP surgery, I can't ever get an appointment or I don't have time to go there because their lifestyle and choices and things. So if they are willing to engage with*	3e. Accessibility (flexible session times)

			their local pharmacy I would say its surely better that they engage with somebody and receive that advice and education that they need than getting signposted to somewhere that they are not going to follow-up with and not get any education at all" [P18-Nurse]	
	Time pressure barrier to delivering diabetes prevention services Pharmacist time constraints hindering delivery of services		*"I can see this eruption this volcano erupting and suddenly not only will general practice be overwhelmed but so will the pharmacist delivering one to one because its very time consuming"* [P16-Nurse]	4a. Time (availability)
	Time pressures leading to low quality service delivery	Delivery of public health services need adequate time	*"With diabetes our main problem is that we don't have time of such for these kind of things we do them of course but there are a lot of time restraints that limit of us to the sort of quality that we may be able to give our patients with the services"* [P9-Pre-registration pharmacist]	4b. Time (delivery)
	Space challenges		*"In terms of other barriers some pharmacies it would be their consultation rooms aren't necessarily ideal"* [P20-Commissioner]	5. Suitable consultation rooms (space)
	Lack of access to medical records		*"The only thing I would say is that I don't see how a pharmacy can help with medication reviews and tell patients they shouldn't be taking certain drugs when they don't have access to their blood results for some cases [laughter]"* [P16-Nurse]	6. Access to patient medical records

	Funding cuts a barrier to CP delivering more services	Future CP services would need to be well funded	*"You know what 6% shaved off! I mean that 6 seems like a small number but that's big money you know because it's paying for your staff to be able to deliver these services so that's what it comes down to…we're in this difficult situation right now… we want to be doing more we want to be involved more and like we're tied, really we're tied to the dispensary, we're tied to these prescriptions"* [P8-Pharmacist]	7a. Funding (cuts)
	Lack of resources to deliver beneficial services		*"To give those services out and be beneficial to the patients a second pharmacist is always good...I mean we've got a second pharmacist in in our pharmacy for at least 4 days a week haven't we but they said you know they are trying to that is getting harder and harder to fund "*[P11-Pharmacy technician]	7b. Funding (resources)
	Current CP services not Integrated in primary care Pharmacists cannot deliver DPS without general practice Perceives CP diabetes prevention services as fragmentation of primary care services	Integration in primary care Commissioning model and integration fundamental CP and GP need to work together more General practice should refer patients into new CP services	*"The issue with all community pharmacy services at the moment is that they are not integrated at the end of the day they are an afterthought a bolt on…work separately"* [P20-Commissioner]	8a. Integration (collaboration with GP)
	Current follow-up systems not sufficient	Effective communication, feedback and referral	*"You need the IT solutions etc. to be able to pass that information back to the GP practice, because at the moment it's not an*	8b. Integration (merged IT facilities)

	Lack of feedback from CP services hindering referrals Poor feedback from GP practice following CP referrals IT systems not merged with GPs hindering GP referrals, follow-up and leading to duplication of work	systems to general practice are needed for the delivery of services IT connectivity fundamental for CP-GP integrated services	*integrated system. So IT connectivity and read write abilities etc. are kind of fundamental I think to the integration of community pharmacy service going forward"* [P20-Commissioner]	
Social opportunity – opportunity afforded by interpersonal influences, social cues and cultural norms that influence the way that we think about things e.g. the words and concepts that make up our language	Challenges in funding services traditionally provided by general practice No dedicated budget pot for commissioning CP services		*"One of the problems at the moment with the way that commissioning happens in the NHS in primary care is if we are commissioned to do something that is a job that traditionally might have been done by the GP practice, how do you release that money?. You are not going to de-commission the GP practices, you're not going to take money away from them etc. so how do you then fund that work that is being transferred to community pharmacy?"* [P20-Commissioner]	7c. Funding (commissioning)
	Commissioners do not prioritise CP Pharmacy underrepresented in CCGs Commissioners envision primary care as primary medical		*"I think the biggest barrier to developing community pharmacy services is the fact that commissioners at a local level do not see it as priority"* [P21-Commissioner]	7d. Commissioning representation

	care (which doesn't include CP)			
		Increased awareness Targeted awareness CP services awareness - responsibility of all HCP including CP	*"I think the diabetes prevention programme would be another good service we provide though provided we create the awareness so that people would know we are doing that, we've got the training to do that" [*P4-Pharmacist]	9a. Awareness/promotion (patients and public)
	Patient barriers - only wanting to engage with prescription services	Need positive promotion of CP i.e. not as cheaper alternative but accessing right level of care Patient need to move in with the times and start using other HCP more rather than expecting to see GP	*"I think also the raising of awareness of pharmacy need to be in a positive way, because you know the stuff that I've seen around pharmacy has been you know doctors too busy so go and see your pharmacist, or medicines are costing too much money go buy them cheaper in the pharmacy, and so I'm not 100% sure that that message is wholly positive"* [P8-Pharmacist]	9a. Awareness/promotion (patients and public)
	Ethical challenges with promoting CP services		*"Then again there's another point with private companies like [pharmacy multiples] trying to advertise for services. It's like this is a health thing do I really advertise it like I'm advertising for maybe perfume or milk? There's that ethical aspect"* [P6-Pharmacist]	9a. Awareness/promotion (patients and public)
	Lack of awareness of CP services (GP) GP only aware of pharmacist role in medication		*"I think that GP's don't understand, have no idea what pharmacists know and what pharmacists could do in community pharmacy… it's just a lack of knowledge about that"* [P19- GP practice pharmacist]	9b. Awareness promotion (General practice)

	Lack of knowledge of CP role and skills			
	Sceptical if prevention service is feasible in CP setting Sceptical if CP is the best setting for delivery of diabetes prevention advice		*"I mean if they've got the appropriate resources then I can't see any major disadvantages, but whether it's feasible to provide all these services in a pharmacy setting I am not so sure, and whether one person can do all these things am not so sure"* [P14-GP]	10. Feasibility
	Sceptical about follow-up following screening in CP CP public health screening services with no follow-on programmes wasting primary care resources		*"In terms of screening I can't see any reason why it can't be done outside of the surgery setting but I am a bit sceptical about how that would be dealt with in by the pharmacist. Meaning is it going to be a case of them just doing a blood test and then if they've got an HbA1c of 42 say oh go and see your GP or whether they can then give any focused advice about that or whether they would be empowered to do the necessary referrals to the say for example the diabetes prevention programme"* [P14-GP]	10. Feasibility
		Commissioning for outcomes better model of demonstrating impact of service	*"They need to know what we they are commissioning and commissioning for outcomes… unless you can say what you are going to deliver and performance manage it then you know it's always going to be questionable as to the impact that you're providing"* [P20-Commissioner]	11. Demonstration of impact (positive health outcomes)

	Commissioning CP services difficult due to multiple contractors		*"Obviously we've got yes some big providers like [name of pharmacy multiples]… but we've also got individuals and if you were an evolving care organisation…an accountable care organisation and you wanted to commission something like that from community pharmacy….how do you manage it…in an area might be 30, 40, 50, 60 different contractors… so you need a vehicle really to actually deliver that"* [P20-Commissioner]	12. Multiple community pharmacy contractors
	Competing interest in delivering services Competing interest with GP practices for services		*"With regards to services moving out of primary care, if GPs provide the screening services then we get...as I said to you earlier we get kind of paid for it and it's a source of income. So even though it might not be a huge source of income but because of the precarious state a lot of GP are around the country even smaller reduction in their income will have a destabilising effect"* [P14-GP]	13. Competing interests
	Competing interest affecting CP-GP relationships		*"There is some competition between services especially the flu vaccination… there's been quite a lot of inappropriate advertising from both sides in the past few years to try to get patients so that's something that kind of ruins the relationship a little bit"* [P12-Pharmacy technician]	13. Competing interests

	GP perceiving that CP has an ulterior motive for providing services Perceives CP delivering pre-diabetes advice as stepping on GPs toes	DPP would need to be positively promoted to practices to ensure they don't see it as challenge upon their services	*"Our satisfaction rates are have always been high in spite of whatever the newspaper say… and that's because we feel that the patients feel that we are doing what we are doing for them rather than for any other ulterior motive. I guess when they going to see a pharmacist even if they are very altruistic, even if they want to be just doing good for the patients, there always the suspicion if is it really just for me or is it because they are after their bottom line yeah so I don't know"* [P14-GP]	13. Competing interests
		Pre-diabetes education not efficient use of GP time	*"We were referring patients to the health trainer…anyone who was diagnosed with [pre-] diabetes was sent her way because it's not actually it's not efficient use of our time to really educate somebody with pre-diabetes"* [P13-GP]	GP time * Not carried forward -related to general practice teams hence not directly linked main research population
	GP practices not referring patients to CP public health services		*"There is an awful lot of surgeries that can't engage because they are busy as well and can't and don't want to engage but they are not necessarily referring patients to community pharmacy"* [P20-Commissioner]	14. GP endorsement/referrals
	Potential patient resistance because historically they would see a nurse or a GP for diabetes services	GP endorsement of CP services would positively influence uptake GP endorsement of CP DPP would be important	*"If the GP's were to promote pharmacy then I think a lot more people will be more willing to uptake services"* [P1-Pharmacist]	14. GP endorsement/referrals

		for instilling confidence in patients		
		CP could help reduce GP workload	*"I think that's good because from our point of view as primary care and GP practice were trying to reduce our footfall as much as possible in terms of patients coming into the surgery for things that can be dealt with by pharmacies"* [P18-Nurse]	15. GP workload
	CP time pressure leading to unwarranted referrals to general practice CP public health screening services creating more referrals and workload for general practice		*" If they are doing those things we need to see it…referring back if we need to something the only problem with that is that its more workload for us but it's only the same as someone getting a private medical and then we have to deal with that so"* [P15-GP]	15. GP workload
	Fear of overwhelming working environment that CP DPS could create in primary care		*"I can see this eruption this volcano erupting and suddenly not only will general practice be overwhelmed, but so will the pharmacist delivering one to one"* [P16-Nurse]	16. CP workload (prescription service) **
	Poor relationships with pharmacy multiples	Positive working relationships with general practice-owned pharmacies Good referral systems depending on relationships	*"I suppose because we have got our own pharmacy we just work through …yes so we know them all so they are employed by the practice so we've got pharmacy patients and dispensary patients so it's all done within the practice"* [P13-GP]	17. Relationships (community pharmacy and general practice)

		GPs need to have confidence in pharmacy team ability to deliver DPP	*"It's you know trying to build the confidence of the doctors in us as well and our teams because at the end of the day if we do something like this it's unlikely it's going to be us that's delivering the service it's going to be our healthcare team so they have to build up confidence in what we're doing"* [P2-Pharmacist]	17. Relationships (community pharmacy and general practice)
		CP need to build trust with GPs	*"Yeah I mean I guess there ought to be a bit more kind of trust in between, I think it's mostly a trust issue. If GPs are to trust that what they are doing they are doing it properly and then the GPs don't have to take up the extra burden but not be paid for it, then I think it would work well"* [P14-GP]	17. Relationships (community pharmacy and general practice)
	Potential resistance from general practice because historically patients go to a GP setting for diabetes services		*"I would imagine that there could potentially be some resistance from obviously places like us as a GP setting, because historically it would always be that you came to your GP and you know if the GP or the practice nurse or whoever would see you and diagnose you and give you advice and so on"* [P18-Nurse]	GP resistance * Explored under relationships (Ref 17)
	GPs perceiving to be better than pharmacists at giving pre-diabetes due to extensive knowledge of diabetes and		*"I think the background knowledge is very important but what is also important is the experience behind it. I mean it will be very difficult for a pharmacist to replicate the experience which a GP will have because diabetes is not just diabetes, its kidney disease, its heart disease, its peripheral*	GP resistance * Explored under relationships (Ref 17)

	associated co-morbidities GPs perceiving to be better placed to give pre-diabetes opportunistic advice due to links with co-morbidities in patients the consult		*vascular disease and we see it day in and day out. I think a pharmacist will be adjunct to this but I don't think pharmacists will be able to do this all on their own."* [P14-GP]	
Reflective motivation – reflective processes involving plans (self-conscious intentions) and evaluations (beliefs about what is good and bad)		Use pharmacy skill mix to deliver diabetes prevention services CP public health interventions don't have to delivered by pharmacists	*"We are supposed to be utilising and making best use of the skills mix … because as much as we get frustrated with the monotony of our role as do our dispensers and our healthcare assistants so introducing these things can make them feel challenged and provide opportunities for growth"* [P8-Pharmacist]	18. Skill mix
	Dispensary role of pharmacist hindering scope to deliver more services Pharmacy workload hindering delivery of services	Appropriate allocation of resources	*"Our employers have to be on-board properly. We need the support unless this can be done by a designated member of staff, but if it's on the pharmacists again then that would be a problem because as it is there is so much that I need to do"* [P6-Pharmacist]	19. Workload (appropriate allocation of resources)
	Inadequate training leading to lack of confidence	Self-efficacy of staff in delivering services enhanced by training and experience	*"I think it's imperative that you know the services are standardised across the board that will instil confidence ok for us and also for the patients you know you don't want your patient to come in and you don't know what you're doing"* [P4-Pharmacist]	20. Self-confidence enhanced by training

		Confidence of patient and GPs on CP delivering services enhanced by training and experience		
	Lack of structure to deliver particular services leading to pressure on pharmacist resources Overwhelming experience created by unstructured delivery of CP services		*" If you get people come marching through your door to speak to your pharmacist, and as you were saying you've got your methadone addicts, and you've got your morning after, and you've got your MUR's, it sometimes as a pharmacist you don't know where your backside is really because you're everywhere"* [P6- Pharmacist]	21. Structure of service delivery
		Implementation of service with GP to alleviate tensions caused by competing interests	*" The worry is if the GP's think oh you're just taking their job away…so it's trying to make sure that we get a good conversation going with the GP's and actually come up with a good way to actually implement the service with them"* [P2-Pharmacist]	22. General practice support
		Delivering pre-diabetes lifestyle advice does not require one to have a medical degree	*"As a GP I mean I do do an awful lot of it [lifestyle advice] opportunistically within the consultation because it relates to so many things… blood pressure and anything but you don't need a medical degree to give lifestyle advice"* [P13-GP]	Training beliefs * Not carried forward – explored under capability
Automatic motivation – Automatic processes involving emotional reactions, desired (wants	GPs will only endorse services if there something in it for them		*"If obviously the doctors have got QOF targets and they will be paid for a similar thing then they're not going to be sending*	23. General practice benefits

and needs), impulses, inhibitions, drive states and reflex responses			*people to me if they can get that money isn't it"* [P5-Pharmacist]	
		CP diabetes prevention services would bring in financial benefits	*"So cost wise in providing the service I think it would be cheaper for the NHS for us to do it [deliver DPS] than to get the GP surgery's to do that…also hopefully they will channel a little bit of money you know from there into the community pharmacy so that they can provide us with a extra hands that we need"* [P1-Pharmacist]	Funding (resources) Explored under physical opportunity (Ref 7b)
	Pharmacists intimidated by GPs - affecting relationships		*"I think as pharmacists we can find it you know really difficult to talk to GP's sometimes… I think of what I used to be like with consultants, they seemed you know they were up here…that's a personality thing sometimes and I think it would be the same"* [P19-GP practice pharmacist]	23. Relationships (communication)

* Numbered phrase taken forward for further COM-B analysis in Chapters 5 and 6

4.3.2.1 Theme two: The community pharmacy setting

This theme largely discussed physical characteristics of the community pharmacy setting such as accessibility in relation to engagement of people with pre-diabetes with DPS. The barriers and facilitators identified in this theme related to delivering DPS in the community pharmacy setting with respect to time and resources. As such, a majority of barriers and facilitators associated with the theme were mapped to the physical opportunity domain of the COM-B.

4.3.2.2 Theme three: Awareness of community pharmacy services

This theme considered the societal role of community pharmacy in public health and primary care. The theme, largely discussing the level of awareness of community pharmacy services by the public, patients and other healthcare professionals, identified barriers and facilitators which were primarily mapped to the social opportunity domain of the COM-B.

4.3.2.3 Theme four: Relationships and communication

This theme discussed current challenges with communication between community pharmacies and other primary care teams, particularly general practices and how relationships play a role in enhancing and hindering communication and delivery of services. Whilst certain aspects of this theme related to physical resources that could enable efficient and effective communication between community pharmacy and general practices, much of the theme identified interpersonal influences behind the poor communication and relationships between the two primary care settings. Therefore, most of the barriers and facilitators relating to this theme were mapped onto the opportunity and motivation domains of the COM-B.

4.3.2.4 Theme five: Delivery of community pharmacy services

This theme examined the practical aspects of delivering public health services, including DPS, in the community pharmacy setting. The theme considered the capability of community pharmacy teams to deliver the services, the physical resources required to deliver the services and the motivation behind wanting to

engage with delivering the services. Hence the theme contributed to all three domains of the COM-B.

Capability

Training was identified as the main enabler for enhancing the capability of community pharmacy teams to deliver DPS. Most participants felt that whilst pharmacists have adequate knowledge to deliver NDH education and interventions, other members of the community pharmacy team, e.g. technicians, would need a sound theoretical understanding of NDH and its management. Pharmacist participants felt that this was crucial as it would give such members more autonomy and subsequently lead to less pharmacist intervention.

Other training requirements highlighted by the participants included coaching, behaviour change skills and consultation skills. These skills were seen as important for supporting people with NDH in the making desired lifestyle changes. In general, all participants including general practice participants and commissioners felt that, with sufficient training, any personnel including community pharmacy teams could deliver DPS.

"I think if the CCG is commissioning a service then they should be able to provide us with the practical training" [P4-Pharmacist]

"I'm sure we've had consultations whether it be with a healthcare assistant or a nurse or a doctor where we think, 'that could have been a little bit better', and so I would want to ensure that when people are coming into our pharmacy that they're having a positive experience with the member of staff who is delivering the services to them" [P8-Pharmacist]

Physical opportunity

The community pharmacy setting was identified as well-placed for delivering NDH screening services that could afford a faster referral pathway into the current national DPP. Most general practice participants felt that screening and referral into

the NHS DPP alone would make no difference to their current NDH management procedures and would therefore be acceptable. Additionally, these participants also felt that community pharmacy delivering DPPs as a follow-up from screening would be a good thing and would not conflict with them as they had no capacity to deliver such services. Accessibility was identified as an enabler for engagement of people with NDH with DPS, with setting characteristics such as location, provision of walk-in services and faster appointment systems considered as important factors.

"Well for a start we are more accessible. We open seven days a week…it's not like Monday to Friday the GP's…they [patients] can come in over the weekend and see someone as well. It might be a good thing [to deliver DPS]" [P5-Pharmacist]

In considering the practical delivery of DPS by community pharmacy teams, participants raised various barriers and facilitators. Community pharmacy participants identified time as a key factor in delivering the services. These participants felt that delivering public health interventions requires adequate time, which when compromised, often lead to low quality, "tick box" services. The feasibility of delivering DPS in the setting also considered factors such as space and resources with most participants acknowledging the inadequacy of most consultation rooms in the community pharmacy setting and some referring to them as 'cupboards'.

"Our main problem is that we don't have time for these kind of things [delivering public health services]. We do them of course, but there are a lot of time restraints that limit the sort of quality that we may be able to give our patients" [P9-Pre-registration pharmacist]

Participants also identified the lack of access to full patient medical records in community pharmacy and IT systems which are not merged as barriers to efficient communication and referrals between the community pharmacy and general practice settings. Community pharmacy participants expressed frustration to the lack of robust feedback systems between the two settings with some feeling that

they have no way of knowing the outcomes of recommendations and referrals they make to general practices. Additionally, participants felt that current public health services receive very few referrals from general practices and proposed that this mainly stemmed from the poor communication and referral systems between the two settings. In confirmation of this, some general practice participants admitted to not referring their patients to community pharmacy services due lack of feedback. A common ground reached by the majority of the participants was that in order to successfully deliver services in a community pharmacy setting, future services would require good referral, communication and feedback systems.

"You need the IT solutions etc. to be able to pass that information back to the GP practice because at the moment it's not an integrated system. So IT connectivity and read write abilities etc. are kind of fundamental I think to the integration of community pharmacy service going forward" [P20-Commissioner]

"It'd be nice to know they've done it [DPS], but equally they are doing something which we don't seem at the moment to be able to provide because at the moment we don't have the resources so that's great" [P15-GP]

Finally, a major concern highlighted by community pharmacy participants and commissioners was the current funding cuts in community pharmacy and the lack of a dedicated budget for commissioning services in this setting. Community pharmacy participants, considering the current strain in funding and resources, felt that sufficient reimbursement would be required to account for the time and resources invested in delivering future services.

"The problem is the chicken and egg. Does pharmacy develop and staff itself for those services, but how does it do so before the funding and everything becomes available?" [P20-Commissioner]

Social opportunity

Community pharmacy was considered to have potential to increase patient centred care by providing service users with more choice. Participants felt community pharmacy could potentially increase reach to regular pharmacy users due to the settings' propensity for normalising care and the non-judgemental and anonymous environment it provides. It was also seen as suitable for accommodating an individualised intervention as an alternative to the current group intervention offered in the national DPP, in particular for regular service users.

"I think another benefit [of community pharmacy-based DPS] is also that they develop that link with their pharmacist. I guess perhaps that would be it, that if you've got somebody that's on quite a few medications anyway they're used to going to the pharmacist, it's not a big deal" [P19- GP practice pharmacist]

"I think perhaps it de-medicalises it. It's not a surgery so patients perhaps, I think, would engage better if it's in community pharmacy" [P13-GP]

Although community pharmacy participants considered the delivery of DPS as part of their public health role, they felt there is a general lack of awareness of this role amongst patients, the public and other primary care teams. This resonated amongst general practice participants who, although aware of medicine related services provided in community pharmacies such as Medicine Use Reviews, seemed unaware of the range of public health interventions delivered in this setting. Community pharmacy participants felt that this lack of awareness hindered referrals and consequently affected service uptake.

"I am not really aware of anything apart from that we do have a pharmacy as part of our practice. We have a very good team there and the pharmacist there does quite a lot of education with patients, but not specifically for pre-diabetes in general, probably more for medicine" [P13-GP]

"I think most of the services we do we haven't really publicised to our customers, so you have somebody walking into the pharmacy they don't have an idea of what other services we do, apart from dispensing" [P4-Pharmacist]

The need to raise awareness of the role, skills and services provided by community pharmacy to both general practices and the public was therefore seen as crucial for service uptake. Participants felt that all healthcare professionals have a role to play in raising awareness of community pharmacy services to patients and the public. However, commissioners and community pharmacy participants expressed some concerns over current NHS promotional campaigns as they felt that the message around promoting community pharmacy had so far presented the community pharmacy as a cheaper alternative to general practice. These participants expressed the need for more positive promotion centred on accessing the right level of care.

"I think we've probably all got some responsibility to make services aware, so the chemist obviously themselves they could have posters" [P18-Nurse]

"If you change the message to, 'you're still going to get primary care services you're just accessing it at a more appropriate place', it's a different message and it might drive behaviours to change because as a patient if you get told you are going to see the cheap alternative you might not want to go there" [P21-Commissioner]

The delivery of DPS by community pharmacy as part of the primary care team was also discussed. Community pharmacy participants felt that service endorsement by key members of the primary care team involved in the diagnoses of the majority of NDH cases, in particular GPs and nurses, was crucial to service uptake. However, community pharmacy participants felt that endorsement of, and referral to, community pharmacy services by general practices was largely dependent on working relationships between general practice and community pharmacy personnel. In general, where community pharmacies were independent or co-located with general practices, participants described amicable and positive working relationships. This was primarily due to prior establishment of roles and

agreed referral pathways in patient management as well as regular communication between the two parties. In these cases, GPs or nurses described not only referring patients to the community pharmacy for services such as new medicine services but also described a culture that promoted inter-professional learning. However, regardless of proximity, practices which were attached to chain community pharmacies or were a dispensing general practice (practices that dispense medicines they prescribe to patients living remotely from a community pharmacy) described negative working relationships, poor communication and lack of trust for community pharmacies. Most community pharmacy participants attributed the poor relationships to competing interests, in particular public health interventions such as influenza vaccinations and NHS Health Checks.

"There has to be a working together you know. If we're going to be delivering a service, then the GP surgery needs to be selling it to the patients, because if patients believe something's been endorsed by their doctor then they are a lot more likely to do it" [P8-Pharmacist]

"In an ideal world they [community Pharmacy] *are joined to us* [General Practice], *we live in the same building, but it's definitely a them and us"* [P17-Nurse]

With reference to community pharmacy's involvement in delivering DPS such as screening and lifestyle programmes, although some participants were sceptical about the feasibility of delivering the services in this setting, most participants, including commissioners, felt that the ability for community pharmacy to deliver public health interventions had been proven by current services which were demonstrating positive outcomes.

However, some participants felt that the delivery of DPS in community pharmacy could generate resistance from both GPs and patients. General practice participants described how such services, particularly screening which mainly refer to general practice for confirmatory tests, could potentially create extra workload for them as well as negatively affect their revenue. This was particularly true for GPs involved in

NDH management in their practices who perceived that community pharmacists delivering prevention programmes as taking resources and services outside of primary care and into the hands of private contractors. This is despite the fact that general practices, like community pharmacies, are also private NHS contractors. One GP in particular felt disadvantaged or somewhat cheated by current community pharmacy screening services which refer patients at high risk of CVD or diabetes to them as they felt that community pharmacy was getting paid to do the easy part whilst general practices were left to deal with the long-term management of the conditions for no extra payment. For this reason, the participant felt that there is a need for community pharmacists to be empowered to do thorough NDH screening tests requiring no referral for confirmatory tests and that community pharmacy teams should also be empowered to either refer straight into the NHS DPP or provide follow-on preventative services. Although this view was not expressed by all the general practice participants, community pharmacy participants also acknowledged the lack of services following screening in this setting.

"I would imagine that there could potentially be some resistance from obviously places like us as a GP setting because historically it would always be that you came to your GP, but I think we have to all move and change with the times you know. We need to stop working so segmentally and start working more collaboratively and recognising that actually we can all help each other" [P18-Nurse]

"If GPs are to trust that what they [community pharmacy teams] are doing, they are doing it properly and then the GPs don't have to take up the extra burden but not be paid for it, then I think it would work well…with regards to services moving out of primary care, I mean, if GPs provide the screening services we get kind of paid for it and it's a source of income. So even though it might not be a huge source of income but because of the precarious state a lot of GPs are around the country even smaller reduction in their income will have a destabilising effect" [P14-GP]

With respect to funding, commissioners stated that the funding of services traditionally delivered via general practices was a major challenge which was somewhat enhanced by the under-representation of pharmacists in CCGs. They also expressed that most commissioners envision primary care as primary medical care, which does not include community pharmacy, and thus do not prioritise it. Commissioners felt that currently there is poor integration of community pharmacy contractual elements with general practices on a national level which hinders the delivery of community pharmacy services as part of the primary care team. These participants felt that in order to deliver DPS as part of the primary care team, community pharmacy services would need to have a commissioning model that is integrated into both parties. All in all, participants felt that future services would have to embrace more integration and encourage the development of positive working relationships between community pharmacy and general practices.

"I think the biggest barrier to developing community pharmacy services is the fact that commissioners at a local level do not see it as priority… when they talk about primary care they talk about primary medical care. A lot of commissioners here know that I would say actually you mean primary medical care, we are talking about primary care" [P21-Commissioner]

Motivation

Community pharmacy participants identified various enablers for increasing motivation of delivering DPS as part of the primary care team. Financial incentives were identified as a key source of motivation, with community pharmacy participants expressing that such services would bring some much-needed funding into community pharmacy following recent funding cuts. Community pharmacy participants also felt that future services should offer financial benefits for general practices as an incentive for them to endorse community pharmacy services and avoid competing services between the two settings.

"So cost wise in providing the service, I think it would be cheaper for the NHS though for us to do it than to get the GP surgeries to do that…also hopefully they will

channel a little bit of money you know from there into the community pharmacy so that they can provide us with extra hands that we need" [P1-Parmacist]

"It will depend on, if obviously the doctors have got QOF targets and they will be paid for a similar thing then they're not going to be sending people to me if they can get that money isn't it" [Quality and Outcomes Framework - a reward and incentive programme for all GP surgeries in England, detailing practice achievement results] [P5-Pharmacist]

However, pharmacy participants did acknowledge that in order for general practices to endorse community pharmacy-based services, positive and strategic promotion would be required in order to avoid them seeing the services as a threat. These participants felt that it was community pharmacy's responsibility to engage with such promotion as they perceived that community pharmacy needs general practice support rather than the other way around. This said, some participants felt that community pharmacists may be intimidated by GPs and hence struggle to build positive working relationships with general practices.

"The worry is if the GP's think oh you're just taking their job away…so it's trying to make sure that we get a good conversation going with the GP's and actually come up with a good way to actually implement the service with them" [P2-Pharmacist]

"I think as pharmacists we can find it really difficult to talk to GP's sometimes… I think of what I used to be like with consultants, they seemed you know, they were up here… that's a personality thing sometimes and I think it would be the same" [P19- GP practice pharmacist]

Self-efficacy, which could be enhanced by adequate training and experience, was seen as fundamental for motivating community pharmacy teams to deliver DPS. Some participants felt that it was also important for other members of the primary care team, particularly GPs and nurses, to have confidence in the community pharmacy teams' ability to deliver the services. These participants reasoned that

since patients are usually more receptive to nurse and GP advice, referrals from these healthcare providers would increase uptake and patients' confidence in community pharmacy services. Community pharmacy participants particularly expressed that referrals from practices would address the fluctuations seen in the uptake of their current services which often lead to lack of concentrated skills and subsequent de-skilling of the pharmacy teams.

The biggest barrier to motivation stemmed from pharmacists feeling overwhelmed in their current role. Participants felt that their dispensary role and the current lack of working structure, due to the provision of largely walk-in services, could be a barrier to them engaging in the delivery of DPS. To this extent participants felt that extra resources and improved utilisation of current skill mix, particularly technicians, would be required to deliver the services.

"It doesn't need to be pharmacists necessarily, we've got technicians, we've got skill mix there… and in health checks most of the health checks are not done by pharmacists. The pharmacists does the risk communication but most of the work, the check is done by a technician or somebody else" [P20-Commissioner]

4.4 Discussion

This study highlights the potential for community pharmacy to deliver diabetes prevention services and presents factors in terms of Capability, Opportunity and Motivation at both local and national levels that could facilitate implementation. The study identified fundamental factors that could enhance opportunity for community pharmacy teams to deliver diabetes prevention services including time, resources and funding. Such factors, particularly lack of time and funding have also been identified as major hindrances in delivering public health interventions in previous research (276, 277).

The need for integration of community pharmacy services in primary care has also been identified as central for the provision of future services. These factors,

identified as both physical (e.g. integration of IT systems with general practices and access to patient medical records) and social opportunities (e.g. lack of awareness of community pharmacy role and skills by both patients and other healthcare professionals), highlight the importance of considering potential impact of physical and social contexts when developing interventions. Previous research has also identified social interactions and relationships between the community pharmacy and general practice teams as key for successful delivery of services by community pharmacists (37). In England, the integration of community pharmacy within primary care including the development of positive working relationships between GPs and community pharmacists has also been identified as central for the provision of clinical services (257). In 2019, NHS England introduced primary care networks (PCNs) as part of the NHS Long Term Plan to provide structure and funding for services designed to meet local needs (123). General practices, typically covering 30,000 to 50,000 patients are a major part of these network. It is therefore important that community pharmacy teams closely work with such networks when developing future interventions that are successful in meeting local needs.

However, although most factors identified by this study in relation to integration would need to be addressed in developing future interventions, the extent to which they would influence behaviours (i.e. delivering diabetes prevention services) needs further clarification. For example, the extent to which community pharmacy teams would require access to medical records needs to be further investigated. This is because, although the identification of NDH is largely undertaken in general practice settings, most diabetes prevention interventions are conducted in non-clinical community settings (85). Additionally, with research suggesting that the majority of people with NDH are prescribed a combination of a lipid-lowering and anti-hypertensive drugs (278), community pharmacy could already have sufficient information to identify individuals eligible for focused diabetes prevention interventions.

The importance of considering the impact of future community pharmacy services on other primary care providers, particularly general practice was also highlighted

in this study. The findings suggest current community pharmacy screening interventions such as NHS Health Checks (279), which refer individuals with NDH to general practice services for HbA_{1c} testing, to be potentially adding to general practice workload. A recent report on understanding general practice pressures has highlighted changing relationships of general practices with the wider healthcare system as a contributor to workload and has highlighted referrals and communication as factors that take a significant amount of time in general practice, both for medical and administrative staff (280). It is important therefore that future community pharmacy services should seek to reduce pressure on general practice rather than increase it. Additionally, evaluation of the NHS Health Check service has shown poor attendance amongst people referred to general practice services following screening in community pharmacy (137). The evaluation also demonstrated that almost half the people referred to other lifestyle interventions following community pharmacy services were unwilling to engage. This demonstrates that whilst some people are willing to engage with screening services and lifestyle advice in the community pharmacy setting, they may not necessarily be willing to engage with other primary care services. It is therefore important that community pharmacy is empowered to provide robust screening and follow-up services in this population.

With current guidelines for the diagnosis and referral into NHS DPP screening requiring HbA_{1c} testing, community pharmacies need to be empowered to undertake more thorough diabetes screening that does not necessarily need to refer individuals to general practice services (120). Previous research conducted in Australian community pharmacies has demonstrated that risk assessments followed by fasting plasma glucose tests resulted in fewer referrals to General Practice and greater uptake by patients (281). Additionally, more recent research conducted in Norwegian community pharmacies has further demonstrated the feasibility for community pharmacy to implement services that measure HbA_{1c} (162).

Recent systematic review evidence evaluating the effectiveness and analytical quality of point of care testing performed in community pharmacy, including blood glucose testing, found tests conducted in this setting to have satisfactory analytical quality and has recommended their use to allow easier access to various screening tests (282). There is therefore a potential for community pharmacies in England to be involved in delivering comprehensive screening tests without requirement for referral to other primary care teams for confirmatory tests. With previous research also demonstrating that screening for NDH with appropriate intervention appears to be cost effective (125), there is an opportunity for community pharmacy to deliver lifestyle interventions for those that are unwilling to engage with other primary care lifestyle interventions. The provision of diabetes prevention lifestyle interventions in community pharmacy services for people with NDH, although not commonly explored in research, has been implemented in other countries such as the USA. The national DPP in the USA has highlighted a significant role for community pharmacy not only in raising awareness of NDH and screening but also in delivering DPPs (160).

This study has highlighted training and the appropriate use of pharmacy skill mix as key factors that could enhance the capability and motivation respectively for the community pharmacy teams to deliver quality DPS. The pharmacy workforce, the third largest workforce group in the NHS, consisting of pharmacists and pharmacy technicians has in recent years had its potential to contribute to the delivery of public health services identified (257). The use of technicians, trained as lifestyle coaches, in the delivery of DPS has particularly been identified as a viable option in terms of cost and availability in the USA (160). In order to enhance their capability, this research has highlighted that technicians would not only need theoretical training on NDH and its management but would also need to develop skills such as consultation, coaching and behaviour change skills to support people with NDH in making lifestyle changes. In recent years, the increasing involvement of pharmacists and pharmacy technicians' in direct patient care has highlighted that theoretical training is not enough. This has led to the development of multifaceted training materials for community pharmacists, including consultation skills (283). Previous

research has indicated that training not only increases pharmacists' confidence in providing public health services but is also more likely to lead to a positive impact on customer attitudes and health outcomes (258). Therefore, future services in community pharmacy should seek to invest in the development of this workforce in terms of training in order to increase availability of services.

This research has highlighted various motivations for both community pharmacy to deliver services or general practices to refer into community pharmacy-based DPS, including financial incentives. Additionally, the development of positive and trusting working relationships as well as the elimination of perceived competing interests between community pharmacies and general practices have been highlighted as fundamental for the delivery of future community pharmacy services (257).

Finally, these study findings add to an emerging body of research applying the COM-B model to assist a theoretically based approach of developing interventions. The application of the COM-B has also demonstrated success in identifying barriers to engagement in a recent study reported by Handley *et al.* which aimed to design a tailored DPP among women with recently diagnosed gestational diabetes (247). In the study, the findings of the COM-B analysis led to the development of a tailored DPP which addressed barriers to engagement by identifying suitable intervention strategies to increase both social and material supports such as social networks, health coaches and community resources. Therefore, in the same vein, the findings of this research form a foundation for the development of community pharmacy based DPS. Further research to assist the development of interventions with strategies to enable the successful delivery of DPS in this setting are presented in Chapters 6 and 7 of this thesis.

4.4.1 Strengths and limitations

This is the first study exploring community pharmacy for delivering DPS from the perspective of multiple stakeholders. Data collected was contextual and involved a range of views and experiences of stakeholders involved in the delivery of services

for people with NDH. Although this study was conducted in the context of exploring the role of community pharmacy in diabetes prevention, its findings could be applied to the development of other health promotional interventions in this setting. The incorporation of theory using COM-B, which forms the hub of the BCW will enable the identification of behaviour change techniques which could assist the development and implementation of interventions in this setting. Additionally, although the COM-B has been designed for use by researchers without psychologist background, our analysis benefited from the involvement of a psychologist with experience of applying the COM-B in designing interventions.

A limitation of the study was the lack of participants who are directly involved in commissioning the current NHS DPP. Additionally, the use of two different data collection methods, although useful for triangulation, generated two different types of data where interviews with general practice participants and commissioners generated in depth data whilst focus groups with community pharmacy participants generated superficial data. Arguably, more ground was covered with general practice participants than community pharmacy participants, thus inadvertently, this may have caused an imbalance in the data. Furthermore, the community pharmacy background of the main researcher could have influenced perspectives on analysis and presentation of the findings. On reflection, the novelty of the views expressed by general practice participants and commissioners might have stood out more to the main researcher than those of community pharmacy participants due to familiarity with current challenges associated with delivering community pharmacy services. Therefore in order to minimise bias, analyst triangulation was used to provide multiple perspectives in interpretation of results (284). At significant points during the process of data analysis, the main researcher (TK) regularly met with members of the research team [MT and HA] to discuss data interpretation. Additional discussions were also held with the wider research team with extensive qualitative and clinical experience, to discuss the findings (HF, JS, CK).

4.5 Conclusions

This research has highlighted a potential role for community pharmacy in delivering DPS for people with NDH due to its accessibility. In order to enhance this opportunity, investment is needed to ensure adequate time, resources and funding. New models of services should also seek to integrate community pharmacy services in primary care to facilitate better communication (referrals and feedback) with general practices and prevent competing interests. However, in order to sufficiently manage primary care workload and resources, community pharmacy teams should be sufficiently enabled to deliver holistic interventions which require minimal referral to general practices.

To enhance the capability and motivation of community pharmacy to deliver such services, multifaceted training involving coaching and behaviour change skills and the appropriate use of pharmacy skill mix are required. Whilst incentives would motivate both community pharmacy providers to deliver the services and general practices to refer patients to the services, promotion of the services to patients, public and other healthcare professionals could enhance engagement. The lack of clarity of the extent to which some of the factors identified by this study could affect the delivery of DPS in the community pharmacy setting requires further validation of the barriers and facilitators.

Chapter 5: Validation of barriers and facilitators for delivering community pharmacy-based diabetes prevention services: a questionnaire study

5.1 Introduction

Previous research, conducted in people with NDH, has indicated that community pharmacy could serve as an acceptable option for delivering DPS in people who fail to engage with the current NHS DPP due to accessibility (Chapter 3). Additionally, research conducted in primary healthcare personnel and commissioners indicated a potential for delivering interventions which mirror the NHS DPP in community pharmacy settings (Chapter 4). This research identified a number of enablers for delivering the services including collaboration with general practice teams (Chapter 4), a finding supported by a growing recognition that public health interventions delivered in community pharmacy should be integrated into local primary care networks (257).

Findings from previous research were analysed using the COM-B theoretical model and thus could potentially inform the development of interventions to assist community pharmacy teams with delivering accessible DPS to people with NDH. This could be achieved through the application of the Behaviour Change Wheel framework (188, 192). However, as this work was conducted in a small number of practitioners there is a need to triangulate these findings in a larger number of professionals before proceeding with further development. At the same time, it is important to elicit practitioner views on the current NHS DPP and this can be done using the APEASE criteria (192). The APEASE criteria can be used to make context-based decisions when designing or evaluating interventions. The criteria recognises that an intervention design is more than effectiveness as all behaviour change operates within a diverse range of social contexts, affordability, practicability, effectiveness, acceptability, sustainability and equity. The APEASE criteria could therefore be useful for establishing a contextual understanding of views on the NHS DPP to ensure that interpretation of views on the community pharmacy role in diabetes prevention are described within this wider context.

5.1.1 Aim

To assess the acceptability and practicality, from a primary care practitioner's perspective, of the NHS DPP and the potential role of community pharmacy in diabetes prevention.

5.1.2 Objectives

- To examine the perceived role of community pharmacy in diabetes prevention.
- To triangulate findings from previous qualitative work in a larger group of practitioners.
- To conduct a context-based evaluation of the existing NHS DPP.

5.2 Methods

This research involved distributing a questionnaire to community pharmacists as well as GPs and nurses involved in the management of NDH. The project was undertaken in collaboration with five fourth year pharmacy students from the UEA. Ethics approval was obtained from the Health Research Authority (IRAS ID 252420) and UEA Faculty of Medicine and Health Sciences Ethics committee prior commencing the research. The study protocol can be found in Appendix 5.1, together with the ethics approvals (Appendix 5.2) and ethics amendment approvals (Appendix 5.3).

5.2.1 Questionnaire rationale

The use of questionnaires was adopted in this study as the most efficient way, in terms of time and cost, to obtain data from a sample covering a wide geographical distribution (28). It also provided anonymity and thus had the potential to encourage honest answers. Having previously conducted qualitative work in this group of practitioners and with a set of defined criteria forming part of the

evaluation, a questionnaire approach was deemed appropriate to further progress this study.

5.2.2 Participant recruitment

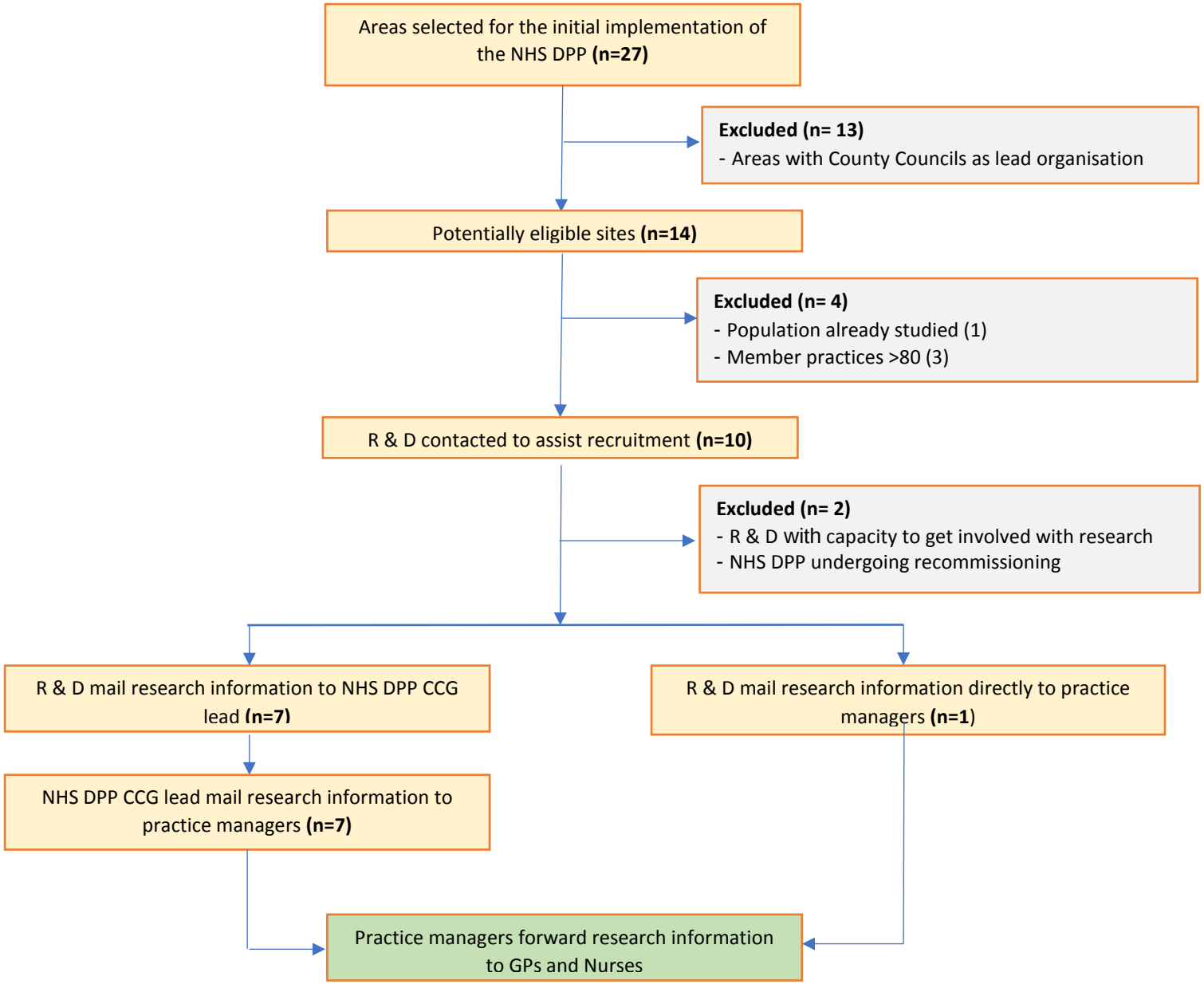
Details of the initial 27 sites across England that had implemented the NHS DPP were obtained from the NHS website. Following this, sites whose lead organisation for implementing the programme was a CCG (and not a County Council) were selected for the study (285). County councils are authorities representing local governments and are responsible for providing majority of public services including education, transport planning and social care. CCGs were the preferred recruiting pathway due to the direct link and governance that they have over General Practices in their area. Ten areas whose lead organisation were CCGs were selected for the study. The procedures for recruiting sites and recruiting GPs, nurses and pharmacists are summarised below:

5.2.2.1 GPs and nurses

Figure 5.1 presents a flow diagram of the recruitment process of GPs and Nurses. R and D departments in the selected ten areas were contacted via e-mail asking them to assist in distributing an 'initial approach letter' (Appendix 5.4) to a nominated lead for the NHS DPP in the identified CCGs.

The initial approach letter requested that the NHS DPP lead e-mail an invitation letter (Appendix 5.5) to each practice in their area that participates in the NHS DPP. Where the CCG did not have a member of staff responsible for this programme then the R and D department was asked to e-mail the invitation letter (Appendix 5.5) directly to each practice involved in referring patients to the NHS DPP. The invitation letter, sent to practice managers, contained a copy of the participant information sheet (Appendix 5.6) and a link to an electronic version of the questionnaire (Appendix 5.7). Practice managers were asked to forward this directly to GPs and nurses in their practice with a special interest in diabetes. To improve response rates, follow-up e-mails (Appendix 5.8) were sent to practices two weeks after initial e-mails were sent, and phone calls made a week after to highlight the e-mails that had been sent.

Figure 5.1: Flow diagram of the recruitment of GPs and nurses

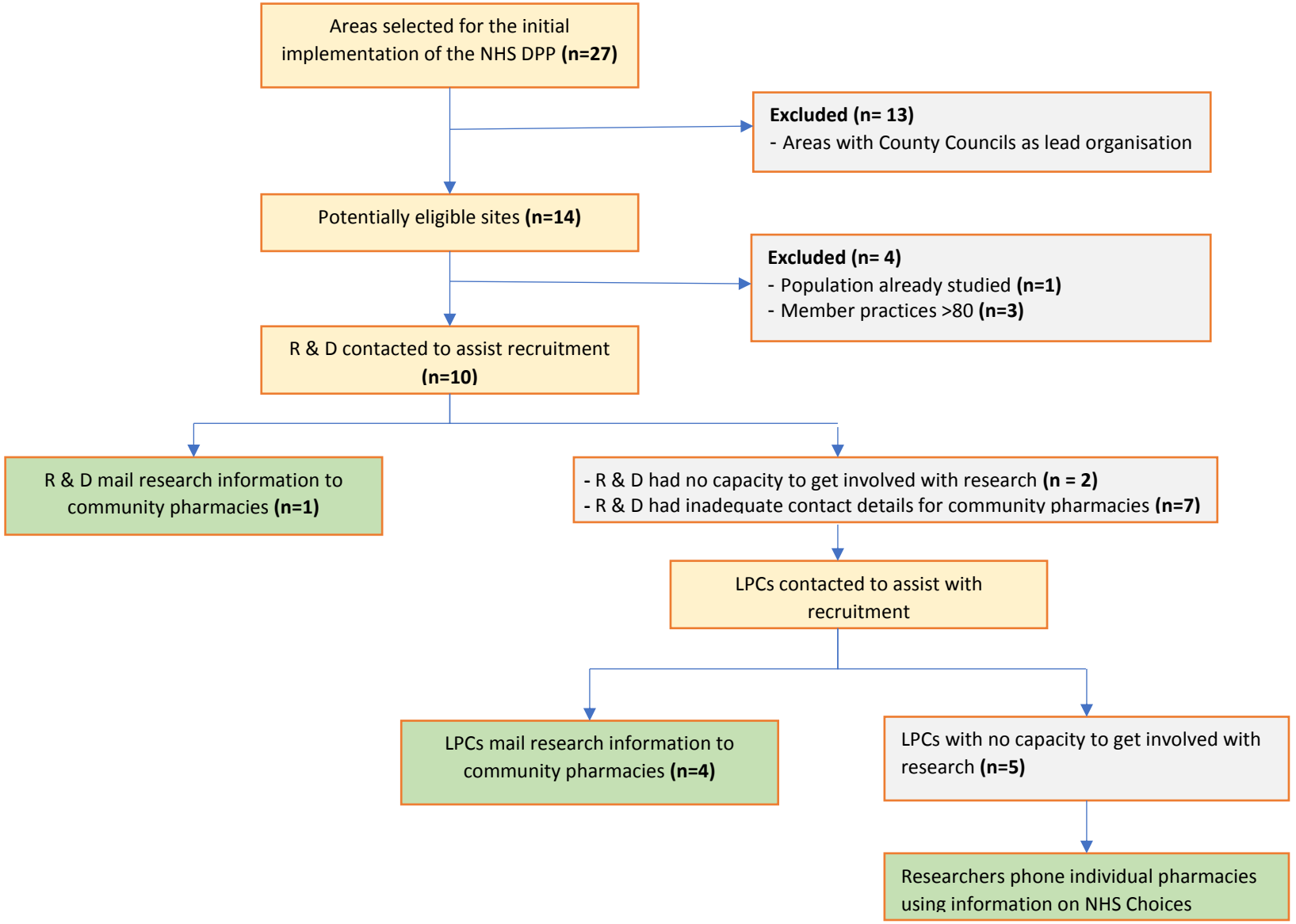


5.2.2.2 Community pharmacists

Figure 5.2 presents the recruitment process for community pharmacists. In the CCGs identified above, the R and D departments were also asked to e-mail an invitation letter (Appendix 5.9), participant information sheet (Appendix 5.6) and a link to an electronic version of the questionnaire (Appendix 5.7) to all community pharmacies in their area. As above, this e-mail was re-sent two weeks after as a follow-up to increase the response rate. Depending on the response rate, a week after the follow-up e-mail the research team called the pharmacies in these areas using telephone numbers readily available on the NHS Choices website. If pharmacists had already completed the questionnaire then no further action was taken and the participant was thanked for their involvement. However, if they had not completed the questionnaire the research team highlighted the study to them and resent the information and questionnaire link to them. No further follow-up occurred after this point.

Where R and D departments did not have the capacity or contact list to enable dissemination of the questionnaire, LPCs were approached to assist dissemination of the research information. Where LPCs were also unable to assist in disseminating the questionnaire, pharmacies in these areas were contacted using telephone numbers readily available on the NHS Choices website.

Figure 5.2: Flow diagram of the recruitment of community pharmacists



5.2.3 Sampling and sample size

To gather data from practices with substantial experience of referring into the NHS DPP, participants from the 27 areas where the programme was first implemented were recruited. Purposive sampling based on CCG deprivation scores and diabetes prevalence data was used to select 10 areas to target from the first wave sites with the aim of achieving an even representation of deprivation and diabetes prevalence across England (286). Based on the assumption that 10 areas with the lowest number of practices and led by an NHS organisation (i.e. CCG rather than the County Councils leading NHD DPP implementation) were to be selected, a potential recruitment sample of 400 practices was expected. With two potential practitioners in each practice (one GP and one nurse), it was estimated that this would yield a potential sample size of 800 practitioners.

Estimating a response rate of 10% (287) we expected a final sample size of 80 questionnaire responses. This yielded a confidence interval around a proportion of 10% (3.4-16.6) which is deemed an appropriate range. Community pharmacists were sampled using a convenience sample; however, the target for responses was similar to that for the GPs and nurses, yielding a similar accuracy level.

5.2.4 Piloting

Prior to distribution to the main sample, the questionnaire was e-mailed out to one GP, one nurse and one pharmacist who had participated in previous qualitative research for piloting (Chapter 4). The practitioners were asked to complete the questionnaire and provide feedback on the structure of the questions and the relevance of the contents to their everyday practice. Two out of three practitioner completed the questionnaire. Both practitioners felt that the questionnaire statement were easy to understand and were relevant to the practice. As a result, no changes were made to the questionnaire following piloting.

5.2.5 Data collection

Data collection was undertaken using an electronic questionnaire (Appendix 5.6) that was distributed to eligible participants. The electronic questionnaire was hosted online by JISC Online Surveys (288). The questionnaire consisted of five sections. The first section gathered participant demographics and current management of NDH. The second section evaluated the existing NHS DPP using the APEASE criteria as described above. The third section examined practitioners' views on the perceived role of community pharmacy in diabetes prevention. The fourth section asked for any additional comments.

The questionnaire was estimated to take approximately 10 minutes to complete as the majority of questions consisted of a Likert scale response from strongly agree to strongly disagree. It was anonymous with consent confirmed by ticking a box on the first page of the questionnaire.

5.2.6 Incentives

Participants were given the option of entering a prize draw to win a £50 voucher. Following completion of the questionnaire, participants were directed to a second questionnaire (Appendix 5.10) to enter their details for entry into the prize draw. This information was not linked to the first questionnaire and therefore responses

remained anonymous. Ten entries into the prize draw were selected to receive a gift voucher of £50 using random name picking. Successful participants were notified by e-mailed and sent vouchers by post or electronically.

5.2.7. Data analysis

Questionnaire data were analysed quantitatively. A descriptive analysis of participants' demographics and work setting characteristics was carried out using SPSS. Data were also explored to describe current experience with managing NDH. Median (IQ) was employed to examine how the NHS DPP was rated by practitioners using aspects of the APEASE criteria as this was a Likert scale. Similarly, appropriate statistical tests were employed to examine practitioners' perceptions on feasibility of community pharmacy activity in the management of NDH. Summarised responses to open ended sections of the questionnaire were coded and mapped to the COM-B framework (192).

5.3 Results

In total seven CCGs, one R & D office and four LPCs assisted with disseminating the questionnaire. Of the 761 community pharmacies and 383 general practices who received the research information, 96 healthcare professionals completed the questionnaire (60% of overall estimated response rate). Table 5.1 presents participant demographics.

Table 5.1 Questionnaire participant characteristics

Characteristics	N	Measure	Classification	Response
Replied	160*	% (n)		60 (96)
Male	96	% (n)		57.3 (55)
Age (years)	96	Mean (sd)		44 (11.8)
Profession	96	% (n)	Pharmacist	84.4 (81)
			GP	7.3 (7)
			Nurse	8.3 (8)
Years of practice	96	Mean (sd)		16.3 (11.6)

* Estimated response rate

5.3.1 Community pharmacy setting characteristics

Pharmacists reported dispensing a median (IQ) of 6,500 (5000, 9900) prescription items per month. A quarter of pharmacist respondents reported having an accuracy checking technician, the majority of whom were routinely involved in checking prescription items, (n=19, (90.5%)). Most pharmacists reported having a consultation room (n=80, (98.8%)) and delivering locally commissioned services (n=69, (85.2%)). Reported community pharmacy services, including diabetes screening, are listed in Table 5.2.

Table 5.2 Types of commissioned services delivered in community pharmacies

Type of service	Details (Summarised from open ended responses)
Medication related services	Healthy start vitamins
	Emergency Supply Services
	Nutrition and dietetic vouchers
	Palliative care supply
	Medicines management service
	Blister pack and Monitored Dosage System scheme
Minor ailment scheme	Urinary tract infection treatment
	Minor eye conditions
	Impetigo treatment
	Oral candidiasis
	Seasonal rhinitis
Screening services	Blood pressure monitoring
	Diabetes checks
	Latent TB screening and treatment
Weight management services	Help-to-Slim
Sexual health services	Emergency hormonal contraception
	Chlamydia test and treatment
	STI screening
	Condom distribution (C-card scheme)
	Pregnancy testing
Smoking cessation services	Nicotine replacement therapy
	Varenicline patient group direction
Drug user services	Supervised methadone and buprenorphine consumption
	Needle exchange scheme
Vaccinations	Influenza vaccination
	Pneumococcal vaccination (PPV)
	Meningitis vaccination
	Travel vaccinations
Others	Anti-coagulation services
	Falls prevention project
	Carpel Tunnel service
	Community equipment

5.3.2 General practice setting characteristics and NHS DPP evaluation

General practitioners and nurses reported having a median (IQ) patient list size of 8,420 (3500, 12000) and a median (IQ) of 5 (3, 8) GPs and 4 (2, 5) nurses per

practice. Approximately two-thirds (n=9, (60.0%)) of the practices reported opening longer hours e.g. evenings and weekends. Just over half of the general practices were co-located with a community pharmacy (n=8, (53.3%)) and a fifth (n= 3, (20.0%)) reported having a dispensing practice.

Most GP and nurse respondents (n=13, (86.7%)) had a special interest in diabetes. Practitioners reported using a combination strategy to manage NDH including referral to NHS DPP (n=12, (80.0%)), face to face lifestyle advice (n=13, (86.7%)), written information (n=11, (73.3%)) and signposting to online information sources (n=6, (40.0%)). Table 5.3 presents findings of the evaluation of the NHS DPP using the APEASE criteria. Generally, practitioners agreed that the service was acceptable and that referring patients to the programme was easy for them. They also felt that the programme had no unwanted/unintended consequences. However, practitioners seemed uncertain about the availability of NHS funding to deliver the programme long term. Neither were they certain of the programmes' effectiveness, cost effectiveness and equity.

Table 5.3 NHS DPP evaluation using the APEASE criteria

Criteria	Questionnaire statement	Median (IQ)*
Affordability	There are adequate funds to continue delivering the service in the future	3 (3,3)
Practicability	Referring patients to the programme is easy for me	4 (3,5)
Effectiveness and cost-effectiveness	This programme is good use of NHS money	3 (3,4)
Acceptability	The programme is an acceptable service for these patients	4 (3,4)
Side effects/safety	The NHS DPP has not had any unwanted/unintended consequences	4 (3,4)
Equity	This programme does not disadvantage any groups of people	3 (3,4)

*Likert scale: 1: Strongly disagree, 2: Disagree, 3: Neutral, 4: Agree, 5: Strongly agree (N=15)

5.3.3 Delivery of community pharmacy-based diabetes prevention services: COM-B analysis of questionnaire statements and open-ended section

Practitioner's views on the delivery of community pharmacy-based DPS in primary care are presented in Table 5.4. The questionnaire statements are presented under the domains of the COM-B together with the domain definitions. Each statement has a reference linking it to the COM-B analysis of barriers and facilitators conducted in the previous chapter (Chapter 4, Table 4.3). Twenty-three participants, including 19 pharmacists, three nurses and one GP responded to the open-ended section of the questionnaire. Responses associated with delivering community pharmacy-based DPS were mapped onto the COM-B framework. The following section describes the responses to the questionnaire statements supported by illustrative quotes from the open-ended sections. The descriptions are presented in the categories of the COM-B and represent views across the professions.

Table 5.4 Practitioners views' regarding delivery of community pharmacy-based diabetes prevention services

	Questionnaire statement	Median (IQ)*	GPs and Nurses	Community pharmacists
			Agree and strongly agree (N (%))	
Ref no. and summary phrase	**Capability (physical skill, knowledge or psychological skills, strength or stamina to engage in the necessary behaviour)**			
1.Training	Community pharmacy teams would need additional training to deliver diabetes prevention services	4 (4,4)	12 (80.0)	65 (80.2)
1.Training	Once trained, community pharmacy teams would be capable of delivering pre-diabetes screening services	5 (4,5)	12 (80.0)	76 (93.8)
1.Training	Once trained, community pharmacy teams would be capable of delivering one-off diet and lifestyle advice for people with pre-diabetes following screening	5 (4,5)	12 (80.0)	76 (93.8)
1.Training	Once trained, community pharmacy teams would be capable of delivering ongoing diet and lifestyle advice for people with pre-diabetes following screening	5 (4,5)	10 (66.7)	76 (93.8)
Ref no. and summary phrase	**Physical opportunity (opportunity afforded by the environment involving time, resources, locations, cues, physical affordance)**			
3. Accessibility	The community pharmacy is an accessible setting for delivering diabetes prevention services	5 (4,5)	10 (66.7)	79 (97.5)
3. Accessibility	Diabetes prevention services in this setting would likely have shorter waiting times than the NHS DPP	5 (4,5)	6 (40.0)	71 (88.8)
3. Accessibility	Community pharmacy is an acceptable setting for the delivery of diabetes prevention services for people unable to engage with the NHS DPP	4 (4,5)	11 (73.3)	72 (88.9)
4. Time	Community pharmacy teams could create time to deliver diabetes prevention services	4 (3,4)	5 (33.3)	44 (55.0)
5. Suitable consultation rooms	Consultation rooms in community pharmacies are adequate for delivering services	4 (3,5)	3 (20.0)	63 (77.8)

6. Access to medical records	Community pharmacy has adequate access to patient medical records to facilitate the delivery of diabetes prevention services	3 (2,4)	1 (6.7)	45 (55.6)
7. Funding	Community pharmacy would need extra funding and resources to deliver diabetes prevention services	5 (4,5)	10 (66.7)	79 (97.5)
8. Integration	Current IT systems are enough for communication and feedback with general practice	3 (2,4)	3 (13.3)	31 (38.3)
Ref no. and summary phrase	**Social opportunity (opportunity afforded by interpersonal influences, social cues and cultural norms that influence the way that we think about things)**			
8. Integration	Community pharmacy diabetes prevention services should be integrated with general practice	4 (4,5)	11 (73.3)	67 (83.8)
9.Awareness/promotion	Diabetes prevention services in this setting would need to be promoted to both patients and practitioners	4 (4,5)	11 (73.3)	71 (88.8)
9.Awareness/promotion	GPs and nurses have adequate knowledge of services provided in community pharmacy	3 (2,4)	10 (66.7)	25 (30.9)
10. Feasibility	It is feasible to implement diabetes prevention services in community pharmacy	4 (4,5)	8 (53.3)	67 (82.7)
14. GP/Nurse endorsement	Community pharmacy diabetes prevention services would need referral from general practice	3 (2,4)	5 (33.3)	24 (29.6)
15. GP workload	Any new services in community pharmacy should minimize creating additional workload for general practice	4 (4,5)	10 (66.7)	64 (79.0)
17. Relationships	Successful delivery of diabetes prevention services in community pharmacy depends on positive relationships with general practices	4 (4,5)	11 (73.3)	69 (85.2)
17. Relationships	Community pharmacy teams could be trusted to deliver diabetes prevention services properly	4 (4,5)	9 (60.0)	75 (93.8)
Ref no. and summary phrase	**Motivation (reflective processes involving plans (self-conscious intentions) and evaluations (beliefs about what is good and bad)**			
23. General practice benefits	GP practices would need to be reimbursed appropriately for referring patients to diabetes prevention services in community pharmacy and acting on their feedback	3 (3,4)	8 (53.3)	28 (34.6)

*Likert scale: strongly disagree (1), disagree (2), neither agree nor disagree (3), agree (4), strongly agree (5)

5.3.3.1 Capability

Training was viewed as essential for the enablement of community pharmacy teams to deliver DPS (Median, 4). Practitioners strongly agreed that once trained community pharmacy teams would be able to deliver interventions including one-off or ongoing diet and interventions (Median, 5).

"Need better training … for scheme to work" [P21-Pharmacist]

However, with community pharmacy services in England being provided by multiple contractors, there were concerns around standardisation of services to ensure high quality service delivery.

"Concern that not all community pharmacies would provide same level of service" [P32- Pharmacist]

5.3.3.2 Physical opportunity

Participants were largely positive about the involvement of community pharmacy in diabetes prevention and felt that services in this setting could target people who are willing but unable to engage with the current national programme (Median (IQs), 4 (4, 5)). The community pharmacy setting was viewed to be accessible (Median (IQs), 5 (4, 5)) and convenient for delivering DPS by most practitioners. However, although current facilities e.g. consultation room, were generally deemed adequate for the provision of the services (Median (IQs), 4 (3, 5)), a larger proportion of this view was held amongst pharmacists (77.8%) than general practitioners and nurses (20%).

The setting was also perceived to have potential for affording shorter waiting times than the current national DPP (Median (IQs), 5 (4, 5)). This was supported by qualitative responses by general practice respondents highlighting location, session times and transportation and work commitments as common barriers for engagement with the current NHS DPP. Some participants noted that uptake was

noticeably low amongst people living in deprived areas. To this end it was highlighted that community pharmacy's involvement in delivering DPS could enhance engagement amongst this population.

"We are a rural practice. Poor public transport therefore difficult to get to. Also, our local courses are only done in working hours. Not suitable if you have a job." [P58-GP]

"It would be a great opportunity to play a big role in this important area of disease prevention and treatment. Community pharmacy is easily accessible to all and at times when other services are unavailable." [P2-Pharmacist]

"Approx. 90% of my clients decline DPP, I have a very deprived client group but they do engage with the pharmacy so this would be excellent to implement in my area" [P24-Nurse]

However, practitioners were uncertain with regards to whether current primary care IT facilities and current access to patient medical records in community pharmacy are sufficient to enable successful service delivery and communication (Median (IQs), 3 (2, 4)). Additionally, most respondents agreed that community pharmacy would need to be funded and appropriately resourced to enable the delivery of the services (Median (IQs), 5 (4, 5)).

"Community pharmacy is severely underfunded…If remunerated correctly Pharmacy can play a vital role in diabetes prevention…before any service is considered funding must be addressed." [P8-Pharmacist]

5.3.3.3 Social opportunity

Delivering DPS in community pharmacy, was viewed to be feasible (Median (IQs) 4 (4, 5)), with most practitioners perceiving that community pharmacy teams could be trusted to deliver the services successfully (Median (IQs), 4 (4, 5)). Overall practitioners felt that delivery of the services should be integrated with general

practice and eliminate any competition between the two settings (Median (IQs) 4 (4, 5)). Positive working relationships between general practices and community pharmacists were perceived to be crucial for the successful delivery of the services (Median (IQs) 4 (4, 5)).

"This has to be seen as complementary to GP services and not in competition. Where GP's feel threatened at loss of income they will rail against a service" [P31-Pharmacist]

There was uncertainty as to whether community pharmacy services would require referral from general practices (Median (IQs) 3 (2, 4)). Respondents were also uncertain if GPs and Nurses had adequate knowledge of current community pharmacy services to enable referrals (Median (IQs) 3 (2, 4)). It was therefore of no surprise that practitioners felt that there would be a need to raise awareness of community pharmacy-based DPS to both patients and other practitioners (Median (IQs) 4 (4, 5)).

With regards to transfer of workloads between the community pharmacy and general practice settings, most respondents felt that community pharmacy-based DPS should avoid creating additional work for general practices (Median (IQs) 4 (4, 5)). However, there was a concern that the transfer of workload from general practice to community pharmacy could create pressure on community pharmacy if the service was not appropriately resourced.

"No one seems to realise that the workload in the community pharmacies is increasing. More services are being "dumped" on the community pharmacy teams in order to relieve the pressures GPs are facing but it seems like there is no adequate reimbursement" [P3-Pharmacist]

5.3.3.4 Motivation

Although some participants involved in referring patients to the NHS DPP were uncertain about the current benefit and uptake of the programme, they highlighted the need for good local service for people with NDH.

"We refer patients to NHS DPP but not sure if of benefit or uptake we have a very good local service called Diabetes essentials for these patients" [P9- Nurse]

Delivering DPS in community pharmacy was viewed as something that could be of benefit to both community pharmacists and general practices. Although participants seemed uncertain as to whether general practices ought to be reimbursed for referring patients to community pharmacy-based DPS and acting on their feedback, respondents felt that DPS could save GP time as well as contribute to quality of framework (QOF) points. Quality of Framework is an incentivised scheme for all general practices in England, designed to outline and reward appropriate resourcing and good practice (308).

"[With] *regards* [to] *payment to the GP's for referring and acting on feedbacks, I think this type of service would be of benefit in two ways. One, the time saved for doing this at the surgery and also they will gain QOF rewards which result in financial gain anyway. So I don't think this should be sold to the GP's with financial payments but benefits to them"* [P26- Pharmacist]

Some respondents also felt that offering incentives to individual pharmacists rather than employers could motivate community pharmacists to deliver the services. This would be different from the current structure which reimburses pharmacy contractors, who often employ pharmacists to deliver community pharmacy services.

"Need to consider payment to pharmacist who take on the services" [P91- Pharmacist]

5.4 Discussion

This research highlights the NHS DPP to be an acceptable and practical intervention for managing NDH by primary care practitioners. The study also confirms previous research findings suggesting a potential role for community pharmacy in delivering DPS that mirror the NHS DPP (Chapter 3 and 4), with likely capacity highlighted by its current involvement in delivering a wide range of locally commissioned services. Although previous research (Chapter 3 and 4) indicated a need for increased access to patient medical records to deliver DPS, this study highlights an uncertainty towards the extent to which community pharmacies would require access to patient medical records. Research evidence demonstrates that community pharmacy could have sufficient patient information to provide targeted lifestyle interventions to people with NDH (278). Therefore, with the current majority of the NHD DPP being delivered by non-healthcare personnel and outside general practice settings, it seems reasonable to suggest that community pharmacy would not require additional access to patient medical records for the provision of DPS.

The study findings also highlight funding uncertainties with regards to the cost-effectiveness and long-term affordability of the NHS DPP and the need to ensure sufficient funding/resources to deliver community pharmacy-based DPS. A recent evaluation of the NHS DPP has indicated the programme as likely to be both cost effective and cost-saving (156). Additionally, with current evidence ranking type 2 diabetes risk factors amongst the top five contributors to premature death in England (289), NHS England has committed to double the funding for the NHS DPP over the next five years (123). However, despite the highlighted plans to expand the current NHS DPP, there is still some concern with regards to appropriate resourcing (290). Therefore, with current demands for the programme outstripping supply in many areas of England since its introduction in 2016 (123) there is a need to explore other pro-active approaches for the management of NDH. The continuing shortfalls in GPs and nurses coupled with the increased practice sizes, also calls for extended roles to be played by other community care providers such as community pharmacy teams (123, 290).

Another concern raised by this study and previous research (Chapter 4), is ensuring the delivery of standardised quality services in community pharmacies, given the multiple contractors involved. These concerns could be addressed by the implementation of recent community pharmacy initiatives which seek to promote the delivery of standardised care. For example, the introduction of the Healthy Living Pharmacy initiative, a tiered commissioning framework for delivering health and wellbeing services tailored to local requirements (291) and the pharmacy quality scheme which remunerates community pharmacies for meeting specified quality criteria including public health (292), provides a platform for the provision of standardised services. Additionally, the proposed Integrated Care Systems (293), where NHS organisations work together with local Councils to meet the needs of the local population, giving commissioners the option to commission services through a single contract would require a shared vision and agreement on common clinical protocols which would further eliminate differences in provision of services. The provision of well-co-ordinated preventative services would therefore demonstrate commitment to improving the health and wellbeing of local communities and aligned patient centred values by primary care providers (290).

This research further highlights the need for the provision of integrated primary care services and positive working relationships between community pharmacy and general practices. In recent years, a growing recognition that integrated primary care services is one way of ensuring efficient use of NHS resources, has led to the development of sustainability and transformation partnerships (STPs) (294, 295). These plans, which include strengthening of prevention and early intervention, recommends that providers and commissioners collaborate and manage the collective resources available for NHS services for their local populations. Therefore, building on the groundwork of the STPs, more integrated models including community pharmacy could facilitate meeting the demands on current DPSs whilst ensuring efficient use of resources.

The provision of integrated DPS through various primary settings including community pharmacy could potentially increase equity of the current programme.

The findings of this study show an uncertainty as to whether the current programme has equity (i.e. the extent to which an intervention may reduce or increase the disparities in health between different sectors of society) and suggests lower engagement amongst people living in deprived regions. With evidence suggesting the risk of developing type 2 diabetes to be up to four times higher in Black, Asian and Minority Ethnic groups (296) there is need to widen patient choice and target inequality. Moreover, with findings from a recent evaluation study suggesting that people of low socioeconomic status or ethnic minority groups may gain fewer health benefits per intervention than obese individuals, it is important to ensure that the NHS DPP does not contribute to widening health inequalities (156). Community pharmacy provides one strategy of targeting these population subgroups. With 99.8% of the population living in areas of highest deprivation estimated to have access to a community pharmacy within 20 min walk, the setting has potential to increase accessibility to these population subgroups (141). Additionally, with community pharmacy staff largely reflecting local populations with respect to ethnicity, culture and language, this setting has potential to increase engagement in particular population subgroups.

This study highlights variations in the current use of the NHS DPP in the management of NDH, also validating previous findings suggesting that DPS should not follow a "one-size-fits-all" approach (Chapter 3). Future designs of DPS delivered in the community pharmacy setting would therefore need to consider the development of tailored services that would increase uptake amongst people not engaging with the current programme. With evidence indicating capacity concerns with regards to suitability of consultation rooms for group-based interventions, perhaps community pharmacy would need to consider delivering a one to one intervention as highlighted by previous research (Chapter 3).

5.4.1 Strengths and limitations

This research promotes the development of an understanding of the role of community pharmacy in diabetes prevention within the wider context of delivering

the NHS DPP in primary care. This study, which included 8 regions in England, confirms that barriers and facilitators for delivering DPS in community pharmacy identified in previous research (Chapter 4) could be generalised across England. These research findings, which have been analysed using the COM-B theoretical framework, provide a basis for the development of interventions which could promote the provision of DPS by community pharmacy teams.

A limitation to this study was the small sample size and low response rates from general practitioners and practice nurses which precluded further statistical analysis comparing responses of community pharmacy and general practice respondents. Another limitation of this study was the use of agree/disagree Likert scale, which research suggests to achieve results which have lower reliability and validity due to acquiescence and cognitive burden (266). However, despite this limitation, the use of the Likert scale was deemed appropriate for this study as it assisted the design of a universal method of data collection that could encompass and enable exploration of a considerably large number of factors.

5.5. Conclusions

This research validates previous findings on the barriers and facilitators for delivering community pharmacy-based diabetes prevention services. The research also suggests that the provision of primary care integrated community pharmacy-based DPS could play a role in increasing equity of the current national programme particularly people living in areas of deprivation. However, with limited available evidence for lifestyle interventions in this setting, further research is needed to investigate both feasibility and cost-effectiveness of diabetes prevention services in this setting.

Chapter 6: Developing a community pharmacy-based diabetes prevention service model using the Nominal Group Technique and the Behaviour Change Wheel framework

6.1 Introduction

Community pharmacy has been identified as a potential setting for delivering accessible diabetes prevention services (DPS) for people with non-diabetic hyperglycaemia (NDH) (Chapter 3 and 4). Previous research has highlighted several interventions that could be delivered in the community pharmacy setting including one to one lifestyle programmes that mirror the NHS Diabetes Prevention Programme (NHS DPP) (Chapter 3, 4 and 5). These interventions; however, need prioritising to assist with the development of community pharmacy-based DPS.

Previous research has also identified several factors that could influence the engagement of people with NDH with community pharmacy-based DPS (Chapter 3) and the delivery of DPS by community pharmacy teams (Chapter 4 and 5). Theoretical analysis of the identified factors has been performed using the COM-B model (188, 192) to provide a better understanding of behaviours that would need changing (both for people with NDH and community pharmacy teams) to facilitate both delivery and engagement. These factors, however, also need prioritising in order to identify key COM-B components (behaviours) influencing both engagement with, and delivery of, DPS. The prioritisation of these components is central to the identification of behaviour change interventions that could facilitate successful implementation of community pharmacy DPS. This development would employ the Behaviour Change Wheel (BCW)) to identify interventions and policies that would facilitate implementation (192).

The Nominal Group Technique (NGT) is one of the most commonly used consensus methods applied in research directed at the identification of research priorities (297). The technique, originally developed by Delbecq *et al.* (298), is a structured consensus method that aims to achieve a general agreement or convergence of opinion around a particular topic (297). The NGT comprises of highly structured face to face group discussions that empower participants to voice their opinions and has an advantage of providing prompt results for researchers.

This study adopted a NGT approach to prioritise types of DPS that could be delivered in a community pharmacy setting and to prioritise COM-B categories that would likely influence engagement with and delivery of community pharmacy-based DPS. This study also employed the BCW to facilitate the selection of appropriate intervention functions, policy categories and behaviour change techniques (BCTs) that are likely to facilitate implementation.

6.1.1 Aims

To identify interventions and policies most likely to facilitate successful implementation of community pharmacy-based DPS.

6.1.2 Objectives

1. To identify and describe intervention characteristics of DPS that could be delivered in the community pharmacy setting.
2. To identify COM-B categories most likely to enhance engagement with community pharmacy-based DPS in people with NDH.
3. To identify COM-B categories most likely to enable the delivery of community pharmacy-based DPS by community pharmacy teams.
4. To identify the intervention functions, BCTs and policy categories that are most likely to facilitate the implementation of community pharmacy-based DPS

6.2. Methods

6.2.1 Study design and ethics approval

This research adopted a modified NGT method comprises of two group discussions with stakeholders to prioritise factors for enhancing engagement with and delivery of community pharmacy-based DPS (239). The research also applied the BCW to identify appropriate intervention functions, BCT and policy categories most likely to

facilitate successful implementation of community pharmacy-based DPS. Ethics approval was obtained from the Health Research Authority (IRAS project ID: 227930 and 233631) and the Faculty of Medicine and Health Sciences Research Ethics committee at the UEA before commencing the research. The relevant study protocols can be found in Appendix 3.1 and 4.1, together with the ethics approvals (Appendix 3.2 and 4.2), ethics amendment approvals (Appendix 3.3 and 4.3) and research and development office approvals (Appendix 3.4 and 4.4). The research was conducted between February and March 2019.

6.2.2 Rationale for using the Nominal Group Technique method and the Behaviour Change Wheel

This research used an adapted NGT to identify key priorities for the development of community pharmacy-based DPS (299-301). The NGT, often used in health services research to explore opinions of health professionals, lay people and carers' views, was identified as appropriate for this research which is exploring the views of multiple stakeholders (300). The NGT was considered to be more suitable for this research than the Delphi technique, another commonly used consensus method applied in research (297). The Delphi technique comprises of multi-stage self-completed questionnaires with individual feedback and is often used for the development of guidelines (297). This technique, although useful for determining consensus from a large group of experts, was not viewed as appropriate for this research which included people with NDH. Furthermore, as this research was also not seeking to achieve consensus for the development of guidelines with health professionals, the Delphi technique was not seen as appropriate. An advantage of using the NGT over the Delphi technique is the provision of prompt results. The multi-stage process of the Delphi technique can take weeks to conclude.

The original NGT comprises of four key stages: silent generation, round robin, clarification and voting (ranking) (298, 302). Over the years, variations in the use of the NGT, often influenced by available research, participant time or the level of clarification, have been adopted. A common variation to the NGT has been the

exclusion of 'generation of ideas', often due to the availability of adequate ideas from literature reviews (301), preliminary qualitative research or surveys (300) and expert opinions (299). Another common variation is in relation to ranking where various methods to prioritise ideas have been used including the allocation of scores (303) and Likert scale rating (299) and re-ranking (300). Re-ranking, often consisting of the revision of original ranking, has often been employed to explore the extent to which discussions influence participants' views.

This study, in contrast with the classic NGT, excluded the silent generation of ideas and included the re-ranking of ideas. As this study was built on previous findings which identified barriers and facilitators for engagement with and delivery of community pharmacy-based DPS (Chapter 3 and 4), the generation of ideas was deemed unnecessary. Additionally, due to the inclusion of multiple stakeholders in this research, re-ranking was seen as an important element in determining how discussion would alter views of stakeholders following discussion.

The rationale for using the BCW has been documented in the theory chapter (Chapter 2). The selection of intervention functions, BCTs and policy categories was guided by the APEASE criteria, a set of principles designed to assist in making strategic judgements in consideration of the context (192). The APEASE criteria therefore consider how factors such as affordability, practicability, effectiveness and cost-effectiveness, acceptability, side-effects/ safety and equity, may affect the development and implementation of interventions.

6.2.3 Participant recruitment

This research involved multiple stakeholders including people with NDH, healthcare personnel and commissioners.

6.2.3.1 People with non-diabetic hyperglycaemia

Participants were eligible if they had completed the questionnaire in the previous study (Chapter 3) and had:

- Expressed an interest to participate in further qualitative studies (Appendix 3.11)
- Not participated in a previous qualitative study for this research

6.2.3.2 Healthcare personnel and commissioners

Eligible participants were community pharmacists, pharmacy technicians, healthcare assistants, general practitioners, nurses and commissioners. Participants were eligible if they had expressed an interest (Appendix 4.8) in the previous study to participate in latter phases of the research (Chapter 4)

Eligible individuals were contacted via e-mail which included a participant information leaflet (Appendices 3.8 and 4.7) and details about scheduled date and times for the group discussions. Participants' e-mail addresses were obtained from completed expression of interest forms (Appendices 3.11 and 4.8) or from existing contacts with the Norfolk Clinical Commissioning Group (CCGs)

6.2.4 Sampling and sample size

Two separate group discussions, one with people with NDH and another with healthcare personnel and commissioners, were planned for the conduct of this research. The aim was to obtain groups consisting of 5 to 12 participants, ensuring diversity to help generate richer discussion (302, 304). People with NDH were purposively sampled, with priority given to people who had not engaged with the NHS Diabetes Prevention Programme (DPP). Other stakeholders were also purposively sampled to ensure a mix of professional backgrounds.

6.2.5 Data collection

6.2.5.1 Nominal group technique procedure

The modified NGT consisted of three main stages involving individual responses (initial ranking), group discussion and individual re-ranking.

Stage 1: Individual responses (initial ranking)

Questionnaire content: Types of community pharmacy-based DPS and factors that could influence both engagement with and delivery of the services identified from previous research (Chapter 3 and 4) were summarised in an electronic questionnaire format (Appendix 6.1). The questionnaire was divided in three main sections:

- Section 1: Participant consent and demographics.
- Section 2: Target services and uptake. These questions were based on summarised statements of the six factors likely to influence engagement with community pharmacy-based DPS (Chapter 3, Table 3.8).
- Section 3: Delivery of community pharmacy services. These questions were based on summarised statements of the factors influencing delivery of community pharmacy-based DPS (Chapter 4, Table 4.3).

Of the twenty-four factors that had been identified in the previous research to have potential in influencing delivery of DPS in community pharmacy, only nineteen were included in section three of the questionnaire. The five factors that were excluded from section three of the questionnaire were time, funding, accessibility, awareness/promotion and feasibility. Two of these factors, time and funding, were identified as central for delivering DPS and thus were excluded on the basis that DPPs are already a nationally funded intervention. Two other factors, accessibility and awareness/promotion, which had been identified from research exploring both engagement and delivery, were viewed as factors more likely to influence engagement than delivery hence were included in section two of the questionnaire. Lastly, feasibility was seen as inappropriate for further exploration in this study as services based on this research would require feasibility testing in future. The decision to include/exclude factors from previous chapters was based on existing literature and discussion amongst the research team (TK, JS, MT).

Questionnaire distribution: Participants who had expressed an interest in participating and had confirmed availability were sent an e-mail describing the NGT process and containing a link to the questionnaire. In the questionnaire,

participants were asked to select one factor from each COM-B category which they perceived to be most important for enhancing engagement with and delivery of community pharmacy-based DPS. Participants were also asked to select one or more DPS which could be delivered in a community pharmacy setting.

The questionnaire was distributed at least one week before the scheduled day for the discussion and participants were asked to complete it at least one day before. This was to ensure that participants could still recall their rationale for the ranking at the time of the group discussion. The questionnaire was designed to take approximately five to ten minutes to complete and responses were anonymous.

Stage 2: Group discussion

Responses to questionnaire statements were summarised in a graphical format and presented as PowerPoint slides and/or handouts on the day of the discussion. This was done primarily to identify statements on which consensus had been reached and therefore which required less discussion.

On the day of the focus group and following the obtaining of written consent (Appendix 3.9 and 4.11), the purpose for conducting the research and process of the discussion was re-iterated to the participants. Following this, topics were introduced and discussed in turn. Participants were asked to expand on their responses or viewpoints to the group in a 'round robin' fashion. Participants were also given the opportunity to discuss the rationale behind their ranking with the group in order to highlight any ambiguities in the statements that may have affected response and therefore subsequent consensus (300, 301).

The discussions were facilitated by two members of the research team, one who took the lead in introducing topics (TK) and another who took field notes and assisted in ensuring progression of the discussions (MT) (305). The discussions were digitally audio recorded. They were held at the UEA and lasted approximately 50 minutes.

Stage 3: Individual re-ranking

Following the group discussion participants were immediately asked to complete a questionnaire, exactly the same as the one completed in stage 1. Participants were again asked to select their top preferences following the opportunity to reconsider their ranking in light of other participants' views. The re-ranking process was anonymous and could only be linked to previous responses by matching participant demographics. This stage took approximately five to ten minutes to complete.

6.2.6 Incentives

Participants involved in nominal group discussions received a £30 voucher for participating and were reimbursed for travel costs where appropriate. Refreshments were provided prior to the discussions.

6.2.7 Analysis

6.2.7.1 Participant demographics, characteristics of community pharmacy-based diabetes prevention services and COM-B categories.

SPSS statistics (version 23; IBM Corp) was used to perform analyses of participant demographics with percentages used to describe the data. Similarly, a descriptive analysis of participant ranking was performed, where ranking was described in percentages and factors with highest percentage were ranked as most important for engaging with or delivery of community pharmacy-based DPPs.

To obtain a deeper understanding of the ranking, analysis of the qualitative data was performed. Qualitative data were transcribed verbatim by a paid transcription contractor, loaded in NVivo 11, and then checked by a member of the research team (TK) by listening back to the original recording. The data were then coded inductively by a member of the research team (TK). Codes and associated extracts describing characteristics of the types of services that could be delivered in a community pharmacy setting were used to support and provide a deeper understanding of the rationale behind the ranking of the services. Codes and

extracts associated with engagement with and delivery of community pharmacy-based DPS were also selected and mapped to relevant COM-B categories (242).

The coding and mapping were conducted by a member of the research team (TK) and then discussed with another member of the research team (MT). Any disagreements were resolved by consensus following discussion and referral to original data. The selected extracts aimed to provide deeper understanding of the rationale behind the ranking and a good representation of participant responses. Extracts related to the COM-B categories that were prioritised from the ranking were selected to represent the rationale behind the ranking. Additionally, extracts relaying strategies that could bring about desired behaviour changes in the target behaviours (engaging with and delivery of community pharmacy-based DPS) were particularly sought to assist the identification of intervention functions and behaviour change techniques.

6.2.7.2 Identifying intervention functions, policy categories and behaviour change techniques

Strategies within selected COM-B categories identified from the discussion were used to identify intervention functions and policy categories most likely to facilitate behaviour change. Following this, BCT linked to the selected intervention functions, were selected from a taxonomy of 93 BCTs (220). The selection of intervention functions and policy categories involved the application of the Behaviour Change Wheel and followed the guidance provided by Michie *et al.* (192). Similarly, the selection of BCTs followed the recommendations of Michel *et al*. by aiming to identify the most frequently used BCTs relevant to the intervention functions.

The selection process was carried independently by two members of the research team (TK and MT). The selected intervention functions, policy categories and BCTs were then discussed by the two members of the research team (TK and MT). Discussions were guided by the researches experience and expertise and considered the APEASE criteria, primarily practicability, acceptability and equity. The final selection was then further analysed by another member of the research

team (HF) with a psychology background. Any disagreements were resolved by consensus, referring to the original ranking and transcripts.

6.3 Results

Fifteen participants completed the questionnaire prior to the group discussion, twelve of whom participated in the group discussions and questionnaire re-ranking. Three participants, two people with NDH and one nurse, could not make it to the group discussion due to unforeseen circumstances.

Two group discussions were conducted, one with people with NDH (n=3) and another with healthcare personnel and commissioners (n=9). Participant characteristics are detailed in Table 6.1. The group discussion with healthcare personnel consisted of a mixture of community pharmacy and general practice personnel, and a representative from the CCG. Participants had a median working experience of 8.6 (1.8, 9 (IQs)) years. Engagement characteristics of people with NDH included waiting for an initial screening assessment, programme completion and drop-out.

Table 6.1 Participant characteristics

Demographic profile	Measure	Stage 1 N=15	Stage 3 N=12
Gender			
Female	N (%)	13 (86.7)	10 (83.3)
Healthcare providers and commissioners			
Pharmacist	N (%)	3 (20)	3 (30)
Technician		1 (6.7)	1 (8.3)
Dispenser		1 (6.7)	1 (8.3)
General practitioner		1 (6.7)	1 (8.3)
Nurse		2 (13.3)	1 (8.3)
Healthcare assistant		1 (6.7)	1 (8.3)
Commissioner		1 (6.7)	1 (8.3)
People with pre-diabetes (Engagement status)			
Waiting	N (%)	2 (13.3)	1 (8.3)
Completed		2 (13.3)	1 (8.3)
Dropped out		1 (6.7)	1 (8.3)

6.3.1 Types of diabetes prevention services that could be delivered in community pharmacy

The selection of services that could be delivered in community pharmacy is presented in Table 6.2. Since participants were asked to select more than one option, it was unclear which service was most preferred. Participants perceived community pharmacy to have potential for delivering alternative one to one DPP as well as NDH screening and monitoring services. Although the ranking of the services did not alter following group discussion, views of participants altered in favour of providing private screening and monitoring services. This was despite being very minimal discussion about private screening services in the discussion. The text below presents a narrative summary of discussions related to types of services that could be delivered in community pharmacy together with illustrative quotes.

Table 6.2 The selection of potential community pharmacy-based diabetes prevention services

Type of service*	Stage 1: Initial ranking (N=15)	Stage 3: Individual re-ranking (N=12)
	n (%)	
One to one DPP	6 (40.0)	5 (41.7)
FPG plus referral to GP for confirmatory HbA1c test	8 (53.3)	6 (50.0)
HbA1c plus referral to NHS DPP	6 (40.0)	4 (33.3)
Monitoring services post NHS DPP e.g. BP	8 (53.3)	5 (41.7)
Private screening and monitoring services	2 (13.3)	6 (50.5)

*Participants could select more than one type of service

Training and cost were the two main factors considered by participants when selecting types of screening services that could be delivered by community pharmacy teams. Over half of the participants selected screening and monitoring services that used the fasting plasma glucose (FPG) test. This was primarily due to familiarity with using the test in current community pharmacy screening services. Consequently, the employment of HbA_{1c} testing, which was perceived to require additional training for community pharmacy, was not favoured amongst the participants.

"The fasting plasma glucose obviously some pharmacies already do the health checks, so you know that training is already out there…with the HbA1c… that's obviously going onto a much you know next level again with that". [P6, pharmacist]

Participants also considered the use of point-of-care-test (POCT) to be a better option for the community pharmacy setting. This was primarily due a lack of current arrangements and facilities for conducting laboratory analysis for venous blood tests in this setting. Although generally the FPG POCT was favoured due to cost, participants acknowledged that if community pharmacy were to be involved in

direct referrals to the current NHS DPP, the HbA_{1c} POCT would need to be employed. Participants considered direct referrals to the NHS DPP through community pharmacy, without confirmatory screening tests by general practices, to be a more efficient use of time and NHS resources.

"We [NHS DPP] *normally go for HbA_{1c} tests rather than fasting plasma glucose and a lot of GP practices do actually do HbA_{1c} testing".* [P12, commissioner]

Participants also felt that community pharmacy has the potential to deliver alternative one to one DPPs and monitoring services to support the maintenance of health outcomes following completion of the NHS DPP. These services were perceived to be a natural progression of current screening services such as the NHS Health Check. Participants felt that, similarly to the NHS DPP, these services would need to provide ongoing support to enable the monitoring of clinical outcomes such as weight loss and blood glucose. However, participants felt that community pharmacy could modify the current delivery of the NHS DPP with respect to intervals for monitoring. Participants felt that monitoring could reflect the level of risk presented by patients in order to reduce cost. Community pharmacy participants related that such modifications could mirror current blood pressure screening services which provide different action points based on specified cut off points.

"*We do blood pressure checks as it is and with our ones at least there's kind of cut off points for what your next advice would be… I think that's something with this as well. If you have got people who are borderline you give the advice and obviously the people that are you know much higher risk you probably want to see a lot sooner um and especially as you were saying you know doing the tests do[es] cost money".* [P6, pharmacist]

However, participants felt that monitoring services delivered following completion of the NHS DPP should provide more regular monitoring (3-6 months) compared to the current annual monitoring offered by general practice.

"Well I do think the follow-up is actually more important because once you finish the programme it stops because they're delivering it elsewhere and you've gone into the past as far as they're concerned and if it means that I've got to make a doctor's appointment to find out what my blood pressure and everything else is then that's not as easy as going into the pharmacy. So the follow-up of people who've been on the programme by a pharmacist would be I think very valuable" [P3, patient].

6.3.2 The development of community pharmacy-based DPS using the Behaviour Change Wheel

The following section presents the application of the BCW to the findings of this research. The section will focus on two behaviours:

- **Behaviour one:** people with NDH engaging with community pharmacy-based DPS
- **Behaviour two:** Community pharmacy teams delivering DPS as part of the primary care team

For each behaviour, COM-B domains prioritised from the questionnaire-based ranking are first presented. Secondly, for each selected domain, suggested strategies for bringing about change identified from the group-based discussion are then presented. Thirdly, the selection of intervention functions, policies and behaviour change techniques for each selected COM-B category is presented and discussed.

6.3.3 Prioritising factors influencing behaviour one

Six barriers/facilitators, mapped to categories of the COM-B model, were identified by previous research to have potential for influencing engagement of people with NDH with community pharmacy-based DPS (Chapter 3, Table 3.8). Table 6.3 documents the ranking of these factors before and after the NGT discussions. Generally, views of participants did not change following the group discussion.

From the ranking, awareness/promotion (psychological capability) and integration/collaboration with GP (social opportunity) were identified as the most important influences of engagement with community pharmacy-based DPS. Participants also suggested strategies that could be used to promote community pharmacy-based DPS and enhance collaboration between community pharmacy and general practice. The suggested strategies together with their illustrative quotes are summarised in Table 6.4. The text that follows is the qualitative analysis related to the selection of awareness/promotion (psychological capability) and integration/collaboration with GP (social opportunity).

Table 6.3 Ranking of factors influencing behaviour one

Behaviour: Engagement with community pharmacy-based services		Stage 1: Individual ranking N=15	Stage 3: Individual re-ranking N=12	Selected
Summary statement (Chapter 3, Table 3.8)	**NGT Questionnaire statement**	N (%)		
A. Knowledge of support options (capability)	Knowing that community pharmacy is an appropriate place to access the service	3 (20%)	2 (16.7%)	✗
B. Awareness/promotion (capability)	Being aware that the services are available in community pharmacies	6 (40%)	5 (41.7%)	✓**
C. Suitable consultation rooms (physical opportunity)	Having the assurance that the service would be private and confidential	1 (6.7%)	-	✗
D. Integration/collaboration with GP (social opportunity)	Making sure that the service is provided in collaboration with general practice	5 (33.3%)	5 (41.7%)	✓**
E. Healthcare professionals (motivation)	Having a recommendation from a GP or nurse	-	-	✗
F. Experience with community pharmacy services (motivation)	Having received a good service from community pharmacy previously			✗

** Explored in more depth in table 6.4

Table 6.4 Suggested strategies for behaviour change (behaviour one)

COM-B domain	Summary statement	Strategies generated from stage group discussion (Stage 2)	Illustrative quotes
Psychological capability	**B. Awareness would increase engagement with CP DPS**	Availability of community pharmacy DPS	*"It's almost like there ought to be hand-outs, leaflets almost to give to people or even a poster in the doctors surgery that says are you aware that you can be tested for diabetes at your local [pharmacy multiple] chemist or whatever. It is even something like that either that or the chemists themselves have some poster or leaflets"*. [P1, patient] *"We can add something to the letter [NHS DPP invitation letter] to say you contact your pharmacy as well that can be added easily"* [P12, commissioner]
		Training and experience of community pharmacy personnel	*"Well in my doctors surgery they've got certificates up on the wall showing who does what and what qualifications they've got. I mean they don't necessarily have to have a qualification but they could have something up to say that they've met these competencies i.e. can take a blood pressure, take blood, couldn't they a tick box just to show…some sort of sign up that said all of our health care assistants and technicians have done this training"* [P1, patient]
		Diabetes risk factors	*"It's raising awareness because had I not have been for my 'MOT' as [P1] called it, I wouldn't have ever thought about the fact that I might have [pre-] diabetes"* [P3, completed].
Social opportunity	**D. Making sure that the service is provided in collaboration with general practice**	General practices referral of patients to community pharmacy-based DPS	*"Obviously most patients they do listen to their GP's and they do listen to them very well. So I'd just say if they were to refer them to the service I think people would definitely come if they were being made aware that… you can go to a community pharmacist if you can get an appointment then people would, they generally come and use us".* [P5, pharmacist]
		Community pharmacy communicating clinical outcomes to general practice	*"If you were in the pharmacy and they picked up that you were actually really bad or your blood test was really bad then you want to know that you can then be possibly even fast tracked into the doctors to get the whatever needs to be done"* [P1, patient]

6.3.3.1 Increasing awareness/promotion (psychological capability)

Increasing awareness/promotion, mapped to the psychological capability category of the COM-B, was identified to be important in influencing engagement. This was primarily due to participants perceiving there to be a lack of knowledge of non-medicine related services delivered in community pharmacy settings. Participants therefore felt that it was important for community pharmacy-based DPS to be promoted amongst both patients and the general public.

Strategies suggested by participants to raise awareness were mainly in relation to the content of the messages. Participants felt that as well as informing people of the availability of DPS in community pharmacy, promotional messages would need to raise awareness of the training and experience of the teams in order to increase patient trust and likelihood for engagement. Participants also felt that promotional messages would need to raise awareness of type 2 diabetes risk factors. This was due to participants with NDH perceiving their diagnosis to be coincidental, with most of them associating their diagnosis with visiting the general practice for 'something else'. Therefore, these participants felt that most members of the public would need some knowledge of what the risk factors for type 2 diabetes are before engaging with DPS.

Participants felt that promotional messages could be conveyed through simple means such as posters and leaflets displayed both in community pharmacy and general practice settings. The inclusion of community pharmacy-based DPS as an option in diagnosis letters sent from general practices was also seen as a viable means of raising patient awareness.

6.3.3.2 Collaboration with general practice (social opportunity)

The provision of integrated services, mapped to social opportunity category of the COM-B, was also perceived to be important for increasing engagement. Strategies for enhancing collaboration between community pharmacy and general practice were mainly in relation to referrals and communication between the two settings.

Participants felt that collaboration would avoid current multiple screening appointments that occur between community pharmacy and general practice, hence saving both patients' time and increasing the likelihood of engaging. Considering this, communication between community pharmacy and general practice teams was seen as crucial for integrating services and maintaining complete and up-to-date medical records. Communication of clinical outcomes between the two settings and the provision of reassurance of collaboration was seen as important for instilling patient trust in community pharmacy based-DPS and facilitating engagement. Additionally, patient referrals from general practice to community pharmacy-based DPS where appropriate, was perceived to have potential in enhancing patient centred care.

6.3.4 Selecting intervention functions, policy categories and behaviour change techniques (behaviour one)

Selected intervention functions, policy categories and BCTs change techniques associated with engaging with community pharmacy-based DPS are presented in Table 6.5. The selection was targeted at strategies for behaviour change identified from the qualitative NGT data. Education and enablement were identified to be the main intervention functions for raising awareness whilst environmental restructuring was identified as a key intervention function for enhancing collaboration between community pharmacy and general practice.

Table 6.5 Intervention functions, policy categories and behaviour change techniques (behaviour one)

Selected COM-B component	Summary statement	Strategies generated from group discussion (Stage 2)	Selected intervention functions	Selected policy categories	Selected BCTs
Psychological capability	**B. Patient awareness would increase engagement with CP DPS**	Raising awareness of availability of community pharmacy DPS	Enablement	Service provision	Social support (unspecified) Adding objects to the environment
		Raising awareness of training and experience of community pharmacy personnel	Enablement	Service provision	Social support Adding objects to the environment
		Raising public awareness of diabetes risk factors	Education	Communication and marketing	Information about health consequence
Social opportunity	**D. Making sure that the service is provided in collaboration with general practice**	General practices referring patients to community pharmacy-based DPS	Environmental restructuring	Guidelines	Prompts and cues
		Community pharmacy reassuring patients that results from interventions will be communicated to general practice	Environmental restructuring	Guidelines	Prompts and cues

6.3.4.1 Increasing awareness/promotion (psychological capability)

Education, which primarily functions to increase knowledge and understanding, was identified as appropriate for raising awareness of diabetes and its risk factors amongst patients and members of the public. Furthermore, the provision of information about health consequences, was identified as the most appropriate intervention (BCT) for delivering knowledge and understanding.

Enablement, an intervention function which goes beyond education in increasing means or reducing barriers to increase capability, was identified as the most appropriate for increasing awareness of both community pharmacy-based DPS and the training/experience of community pharmacy teams. Interventions (BCTs) identified as suitable for increasing such awareness were social support and adding objects to the environment. Social support, particularly from other primary care providers such as general practices, was perceived to be important for raising awareness to both regular and non-regular community pharmacy users. Participants highlighted that support offered by general practices could involve including community pharmacy-based DPS as an option in letters sent out to people with NDH. Additionally, primary care settings, including community pharmacy, could raise awareness by adding objects to their environment such as posters, leaflets and qualification certificates.

Policies identified to support education and enablement were service provision and communication. Increasing awareness is an important element in delivering the NHS DPP (295). The NHS DPP has employed the use of communication, using print, electronic and even media, as means for raising awareness. Similarly, community pharmacy-based DPPs could also employ similar means of raising awareness/service promotion.

6.3.4.2 Collaboration with general practices (social opportunity)

Environmental restructuring, which involves changing physical and social contexts, was identified as a key intervention function for delivering community pharmacy-

based DPS in collaboration with general practice. The provision of guidelines in the form of protocols and standard operating procedures was therefore identified as a policy that could support environmental restructuring. Such protocols installed in clinical systems could ensure that service delivery is integrated and that integrated communication forms are available for use between the two settings.

The intervention (BCT) identified as most appropriate for enhancing environmental restructuring was the use of prompts and cues in both community pharmacy and general practice settings. On screen prompts were identified as a means through which healthcare assistants, nurses and GPs could be reminded to inform people identified with NDH about community pharmacy-based DPS. Similarly, when delivering community pharmacy-based DPS, prompts could be added to documents or on IT systems to remind healthcare providers to inform patients that the service is provided in collaboration with general practice and reassure them that clinical outcomes from the intervention would be communicated to them accordingly.

6.3.5 Prioritising factors influencing behaviour two

Nineteen factors, mapped to categories of the COM-B model, were identified from previous research to have potential for influencing delivery of community pharmacy-based DPS (Chapter 4 and 5). Table 6.6 presents the ranking of these factors (presented under their COM-B categories) before and after the discussion. From the ranking, five factors (theoretical training, adequate staffing levels, demonstration of impact, skill mix and workload) within all three categories of the COM-B, were identified as most important in influencing delivery of community pharmacy-based DPS.

Views of participants concerning training requirements for community pharmacy did not alter following discussion. However, following the discussions, participants' ranking changed in favour of staffing levels, workload, skill mix and the importance of demonstrating impact. The qualitative analysis related to the selection of factors,

including potential strategies for enhancing delivery of the selected factors, has been summarised below and in Table 6.7.

Table 6.6 Ranking of factors influencing behaviour two

Questionnaire statement and summary statement (From chapter 4, Table 4.3)	Phase 1 (N=15)	Phase 3 (N=12)	Selected
	% (n)		
Capability: Which ONE of the following could most likely increase capability of community pharmacy teams to deliver diabetes prevention services?			
1a. Training (practical)	2 (13.3%)	1 (8.3%)	✗
1b. Training (theoretical knowledge)	11 (73.3%)	9 (75%)	✓**
1c. Training (communication skills)	-	-	✗
2. Experience (service delivery)	2 (13.3%)	2 (16.7%)	✗
Physical opportunity: Time and funding are key factors needed to deliver diabetes prevention services. Please select ONE additional factor most likely to increase the opportunity to deliver such services			
5. Suitable consultation rooms (space)	3 (20%)	1 (8.3%)	✗
6. Access to patient medical records	1 (6.7%)	1 (8.3%)	✗
7b. Adequate staffing levels	10 (66.7%)	10 (83.3%)	✓**
8b. Merged IT facilities	1 (6.7%)	-	✗
Social opportunity: Which ONE of the following is most important for the implementation of community pharmacy diabetes prevention services as part of primary care?			
11. Demonstration of impact (positive health outcomes)	7 (46.7%)	9 (75%)	✓**
13. Competing interests	4 (26.7%)	2 (16.7%)	✗
15. GP workload (not creating extra work for general practice)	1 (6.7%)	-	✗

15. GP workload (reducing GP workload)	3 (20%)	1 (8.3%)	✗
16. CP workload (not to affect prescription services)	-	-	✗
Motivation: Financial incentives are a key factor that could increase motivation to deliver diabetes prevention services. Please select ONE additional factor that would most likely motivate community pharmacy teams to deliver such services?			
18. Skill mix	3 (20%)	5 (41.7%	✓**
19. Workload (appropriate allocation of resources)	4 (26.7%)	5 (41.7%)	✓**
20. Self-confidence enhanced by training	3 (20%)	1 (8.3%)	✗
21. Structure of service delivery	2 (13.3%)	-	✗
22. General practice support	3 (20%)	1 (8.3%)	✗
23. Relationships (communication)	-	-	✗

** Explored in more depth in table 6.7

Table 6.7 Suggested strategies for behaviour change (behaviour two)

COM-B domain	Summary statement	What needs to happen for the target behaviour to occur?	Illustrative quotes
Psychological capability	**1b. Theoretical knowledge of pre-diabetes and its management**	Providing theoretical training using online resources	*"So again you know if you're got people in the pharmacy they can sit down and do that online or do it at home or something and you know you're then giving them the knowledge of that as well without kind of having to go too much into extra resources for training"* [P6, pharmacist]
		Standardising training across primary care	*"I think that you obviously do need the training cos you all need to sing off the same hymn sheet…within the sort of GP land we all sort of pretty much sing off the same hymn sheet because we all have the same regulations the same guidelines that we're following so I think that's just something that's expanded out to the community"* [P10, nurse]
		Providing regular updates on training	*"I went to my own GP practice to have the NHS health check and it was just like oh what's going on it was so it was so different… I said 'have you been doing this long she said oh yes I had my training 5 years ago and I thought it shows…I only had mine two years before. So, if you're going to do it, it should be regular updates or one person from the pharmacy is sent for the regular update to then share with the team"* [P9, general practice HCA]
Physical opportunity	**7a. Adequate staffing levels (funding)**	Providing adequate resources to enable the delivery of DPS	*"I mean staff is definitely you know especially in kind of the current climate in community pharmacy that's usually an issue with kind of delivering services. I mean it's not just the staff to be there to be able to do the service, it's the staff to be able to do all the other jobs within the pharmacy at that point as well"* [P6, pharmacist]
		Ensuring that multiple team members are trained to deliver	*"I think over the years we've had um like a certain group of people in the team trained for example smoking cessation you have one person maybe trained in the*

		DPS in order to increase accessibility or availability of services	*team and when it comes to healthy living you have one person you know as a lead in the team when they are not in it means the service cannot be provided… so having everybody in the team trained… would mean that you have so many people available to do the service"* [P4, pharmacist]
Social opportunity	**11. Demonstration of impact (positive health outcomes)**	Reporting clinical outcomes to commissioners	*"From a commissioning point of view yes that's really important [reporting outcomes] and obviously the outcomes from the NDPP have been positive um I think the average patient who does lose weight lose an average of 4kg"* [P12, commissioner]
		General practice sharing clinical progress data of individuals referred onto the NHS DPP through community pharmacy	*"So that would be good for GP's to collaborate with the pharmacies to share this data um cos then they might ah that patient who I referred onto the programme has benefitted from it"* [P12, commissioner]
		Community pharmacy personnel informing patients of previous positive outcomes to enhance programme adherence	*"It is effective as well so when I go to meetings with GP's nurses they always say it is effective and you can inform your patients about this as well cos if a patient isn't aware if it's effective or not then they might be less likely to attend opposed to as if it is effective you will lose weight if you adhere to the programme then it will be more likely to um go onto it yes"* [P12, commissioner]
Motivation	**17. Using whole CP skill mix**	Delivering community pharmacy services through trained healthcare assistants or technicians	*"I think any of those could do it if they've had the training because obviously when you're in hospital although you've got the trained nurse in the background it's usually the health care assistant that comes and does your blood pressure while you're in bed"* [P2, patient]
	18. Adequate staffing levels (workload)	Explored under physical opportunity	

6.3.5.1 Theoretical training (psychological capability)

Theoretical training in NDH and its management was perceived to be important for enhancing the capability of community pharmacy teams to deliver DPS. Participants felt that training would need to be targeted at all team members including healthcare assistants (HCAs). This was due to the key patient facing role that HCAs play in promoting community pharmacy services.

Highlighted strategies for the provision of the theoretical training, included the use of online training platforms. Participants also highlighted the importance of providing training through external sources rather than employers who often cascade training through one trained team member. This, participants felt, would avoid passing on 'bad practice'. Standardisation of training across primary care and the provision of regular updates was also identified as a strategy that could enhance the delivery of up-to-date and collaborated services.

6.3.5.2 Adequate staffing levels (physical opportunity)

Adequate staffing levels were identified as key for increasing the opportunity of community pharmacy teams to deliver DPS. Although participants felt it beneficial for community pharmacy teams to take the 'strain off' general practice, participants felt that community pharmacy would require appropriate investment in people resources to carry this out. Therefore, the availability of multiple trained team members was highlighted as central for service delivery and maintaining the accessibility of community pharmacy services.

6.3.5.3 Community pharmacy skill mix and workload (reflective motivation)

The involvement of the whole team in delivering DPS was identified as a key motivation for the provision of services by pharmacists. Pharmacists, who described feeling 'under pressure' with the delivery of current services including dispensing, reported that the provision of future interventions requiring minimal pharmacist involvement would increase likelihood of delivery.

6.3.5.1 Impact (social opportunity)

Participants also felt that the demonstration of impact, with regards to patient clinical outcomes from community pharmacy based-DPS, would enhance community pharmacy involvement in delivering primary care services. Communication of service clinical outcomes to commissioners was identified as an important determinant of securing funding as was communication of clinical outcomes with general practice in increasing patient referrals. Participants also felt that feedback on the progress of people referred to the NHS DPP from community pharmacy would also increase motivation of community pharmacy teams to continue delivering the services

6.3.6 Selecting intervention functions, policy categories and behaviour change techniques (behaviour two)

Selected intervention functions, policy categories and BCTs associated with delivering community pharmacy-based DPS are presented in Table 6.8. The selection was guided by strategies for behaviour change identified from the NGT discussion (stage 2).

Table 6.8 Intervention functions, policy categories and behaviour change techniques (behaviour two)

COM-B domain	Summary statement	Strategies generated from stage group discussion (Stage 2)	Selected intervention function (s)	Selected policy categories	Selected BCTs
Psychological capability	**1b. Theoretical knowledge of NDH and its management**	Providing theoretical knowledge and training	Education and Training	Service provision	Information about social, environmental and health consequences Demonstration of behaviour and instruction of how to perform the behaviour
		Providing regular training updates	Training	Guidelines	Instruction on how to perform a behaviour
		Standardising training across primary care	Training	Guidelines	Instruction on how to perform a behaviour
Physical opportunity	**7a. Adequate staffing levels (funding)**	Providing adequate resources to enable the delivery of DPS	Enablement	Fiscal measures	Action planning Review of outcome goals
		Ensuring multiple team members can deliver DPS in order to increase service accessibility or availability	Enablement	Environmental/social planning	Action planning Review of outcome goals
Social opportunity	**11. Demonstration of impact (positive health outcomes)**	Communication of clinical outcomes by community pharmacy)	Modelling	Communication and marketing	Demonstration of the behaviour

		Communication of clinical outcomes by general practice	Modelling	Communication and marketing	Demonstration of the behaviour
		Informing patients of service clinical outcomes (by community pharmacy)	Modelling	Communication and marketing	Demonstration of the behaviour
Motivation	**17. Using whole CP skill mix**	Delivery of DPS by trained healthcare assistants or technicians	Incentivisation	Guidelines	Feedback on behaviour Feedback on outcomes of behaviour
	18. Adequate staffing levels (workload)	Explored under physical opportunity			

6.3.6.1 Theoretical knowledge of NDH and its management (psychological capability)

Education, which serves to increase knowledge and understanding, and training which serves to impart skills, were identified as appropriate intervention functions for the provision of theoretical knowledge about NDH and its management in primary care. Interventions (BCTs) identified to enable the delivery of education and training were information provision, demonstration of behaviour and instruction of how to perform a behaviour. As suggested by participants, community pharmacy personnel could utilise online training packages to increase knowledge and understanding about NDH and its management. Additionally, community pharmacy teams could shadow general practice personnel when delivering DPS in order to improve skills.

The provision of guidelines in the form of standard operating procedures was identified as policies that could support the delivery of up-to-date and standardised education and training for all DPS providers in primary care.

6.3.6.2 Adequate staffing levels (physical opportunity)

Enablement was identified as an appropriate intervention function for ensuring adequate resources for delivery of DPS. Since the delivery of the NHS DPP is currently funded by NHS England, fiscal measures and environmental planning were identified as policies that could enhance enablement. Therefore action planning by the funding bodies, involving consideration of the role of community pharmacy in delivering DPPs was identified as an intervention (BCT) that could ensure adequate resources for the provision of DPS. Additionally, the incorporation of interventions that regularly review goals and outcomes of community pharmacy-based DPS was identified as central for ensuring appropriate use of resources.

6.3.6.3 Skill mix (reflective motivation)

Incentivisation was identified as the intervention function which would best motivate the appropriate use of community pharmacy skill mix to deliver DPS.

Incentivisation encompasses interventions which are designed to create an expectation of reward and can be supported by the production of guidelines. The majority of primary care public health services are incentivised with financial rewards. Service providers often provide feedback to commissioners at the point of delivery in order to receive incentives. In community pharmacy such feedback is provided through report platforms such as PharmaOutcomes®. Similar means of reporting outcomes to receive incentives from commissioners could also be employed delivering community pharmacy-based DPS.

6.3.6.4 Demonstration of impact (social opportunity)

In order to promote the delivery of community pharmacy-based DPS within primary care, community pharmacy would have to demonstrate the impact made by the services (BCT). This could be achieved by the provision of information about clinical and patient outcomes to commissioners.

Modelling, an intervention function which involves the provision of an example for people to aspire and imitate, was identified as a means through which community pharmacy could demonstrate such health outcomes. Policies such as communication and marketing were identified as appropriate for supporting the reporting of clinical outcomes to commissioners, general practices and patients.

6.4 Discussion

This research highlights important service characteristics that need consideration when developing community pharmacy-based DPS. The findings also identify potential interventions and policies that could facilitate both engagement with, and delivery of, DPS by people with NDH and community pharmacy teams respectively.

6.4.1 Types of service and service characteristics

This study verifies the potential for community pharmacy to deliver a range of interventions in NDH including one to one DPPs and ongoing monitoring. One of the key factors that would need consideration when designing such services is the types of tests used for assessing glycaemic states. This research particularly highlights views and opinions of stakeholders over the use of HbA_{1c} and FPG tests in community pharmacy settings with regards to their affordability, acceptability and practicability.

The current service specification for the NHS DPP recommends the use of either a HbA_{1c} test (venous or POCT) or FPG test (venous only) for assessing glycaemic status, provided the same test is conducted throughout the programme (85). The use of HbA_{1c} in clinical practice has several advantages over the use of FPG. Firstly, there is no requirement of fasting with the HbA_{1c} test and secondly the results provide an indication of glycaemic control over a period of three months (306). Therefore, although there is no primacy for the use of HbA_{1c} in clinical practice, most service providers, including the current NHS DPP providers, opt for the use of the HbA_{1c} POCT rather than the FPG.

The involvement of community pharmacy in delivering integrated DPS in primary care would therefore require personnel to conduct similar tests. This research indicates the use of POCT devices to be more favourable for community pharmacy use than venous blood tests. POCT devices have been recommended for use in community settings due to increased accessibility for patients and the convenience of providing instant results for both the patient and the provider (32, 307). Previous research conducted in Norway and Canada demonstrated delivery of HbA_{1c} POCT to be feasible for implementation in community pharmacies and indicated successful performance of quality controls on HbA_{1c} instruments by pharmacists (162, 308).

6.4.2 Engagement with community pharmacy-based diabetes prevention services

This research has identified raising awareness of community pharmacy-based DPS and providing collaborated services in primary care as factors that could facilitate patient engagement. A recent systematic review exploring pharmacists' and GPs' views of community pharmacy services in the UK, also highlighted the lack of awareness of extended services in this setting as a barrier to successful uptake (254). The review also highlighted the need for collaborative working between community pharmacists and GPs to achieve better integration within patient primary care pathways.

This research goes beyond the findings of the review by Hindi *et.al.* to identify practical and affordable interventions to facilitate the promotion of community pharmacy-based NDH and collaboration in primary care. The interventions which included social support and marketing and information materials (e.g. leaflets, posters and letters) follow the current means in raising awareness of services in community pharmacy and promote equity through the involvement of other primary care providers.

The use of prompts and cues in both community pharmacy and general practice settings have been identified as an intervention likely to be effective for the provision of collaborative primary care. Prompts and cues, a common behaviour change technique used in healthcare settings, is also likely to be an acceptable, practicable and affordable intervention. Prompts and cues, which act as reminders of recommended standards of clinical practice or guidelines, have been associated with improved delivery of preventative healthcare services (309). Research also shows that embedding such reminders in the flow of care and providing easy access to information is likely to improve patient care (310). Such reminders could occur at the point of decision making in general practice to prompt practitioners to inform eligible patients about community pharmacy DPS. Additionally, the reminders could also occur during consultations in community pharmacy to prompt service providers to inform patients about service collaboration (311). In community pharmacy such prompts could be added to platforms such as PharmaOutcomes® or

dispensing systems which are currently used when delivering public health services such as NHS Heath Check and Emergency Hormonal Contraceptive services (312).

6.4.3 Delivery of community pharmacy-based diabetes prevention services

This research highlights the importance of providing standardised and up-to-date training across primary care settings delivering DPS. Previous chapters have highlighted that standardising community pharmacy services not only ensures the delivery of quality services but could also improve patient trust (Chapter 3, 4 and 5). Therefore, in order to facilitate the provision of collaborative services in primary care, training for community pharmacy personnel delivering DPS would need to align with training provided for NHS DPP providers at a local level.

The current NHS DPP service specification recommends all providers ensure delivery of interventions is by health professionals or suitably trained and competent individuals and that training should be routinely monitored and updated (85). Additionally, although the current service specification does not specify the type and level of qualification, training and/or competence required to deliver DPS, it suggests that qualification levels align with accredited training packages e.g. the Royal Society of Public Health qualifications (85). Current training for community pharmacy, is mostly provided by the Centre for Pharmacy Postgraduate Education (CPPE) (313). The training aims to offer continuing professional development through face-to-face workshops, on-line or distance learning programmes. However, although CPPE provides training for the delivery of public health services, there are currently no training packages specifically focused on the management of NDH in community pharmacy. Therefore, in order to deliver DPS, community pharmacy would need to identify or develop suitable training packages that meet the standards set out in the service specification. Previous research has demonstrated the combination of both face to face and online training to be adequate for enabling implementation of DPS such as HbA_{1c} monitoring in community pharmacy (162). Such training, which closely resembles the current community pharmacy training provided by CPPE, is likely to be acceptable,

practicable and affordable. However, the cost of training would need to be considered when developing community pharmacy-based DPS.

This research also suggests that adequate resources and appropriate use of skill mix can increase both the opportunity and motivation of community teams to deliver DPS. In recent years, an increased strain on primary care services such as general practices, has produced an expansion on clinical and public health services provided through community pharmacy (123, 254). However, as identified by previous research (Chapter 5) (254), this has led to community pharmacy teams feeling under pressure from the increased workload. Therefore, if community pharmacy is to play an extended role in primary care, workforce restructuring is central. A recent report on clinical services provided by community pharmacy also highlighted the need to develop community pharmacy workforce capacity to include models of practice that best utilise the community pharmacy skill mix (257). Therefore, the development of community pharmacy teams and restructuring of skills, beyond the current capacity, would need to be undertaken to enable community pharmacy to take on new roles.

The reporting of clinical outcomes between community pharmacy and general practice as well as to both patients and commissioners has been identified as a key factor for enhancing patient retention, commissioning and integration of community pharmacy-based services in primary care (314). Previous research indicates that community pharmacy interventions demonstrate positive clinical outcomes in interventions including patient education and health/lifestyle interventions with significant reductions demonstrated in blood pressure and HbA_{1c} (281, 314). However, research also indicates a lack of evidence directly linking specific community pharmacy-based interventions to particular clinical outcomes (314).

In recent years the commissioning of services has adopted an outcomes-based approach which has more emphasis on the results of interventions (338). An example of this is the smoking cessation service where community pharmacy only

get reimbursed for the on-going support element following patients completing a 12-week period without smoking (315). Current commissioning therefore aims to develop services specifications that focus on producing improved outcomes for patients, rather than reimbursing providers for activity (316). Thus, providers are required to determine the best service delivery models to meet the outcomes and cost envelope specified by the commissioner. Therefore, for community pharmacy to deliver DPS there is a need to focus more effort on reporting clinical outcomes rather than the delivery activity. With previous chapters highlighting poor representation of pharmacy in commissioning groups, regular reports to commissioners could potentially increase recognition of the contributions made by community pharmacy in the current NHS (particularly in increasing reach to harder to reach groups) and thus increase opportunities for funding.

Finally, in this research the prioritisation of factors important for delivering community pharmacy-based DPS altered following discussion. The main factors altered were those concerned with the need for adequate staff, appropriate allocation of resources and the importance of demonstrating impact. These changes in ranking could indicate the importance of including multiple stakeholders when developing integrated services. For example, views concerning the need to demonstrate impact could have altered following clarification of the commissioning process by one of the participants. Similarly, views concerning the importance of resourcing could have altered following clarification from community pharmacy teams concerning the pressures in current service delivery. The changes in ranking could also indicate that the discussion in the NGT process could have highlighted ambiguities and misunderstandings in the questionnaire statements subsequently affecting later consensus. This finding highlights the importance of the role of community pharmacy representation in primary care commissioning groups.

6.4.4 Strengths and limitations

The research employed modified consensus methods which enabled the prioritisation of factors that could influence the delivery of and engagement with

DPS in community pharmacy. Additionally, the use of data obtained from the qualitative discussion also provided a richer understanding of the prioritisation.

Building on the findings of previous studies, this research has considered the views and perceptions of multiple stakeholders including people with NDH, commissioners, community pharmacy and general practice personnel, to build a model for community pharmacy-based DPS. The application of the BCW framework to the findings of this research has enabled the identification of possible interventions that could be implemented to facilitate the delivery of community pharmacy-based DPS.

A limitation of this study was the inclusion of only a small number of participants in conducting the NGT. The number of participants precluded further ranking of factors such as types of services that could be delivered in the community pharmacy setting to identify the main priorities. Furthermore, the multiple factors that had to be prioritised, precluded clear ordering with regards to ranking the factors. Although this research considered the findings using the APEASE criteria some of the criteria such as cost-effectiveness were outside the scope of this research and thus could not be sufficiently commented on.

6.5 Conclusions

Community pharmacy has potential to deliver a wide range of DPS including on-going lifestyle and monitoring interventions. In order to facilitate patient engagement, such services would need to be provided in collaboration with general practices and would need to be promoted to both patients and members of the public. To enable delivery of integrated services in primary care, training for community pharmacy teams would need to be standardised at a local level and efficient communication of clinical outcomes with commissioners and general practices established. Practical and acceptable interventions that could be implemented in primary care settings to enable the delivery of services have been

identified including the use of prompts and cues and the display of posters and leaflets in various primary care settings. Further work is needed to inform and feasibility test a DPS service model that could be delivered in community pharmacy settings.

Chapter 7: General discussion

7.1 General discussion

The aim of this PhD was to characterise the current and potential role of community pharmacy in the prevention of type 2 diabetes and to explore community pharmacy as an option for delivering DPS in England. To achieve this aim, the BCW framework was employed to firstly, define and understand the problem that community pharmacy could potentially address by delivering DPS and secondly, to inform the design and implementation of potential interventions that could enable delivery of the services.

This chapter presents a discussion of overall findings from the PhD which have been summarised in a logic model. The MRC guidance recommends the use of a logic model to graphically present the theory of an intervention i.e. how an intervention produces its outcomes (226). A logic model is a diagrammatic representation of the relationships between an intervention's context, resources/inputs, activities/outputs and intended outcomes impact (317, 318). Due to variations in the nature of interventions, there are no standard definitions for 'context' or 'outcome' (317). For example, the community pharmacy setting may be part of the context for a diabetes prevention intervention. Alternatively, if an intervention is designed to change the community pharmacy culture to facilitate the provision of diabetes prevention interventions (as is the case for this research), then the community pharmacy is part of the intervention not the context. Additionally, when developing a logic model for exploratory interventions, where an intervention (e.g. DPP) is being delivered in a new setting (e.g. community pharmacy), some aspects of how the intervention might work or processes that could occur may be largely unknown due to uncertainties in participant responses (317). Therefore, in such cases there may be gaps in logic models which can be specifically explored during process evaluation, with the findings contributing to a more complete logic model at the end of the study.

This chapter adopts the use of a logic model to graphically present the theory underpinning the delivery of community pharmacy-based DPS. The logic model has been populated with findings from each chapter of the thesis. Since the nature of the interventions proposed by this research are exploratory, certain aspects of the behaviours explored are somewhat incomplete and would require process evaluation in order to produce a complete model. Below are the definitions used for the sections of the logic model (318, 319).

- **Background:** a summary of existing literature outlining the problem being addressed by this PhD.
- **Assumptions:** a hypothesis of the causes of the problem and possible solutions.
- **Outcomes:** the ultimate aims of the intervention i.e. an indication of changes that need to be observed. This consists of short, medium- and long-term outcomes.
- **Activities and outputs:** activities needed to be undertaken in order to achieve the outcomes and by whom.
- **Inputs:** resources required to facilitate the implementation and performance of activities.
- **Target population:** the population affected with respect to delivering and receiving the intervention.

What follows is therefore a discussion of the components of the logic model according to current guidelines, evidence and findings of this research.

7.1.1 Background: ‘an update of evidence’

This section consists of a discussion of the research evidence that formed the rationale for selecting ‘low engagement in DPPs’ as a research problem that needs addressing. The evidence discussed is summarised in the ‘Background’ section of the logic model (See Table 7.1) and has been derived from Chapter 1 of this thesis.

Table 7.1: Logic model - background

'State of the nation'

- Increasing prevalence of type 2 diabetes and NDH in England.
- 5-10% of people with NDH will develop type 2 diabetes within a year.
- Individual and societal costs associated with type 2 diabetes.

'Potential solution'

- Early identification of NDH followed by intensive diet and lifestyle interventions may delay or prevent progression to T2D.
- NHS England has implemented a national DPP in light of this evidence.

'The problem'

- Evidence shows that the impact of implementing a national DPP could be undermined by poor uptake amongst people with T2D.
- Progress report on the NHS DPP has indicated that of those referred onto the programme, 49% attend the initial assessment meeting.
- The report also indicates that between 36% and 55% of people referred into the NHS DPP decline the service and between 26% and 50%, do not progress onto the group-based sessions.

A review of the literature, conducted at the beginning of the PhD, highlighted poor engagement in DPPs as a potential 'problem' with current diabetes prevention interventions that could be addressed by community pharmacy (Chapter 1). The evidence suggested that although DPPs are an effective intervention for delaying or preventing development of type 2 diabetes in people with NDH (100), the potential impact of implementing such programmes on a national level could be undermined by poor uptake (78). In England, a national programme was implemented in 2016, to tackle the increasing prevalence of type 2 diabetes (115). Analysis of the projected impact of the NHS DPP suggested potential for the programme to be both cost-effective and cost-saving, provided assumptions of uptake were met (128, 156). However, uncertainties in the projected uptake of the programme were highlighted as the biggest risk of implementing the programme nationally (128). Furthermore, the programme was shown to create less value for money for low socioeconomic status and ethnic minority groups, a factor that could contribute to widening health inequalities (156).

The progress report of the NHS DPP, published in 2018, included an initial report on programme uptake and suggested that amongst those referred into the NHS DPP, 49% attend the initial assessment (264). Furthermore, a more recent report on programme uptake, published within an updated service specification in 2019, has indicated that between 36% and 55% of people referred into the NHS DPP decline the service and between 26% and 50%, do not progress onto the group-based sessions (124).

In response to the low service uptake, in 2019, NHS England announced plans to implement a digital stream of the programme as an alternative route (124). However, although the pilot scheme for a digital-based DPP demonstrated increased uptake (124), there is currently a lack of evidence for the effectiveness of digital-based diabetes interventions compared to face to face. A recent systematic review, investigating the effectiveness of digital health interventions compared to non-technology-based interventions on weight loss and lifestyle habit changes, has suggested digital interventions to be less effective at achieving long-term

outcomes, an important factor that determines impact of DPPs in reducing the incidence of diabetes (320). Additionally, the review highlighted high attrition rates in digital health interventions, suggesting participant engagement and motivation to be a major barrier. Although digital interventions may be acceptable due to the empowerment of individuals to manage their own conditions, qualitative research suggests that factors such as digital exclusion, and concerns around privacy and confidentiality, could also limit engagement with the interventions (321). Therefore, to date evidence still suggests programme uptake to be an important barrier to the potential impact of NHS DPP. There is, therefore, still a need to explore alternative routes of increasing uptake in DPPs.

7.1.2 Logic model assumptions

Assumptions can be defined as a hypothesis of why and how certain activities will achieve the desired outcomes (319). Therefore, this section outlines a discussion of why and how delivering community pharmacy-based DPS could potentially increase uptake of DPPs amongst people with NDH. The presented assumptions, summarised in the logic model (See Table 7.2), have been derived from a review of literature (including guideline recommendations) and empirical research conducted in people with NDH and other stakeholders (Chapter 3-6).

Table 7.2 Logic model - assumptions

Accessibility • Community pharmacy is an accessible primary care setting for the provision of public health interventions. • Increased representativeness of the population. • Majority of people with NDH already on medication and visit CP regularly.
Current uptake in the NHS DPP • Accessibility barriers such as inconvenient session times and location feature in the NHS DPP. • Current time-lag between referral and initial assessment has also been identified as a barrier in the NHS DPP. • This research has shown that people with NDH are willing to engage in community pharmacy based DPP. • Community pharmacy has a potential role for increasing uptake in individuals motivated to change behaviour but limited due to accessibility and programme capacity.
Guidance supporting delivery of lifestyle interventions by community pharmacy • The provision of community pharmacy based DPP aligns with NICE guidance. • The provision of CP based DPP aligns with the NHS Long term plan and the CPCF which advocate increased involvement of CP in provision of services for people with high risk conditions.
Potential capacity to deliver DPS • Community pharmacy teams are currently involved in delivering lifestyle interventions. • Community pharmacy has potential infrastructure for delivering lifestyle intervention through the Healthy Living Pharmacy framework. • There is potential capacity for community pharmacy to deliver DPS due to the expanding role of technicians.

Research evidence highlights accessibility as a barrier to the uptake of DPPs in countries such as USA and Australia (131-133, 322). This thesis presents the first studies to investigate barriers and facilitators of programme uptake in the NHS DPP in England and from the perspective of people with NDH (Chapter 3) and healthcare providers (Chapters 4 and 5). This research employed the COM-B as a theoretical model for understanding the problem with uptake in the NHS DPP and why community pharmacy is a potential setting for addressing this problem. The findings highlight opportunity and motivation as the primary COM-B components that influence engagement in the NHS DPP (Chapter 3).

Motivation is defined in the psychology literature as *'the psychological forces or energies that impel a person towards a specific goal' (323)*. Many psychological theories identify motivation as a key behavioral determinant. In this research, the use of the COM-B assisted in identifying several motivational factors which align with most psychological theories and frameworks, thus demonstrating the efficiency of using the model to provide a thorough understanding of behaviours. For example, this research identified family history, including bad experiences with family members with type 2 diabetes as a facilitator for engaging with DPPs. This aligns with the health belief model which emphasizes that motivation could be based on beliefs about susceptibility to a particular disease (174). Additionally, perceptions of the benefits of engaging with the NHS DPP, a factor identified as both a barrier or facilitator in this research, aligns with the theory of reasoned action which suggest beliefs about outcomes of the behaviours and the value attached to these outcomes to be important for performing certain behaviours (196, 324). The findings of this research were also closely aligned with two domains of the TDF related to motivation (193, 325). The domains, which are 'beliefs about capabilities' and 'motivation and goals', have constructs such as 'self-efficacy' and 'goal priority' respectively that were also identified as important for motivation in this research.

The wide variety of motivational influences identified by this research suggests the importance of assessing individuals' motivation when referring to current DPPs. The

Trans theoretical model, a well-known theory discussed in chapter 2, identifies a series of motivational stages through which people progress and relapse in order to achieve health related goals (178). The theory, which has been widely used in health education and promotion services (202, 203), could be used to assess readiness of change in people who are referred onto current DPS. Currently, with most people being referred to the NHS DPP through a letter sent from general practices, there is little opportunity for providing consultations for assessing readiness of change. Therefore, readiness for change could be assessed at the initial programme assessment. With this research identifying that the one-size-fits-all approach does not apply for delivering DPPs, the assessment of motivation could be key for the provision of focused efforts to preventing type 2 diabetes.

This research has identified barriers within the opportunity component of the COM-B such as lack of transportation, inconvenient location, inconvenient session times, healthcare professional influence and employer support, which were similar to those highlighted by other research (131, 132). Additionally, community pharmacy has been highlighted as a potential setting for addressing current physical opportunity barriers to engaging with the NHS DPP. The COM-B model proposes that motivation is increased by increasing opportunity (188, 192). Therefore, the use of community pharmacy to deliver services for those unable to access the current programme due to competing commitments, could indirectly increase motivation for engaging with DPPs. Views from nurses and GPs involved in referring patients to the current national programme also indicated that the involvement of community pharmacy in delivering DPS could potentially increase uptake in areas of high deprivation where community pharmacy has high accessibility (Chapter 5) (141).

The involvement of community pharmacy in delivering DPS also has a potential for addressing the ‘waiting list’ of the NHS DPP (264). The findings of this research, suggested that the potential time lag between referral and commencement of the programme, attributed to challenges in arranging suitable location and session times, is a major barrier to uptake. The questionnaire study conducted in people

with NDH (Chapter 3) showed that almost a quarter of respondents were on the waiting list due to challenges of arranging suitable time and location. The progress report on the NHS DPP has highlighted that the time delay between referral and initial assessment is a cause of the significant variation in uptake (16% to 86%) across local health economies (264). The involvement of community pharmacy DPS could therefore be presented as an alternative for those on waiting lists.

Furthermore, this research highlighted a potential monitoring role for community pharmacy in people who have completed the NHS DPP (Chapter 3 and 6). The new NHS DPP service specification highlights the need to assess progress of the programme against the outcome of reducing glycemic parameters at nine months and beyond (124). The service specification suggests that currently NHS England are exploring options to work with primary healthcare providers to undertake this function. Community pharmacy, could therefore undertake such a function and thus contribute to assessing the long-term outcomes of the NHS DPP (i.e. maintenance of lifestyle changes and reduction in the incidence of type 2 diabetes)

Current NICE guidelines support the provision of lifestyle interventions for people at high risk of diabetes in community pharmacy setting (32). The NHS Long Term Plan (LTP) and the new community pharmacy contractual framework (CPCF), clearly support the provision of services such as the DPS in the community pharmacy setting (123, 143). The NHS LTP is an NHS document which outlines priorities for healthcare over the next 10 years and shows how government funding should be utilised. The current version, released in 2019, highlights services that identify and treat high risk conditions as a key area for improvement. The document also identifies community pharmacy as a setting with potential to provide opportunities for the public to identify and manage high risk conditions (123). Similarly the new CPCF highlights a role for community pharmacy in improving current public health and prevention services (143). The framework, which proposes plans of how community pharmacy could deliver the NHS LTP, also suggests piloting prevention and detection services which, if found best implemented in the community pharmacy setting, could be rolled out within the contractual framework.

7.1.3 Logic model inputs and outputs

Inputs constitutes resources needed to be implemented in order to perform certain activities and outputs refers to the activities needed to be undertaken in order to achieve the outcomes and by whom. In this section, resources needed to enable uptake of community pharmacy DPS by people with NDH and resources required to deliver the services by community pharmacy teams are firstly discussed. Secondly discussed are activities that need to be performed to ensure both uptake and delivery of the services. As the findings of this research are suggesting a potential role for community pharmacy teams to deliver DPS for people with NDH in primary care, the target population referred to in the logic model are people with NDH, community pharmacy personnel, general practice personnel and commissioners. These findings are summarised in the inputs and outputs section of the logic model (See Table 7.3) and have been extracted primarily from empirical research presented in chapters three to six.

7.1.3.1 Inputs/resources

Time and funding, mapped to the physical opportunity domain of the COM-B, were identified as the main resources required for community pharmacy teams to deliver DPS (Chapter 4 and 5). The research also highlighted the importance of ensuring adequate staffing levels, to enable the availability and accessibility of community pharmacy DPS. A recent systematic review, exploring the views of pharmacists and GPs of extended community pharmacy services in the UK, has shown that the provision of dispensing services alongside extended services often pose time constraints for pharmacists (254). The review also highlighted the need for the provision of sufficient remuneration for the additional time and resources required to perform additional services.

Table 7.3 Logic model - inputs, outputs and outcomes

Background (See Table 7.1)

Inputs	Outputs		Outcomes		
	Activities	**Participation**	**Short Term**	**Medium Term**	**Long Term**
Funding from CCGs Adequate resources and the use of skill mix to ensure accessibility or availability of services (Skill mix) Community pharmacy personnel must be sufficiently trained to deliver the activities and contents of diabetes prevention interventions	Raising awareness of: **1.** Diabetes risk factors **2.** Community pharmacy-based DPS **3.** Qualification of community pharmacy teams	By community pharmacy and general practice personnel To people with NDH and members of the public	Increased uptake and retention in DPS amongst regular service users and working populations Increased knowledge and awareness of community pharmacy role in public health by patients	HbA1c reduction, weight loss, increased physical activity	Reduced incidence of type 2 diabetes
	Delivering collaborative services in primary care	Community pharmacy and general practice personnel			
	Reporting of patient clinical outcomes	By community pharmacy teams To commissioners	Initial engagement with GPs and Commissioners	Community pharmacy team development and better use of skill mix Increased contact with GPs and commissioners	Decreased NHS and societal costs
	Sharing clinical progress of individuals referred to the NHS DPP through community pharmacy	By general practice teams To community pharmacy teams			

Assumptions (See Table 7.2)

The CPCF outlines an important role for community pharmacy in improving public health and disease prevention and has highlighted the need to release pharmacist capacity from existing work in order to provide expanded services (143). The CPCF also acknowledges the need to maximise developments in skill mix in order to deliver both dispensing and extended services that do not create additional pressure on pharmacists' time. The NHS DPP is funded by NHS England and commissioned locally through CCGs (124). In 2019, NHS England committed to doubling the funding for the programme over the next five years, in order to widen patient choice and reduce inequality (123). Therefore, the provision of community pharmacy DPS would need to be commissioned in order to ensure sufficient funding and resources.

Training has been identified as central to the provision of DPS by community pharmacy personnel. The service specification for the NHS DPP highlights key areas of service provision including identification of eligible population, intervention provision (including both dietary and physical activity components of promote weight loss) and monitoring (124). The specification also recommends the provision of stop smoking interventions to individuals who smoke (124). Although community pharmacy currently provides all these interventions, the services are segmented, not focused on diabetes prevention and have different durations . In order to deliver DPS, community pharmacy personnel would need to be appropriately trained to deliver the activities and content of the interventions. Additionally, training needs to be regularly monitored and kept up to date.

7.1.3.2 Outputs/ activities

Raising awareness of diabetes risk factors, the availability of community pharmacy based DPS and the qualifications and role for community pharmacy in public health were identified as important activities that need to be undertaken to ensure that people with NDH engage with the services. This research identified simple interventions such as the display of posters and leaflets in both general practice and community pharmacy settings that could effectively raise awareness of both

patients and the public. Additionally, collaboration between community pharmacy and general practice in the provision of DPS was identified as important for patients engagement with community pharmacy-based DPS. Both the endorsement and referral of community pharmacy-based DPS and efficient communication of outcomes were identified as key intervention activities that could promote collaboration between the two settings.

The use of social support interventions including endorsement by general practice personnel, has been identified as an effective means of raising awareness of extended services in the community pharmacy (326, 327). Additionally, recommendations of services through public health campaigns have been identified as a means of raising awareness of extended services in community pharmacy (277, 328). In England, community pharmacy participates in six campaigns set by NHS England by distributing leaflets and posters provided by NHS England. Under the new contract, community pharmacy has agreed to align its campaigns to that of general practice as part of their commitment to provide more integration across primary care (143). Therefore, activities highlighted by this research to the raising of awareness align with current models of promotion.

Although interventions to ensure collaboration between community pharmacy and general practice have been identified in this research, evidence suggests that current collaboration amongst the two settings is poor (254). Qualitative research has suggested that poor collaboration between the two settings stem from poor relationships (329-331) and infrequent communication (332). This research had identified a number of interventions that could be introduced in both settings to enhance communication including the use of prompts and cues as reminders to make referrals or to communicate clinical outcomes. Additionally, activities that have been identified to support the delivery of the intervention include interventions that would enhance communication between community pharmacy and both general practice and commissioners. This research suggests that as part of the service community pharmacy would need to engage regularly with commissioners to report clinical outcomes. Additionally, the research suggested

that general practice could regularly communicate clinical progress data of individuals referred onto the NHS DPP through community pharmacy. Therefore, the proposed model of inputs and outputs for delivering promotes integration and collaboration between community pharmacy and other primary care providers.

7.1.4 Logic model - outcomes

Outcomes constitute the ultimate aims of the intervention and consists of short, medium- and long-term outcomes (319). In this section the outcomes associated with delivering community pharmacy-based DPS are discussed. These outcomes have been derived from both literature and empirical research (Chapters 3-5) and are summarised in Figure 7.3.

To facilitate integration in primary care and to enable an efficient outcome evaluation, patient outcomes of providing community pharmacy-based DPS would need to reflect those of the NHS DPP (128). However, increased uptake and retention, particularly amongst regular community pharmacy users, people with work and social commitments and those on the waiting list would be the key patient outcome. Therefore, in the short-term, community pharmacy-based DPS would aim to increase uptake and retention of people on the programme, in the medium-term it would aim to achieve weight and risk reduction and in the long-term a reduction in the incidence of type 2 diabetes and of NHS resources. The delivery of community pharmacy-based DPS could also increase awareness of the role of community pharmacy in delivering public health interventions. Evidence suggests that a lack awareness of the role of community pharmacy in public health could act as a potential barrier to engaging with community pharmacy services (249, 253). Therefore, with the current contract and LTP highlighting an important role for community pharmacy in identifying and treating high risk conditions, raising public awareness is important for the successful provision of services going forward.

The provision of DPS as part of primary care could also increase the opportunity for providing integrated care systems, a key focus highlighted as central for the delivery of the LTP (123). Therefore, the increased integration between community pharmacy and general practice as proposed in the model could lead to increased engagement between the two settings through referrals and regular communication of outcomes. Furthermore, communication of outcomes to commissioners could also increase the profile and trust of community pharmacy to provide public health interventions thus increasing participation in primary care networks.

The provision of community pharmacy-based DPS would require staff to be trained and would need to explore more efficient use of skill mix. This could lead to development of the community pharmacy workforce thus harnessing the third largest workforce group in the NHS (257). Such services could lead to the development of models of practice that best utilise the community pharmacy skill mix (257).

7.2 Strengths and Limitations

This thesis constitutes one of the first studies to investigate the role of community pharmacy in diabetes prevention in England. The thesis proposes a model which outlines the theory for implementing DPS in the community pharmacy setting. The findings of this research, although focused on diabetes prevention, are applicable when considering the implementation of other public health interventions in the community pharmacy.

7.2.1 Trustworthiness of the findings

Rigorous methods were adopted for the conduct and reporting of this research to ensure trustworthiness of the findings (359).

7.2.1.1 Participants and demographics

This research elicited contributions from a broad range of stakeholders, purposely selected to ensure diverse experiences with the NHS DPP and community pharmacy (333). This facilitated the incorporation of different perspectives and helped to ensure that no particular groups' views were privileged over others (284)(303). For example, most participants who attended NHS DPP were in favour of the current set-up of the programme and those unable to access the programme were in favour of community pharmacy as an alternative setting. Thus, in the conclusion community pharmacy has been presented as a potential alternative to the current programme. The inclusion of multiple stakeholders has also paved a way for the development of a model that considered collaboration and integration in primary care. The proposed model therefore fits in with current developments of primary care networks to ensure integrated pathways for providing patient care (123, 143).

A limitation in the selection of participants for this research however was the exclusion of non-English speakers due to limited time and resources to enable translation of research materials. The exclusion of non-English speaking participants limited the ability for the research to explore language as a potential barrier/facilitator for participation in the NHS DPP. Additionally, this research was primarily conducted in Norfolk which largely consists of a white population with a relatively older age profile compared to the rest of England (261). This therefore limits the generalisability of this research to other parts of England (e.g. London) which are largely multicultural and consists of a greater proportion of younger working population.

Additionally, although steps were taken to triangulate some of research findings in other areas of England (Chapter 5), limited time and resources led to the purposive selection of areas with the least numbers of general practices and the exclusion of areas where the NHS DPP was being implemented through County Councils. This selection criteria precluded inferential analysis to be made on areas where implementation of the NHS DPP was led by Councils versus those by CCGs and might have excluded multi-ethnic populations. Additionally, although the

questionnaire study presented in Chapter 5 validated views of practitioners, the views of people with NDH were not validated. Therefore, the views of people with NDH expressed in this research might not be representative of other parts of the country. Therefore, with previous research demonstrating language, social roles, cultural and religious understanding of healthcare professional as potential barriers to uptake in DPPs (135, 145-148), and future research would need to investigate the impact of different contexts on the uptake of the NHS DPP. Such factors would also need to be considered when implementing community pharmacy-based DPS. Another limitation of this research is the small sample sizes obtained in questionnaire studies, which precluded important inferences about engagement (Chapter 3) and delivery of DPS in primary care (Chapter 5) being made.

7.2.1.2 Data collection

In designing the qualitative research, the preferred data collection method was focus groups. This was because obtaining perspectives from a wide variety of stakeholders was an important factor for sufficiency describing the potential role of community pharmacy in diabetes prevention. Focus groups therefore offered the opportunity to explore multiple views and experiences of participating in the NHS DPP and delivering community pharmacy services. Additionally, focus groups afforded the opportunity for participants to exchange viewpoints and experiences and reflect on their own standpoint in light of what others had said. Furthermore, despite focus groups being the preferred data collection method participants were also offered interview options. This offered a more accessible option to participants who could not or preferred not to participate in focus group discussion. This option particularly increased the participation of people with NDH who had declined or dropped out of the NHS DPP by offering them convenience whilst allowing the freedom to express their views. However, a limitation of this research is that the interview option was only made available to people with NDH (particularly non-engagers), GPs, nurses and commissioners. This therefore limited the opportunity for obtaining similarly rich and in-depth perspectives from community pharmacy participants.

Triangulation, achieved by using multiple methods of data collection including questionnaires, added to the credibility of the research findings (334). Questionnaires employed in this research (Chapter 3 and 5) primarily adopted the agree/disagree Likert Scale format. This type of format was considered appropriate due to the exploratory nature of this research and the need to explore multiple topics within the same group of participants. The scale therefore provided a universal method for collecting data that could easily be understood by a wide variety of participants. It also provided a quick, efficient and inexpensive method to collect data from participants with time constraints (e.g. pharmacists and GPs) and allowed for the data to be easily quantifiable and subjective to statistical analysis. However, Saris et al. have argued that the agree/disagree rating scale questions yield lower quality responses to comparable questions offering item specific response options (266). The authors primarily attribute this to acquiescence (reluctant acceptance without protest) which could result from personality dispositions where some individuals feel obliged to be polite and to avoid social friction, leading them to be especially agreeable (266). They also propose that, considering a general bias in hypothesis testing toward confirmation rather than disconfirmation, the agree/disagree scale inclines some respondents toward agreeing with assertions presented to them in this manner (266). Saris et al. propose the use of item specific scales (e.g."How would you rate your health – excellent, very good, good, fair, or bad?) as a more direct way of collecting opinion from individuals. Therefore, in light of this, the present research does acknowledge acquiescence to be a potential limitation to the quality of responses obtained (Chapter 3 and 5).

Finally, this research used an adapted NGT to assist the prioritising of factors needed to facilitate the implementation of community pharmacy based DPS. This method provided immediate results, whilst allowing for an opportunity for results to stem from a discussion of stakeholders. However, due to lack of time and resources, the ranking process was limited to a single group discussion rather than multiple rounds of discussions. Typically, NGT discussions take from 1.5-6 hours to complete as they consist of an iterative process of feedback and re-ranking until a

complete agreement of ideas is obtained (302). This limitation had therefore led to a presentation of a wider number of factors that could influence participation in and delivery of community pharmacy-based DPS in the final logic model.

7.2.1.3 Data analysis

The use of the BCW provided a transparent structure for the conduct and analysis of this research which followed the steps for developing interventions outlined by Michie *et al.* (188, 192). The use of the COM-B model to explore behaviours, enabled the identification of a variety of influences on behaviour change that fit in with constructs of most theoretical models. Thus, demonstrating the coherence of the components of the COM-B and the efficiency in providing an integrated framework for understanding behaviour.

Investigator triangulation was applied by involving several researchers, with a range of expertise, in conducting data analysis (334). This served to provide multiple perspectives in the interpretation of findings and helped to minimize the main researcher's (TK) subjective influence on the interpretation of the findings (284). At significant points during the process of data analysis, the main researcher (TK) regularly met with the supervisor (MT) to discuss data collection. Discussions were also held with the wider research team with extensive qualitative and clinical experience, to discuss the findings until the interpretation which we felt best represented the meaning of the data was found. The mapping of barriers and facilitators to the COM-B theoretical model, was examined by an external psychologist (HF) with experience of applying the COM-B in designing interventions. This ensured that the interpretation of the findings was supported by data received from participants of the study, hence enhancing dependability and confirmability of the research findings (335).

A potential source of bias in the analysis and presentation of findings, however, was the community pharmacy background of the research team (336) which included either pharmacists (TK, JS, HA and TK) or those with previous and current involvement in community pharmacy research (HF and CK). This potential bias was

mitigated by ensuring that data analysis primarily involved the use of raw data and interpretation of the research was primarily guided by the definitions of the COM-B domains (188, 192). Additionally, the selection of illustrative quotes was purposive and aimed at presenting findings which represented the multiple stakeholders who were involved as participants in this research.

7.3 Conclusion

Diabetes Prevention Programmes are an effective behaviour change intervention for preventing and delaying progression to type 2 diabetes in individuals with non-diabetic hyperglycemia. In England research evidence suggests the implementation of a national DPP to be potentially cost-effective and cost-saving. However, the impact of the programme could be undermined by poor uptake amongst people with NDH. Accessibility barriers to uptake, including lack of transportation, inconvenient location and session times have been identified amongst people with NDH who are currently not engaging with the NHS DPP. These barriers could be addressed by delivering programmes that mirror the current NHS DPP in alternative accessible settings such as community pharmacies. Additionally, with the NHS LTP committing to expand the programme, capacity could be maximised by utilising alternative settings such as community pharmacies.

Interventions for implementing diabetes prevention services in the community pharmacy would need to target people with NDH, community pharmacy teams and general practice personnel. Interventions for people with NDH would need to focus on raising awareness of the services including the risk factors for type 2 diabetes. The interventions would also need to ensure a clear and integrated pathway for people with NDH in order to ensure engagement. Interventions targeted at community pharmacy teams would need to focus on providing adequate funding and people resources. They would also need to ensure that community pharmacy personnel delivering DPS are appropriately trained and interventions targeted at

general practices would need to focus on enhancing communication and integration with community pharmacy teams.

This thesis provides a logic model of the underpinning theory behind delivering community pharmacy-based diabetes prevention services. Further research is needed to test the feasibility of implementing such services in this setting in order to establish a clear role for community pharmacy in diabetes prevention in England.

7.4 Research recommendations

7.4.1 Feasibility study

This thesis has a proposed model for delivering community pharmacy-based DPS. This model could be further developed by conducting a feasibility study to assess both the effectiveness and cost-effectiveness of implementing DPS in community pharmacy settings. The feasibility study would consider factors such as uptake and retention rates and could include a process evaluation to examine the reach of the intervention in terms of the characteristics of the population accessing the services.

The process evaluation could also examine the feasibility of implementation and the fidelity of the intervention model. This would assess the ability of staff to deliver the intervention in accordance to DPP service specifications and the acceptability of the intervention from the perspective of community pharmacy staff and people with NDH. The suitability and acceptability of the proposed outcome measures to patients, commissioners and other healthcare providers would also need to be established.

7.4.2 Development of motivation assessment tools

This research has suggested motivation to be an important influence in making decisions to engage with DPPs. The initial assessment session of the DPP could therefore benefit from an assessment of motivation to decipher suitability of

interventions. Therefore, future work could develop assessment tools underpinned by theoretical models such as the trans-theoretical model to assess readiness for change and guide referral to appropriate services. Such tools would be designed to assess patients individually and tailor the service to their needs.

7.4.3 Development of monitoring services post NHS DPP

This research has identified a potential role for community pharmacy to monitor long-term outcomes of the NHS DPP following completion of the nine-month intervention. NHS England has identified this as an area requiring further exploration and collaboration between local commissioners and primary care providers. Therefore, there is scope for community pharmacy to delivery such services given their accessibility. Future work could therefore explore how community pharmacy can work with local commissioners to monitor clinical outcomes in those who have completed the NHS DPP.

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